Ascendis Pharma A/S Reports Third Quarter 2015 Financial Results

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COPENHAGEN, Denmark, Nov. 12, 2015 /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 three and nine months ended September 30, 2015.

Ascendis Pharma reported a cash balance of €128.2 million at September 30, 2015.

"Our recent Phase 2 pediatric study presentation at the 54th Annual Meeting of the European Society of Pediatric Endocrinology confirmed once-weekly TransCon Growth Hormone's attractive profile to a large, international clinically-focused audience," stated Jan Mikkelsen, President and Chief Executive Officer of Ascendis Pharma. "Our solution remains unique among long-acting growth hormone programs in development as it releases unmodified growth hormone into the blood stream, preserving the same mode-of-action as gold standard daily growth hormone therapy. We continue to plan to initiate a Pivotal Phase 3 trial in pediatric growth hormone deficient patients in mid-2016."

Mr. Mikkelsen continued, "In addition to our TransCon Growth Hormone program, we continue to build our early-stage, internally-developed pipeline of differentiated TransCon product candidates addressing significant unmet medical needs."

Three months ended September 30, 2015 financial results

Total revenue for the three months ended September 30, 2015 was €2.1 million, a decrease of €1.2 million, or 35%, compared to total revenue of €3.3 million for the three months ended September 30, 2014. This change was primarily driven by a decrease of €1.1 million in revenue from our collaboration with Sanofi and a decrease of €0.1 million from our collaboration with Genentech.

Research and development costs were €8.0 million for the three months ended September 30, 2015, an increase of €4.1 million, or 104%, compared to research and development costs of €3.9 million for the three months ended September 30, 2014. The increase is primarily attributable to a €3.2 million increase in external costs related to our TransCon hGH project. Costs related to basic research in support of new and existing development programs increased by €0.4 million, and other research and development expenses increased by €0.5 million, primarily driven by an increasing number of employees in our research and development functions. Research and development costs included non-cash share-based payment expenses of €0.1 million for the three months ended September 30, 2015 which was in line with the €0.1 million for the three months ended September 30, 2014.

General and administrative expenses were €1.4 million for the three months ended September 30, 2015, a decrease of €0.2 million, or 10%, compared to general and administrative expenses of €1.6 million for the three months ended September 30, 2014. The decrease is primarily due to a decrease in professional fees of €0.2 million and a decrease in share-based compensation expenses of €0.3 million, partially offset by an increase in other general and administrative expenses by a net amount of €0.3 million. General and administrative expenses included a net credit to non-cash share-based payment expenses of €9 thousand for the three months ended September 30, 2015, compared to a net expense of €0.3 million for the three months ended September 30, 2014. The non-cash share based payment expenses for the three months ended September 30, 2015 were eliminated by the impact of forfeited warrants previously recognized.

Net loss for the three months ended September 30, 2015 was €7.3 million, or €0.30 per share (basic and diluted), compared to a net loss of €2.0 million, or €0.18 per share (basic and diluted), for the three months ended September 30, 2014. The weighted average number of shares used to calculate basic and diluted net loss per share was 24,536,580 and 10,801,948, respectively, for the three months ended September 30, 2015 and 2014. As of September 30, 2015, there were 25,128,242 ordinary shares and 1,596,795 warrants outstanding. Each warrant entitles a warrant holder to subscribe for one ordinary share. As of September 30, 2015, the weighted average exercise price of all outstanding warrants was approximately €7.48.

Nine months ended September 30, 2015 financial results

Total revenue for the nine months ended September 30, 2015 was €6.1 million, a decrease of €5.1 million, or 45%, compared to total revenue of €11.2 million for the nine months ended September 30, 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 period ending at June 30, 2014. Revenue from our collaboration with Sanofi decreased by €1.8 million whereas revenue from our collaboration with Genentech decreased by €0.1 million compared to the same period in 2014.

Research and development costs were €28.0 million for the nine months ended September 30, 2015, an increase of €15.8 million, or 130%, compared to research and development costs of €12.2 million for the nine months ended September 30, 2014. This increase is primarily attributable to a €13.1 million increase in external costs related to our TransCon hGH project for which we reported positive top-line results for our Phase 2 pediatric study in July 2015, and a €1.5 million increase in external costs related to our TransCon Treprostinil project, which we assumed after the termination of our collaboration with United Therapeutics in 2014. Costs related to basic research in support of new and existing development programs increased by €0.9 million, and other research and development expenses increased by €0.3 million, primarily driven by an increasing number of employees in our research and development functions. Research and development costs included non-cash share-based payment expenses of €0.5 million for the nine months ended September 30, 2015 and €0.2 million for the nine months ended September 30, 2014.

General and administrative expenses were €5.9 million for the nine months ended September 30, 2015, an increase of €2.0 million, or 52%, compared to general and administrative expenses of €3.9 million for the nine months ended September 30, 2014. The increase is primarily due to an increase in

administrative personnel costs of €0.9 million in support of our IPO in February 2015 and as part of operating as a publicly listed company. Despite a decrease in professional fees of €0.3 million, other general and administrative expenses increased by a net amount of €1.1 million, primarily due to additional costs of operating as a publicly listed company, including listing fees and expenses for investor relations activities. General and administrative expenses included non-cash share-based payment expenses of €0.6 million for the nine months ended September 30, 2015, and €0.6 million for the nine months ended September 30, 2014.

Net loss for the nine months ended September 30, 2015 was €20.9 million, or €0.90 per share (basic and diluted), compared to a net loss of €4.6 million, or €0.43 per share (basic and diluted), for the nine months ended September 30, 2014. The weighted average number of shares used to calculate basic and diluted net loss per share was 23,307,976 and 10,801,948, respectively, for the nine months ended September 30, 2015 and the nine months ended September 30, 2014. As of September 30, 2015, there were 25,128,242 ordinary shares and 1,596,795 warrants outstanding. Each warrant entitles a warrant holder to subscribe for one ordinary share. As of September 30, 2015, the weighted average exercise price of all outstanding warrants was approximately €7.48.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative TransCon technology, which combines the benefits of prodrug and sustained release technologies, to develop a pipeline of therapeutics with best-in-class profiles that address significant unmet medical needs. The TransCon technology can be applied to existing drug therapies, including proteins, peptides and small molecules, to create prodrugs that provide for the predictable and sustained release of an unmodified parent drug.

The Ascendis Pharma pipeline includes TransCon Growth Hormone, a proprietary program that has completed Phase 2 studies in adults and children with growth hormone deficiency. Ascendis Pharma expects to initiate a Phase 3 pediatric study of TransCon Growth Hormone in mid-2016. Ascendis Pharma is also developing its wholly-owned TransCon Treprostinil for the treatment of pulmonary arterial hypertension. In addition to its proprietary programs, Ascendis Pharma has formed collaborations focused on leading products in large markets that are of strategic importance to its collaboration partners. These collaborations are with Sanofi in diabetes and Genentech in the field of ophthalmology.

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 strategy, future operations, future financial position, future revenues, projected expenses, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to our plans to initiate a Pivotal Phase 3 pediatric study of TransCon Growth Hormone 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, TransCon Treprostinil or other development programs; unforeseen expenses related to the development of TransCon Growth Hormone, TransCon Treprostinil 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 ongoing and 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, including our Annual Report on Form 20-F for the year ended December 31, 2014 and our Report on Form 6-K which we expect to be submitted 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
Unaudited Condensed Consolidated Interim Statements of Profit or Loss and Other Comprehensive Income
(in Euro '000s, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenue	2,117	3,250	6,141	11,157
Research and development costs	(8,038)	(3,932)	(28,013)	(12,177)
General and administrative expenses	(1,396)	(1,556)	(5,945)	(3,908)
Operating profit / (loss)	**(7,317)**	**(2,238)**	**(27,817)**	**(4,928)**
Finance income	126	344	9,266	493
Finance expenses	(279)	(37)	(2,774)	(102)
Profit / (loss) before tax	**(7,470)**	**(1,931)**	**(21,325)**	**(4,537)**
Tax on profit / (loss) for the period	160	(49)	398	(83)
Net profit / (loss) for the period	**(7,310)**	**(1,980)**	**(20,927)**	**(4,620)**
Other comprehensive income				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations	5	5	(13)	3

Other comprehensive income / (loss) for the period, net of tax	**5**	**5**	**(13)**	**3**
Total comprehensive income / (loss) for the period, net of tax	**(7,305)**	**(1,975)**	**(20,940)**	**(4,617)**
Profit / (loss) for the period attributable to owners of the Company	(7,310)	(1,980)	(20,927)	(4,620)
Total comprehensive income / (loss) for the period attributable to owners of the Company	(7,305)	(1,975)	(20,940)	(4,617)
Basic earnings per share	(0.30)	(0.18)	(0.90)	(0.43)
Diluted earnings per share	(0.30)	(0.18)	(0.90)	(0.43)

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

	Consolidated	
	September 30, 2015	**December 31, 2014**
Assets		
Non-current assets		
Intangible assets	3,495	3,495
Property, plant and equipment	2,145	1,874
Deposits	265	140
	5,905	**5,509**
Current assets		
Trade receivables	737	1,292
Other receivables	1,480	210
Prepayments	3,386	620
Income taxes receivable	1,508	873
Cash and cash equivalents	128,247	50,167
	135,358	**53,162**
Total assets	**141,263**	**58,671**
Equity and liabilities		
Equity		
Share capital	3,374	2,272
Other reserves	5,069	3,979
Retained earnings	123,273	39,559
Total equity	**131,716**	**45,810**
Current liabilities		
Trade payables and other payables	5,387	4,956
Deferred income	4,160	7,905
	9,547	**12,861**
Total liabilities	**9,547**	**12,861**
Total equity and liabilities	**141,263**	**58,671**

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