Ascendis Pharma A/S Reports Second Quarter 2019 Financial Results

August 28, 2019

– TransCon hGH moves towards Biologics License Application submission following completion of heiGHt and fliGHt Trials –

– Global reach of endocrinology rare disease programs expands –

– Conference call today at 4:30 p.m. Eastern Time–

COPENHAGEN, Denmark, Aug. 28, 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 June 30, 2019.

“The achievements across our three rare disease endocrinology product candidates during the first half of 2019 show we are on track to fulfill our ’Vision 3x3’ to become a leading biopharma company,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “Based on the integrated, holistic view of our data, we expect TransCon hGH to raise the bar in the treatment of growth hormone deficiency, and we are getting even more confident that we will also set a new standard with TransCon PTH and TransCon CNP.”

Corporate Highlights & Progress

- On track for a planned Biologics License Application (BLA) in the first half of 2020 and a marketing application (MAA) in Europe in the second half of 2020 for TransCon hGH, a long-acting prodrug of human growth hormone (hGH) in development as a once-weekly therapy for pediatric growth hormone deficiency (GHD). Results from the phase 3 program demonstrated statistically significantly greater efficacy (heiGHt Trial) and comparable safety and tolerability to a daily hGH (heiGHt Trial and fliGHt Trial). Additionally, Ascendis is working in collaboration with VISEN Pharmaceuticals to initiate a phase 3 trial later this year in subjects with pediatric GHD in China, and plans to initiate a global program for adult GHD in 2020.
- Introduced the TransCon hGH Auto-Injector and dual-chamber cartridge (DCC) combination product as planned into the enliGHten Trial, a long-term extension trial for TransCon hGH. Data from the enliGHten Trial, including long-term safety data, will support the planned BLA and planned MAA for TransCon hGH.
- Ongoing enrollment in the PaTH Forward Trial, a global, phase 2 trial designed to evaluate the safety and efficacy of TransCon PTH in adult subjects with hypoparathyroidism. TransCon PTH is a long-acting prodrug of parathyroid hormone (PTH) in development for the treatment of adult hypoparathyroidism. TransCon PTH has been designed to provide physiologic levels of PTH for 24 hours a day, seven days a week.
- Completed filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for initiation of the ACcomplisH Trial, a global, phase 2, randomized, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of TransCon CNP at escalating doses in children with achondroplasia (ACH). TransCon CNP is a long-acting prodrug of C-type natriuretic peptide (CNP) that has been designed to provide continuous exposure to CNP at therapeutic levels with once-weekly dosing. All subjects who complete the ACcomplisH Trial will have the opportunity to receive TransCon CNP in a long-term safety extension trial.
- Introduced the company’s oncology vision and programs.
- Ended the second quarter of 2019 with cash and cash equivalents of €690.4 million.

Second Quarter 2019 Financial Results

For the second quarter, Ascendis Pharma reported a net loss of €58.9 million, or €1.25 per share (basic and diluted) compared to a net loss of €22.8 million, or €0.55 per share (basic and diluted) for the same period in 2018.

Revenue for the second quarter was €3.2 million compared to €18 thousand in the same quarter of 2018. The increase reflects recognition of revenue related to our strategic investment in VISEN Pharmaceuticals.

Research and development (R&D) costs for the second quarter were €43.8 million compared to €40.2 million during the same period in 2018. Higher R&D costs in 2019 primarily reflect an increase in personnel-related costs to support development and manufacturing of TransCon hGH, TransCon PTH and TransCon CNP, as well as increased costs for other research programs, partly offset by a decrease in costs associated with TransCon hGH due to completion of the phase 3 heiGHt Trial.

General and administrative expenses for the second quarter were €11.0 million compared to €5.2 million during the same period in 2018. The increase is primarily due to higher personnel-related costs and other increasing costs of preparing to become a commercial organization.

As of June 30, 2019, Ascendis had cash and cash equivalents of €690.4 million compared to €696.7 million as of March 31, 2019. As of June 30, 2019, Ascendis Pharma had 47,545,204 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 second quarter 2019 financial results. Details include:

Date	Wednesday, August 28, 2019
Time	4:30 p.m. ET
Dial In (U.S.)	844-290-3904
Dial In (International)	574-990-1036
Access Code	4793306

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 in Europe in the second half of 2020 for TransCon hGH, (ii) our plans to initiate a phase 3 trial of TransCon hGH in subjects with pediatric GHD in China in collaboration with Visen Pharmaceuticals later this year, and a global TransCon hGH program for adult GHD in 2020; (iii) our phase 2 ACcomplisH Trial of TransCon CNP in children with achondroplasia, (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.

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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue	3,211	18	8,625	46
Research and development costs	(43,826)	(40,235)	(95,085)	(70,775)

General and administrative expenses	(10,960)	(5,226)	(21,396)	(9,888)
Operating profit / (loss)	**(51,575)**	**(45,443)**	**(107,856)**	**(80,617)**
Share of profit / (loss) of associate	(2,262)	-	(4,114)	-
Finance income	3,362	22,573	4,917	16,270
Finance expenses	(8,494)	(6)	(5,623)	(11)
Profit / (loss) before tax	**(58,969)**	**(22,876)**	**(112,676)**	**(64,358)**
Tax on profit / (loss) for the period	65	99	135	206
Net profit / (loss) for the period	**(58,904)**	**(22,777)**	**(112,541)**	**(64,152)**
Other comprehensive income / (loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations	(594)	2	(35)	(7)
Other comprehensive income / (loss) for the period, net of tax	**(594)**	**2**	**(35)**	**(7)**
Total comprehensive income / (loss) for the period, net of tax	**(59,498)**	**(22,775)**	**(112,576)**	**(64,159)**
Profit / (loss) for the period attributable to owners of the Company	(58,904)	(22,777)	(112,541)	(64,152)
Total comprehensive income / (loss) for the period attributable to owners of the Company	(59,498)	(22,775)	(112,576)	(64,159)
	EUR	**EUR**	**EUR**	**EUR**
Basic and diluted earnings / (loss) per share	(1.25)	(0.55)	(2.48)	(1.60)
Number of shares used for calculation (basic and diluted)	47,190,717	41,650,907	45,291,688	40,182,701

Ascendis Pharma A/S
Unaudited Condensed Consolidated Interim Statements of Financial Position
(In EUR'000s)

	June 30, 2019	**December 31, 2018**
Assets		
Non-current assets		
Intangible assets	3,495	3,495
Property, plant and equipment	42,537	4,325
Investment in associate	16,885	17,083
Deposits	1,410	1,158
	64,327	**26,061**
Current assets		
Trade receivables	-	6
Other receivables	1,451	1,775
Prepayments	9,891	12,415
Income taxes receivable	1,133	849
Cash and cash equivalents	690,355	277,862
	702,830	**292,907**
Total assets	**767,157**	**318,968**
Equity and liabilities		
Equity		
Share capital	6,384	5,659
Distributable equity	668,691	274,391
Total equity	**675,075**	**280,050**
Non-current liabilities		
Lease liabilities	31,461	-
	31,461	-

Current liabilities		
Lease liabilities	4,841	-
Contract liabilities	2,156	6,902
Trade payables	21,235	19,740
Other payables	32,337	12,267
Income taxes payable	52	9
	60,621	**38,918**
Total liabilities	**92,082**	**38,918**
Total equity and liabilities	**767,157**	**318,968**

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