Ascendis Pharma A/S Reports Full Year 2015 Financial Results

April 14, 2016

COPENHAGEN, Denmark, April 14, 2016 /PRNewswire/ -- Ascendis Pharma A/S (Nasdaq: ASND), a clinical stage biotechnology company that applies its innovative TransCon technology to address significant unmet medical needs, today announced financial results for the twelve months ended December 31, 2015.

"2015 was a transformative year for Ascendis highlighted by our positive results from our TransCon Growth Hormone Phase 2 pediatric study last July," commented Jan Mikkelsen, President and Chief Executive Officer of Ascendis.

Mr. Mikkelsen continued, "TransCon Growth Hormone is the only long-acting growth hormone in development that has been shown to provide sustained-release of native growth hormone into the bloodstream at the same peak and total exposure levels as approved daily growth hormone, differentiating its mode-of-action from other long-acting growth hormone programs in development. Preparations remain on track to support the initiation of our TransCon Growth Hormone pivotal Phase 3 heiGHt pediatric trial, which we expect to begin in mid-2016."

2015 and Recent Highlights

- Reported positive top-line results in July 2015 in a Phase 2 study of TransCon Growth Hormone in pediatric growth-hormone deficient (GHD) patients
- Presented positive final Phase 2 pediatric GHD data at the 54th Annual Meeting of the European Society for Paediatric Endocrinology (ESPE) in October 2015
- An oral presentation and two poster abstracts on TransCon Growth Hormone were presented at the Endocrine Society's 98th Annual Meeting & Expo (ENDO 2016) held in April 2016
- Completed successful IPO in February 2015, with $111.5 million in net proceeds raised
- Several key additions made to Ascendis' executive management team in 2015 and early 2016
    - Jonathan A. Leff, M.D. joined as Senior Vice President and CMO
    - Kennett Sprogøe, Ph.D. promoted to Senior Vice President, Product Innovation
    - Flemming Steen Jensen joined as Senior Vice President, Product Supply

Full Year 2015 Consolidated Financial Results

Revenue for the year ended December 31, 2015 was €8.1 million, a decrease of €5.9 million, or 42%, compared to €14.0 million for the year ended December 31, 2014. This change was primarily driven by a decrease of €3.2 million in revenue from our collaboration with United Therapeutics as a result of the collaboration ending at June 30, 2014. Revenue from our collaboration with Sanofi decreased by €2.5 million due to fewer services rendered by us under our collaboration, whereas revenue from our collaboration with Genentech decreased by €0.2 million compared to the same period in 2014.

Research and development costs were €40.5 million for the year ended December 31, 2015, an increase of €20.8 million, or 106%, compared to €19.7 million for the year ended December 31, 2014. This change was primarily attributable to an increase of €16.6 million in external costs associated with our Phase 2 TransCon hGH pediatric study, manufacturing costs and preparation for our Phase 3 study, and continued development of our pen device. External costs associated with our other proprietary product candidates increased by €1.7 million, primarily related to our TransCon Treprostinil project, which we assumed after termination of our collaboration with United Therapeutics in 2014. Personnel costs increased by €1.2 million and recruiting costs increased by €0.7 million due to an increase in the number of employees in research and development functions. General costs such as rent and facility costs, supplies, and consultancy services allocated to research and development increased by €0.6 million. Research and development costs included non-cash share-based payment of €0.7 million for the year ended December 31, 2015 and €0.3 million for the year ended December 31, 2014.

General and administrative expenses were €9.4 million for the year ended December 31, 2015, an increase of €3.1 million, or 50%, compared to €6.3 million for the year ended December 31, 2014. Our overhead expenses are allocated to general and administrative and research and development functions based on the proportion of general and administrative to research and development employees. This increase is primarily due to an increase in personnel costs of €1.9 million for additional administrative personnel and more resources being allocated to general and administrative functions, and increases in other costs such as investor relation activities, facility costs, traveling and insurance totaling €1.2 million reflecting the growth of the organization and the increasing requirements of operating as a publicly traded company. General and administrative expenses included non-cash share-based payment of €1.0 million for the year ended December 31, 2015 and €0.9 million for the year ended December 31, 2014.

Net finance income increased by €6.7 million to €8.3 million for the year ended December 31, 2015 compared to €1.6 million for the year ended December 31, 2014. The significant increase in net finance income was due to positive exchange rate fluctuations, primarily between the U.S. dollars and Euro. We maintained the funds from our series D financing in November 2014 and IPO in February 2015 in U.S. dollars for a portion of the first quarter of 2015, generating a significant exchange rate gain. At the end of March 2015, we converted approximately $90 million to Euros and British Pounds, thereby realizing a significant exchange rate gain and reducing our exposure to exchange rate fluctuations, as these cash positions more closely reflect the currencies in which we expect to incur the majority of our future expenses. We attempt to limit our exposure to exchange rate risks by maintaining cash positions in the currencies in which we expect to incur the majority of our future expenses.

Net loss for the year ended December 31, 2015 was €32.9 million, or €1.39 per share (basic and diluted), compared to a net loss of €9.7 million, or €0.85 per share (basic and diluted) for the year ended December 31, 2014. The weighted average number of shares used to calculate basic and diluted net loss per share was 23,766,783 for the year ended December 31, 2015. The weighted average number of shares used to calculate basic and diluted loss per share was 11,406,929 for the year ended December 31, 2014. As of December 31, 2015, there were 25,128,242 ordinary shares outstanding and 2,615,903 ordinary shares underlying outstanding warrants. As of December 31, 2015, the weighted average exercise price of all outstanding warrants was approximately €10.69.

As of December 31, 2015, we had cash and cash equivalents totaling €119.6 million compared to €50.2 million as of December 31, 2014.

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 our product pipeline, including our plans to initiate our global Phase 3 heiGHt trial in GHD children in mid-2016. 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, which we expect to file with the SEC in April 2016 and our Report on Form 6-K which we submitted with the SEC on November 16, 2015. 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
Consolidated Statements of Profit or Loss and Other Comprehensive Income
(In EUR'000s, except share and per share data)

	Year ended December 31,	
	2015	**2014**
Revenue	8,118	13,983
Research and development costs	(40,528)	(19,698)
General and administrative expenses	(9,415)	(6,274)
Operating profit / (loss)	**(41,825)**	**(11,989)**
Finance income	11,048	1,877
Finance expenses	(2,797)	(228)
Profit / (loss) before tax	**(33,574)**	**(10,340)**
Tax on profit / (loss) for the year	652	682
Net profit / (loss) for the year	**(32,922)**	**(9,658)**
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	(14)	(14)
Other comprehensive income / (loss) for the year, net of tax	**(14)**	**(14)**
Total comprehensive income / (loss) for the year, net of tax	**(32,936)**	**(9,672)**

Profit / (loss) for the year attributable to owners of the Company	(32,922)	(9,658)
Total comprehensive income / (loss) for the year attributable to owners of the Company	(32,936)	(9,672)
Basic earnings / (loss) per share	**(1.39)**	**(0.85)**
Diluted earnings / (loss) per share	**(1.39)**	**(0.85)**
Number of shares used for calculation (basic)	23,766,783	11,406,929
Number of shares used for calculation (diluted)	23,766,783	11,406,929

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

	December 31,	
	2015	**2014**
Assets		
Non-current assets		
Intangible assets	3,495	3,495
Property, plant and equipment	2,355	1,874
Deposits	270	140
	6,120	**5,509**
Current assets		
Trade receivables	1,064	1,292
Other receivables	338	210
Prepayments	3,819	620
Income taxes receivable	784	873
Cash and cash equivalents	119,649	50,167
	125,654	**53,162**
Total assets	**131,774**	**58,671**
Equity and liabilities		
Equity		
Share capital	3,374	2,272
Other reserves	5,678	3,979
Retained earnings / (accumulated deficit)	111,277	39,559
Total equity	**120,329**	**45,810**
Current liabilities		
Trade payables and other payables	8,373	4,956
Deferred income	3,072	7,905
	11,445	**12,861**
Total liabilities	**11,445**	**12,861**
Total equity and liabilities	**131,774**	**58,671**

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