Ascendis Pharma A/S Reports First Quarter 2016 Financial Results

May 19, 2016

COPENHAGEN, May 19, 2016 /PRNewswire/ -- Ascendis Pharma A/S (Nasdaq: ASND), a clinical stage biopharmaceutical company that applies its innovative TransCon technology to address significant unmet medical needs, today announced financial results for the three months ended March 31, 2016.

"The execution of our TransCon Growth Hormone clinical development plan remains on track and we look forward to the initiation of our global pediatric Phase 3 heiGHt trial, expected in mid-2016," commented Jan Mikkelsen, President and Chief Executive Officer of Ascendis. "The positive poster and oral presentations of our TransCon Growth Hormone Phase 2 pediatric trial data at the recent ENDO and PES 2016 conferences confirmed that our once-weekly, sustained-release delivery of native growth hormone represents a differentiated approach with a potential best-in-class profile among long-acting growth hormone therapies."

Mr. Mikkelsen continued, "We believe the success of our growth hormone program establishes the TransCon technology platform as a powerful drug development engine. We continue to apply our TransCon technology to the creation of product candidates to address significant unmet medical needs in other rare disease indications."

First Quarter 2016 Consolidated Financial Results

Total revenue for the three months ended March 31, 2016 was €1.3 million, a decrease of €0.8 million, or 40%, compared to total revenue of €2.1 million for the three months ended March 31, 2015. This change was driven by a decrease of €0.6 million in revenue from our collaboration with Genentech, primarily caused by an extension of the period over which the license income will be recognized, and a decrease of €0.2 million in revenue from our collaboration with Sanofi due to fewer services rendered by us.

Research and development costs increased to €16.2 million for the three months ended March 31, 2016 from €7.3 million for the three months ended March 31, 2015. The increase of €8.9 million, or 121%, is primarily attributable to an increase of €7.1 million in external costs associated with our TransCon hGH manufacturing costs and preparation for our Phase 3 study, and continued development of our pen device. External costs related to our TransCon Treprostinil project decreased by €0.7 million following completion of the Phase 1 study in April 2015, and costs for other projects increased by €0.1 million. Other research and development costs increased by approximately €2.4 million, primarily driven by an increase in personnel costs of €2.1 million due to an increase in the number of employees in research and development functions.

General and administrative expenses were €2.9 million for the three months ended March 31, 2016, an increase of €0.5 million, or 21%, compared to general and administrative expenses of €2.4 million for the three months ended March 31, 2015. The increase is primarily due to an increase in personnel costs of €0.9 million for additional administrative personnel to respond to the increasing requirements of operating as a publicly traded company, partly offset by a decrease in professional fees of €0.4 million.

Net finance expenses for the three months ended March 31, 2016 were €2.7 million compared to net finance income of €9.1 million for the three months ended March 31, 2015. During the three months ended March 31, 2016, the US Dollar and the British Pound weakened against the Euro, and we recognized an unrealized exchange rate loss of €2.8 million on our cash positions maintained in US Dollars and British Pounds.

Net loss for the three months ended March 31, 2016 was €20.5 million, or €0.82 per share (basic and diluted), compared to a net profit of €1.4 million, or €0.07 per share (basic) and €0.06 per share (diluted), for the three months ended March 31, 2015. As of March 31, 2016, there were 25,128,242 ordinary shares outstanding and 2,790,859 ordinary shares underlying outstanding warrants. As of March 31, 2016, the weighted average exercise price of all outstanding warrants was approximately €11.05.

As of March 31, 2016, we had cash and cash equivalents totaling €101.9 million compared to €119.6 million as of December 31, 2015.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative TransCon technology to develop an internal pipeline of therapeutics to address unmet medical needs in rare disease indications carrying billion-dollar potential. The Ascendis Pharma internal pipeline consists of existing parent drugs with known pharmacology, and features TransCon Growth Hormone, a wholly-owned program that has completed Phase 2 studies in adults and children with growth hormone deficiency. TransCon Growth Hormone is expected to begin its global Phase 3 heiGHt trial in mid-2016.

Additionally, Ascendis Pharma has formed collaborations with Sanofi in diabetes and Genentech in the field of ophthalmology, which are focused on developing leading products in large markets of strategic importance to these partners.

The TransCon technology combines the benefits of prodrug and sustained-release technologies, and is the key driver of Ascendis Pharma's mission to develop a pipeline of therapeutics with best-in-class profiles. The TransCon technology can be applied to a broad range of drug therapies, including proteins, peptides and small molecules, to create prodrugs that provide for the predictable and sustained-release of an unmodified parent drug.

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 product pipeline, including our plans to initiate our global

Phase 3 heiGHt trial in GHD children in mid-2016 and (ii) the application of our TransCon technology to the creation of product candidates to address significant unmet medical needs in other rare disease indications. 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 lead development program TransCon Growth Hormone or other development programs; unforeseen expenses related to the development of TransCon Growth Hormone or other development programs, general and administrative expenses, other research and development expenses and our business generally; delays in the development of TransCon Growth Hormone 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, 2015 and our Report on Form 6-K which we expect to submit to the SEC in May 2016. 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
(In EUR'000s, except share and per share data)

	Three Months ended March 31,	
	2016	**2015**
Revenue	1,258	2,081
Research and development costs	(16,242)	(7,334)
General and administrative expenses	(2,908)	(2,405)
Operating profit / (loss)	**(17,892)**	**(7,658)**
Finance income	20	9,135
Finance expenses	(2,764)	(9)
Profit / (loss) before tax	**(20,636)**	**1,468**
Tax on profit / (loss) for the year	118	(46)
Net profit / (loss) for the year	**(20,518)**	**1,422**
Other comprehensive income / (loss)		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	21	(18)
Other comprehensive income / (loss) for the period, net of tax	**21**	**(18)**
Total comprehensive income / (loss) for the period, net of tax	**(20,497)**	**1,404**
Profit / (loss) for the period attributable to owners of the Company	(20,518)	1,422
Total comprehensive income / (loss) for the period attributable to owners of the Company	(20,497)	1,404
Basic earnings / (loss) per share	**(0.82)**	**0.07**
Diluted earnings / (loss) per share	**(0.82)**	**0.06**
Number of shares used for calculation (basic)	25,128,242	21,382,447
Number of shares used for calculation (diluted)	25,128,242	24,382,271

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

	March 31, 2016	December 31, 2015
Assets		
Non-current assets		
Intangible assets	3,495	3,495
Property, plant and equipment	2,331	2,355
Deposits	297	270
	6,123	**6,120**

Current assets		
Trade receivables	888	1,064
Other receivables	690	338
Prepayments	2,132	3,819
Income taxes receivable	981	784
Cash and cash equivalents	101,865	119,649
	106,556	**125,654**
Total assets	**112,679**	**131,774**
Equity and liabilities		
Equity		
Share capital	3,374	3,374
Other reserves	7,779	5,678
Retained earnings	90,759	111,277
Total equity	**101,912**	**120,329**
Current liabilities		
Trade payables and other payables	8,337	8,373
Deferred income	2,327	3,072
Income taxes payable	103	-
	10,767	**11,445**
Total liabilities	**10,767**	**11,445**
Total equity and liabilities	**112,679**	**131,774**

Investor contact:
Martin Auster, M.D.
Chief Business Officer
(650) 352-8389
ir@ascendispharma.com

Logo - http://photos.prnewswire.com/prnh/20150824/260617LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/ascendis-pharma-as-reports-first-quarter-2016-financial-results-300271881.html

SOURCE Ascendis Pharma A/S