
**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, 2019

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 333-228576, 333-203040, 333-210810, 333-211512, 333-213412, 333-214843 and 333-216883) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 September 30, 2019.

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 November 18, 2019.
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.

Ascendis Pharma A/S

Date: November 18, 2019

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 Other Comprehensive Income / (Loss) for the Three and Nine Months Ended September 30**

	Notes	Three Months Ended September 30		Nine Months Ended September 30	
		2019	2018	2019	2018
		(EUR'000)		(EUR'000)	
Revenue	4	2,243	20	10,868	66
Research and development costs		(46,258)	(31,511)	(141,343)	(102,286)
General and administrative expenses		(10,000)	(6,796)	(31,396)	(16,684)
Operating profit / (loss)		(54,015)	(38,287)	(161,871)	(118,904)
Share of profit / (loss) of associate		(1,338)	—	(5,452)	—
Finance income		30,547	4,262	30,285	20,532
Finance expenses		(368)	(42)	(812)	(53)
Profit / (loss) before tax		(25,174)	(34,067)	(137,850)	(98,425)
Tax on profit / (loss) for the period		61	100	196	306
Net profit / (loss) for the period		(25,113)	(33,967)	(137,654)	(98,119)
Other comprehensive income / (loss)					
<i>Items that may be reclassified subsequently to profit or loss:</i>					
Exchange differences on translating foreign operations		37	(9)	2	(16)
Other comprehensive income / (loss) for the period, net of tax		37	(9)	2	(16)
Total comprehensive income / (loss) for the period, net of tax		(25,076)	(33,976)	(137,652)	(98,135)
Profit / (loss) for the period attributable to owners of the Company		(25,113)	(33,967)	(137,654)	(98,119)
Total comprehensive income / (loss) for the period attributable to owners of the Company		(25,076)	(33,976)	(137,652)	(98,135)
		EUR	EUR	EUR	EUR
Basic and diluted earnings / (loss) per share		(0.53)	(0.81)	(2.99)	(2.41)
Number of shares used for calculation (basic and diluted) ⁽¹⁾		47,590,837	41,888,908	46,066,493	40,757,686

(1) A total of 5,138,389 warrants outstanding as of September 30, 2019 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 4,480,805 warrants outstanding as of September 30, 2018 are also considered antidilutive for the periods presented and have not been included in the calculation.

Unaudited Condensed Consolidated Interim Statements of Financial Position

	<u>Notes</u>	<u>September 30, 2019</u>	<u>December 31, 2018</u>
<u>(EUR'000)</u>			
Assets			
Non-current assets			
Intangible assets		3,495	3,495
Property, plant and equipment	7	43,272	4,325
Investment in associate		17,073	17,083
Deposits		1,469	1,158
		<u>65,309</u>	<u>26,061</u>
Current assets			
Trade receivables		—	6
Other receivables		1,755	1,775
Prepayments		7,937	12,415
Income taxes receivable		1,298	849
Cash and cash equivalents		658,660	277,862
		<u>669,650</u>	<u>292,907</u>
Total assets		<u>734,959</u>	<u>318,968</u>
Equity and liabilities			
Equity			
Share capital	8	6,410	5,659
Distributable equity		654,515	274,391
Total equity		<u>660,925</u>	<u>280,050</u>
Non-current liabilities			
Lease liabilities	2, 7	31,503	—
		<u>31,503</u>	<u>—</u>
Current liabilities			
Lease liabilities	2, 7	5,424	—
Contract liabilities		1,373	6,902
Trade payables		24,346	19,740
Other payables		11,364	12,267
Income taxes payable		24	9
		<u>42,531</u>	<u>38,918</u>
Total liabilities		<u>74,034</u>	<u>38,918</u>
Total equity and liabilities		<u>734,959</u>	<u>318,968</u>

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, 2019	5,659	625,250	3	42,445	(393,307)	280,050
Loss for the period	—	—	—	—	(137,654)	(137,654)
Other comprehensive income / (loss), net of tax	—	—	2	—	—	2
Total comprehensive income / (loss)	—	—	2	—	(137,654)	(137,652)
Share-based payment (Note 6)	—	—	—	26,205	—	26,205
Capital increase	751	523,272	—	—	—	524,023
Cost of capital increase	—	(31,701)	—	—	—	(31,701)
Equity at September 30, 2019	6,410	1,116,821	5	68,650	(530,961)	660,925

	Distributable Equity					Total
	Share Capital	Share Premium	Foreign Currency Translation Reserve	Share-based Payment Reserve	Accumulated Deficit	
	(EUR'000)					
Equity at January 1, 2018	4,967	422,675	(14)	22,793	(263,210)	187,211
Loss for the period	—	—	—	—	(98,119)	(98,119)
Other comprehensive income / (loss), net of tax	—	—	(16)	—	—	(16)
Total comprehensive income / (loss)	—	—	(16)	—	(98,119)	(98,135)
Share-based payment (Note 6)	—	—	—	12,787	—	12,787
Capital increase	678	214,782	—	—	—	215,460
Cost of capital increase	—	(13,118)	—	—	—	(13,118)
Equity at September 30, 2018	5,645	624,339	(30)	35,580	(361,329)	304,205

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

	Notes	2019	2018
(EUR'000)			
Operating activities			
Net profit / (loss) for the period		(137,654)	(98,119)
Reversal of non-cash consideration relating to revenue		(5,334)	—
Reversal of share of profit/(loss) of associate		5,452	—
Reversal of finance income		(30,285)	(20,532)
Reversal of finance expenses		812	53
Reversal of tax charge		(196)	(306)
Adjustments for:			
Share-based payment		26,205	12,787
Depreciation		4,716	631
Changes in working capital:			
Deposits		(310)	(948)
Trade receivables		6	167
Other receivables		19	(1,340)
Prepayments		4,478	(5,482)
Contract liabilities (deferred income)		(5,529)	—
Trade payables and other payables		3,596	7,237
Cash flows generated from / (used in) operations		(134,024)	(105,852)
Finance income received		8,087	3,065
Finance expenses paid		(526)	(53)
Income taxes received / (paid)		(237)	(400)
Cash flows from / (used in) operating activities		(126,700)	(103,240)
Investing activities			
Acquisition of property, plant and equipment		(4,030)	(1,587)
Cash flows from / (used in) investing activities		(4,030)	(1,587)
Financing activities			
Payment of finance lease liabilities		(2,992)	—
Capital increase		524,023	215,460
Cost of capital increase		(31,701)	(13,118)
Cash flows from / (used in) financing activities		489,330	202,342
Increase / (decrease) in cash and cash equivalents		358,600	97,515
Cash and cash equivalents at January 1		277,862	195,351
Effect of exchange rate changes on balances held in foreign currencies		22,198	17,467
Cash and cash equivalents at September 30		658,660	310,333
Restricted cash included in cash and cash equivalents		5,935	5,507

Notes to the Unaudited Condensed Consolidated Interim Financial Statements

Note 1—General Information

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

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

On February 2, 2015, the Company completed an initial public offering which resulted in the listing of American Depositary Shares, 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 November 18, 2019.

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 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 annual consolidated financial statements for the year ended December 31, 2018 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 preparation of financial statements in conformity with IFRS requires the use of certain critical 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.

Changes in Accounting Policies

As of January 1, 2019, the Company has adopted IFRS 16, “Leases” (“IFRS 16”). IFRS 16 requires, with a few exceptions, lessees to recognize assets (“right-of-use assets”) and liabilities for most leases. Accordingly, lease payments under most contracts previously classified as operating leases, will be recognized over the non-cancellable lease period as depreciation included in research and development costs and general and administrative expenses, and as interest expenses included in finance expenses. Previously, lease payments under all operating leases were recognized as either research and development costs or general and administrative expenses.

Impact from IFRS 16 “Leases”

The Company primarily leases office- and laboratory facilities, and equipment. Lease arrangements are typically entered into for fixed periods but may have extension options, and options to terminate the lease within the enforceable lease term. Lease terms are negotiated on an individual basis and contain a range of different terms and conditions.

We have implemented IFRS 16 by applying the modified retrospective approach. Accordingly, no comparative information is restated. The lease liability and corresponding right-of-use assets is measured at the present value of the remaining lease payments, discounted using an estimated incremental borrowing rate at January 1, 2019.

In connection with the transition to IFRS 16, we have reviewed our operating lease agreements’ contractual terms including the lease payment structure. Fixed payments, and variable lease payments that depend on an index or a rate, are included in lease payments, whereas variable lease payments are excluded. Additionally, payments related to non-lease components are excluded, and thus treated as either research and development costs or general and administrative expenses.

Notes to the Unaudited Condensed Consolidated Interim Financial Statements

For lease arrangements other than those relating to short-term leases and leases of low value assets, lease liabilities have been determined according to the fixed lease payments and variable lease payments that depend on an index or a rate in the non-cancellable periods, discounted by the incremental borrowing rate. Accordingly, at January 1, 2019, we have recognized a lease liability of €17.7 million.

Operating lease commitments under IAS 17 “Leases”, and as disclosed for the annual reporting period ended December 31, 2018 was €19.6 million. The transition to the lease liabilities recognized in the unaudited condensed consolidated interim financial position at January 1, 2019, in accordance with IFRS 16, is summarized below:

	(EUR '000)
Operating lease commitments as per December 31, 2018	19,627
Short-term contracts, and low value assets	(169)
Undiscounted, operating lease commitments as per January 1, 2019	19,458
Lease liabilities discounted by incremental borrowing rates as per January 1, 2019	<u>17,700</u>

At January 1, 2019, right-of-use assets of €18.4 million, which include prepaid leases, were recognized as property, plant and equipment.

The transition to IFRS 16 had no impact on retained earnings.

Separate note disclosures on right-of-use assets, and lease liabilities and payments for the nine months ended September 30, 2019, are included in Note 7.

Several other amendments to and interpretations of IFRS apply for the first time in 2019, but do not have an impact on the accounting policies applied by the Company. Thus, except for the adoption of IFRS 16, the accounting policies applied when preparing these unaudited condensed consolidated interim financial statements have been applied consistently to all the periods presented, unless otherwise stated, and are consistent with those of the Company’s most recent audited annual consolidated financial statements.

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, 2018.

Note 3—Critical Accounting Judgments and Key Sources of Estimation Uncertainty

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The 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.

Critical judgments made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in our unaudited condensed consolidated interim financial statements relate to revenue recognition, share-based payment, internally generated intangible assets, and to our joint arrangements / collaboration agreements.

Except for the adoption of IFRS 16, 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 relate to recognition of accruals for manufacturing and clinical trial activities. No significant adjustments to accruals have been recognized during the first nine months of 2019 or 2018, due to conditions that existed at December 31, 2018, or 2017, respectively. Additionally, there have been no changes to the application of significant accounting estimates, and no impairment losses have been recognized during the first nine months of 2019 or 2018.

Notes to the Unaudited Condensed Consolidated Interim Financial Statements

In connection with adopting IFRS 16, the following are assessed as key assumptions concerning estimation uncertainty that have a significant risk of causing a material adjustment to the carrying amount of right-to-use assets and lease liabilities within the next financial year.

Lease Term

Certain lease arrangements provide us with a contractual right (not obligation) to either extend the lease after the initial term, or to terminate the lease within the enforceable lease term, i.e. periods where lessor cannot terminate the lease. Those options cover periods in the range from 1-6 years in addition to the non-cancellable periods. Based on our assessment at September 30, 2019, the lease terms reflect only thenon-cancellable periods.

Incremental Borrowing Rate

Lease payments are discounted over the non-cancelable periods, applying each contract's incremental borrowing rate. In determining incremental borrowing rates, we have considered the contracts' specific payment profiles and relevant currencies, and applied a corresponding risk-free interest rate, credit spread, and an asset specific adjustment, if applicable. The incremental borrowing rates applied are 2.25-2.5% and 4.25-5.0% for lease contracts denominated in EUR or Danish Kroner, and U.S. Dollars, respectively.

The unaudited condensed consolidated interim financial statements do not include all disclosures for critical accounting estimates and judgments that are required in the annual consolidated financial statements and should be read in conjunction with the Company's audited consolidated financial statements as of and for the year ended December 31, 2018.

Note 4—Revenue

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(EUR'000)		(EUR'000)	
Revenue from the rendering of services (recognized over time)	1,586	20	8,874	66
License income (recognized at a point in time)	657	—	1,994	—
Total revenue (1)	2,243	20	10,868	66
Revenue from external customers (geographical)				
North America	2,243	20	10,868	66
Total revenue (1)	2,243	20	10,868	66

(1) For the three and nine months ended September 30, 2019, "Total revenue" includes recognition of previously deferred revenue from associate of €1,461 thousand, and €5,337 thousand, respectively.

Note 5—Segment Information

We are 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, we do not disclose information on business segments or geographical markets, except for the geographical information on revenue included in Note 4.

Note 6—Warrants and Share-based Payment

Share-based Payment

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

Notes to the Unaudited Condensed Consolidated Interim Financial Statements

Warrants are granted by the Company's Board of Directors in accordance with authorizations given to it by the shareholders of Ascendis Pharma A/S. As of September 30, 2019, 8,443,687 warrants had been granted, of which 19,580 warrants have been cancelled, 3,025,060 warrants have been exercised, 2,168 warrants have expired without being exercised, and 258,490 warrants have been forfeited. As of September 30, 2019, the Company's Board of Directors was authorized to grant up to 2,172,625 additional warrants to employees, board members and select consultants without pre-emptive 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 €107.14 depending on the grant dates. Vested warrants may be exercised in two or four annual exercise periods. Apart from exercise prices and exercise periods, the programs are similar.

Warrant Activity

The following table specifies the warrant activity during the nine months ended September 30, 2019:

	Total Warrants	Weighted Average Exercise Price EUR
Outstanding at January 1, 2019	5,611,629	29.03
Granted during the period	365,500	97.10
Exercised during the period	(812,532)	14.90
Forfeited during the period	(26,208)	52.23
Expired during the period	—	—
Outstanding at September 30, 2019	5,138,389	35.99
Vested at the balance sheet date	2,609,412	22.83

Warrant Compensation Costs

Warrant compensation costs are determined with basis in the grant date fair value of the warrants granted and recognized over the vesting period.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(EUR'000)		(EUR'000)	
Research and development costs	5,060	1,963	15,239	6,313
General and administrative expenses	3,015	1,922	10,966	6,474
Total warrant compensation costs	8,075	3,885	26,205	12,787

Note 7—Leases

The following sections summarize the disclosures of the Company's lease arrangements for the nine months ended September 30, 2019. Additional information on the exposure from the Company's lease arrangements is included in Note 2 and 3.

Right-of-use Assets

As of September 30, 2019, the total balance of property, plant and equipment of €43.3 million includes right-of-use-assets of €35.9 million. For the nine months ended September 30, 2019, additions to right-of-use assets were €20.2 million and related to office- and laboratory facilities.

Notes to the Unaudited Condensed Consolidated Interim Financial Statements

For the nine months ended September 30, 2019, depreciation of right-of-use assets amounts to €3.7 million, recognized as research and development costs, and general and administrative expenses, by €2.8 million and €0.9 million, respectively.

Lease Liabilities and Payments

In the unaudited condensed consolidated interim statement of financial position as of September 30, 2019, the carrying amount of lease liabilities of €36.9 million is presented as non-current and current liabilities by €31.5 million and €5.4 million, respectively.

The table below summarizes the maturity profile of the Company's lease liabilities based on contractual undiscounted payments:

	Carrying amount	<1 year	1-5 years	>5 years	Total contractual cash flows
(EUR'000)					
September 30, 2019					
Lease liabilities	<u>36,927</u>	<u>5,524</u>	<u>19,819</u>	<u>18,185</u>	<u>43,528</u>

For the nine months ended September 30, 2019, interest on lease liabilities amounts to €0.7 million, which is recognized as finance expenses.

Payments relating to short-term leases and leases of low value assets are recognized either as research and development costs or general and administrative expenses, respectively, on a straight-line basis according to their lease term. Additionally, lease payments classified as variable, that do not depend on an index or a rate, are expensed as incurred.

As of September 30, 2019, the Company's commitments for short-term leases, and leases of low-value assets, are deemed immaterial for the unaudited condensed consolidated interim financial statements.

Note 8—Share Capital

The share capital of Ascendis Pharma A/S consists of 47,739,647 shares at a nominal value of DKK 1, all in the same share class.

On March 14, 2019, the Company completed the sale and issuance of 4,791,667 ADSs in a public offering, increasing the Company's share capital from 42,135,448 shares to 46,927,115 shares.

In April, June, and September 2019, an aggregate of 812,532 warrants were exercised, increasing the Company's share capital from 46,927,115 shares to 47,739,647 shares.

Note 9—Subsequent Events

No events have occurred after the balance sheet date that would have a significant impact on the results or financial position of the Company.

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, 2018 – "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:

- our ongoing phase 3 pediatric long-term extension trial of TransCon Growth Hormone, or hGH, our ongoing phase 2 study of TransCon Parathyroid Hormone, or PTH, and our ongoing phase 2 study of TransCon C-Type Natriuretic Peptide, or CNP;
- our pursuit of oncology as our second of three independent therapeutic areas of focus, and our development of a pipeline of product candidates in this therapeutic area;
- our receipt of future milestone or royalty payments from our collaboration partners, and the expected timing of such payments;
- 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 equivalents 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 equivalents 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 timing or likelihood of regulatory filings and approvals for our product candidates;
- 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 technology;

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- 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; and
 - developments and projections relating to our competitors and our industry.

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, 2018 — "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 have created a portfolio of potential best-in-class endocrinology rare disease product candidates to address unmet medical needs by utilizing our TransCon technologies with clinically validated parent drugs. We currently have three product candidates in clinical development in endocrinology rare diseases and we are working to apply our TransCon technology platform in additional therapeutic areas, including oncology. We recently established oncology as our second therapeutic area and are developing a pipeline of systemic and localized prodrug product candidates to address unmet medical needs in this therapeutic area. Additionally, we have developed a pipeline of long-acting prodrug product candidates through strategic collaborations and we are working with these collaboration partners in the areas of ophthalmology and diabetes.

Our most advanced investigational product candidate, TransCon hGH, is in development as a once-weekly long-acting prodrug of recombinant human growth hormone, also referred to as hGH, as a potential treatment for growth hormone deficiency, or GHD. Our phase 3 program for TransCon hGH consists of the heiGHt, fliGHt and enliGHten Trials.

In March 2019, we announced top-line results from the pivotal, phase 3 heiGHt Trial, in which TransCon hGH was observed to have superior efficacy and comparable safety and tolerability to that of a daily hGH. Results from the trial indicate that TransCon hGH was generally safe and well-tolerated, with adverse events consistent with the type and frequency observed with the daily hGH therapy and comparable between arms of the trial. No serious adverse events related to study drug were observed in either arm. No treatment-emergent adverse events leading to discontinuation of study drug were observed in either arm.

In May 2019, we announced results from the single arm phase 3 fliGHt Trial of TransCon hGH, which was designed to expand the safety database on TransCon hGH in pediatric subjects. The results indicated treatment with TransCon hGH was safe and well-tolerated in subjects with pediatric GHD who were previously treated with commercially-available daily growth hormone therapies. In the trial, the adverse event profile of TransCon hGH was similar to the published safety profile of daily growth hormone therapies. Results from the fliGHt Trial also support safety of TransCon hGH in subjects under three years of age.

Nearly all subjects who completed the heiGHt or fliGHt Trials have enrolled in the open-label extension study, the enliGHten Trial, which is designed to provide long-term safety data to support the planned regulatory filings for TransCon hGH. We initiated the enliGHten Trial in 2017 as the first subjects began to roll over from the heiGHt Trial, and we have enrolled approximately 300 subjects, which will form a safety database consistent with input from regulatory authorities.

In September 2019, we completed the last subject visit forming the two-year follow up for the TransCon hGH phase 3 program in pediatric GHD. These data, including results from approximately 300 subjects treated with TransCon hGH (approximately 300 for six months, 120 for 12 months and 45 for 24 months), will form the safety database to support a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or the FDA, for TransCon hGH to treat pediatric GHD expected in the first half of 2020 and a Marketing Authorisation Application to the European Medicines Agency expected in the second half of 2020.

In October 2019, we received Orphan Designation from the European Commission for TransCon hGH for pediatric 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 (EU), and which may provide significant additional benefit over existing therapies.

We believe that TransCon hGH, if approved, may offer a once-weekly therapy for GHD with the potential to improve outcomes compared to currently approved daily hGH. We have also conducted a phase 2 clinical trial in adult subjects with GHD that will form the basis of designing future clinical research in adult GHD. If approved, TransCon hGH may reduce the burden of daily treatment by requiring significantly fewer injections, which may improve compliance and treatment outcomes.

We are also using our TransCon technology platform to develop TransCon PTH, an investigational once-daily long-acting prodrug of parathyroid hormone, or PTH, as a potential treatment for hypoparathyroidism, a rare endocrine disorder of calcium and phosphate metabolism. We completed a phase 1 trial in healthy subjects in May 2018, the results of which were consistent with our target product profile for TransCon PTH as a true replacement therapy. In this trial, TransCon PTH showed the predicted pharmacokinetic and pharmacodynamic response, suggesting the ability to normalize serum and urinary calcium levels in patients with hypoparathyroidism. We believe TransCon PTH may provide patients suffering from hypoparathyroidism with a PTH replacement therapy that is designed to fully address all aspects of the disease more than standard of care or currently approved therapies. In June 2018, we were granted Orphan Drug Designation, or ODD, by the FDA for TransCon PTH. ODD is provided to drugs that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. PaTH Forward is evaluating the safety, tolerability and efficacy of three fixed doses of TransCon PTH using a ready-to-use prefilled pen device. The goal of PaTH Forward is to evaluate TransCon PTH control of serum and urinary calcium, and identify a titration regimen for complete withdrawal of standard of care (i.e., active vitamin D and calcium supplements).

On November 14, 2019, the Company announced an expansion of the patient population in the Company's PaTH Forward phase 2 trial to facilitate enrollment of subjects previously treated with NATPARA, a parathyroid hormone. Previously, patients treated with NATPARA were required to undergo a long washout period prior to entering screening in PaTH Forward. In response to the recent recall of NATPARA in the United States, the Company has been evaluating pathways to help enroll patients affected by the recall. Under the protocol addendum, patients previously treated with NATPARA in the United States will now have an expedited pathway to enroll in PaTH Forward. The Company expects top-line data from the expanded PaTH Forward Trial in the first quarter of 2020. Our plan for our phase 3 program for TransCon PTH includes incorporating trial sites in the United States, Europe, Australia, Canada, Japan and possibly other Asian countries.

We are also developing TransCon CNP, an investigational long-acting prodrug of C-type natriuretic peptide, or CNP, as a potential therapeutic option for achondroplasia, the most common form of dwarfism. Currently, there are no medical therapies for achondroplasia approved by the FDA. TransCon CNP utilizes our TransCon technology platform to create a long-acting CNP prodrug as a potential therapeutic option for achondroplasia and potentially other skeletal disorders. CNP as a therapeutic approach is supported by extensive preclinical and clinical data. In November 2018, we completed a phase 1 clinical trial in healthy adult subjects, which demonstrated that TransCon CNP provided continuous exposure to CNP with a pharmacokinetic profile designed to maximize efficacy with once-weekly dosing. In February 2019, we were granted ODD by the FDA for TransCon CNP. Following successful submission of an IND application in July 2019, we initiated the phase 2 ACcomplisH Trial, a global phase 2 trial designed to evaluate the safety and efficacy of TransCon CNP in children with achondroplasia. Our goal is to develop TransCon CNP as a safe and effective therapeutic option for achondroplasia and potentially other related growth disorders.

In addition to our pipeline of endocrinology rare disease candidates, we have 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 sustained localized delivery systems using our TransCon platform. In June 2019, we presented preclinical data on three of the programs currently in our oncology pipeline: TransCon Toll-like Receptor (TLR) 7/8 Agonist, TransCon Interleukin-2 (IL-2) β/γ and TransCon Vascular Endothelial Growth Factor-Tyrosine Kinase Inhibitor (VEGF-TKI). Our goal is to file an IND or equivalent in oncology by the end of 2020.

In November 2018, we announced the formation of 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. In connection with the formation of Visen, we granted Visen exclusive rights to develop and commercialize certain product candidates based on our proprietary TransCon technologies, including TransCon hGH, TransCon PTH and TransCon CNP, in Greater China for use in all human indications, subject to certain exceptions. As consideration for the rights granted to Visen, we received 50% ownership in the outstanding shares of Visen and concurrently with the rights we granted to Visen, entities affiliated with Vivo Capital and Sofinnova Ventures purchased shares in Visen for an aggregate purchase price of \$40 million in cash.

In October 2019, Visen initiated a phase 3 trial for TransCon hGH in pediatric GHD in China. We expect that the trial will enroll at least 75 subjects.

We believe our strategic investment in Visen supports our strategy to extend our endocrinology rare disease portfolio globally and establish a presence in China in partnership with collaborators who have significant experience and knowledge of the biopharmaceutical opportunity in China. In part because Visen was established in China, we believe Visen will be able to effectively develop and, if approved, market our innovative technologies to address the needs of the local markets in Greater China.

In addition, we have strategic collaborations for TransCon anti-VEGF in the field of ophthalmology, which is partnered with Genentech, and the TransCon peptide program for the treatment of diabetes, which is partnered with Sanofi. We are eligible to receive up to an aggregate of €200 million in development and regulatory milestone payments for products currently being developed under our collaboration agreements, as well as sales-based milestone payments and royalties on future net sales of products.

We believe that the effectiveness of our TransCon technologies is supported by data from our preclinical research and the ongoing clinical programs, including our TransCon hGH, TransCon PTH and TransCon CNP programs, as well as findings from our ongoing development of other product candidates, including our multi-product collaborations with Sanofi and Genentech. We have applied the TransCon technologies in combination with parent drugs with clinical proof of concept using our algorithm for creating products with the potential to be best-in-class in endocrinology rare diseases, and we will continue to apply this algorithm for product selection in new therapeutic areas. We believe this approach may reduce the risks associated with traditional drug development.

Our TransCon technologies enable us to create long-acting prodrug therapies with potentially significant advantages over existing marketed drug products. Our TransCon technologies transiently link an unmodified parent drug to a TransCon carrier via our proprietary TransCon linkers. Our TransCon linkers predictably release an unmodified active parent drug at predetermined rates governed by physiological pH and temperature conditions, supporting administration frequencies from daily to more than every six months. 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.

We commenced operations in December 2007 in connection with the acquisition of the company that invented our TransCon technologies, Complex Biosystems GmbH. Since we commenced operations in 2007, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations. We do not have any approved products and have never generated any revenue from product sales.

We had a net loss of €137.7 million for the nine months ended September 30, 2019 and a net loss of €130.1 million for the year ended December 31, 2018. Our total equity was €660.9 million as of September 30, 2019 compared to €280.1 million as of December 31, 2018. The increase in equity primarily reflects the follow-on public offering of ADSs in March 2019.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018 (unaudited):

	Three Months Ended	
	September 30,	
	2019	2018
	(EUR'000)	
Revenue	2,243	20
Research and development costs	(46,258)	(31,511)
General and administrative expenses	(10,000)	(6,796)
Operating profit / (loss)	(54,015)	(38,287)
Share of profit / (loss) of associate	(1,338)	—
Finance income	30,547	4,262
Finance expenses	(368)	(42)
Profit / (loss) before tax	(25,174)	(34,067)
Tax on profit / (loss) for the period	61	100
Net profit / (loss) for the period	(25,113)	(33,967)

Revenue

Total revenue for the three months ended September 30, 2019 was €2.2 million compared to €20 thousand for the three months ended September 30, 2018. This increase was due to recognition of revenue related to our investment in Visen.

As of September 30, 2019, we had deferred income of €1.4 million under the agreement with Visen, which will be recognized as revenue as we advance the projects that are subject to our collaborations with Visen.

Research and Development Costs

Research and development costs were €46.3 million for the three months ended September 30, 2019, an increase of €14.8 million, or 47%, compared to €31.5 million for the three months ended September 30, 2018. External development costs related to our TransCon hGH product candidate increased by €5.1 million, primarily driven by manufacturing of validation batches, or process performance qualification batches, and initial costs of pre-launch inventories, partly offset by a reduction in clinical trial costs reflecting the completion of the phase 3 heiGHt Trial. The process performance qualification batches are required as part of the regulatory approval process with the FDA, and, as well as the pre-launch inventories, are recognized as development costs when incurred. However, after potential marketing approval, the products from these process performance qualification batches and pre-launch inventories may be used for commercial sales, thereby reducing the costs for the first period after market launch.

External development costs related to our TransCon PTH product candidate decreased by €0.6 million, primarily reflecting lower manufacturing costs and preclinical costs, whereas clinical trial costs increased compared to the same period of last year, reflecting the initiation of our phase 2 PaTH Forward clinical trial.

External development costs related to our TransCon CNP product candidate increased by €0.5 million, primarily reflecting an increase in clinical trial costs for our phase 2 ACcomplisH Trial which was initiated in the third quarter of 2019, partly offset by a reduction in preclinical costs.

Other research and development costs increased by €9.8 million, primarily driven by an increase in personnel costs of €3.6 million and non-cash share-based payment of €3.1 million due to a higher number of employees in research and development functions, but also reflecting increases of €0.7 million in travel costs, and €0.6 million in facility costs allocated to research and development functions including the impact from the implementation of IFRS 16, "Leases", which was adopted as of January 1, 2019. Costs related to laboratory operations and early stage development activities increased by €1.8 million compared to the same period of last year, primarily reflecting our new activities within oncology.

Research and development costs included non-cash share-based payment of €5.1 million for the three months ended September 30, 2019, compared to €2.0 million for the three months ended September 30, 2018.

General and Administrative Expenses

General and administrative expenses were €10.0 million for the three months ended September 30, 2019, an increase of €3.2 million, or 47%, compared to general and administrative expenses of €6.8 million for the three months ended September 30, 2018. The increase is primarily due to an increase in personnel costs of €1.6 million and non-cash share-based payment of €1.1 million for additional administrative personnel, but also reflecting increases of €0.2 million in IT costs, and €0.3 million in facility costs including the impact from the implementation of IFRS 16, "Leases", which was adopted as of January 1, 2019.

General and administrative expenses included non-cash share-based payment of €3.0 million for the three months ended September 30, 2019, compared to €1.9 million for the three months ended September 30, 2018.

Net Profit / (Loss) in Associate

Net loss in associate was €1.3 million, which represents our share of net result from Visen. As Visen was established in November 2018, no comparative figures are presented for the three months ended September 30, 2018.

Finance Income and Finance Expenses

Finance income was €30.5 million for the three months ended September 30, 2019, an increase of €26.2 million compared to €4.3 million for the three months ended September 30, 2018. Finance expenses were €0.4 million for the three months ended September 30, 2019, an increase of €0.3 million compared to the same period of 2018.

The €26.0 million increase in net finance income was due to positive exchange rate fluctuations, primarily between the U.S. Dollar and Euro in the three months ended September 30, 2019, primarily affecting our cash position maintained in U.S. Dollars.

We did not hold any interest-bearing debt for any of the periods presented. However, as of January 1, 2019, we have adopted IFRS 16, "Leases", which requires interest expenses to be recognized on lease liabilities.

Tax for the Period

Tax for the three months ended September 30, 2019 was a net tax credit of €61 thousand compared to a net tax credit of €100 thousand for the three months ended September 30, 2018. Taxes for the three months ended September 30, 2019 comprised an estimated tax credit of €184 thousand in the group of Danish companies, partly offset by tax payments of €123 thousand in our U.S. and German subsidiaries.

Comparison of the Nine Months Ended September 30, 2019 and 2018 (unaudited):

	Nine Months Ended September 30,	
	2019	2018
	(EUR'000)	
Revenue	10,868	66
Research and development costs	(141,343)	(102,286)
General and administrative expenses	(31,396)	(16,684)
Operating profit / (loss)	(161,871)	(118,904)
Share of profit / (loss) in associates	(5,452)	—
Finance income	30,285	20,532
Finance expenses	(812)	(53)
Profit / (loss) before tax	(137,850)	(98,425)
Tax on profit / (loss) for the period	196	306
Net profit / (loss) for the period	(137,654)	(98,119)

Revenue

Total revenue for the nine months ended September 30, 2019 was €10.9 million compared to €0.1 million for the nine months ended September 30, 2018. This increase was due to recognition of revenue related to our investment in Visen.

As of September 30, 2019, we had deferred income of €1.4 million under the agreement with Visen, which will be recognized as revenue as we advance the projects that are subject to our collaborations with Visen.

Research and Development Costs

Research and development costs were €141.3 million for the nine months ended September 30, 2019, an increase of €39.0 million, or 38%, compared to €102.3 million for the nine months ended September 30, 2018.

External development costs related to our TransCon hGH product candidate increased by €9.8 million, primarily driven by manufacturing of validation batches, or process performance qualification batches, and initial costs of pre-launch inventories, partly offset by a decrease in clinical trial costs, reflecting the completion of the phase 3 heiGHt Trial in the first quarter of 2019. The process performance qualification batches are required as part of the regulatory approval process with the FDA, and, as well as the pre-launch inventories, are recognized as development costs when incurred. However, after potential marketing approval, the products from these process performance qualification batches and pre-launch inventories may be used for commercial sales, thereby reducing the costs for the first period after market launch.

External development costs related to our TransCon PTH product candidate increased by €1.3 million, primarily reflecting higher clinical trial costs, whereas manufacturing and preclinical costs decreased compared to the same period of last year.

External development costs related to our TransCon CNP product candidate decreased by €0.3 million, primarily due to lower manufacturing and preclinical costs, partly offset by an increase in clinical trial costs, reflecting the phase 2 ACcomplish Trial which was initiated in the third quarter of 2019.

Other research and development costs increased by €28.2 million, primarily driven by an increase in personnel costs of €11.2 million and non-cash share-based payment of €8.9 million due to a higher number of employees in research and development functions. IT costs allocated to research and development functions increased by €1.4 million and travel costs increased by €1.5 million. Cost of facilities allocated to research and development functions increased by €1.9 million, including net impact from the implementation of IFRS 16, "Leases", which was adopted as of January 1, 2019. Costs related to laboratory operations and early stage development activities increased by €3.0 million compared to the same period of last year, primarily reflecting our new activities within oncology. Other costs allocated to research and development functions increased by net €0.3 million.

Research and development costs included non-cash share-based payment of €15.2 million for the nine months ended September 30, 2019, compared to €6.3 million for the nine months ended September 30, 2018.

General and Administrative Expenses

General and administrative expenses were €31.4 million for the nine months ended September 30, 2019, an increase of €14.7 million, or 88%, compared to general and administrative expenses of €16.7 million for the nine months ended September 30,

2018. The increase is primarily due to an increase in personnel costs of €5.1 million and non-cash share-based payment of €4.5 million for additional administrative personnel, but also reflecting increases of €1.9 million in professional fees, €1.5 million in IT costs, and €0.7 million in cost of facilities, including net impact from the implementation of IFRS 16, “Leases”, which was adopted as of January 1, 2019. Other costs allocated to general and administrative functions increased by net €1.0 million.

General and administrative expenses included non-cash share-based payment of €11.0 million for the nine months ended September 30, 2019, compared to €6.5 million for the nine months ended September 30, 2018.

Net Profit / (Loss) in Associate

Net loss in associate was €5.4 million, which represents our share of net result from Visen. As Visen was established in November 2018, no comparative figures are presented for the nine months ended September 30, 2018.

Finance Income and Finance Expenses

Finance income was €30.3 million for the nine months ended September 30, 2019, an increase of €9.8 million compared to €20.5 million for the nine months ended September 30, 2018. Finance expenses were €0.8 million for the nine months ended September 30, 2019, an increase of €0.7 million compared to the same period of 2018, reflecting the recognition of interest expenses on lease liabilities.

The €9.0 million increase in net finance income was due to positive exchange rate fluctuations, primarily between the U.S. Dollar and Euro in the nine months ended September 30, 2019, primarily affecting our cash position maintained in U.S. Dollars.

We did not hold any interest-bearing debt for any of the periods presented. However, as of January 1, 2019, we have adopted IFRS 16, “Leases”, which requires interest expenses to be recognized on lease liabilities.

Tax for the Period

Tax for the nine months ended September 30, 2019 was a net credit of €0.2 million compared to a net credit of €0.3 million for the nine months ended September 30, 2018. Taxes for the nine months ended September 30, 2019 were comprised of an estimated tax credit of €0.6 million in the group of Danish companies partly offset by tax expenses of €0.4 million in our U.S. and German subsidiaries.

Liquidity and Capital Resources

As of September 30, 2019, we had cash and cash equivalents totaling €658.7 million compared to €277.9 million as of December 31, 2018. We have funded our operations primarily through issuance of preference shares, ordinary shares and convertible debt securities and payments to us under our collaboration agreements. Our expenditures are primarily related to research and development activities and general and administrative activities to support research and development.

In February 2015, we announced the closing of our initial public offering, with net proceeds of \$111.5 million (or €101.4 million). In 2016, we completed a follow-on public offering of American Depositary Shares, or ADSs, with net proceeds of \$127.1 million (or €116.6 million) and in 2017, we completed a follow-on public offering of ADSs, with net proceeds of \$145.2 million (or €123.1 million). In February 2018, we completed a follow-on public offering of ADSs, with net proceeds of \$242.5 million (or €196.9 million), and in March 2019, we completed a follow-on public offering of ADSs, with net proceeds of \$539.4 million (or €480.3 million).

Based on our current operating plan, we believe that our existing cash and cash equivalents as of September 30, 2019 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:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from our collaboration partners of contractual milestone payments and the timing of receipt of such payments, if any;
- the progress, timing, scope, results and costs of our preclinical studies and clinical trials for our product candidates and manufacturing activities 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 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;
- 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;
- our progress (and the progress of our collaboration partners, if any) 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, preclinical studies and clinical trials for our product candidates for which we retain such responsibility and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

The following table summarizes our cash flows for each of the unaudited nine months periods ended September 30, 2019 and 2018:

	Nine Months Ended	
	September 30,	
	2019	2018
	(EUR'000)	
Cash flows from / (used in) operating activities	(126,700)	(103,240)
Cash flows from / (used in) investing activities	(4,030)	(1,587)
Cash flows from / (used in) financing activities	489,330	202,342
Net increase / (decrease) in cash and cash equivalents	358,600	97,515

Cash Flows From / (Used in) Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2019 was €126.7 million compared to €103.2 million for the nine months ended September 30, 2018. The net loss for the nine months ended September 30, 2019 of €137.7 million included non-cash charges of €30.9 million, comprising share-based payment and depreciation, and non-cash net income, including net financial income and taxes, of €22.2 million. The net change in working capital contributed positively to cash flows by €2.3 million, primarily due to a net increase in trade payables and other payables of €3.7 million, a decrease in receivables and prepayments of €4.4 million, partly offset by a decrease in deferred income of €5.5 million and an increase in deposits of €0.3 million.

Net cash used in operating activities for the nine months ended September 30, 2018 was €103.2 million. The net loss for the nine months ended September 30, 2018 of €98.1 million included non-cash charges of €0.6 million for depreciation and €12.8 million for share-based payment. Net finance income of €20.5 million, primarily comprising exchange rate adjustments, and net tax credits of €0.3 million, were reversed. The net change in working capital contributed negatively to cash flow by €0.4 million, comprising a €7.2 million increase in trade payables and other payables, offset by a €5.5 million increase in prepayments, a €1.2 million increase in trade receivables and other receivables and a €0.9 million increase in deposits. We received net finance income of €3.0 million and paid income taxes of €0.4 million in the nine months ended September 30, 2018.

Cash Flows From / (Used in) Investing Activities

Cash flows used in investing activities for the nine months ended September 30, 2019 of €4.0 million were related to acquisition of property, plant and equipment, primarily equipment for use in the laboratories of our German facility and in our oncology laboratories in the United States.

Cash flows used in investing activities for the nine months ended September 30, 2018 of €1.6 million were related to acquisition of property, plant and equipment, primarily furniture and equipment for use in our new offices in Denmark and in the United States, and equipment for use in the laboratories of our German facility.

Cash Flows From / (Used in) Financing Activities

Cash flows from financing activities for the nine months ended September 30, 2019 of €489.3 million were comprised of €480.3 million in net proceeds from our follow-on public offering of ADSs completed in March 2019 and €12.0 million in net proceeds from warrant exercises in April, June, and September 2019, partly offset by payments on lease liabilities of €3.0 million.

Cash flows from financing activities for the nine months ended September 30, 2018 of €202.3 million were comprised of €196.9 million in net proceeds from our follow-on public offering of ADSs completed in February 2018 and €5.4 million in proceeds from exercise of warrants in April, June and September 2018.

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 primarily 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.

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. Our functional currency is the Euro, but we have received payments in U.S. Dollars under our collaborations. Further, the proceeds from our series D financing in November 2014, our initial public offering in February 2015 and our follow-on public offerings in October 2016, September 2017, February 2018 and March 2019 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 budgeted future expenses and we make payments from those positions.

Interest Rate Risk

As we have no interest-bearing debt to third parties, derivatives or financial assets and liabilities measured at fair value, our exposure to interest rate risk primarily relates to the interest rates for our positions of cash and cash equivalents. Our future interest income from interest-bearing bank deposits and short-term investments may fall short of expectations due to changes in interest rates. We do not consider the effects of interest rate fluctuations to be a material risk to our financial position.

As of January 1, 2019, we have adopted IFRS 16, "Leases", which requires interest expenses to be recognized on lease liabilities over the lease term, applying each contract's incremental borrowing rate. The incremental borrowing rates applied are determined at the lease commencement date and are fixed over the lease term. Accordingly, for leases recognized at September 30, 2019, we are not exposed to changes in interest rates.

We have adopted an investment policy with the primary purpose of preserving capital, fulfilling our liquidity needs and diversifying the risks associated with marketable securities. This 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 that we may hold.

Credit Risk

We consider all of our material counterparties to be creditworthy. While the concentration of credit risk is significant, we consider the credit risk for each of our individual counterparts to be low. Accordingly, since we had no significant trade receivables at September 30, 2019 or December 31, 2018, and our deposits are held with suppliers that are frequently used in our operations, we have made no provision for trade receivables or deposits.

Our exposure to credit risk primarily relates to our cash and cash equivalents. The credit risk is considered limited because the counterparties holding significant deposits are banks with high credit-ratings assigned by international credit-rating agencies. We have considered the expected credit loss on our cash deposits. Our assessment did not reveal any material impairment loss, and accordingly we have made no provision for bank deposits.

Liquidity Risk

We manage our liquidity risk by maintaining adequate cash reserves and banking facilities, and by continuously monitoring our cash forecasts and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.



Ascendis Pharma A/S Reports Third Quarter 2019 Financial Results

- *Continued execution of global endocrinology rare disease programs as planned regulatory filings for TransCon™ hGH in 2020 advance on track* –
- *Expanded PaTH Forward Trial expedites enrollment of subjects previously treated with parathyroid hormone (PTH)* –
- *Conference call today at 4:30 p.m. Eastern Time* –

COPENHAGEN, Denmark, November 18, 2019 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND), a biopharmaceutical company that utilizes its innovative TransCon technologies to address unmet medical needs, today announced financial results for the quarter ended September 30, 2019.

“Our achievements this year reflect our ability to bring a product from idea stage all the way through clinic, as we near the finish line for TransCon hGH and approach our planned regulatory filings in the United States (U.S.) and Europe,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “Our recent progress in the TransCon hGH program, including both in Europe and China, also support our strategy to establish global reach. The power of the TransCon technology is enabling us to build a leading fully integrated patient-focused biopharma company, and advance towards our ‘Vision 3x3’ goals.”

He continued, “One of our driving values at Ascendis is patient focus. In response to the recent recall of NATPARA® in the U.S., we recently expanded our TransCon PTH Phase 2 PaTH Forward Trial with a protocol addendum to help expedite participation of some of those patients affected by the recall. We believe the expanded trial will provide meaningful clinical data to help patients, both naïve to PTH and previously treated with PTH, and further demonstrate the value of our unique approach to product development.”

Corporate Highlights & Progress

- Completed the last subject visit for the long-term clinical database for TransCon hGH, paving the way for the company’s planned Biologics License Application to the U.S. Food and Drug Administration in the first half of 2020 and the Marketing Authorisation Application to the European Medicines Agency in the second half of 2020. TransCon hGH is a long-acting prodrug of human growth hormone (hGH) in phase 3 development as a once-weekly therapy for pediatric growth hormone deficiency (GHD).
- Completed the manufacturing of drug product Process Performance Qualification (PPQ) batches required to support the planned regulatory filings in 2020 for TransCon hGH. The company is now finalizing the associated analytics and preparing qualification reports.
- Advanced the TransCon hGH program in Greater China with VISEN Pharmaceuticals, who initiated a phase 3 trial for TransCon hGH in pediatric GHD.
- Received Orphan Designation from the European Commission for TransCon hGH, which is provided to therapies aimed at treating, preventing or diagnosing 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 therapy is available.

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- Announced a protocol addendum in the U.S. designed to expedite enrollment of subjects previously treated with NATPARA in the TransCon PTH PaTH Forward Trial, a global phase 2 trial evaluating the safety, tolerability and efficacy of TransCon PTH in adult subjects with hypoparathyroidism (HP). TransCon PTH is an investigational long-acting prodrug of PTH in development as a potential once-daily replacement therapy for HP, designed to provide physiologic levels of PTH for 24 hours a day, seven days a week. Under the addendum, patients previously treated with NATPARA in the U.S. will now have an expedited pathway to enroll in PaTH Forward. As a result, the company expects to exceed targeted enrollment of 40 subjects, and plans to report top-line data from the expanded trial in first quarter of 2020. The goal of PaTH Forward is to evaluate TransCon PTH control of serum and urinary calcium, and identify a titration regimen for complete withdrawal of standard of care (i.e., active vitamin D and calcium supplements).
 - Initiated the ACcomplish Trial, a global, phase 2, randomized, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of TransCon CNP, a long-acting prodrug of C-type natriuretic peptide (CNP), at escalating doses in children with achondroplasia (ACH). TransCon CNP is designed to provide continuous exposure to CNP at therapeutic levels with once-weekly dosing.
 - Presented preclinical data for TransCon TLR7/8 Agonist, a product candidate in development for oncology, at the Society of Immunotherapy of Cancer annual meeting. TransCon TLR7/8 Agonist is prodrug of resiquimod, a small molecule with immune-activating and anti-tumor properties that is transiently conjugated to a hydrogel carrier via a TransCon linker. Administered as an intratumoral injection, TransCon TLR7/8 Agonist delivered sustained local release of resiquimod over weeks directly to the tumor site and demonstrated potent anti-tumor activity as a monotherapy, as well as in combination with interleukin-2 (IL-2).
 - Ended the third quarter of 2019 with cash and cash equivalents of €658.7 million.

Third Quarter 2019 Financial Results

For the third quarter, Ascendis Pharma reported a net loss of €25.1 million, or €0.53 per share (basic and diluted) compared to a net loss of €34.0 million, or €0.81 per share (basic and diluted) for the same period in 2018.

Revenue for the third quarter was €2.2 million compared to €20 thousand in the same quarter of 2018. The increase relates to our November 2018 strategic investment in VISEN Pharmaceuticals.

Research and development (R&D) costs for the third quarter were €46.3 million compared to €31.5 million during the same period in 2018. Higher R&D costs in 2019 reflect an increase in personnel-related costs to support development and manufacturing of TransCon hGH, TransCon PTH and TransCon CNP, increasing clinical trial costs for the PaTH Forward Trial and the ACcomplish Trial, as well as increased costs for other research programs, including oncology.

General and administrative expenses for the third quarter were €10.0 million compared to €6.8 million during the same period in 2018. The increase is primarily due to higher personnel-related costs and other increasing costs of expanding the company and preparing to become a commercial organization.

As of September 30, 2019, Ascendis Pharma had cash and cash equivalents of €658.7 million compared to €690.4 million as of June 30, 2019. As of September 30, 2019, Ascendis Pharma had 47,739,647 ordinary shares outstanding.

Conference Call and Webcast information

Ascendis Pharma will host a conference call and webcast today at 4:30 p.m. ET to discuss its third quarter 2019 financial results. Details include:

Date	Monday, November 18, 2019
Time	4:30 p.m. ET
Dial In (U.S.)	844-290-3904
Dial In (International)	574-990-1036
Access Code	5897398

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 also be available on this website shortly after conclusion of the event for 30 days.

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 in clinical development and has established oncology as its second therapeutic area of focus. Additionally, Ascendis Pharma has multi-product collaborations with Sanofi in diabetes and Genentech in the field of ophthalmology and continues to expand into additional therapeutic areas for both internal and external development.

Ascendis is headquartered in Copenhagen, Denmark, with offices in Heidelberg, Germany and Palo Alto, California.

For more information, please visit www.ascendispharma.com.

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 our 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) our plans to submit a BLA with the FDA in the first half of 2020 and a MAA with the EMA in the second half of 2020 for TransCon hGH, (ii) the plans to initiate a phase 3 trial for TransCon hGH in pediatric GHD in Greater China in collaboration with Visen Pharmaceuticals, (iv) our ability to apply our TransCon platform to build a leading, fully integrated biopharma company, (v) our expectations regarding our ability to create new and potentially best-in-class therapies and (vi) our product pipeline. We 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 we make, including the following: unforeseen safety or efficacy results in our TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to the development and potential commercialization of TransCon hGH, TransCon PTH and TransCon CNP or other development programs, general and administrative expenses, other research and development expenses and our business generally; delays in the development of TransCon hGH, 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; and our ability to obtain additional funding, if needed, to support our business activities. 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 our business in general, see our current and future reports filed with, or submitted to, the U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F for the year ended December 31, 2018, which we filed with the SEC on April 3, 2019. Forward-looking statements do not reflect the potential impact of any future in-licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments we may enter into or make. We do not assume any obligation to update any forward-looking statements, except as required by law.

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FINANCIAL TABLES FOLLOW

Ascendis Pharma A/S

Unaudited Condensed Consolidated Interim Statements of Profit or Loss and Other Comprehensive Income / (loss)

(In EUR'000s, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	2,243	20	10,868	66
Research and development costs	(46,258)	(31,511)	(141,343)	(102,286)
General and administrative expenses	(10,000)	(6,796)	(31,396)	(16,684)
Operating profit / (loss)	(54,015)	(38,287)	(161,871)	(118,904)
Share of profit / (loss) of associate	(1,338)	—	(5,452)	—
Finance income	30,547	4,262	30,285	20,532
Finance expenses	(368)	(42)	(812)	(53)
Profit / (loss) before tax	(25,174)	(34,067)	(137,850)	(98,425)
Tax on profit / (loss) for the period	61	100	196	306
Net profit / (loss) for the period	(25,113)	(33,967)	(137,654)	(98,119)
Other comprehensive income / (loss)				
<i>Items that may be reclassified subsequently to profit or loss:</i>				
Exchange differences on translating foreign operations	37	(9)	2	(16)
Other comprehensive income / (loss) for the period, net of tax	37	(9)	2	(16)
Total comprehensive income / (loss) for the period, net of tax	(25,076)	(33,976)	(137,652)	(98,135)
Profit / (loss) for the period attributable to owners of the Company	(25,113)	(33,967)	(137,654)	(98,119)
Total comprehensive income / (loss) for the period attributable to owners of the Company	(25,076)	(33,976)	(137,652)	(98,135)
	EUR	EUR	EUR	EUR
Basic and diluted earnings / (loss) per share	(0.53)	(0.81)	(2.99)	(2.41)
Number of shares used for calculation (basic and diluted)	47,590,837	41,888,908	46,066,493	40,757,686

Ascendis Pharma A/S

Unaudited Condensed Consolidated Interim Statements of Financial Position

(In EUR'000s)

	September 30, 2019	December 31, 2018
Assets		
Non-current assets		
Intangible assets	3,495	3,495
Property, plant and equipment	43,272	4,325
Investment in associate	17,073	17,083
Deposits	1,469	1,158
	65,309	26,061
Current assets		
Trade receivables	—	6
Other receivables	1,755	1,775
Prepayments	7,937	12,415
Income taxes receivable	1,298	849
Cash and cash equivalents	658,660	277,862
	669,650	292,907
Total assets	734,959	318,968
Equity and liabilities		
Equity		
Share capital	6,410	5,659
Distributable equity	654,515	274,391
Total equity	660,925	280,050
Non-current liabilities		
Lease liabilities	31,503	—
	31,503	—
Current liabilities		
Lease liabilities	5,424	—
Contract liabilities	1,373	6,902
Trade payables	24,346	19,740
Other payables	11,364	12,267
Income taxes payable	24	9
	42,531	38,918
Total liabilities	74,034	38,918
Total equity and liabilities	734,959	318,968

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