



Ascendis Pharma A/S Reports Third Quarter 2021 Financial Results

November 10, 2021

- SKYTROFA® (lonapegsomatropin-tcgd) approved by the FDA in the U.S. as a once-weekly treatment for pediatric growth hormone deficiency (GHD); commercially launched in October 2021.
- Completed enrollment in Phase 3 PaTHway Trial of TransCon™PTH. Topline results expected Q1 2022 and 84-week topline results from Phase 2 PaTH Forward Trial expected later this quarter.
- Company to hold a virtual R&D update on TransCon PTH, TransCon CNP, and TransCon TLR7/8 Agonist in mid-December to review continued pipeline progress.
- Strengthened balance sheet with a successful public offering of American Depositary Shares raising net proceeds of approximately \$436 million.

COPENHAGEN, Denmark, Nov. 10, 2021 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND), today announced financial results for the third quarter ended September 30, 2021.

“We are at a defining moment on our way to fulfilling Vision 3x3, our strategy to build a leading global biopharma company. In late August, we received U.S. FDA approval for TransCon hGH, and in mid-October we launched in the U.S.,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “We believe this first FDA-approval for a TransCon product validates our technology platform, product innovation algorithm, and product development capabilities. Our robust, diverse pipeline, which today includes five unique clinical stage product candidates across endocrinology rare diseases and oncology, demonstrates our passion for following the science to address important unmet patient needs.”

Company Highlights & Progress

- TransCon hGH
 - Now commercially available in the U.S. for the treatment of pediatric GHD. Sales in the U.S. will be reported under the brand name.
 - In Europe, final decision anticipated from the European Commission on our Marketing Authorisation Application, for TransCon hGH in pediatric GHD by the end of 2021 or early 2022.
 - Enrollment continues in our foresiGHt Trial, a global Phase 3 trial in adult GHD and in the riGHt Trial, a Phase 3 trial in Japan in pediatric GHD.
- TransCon PTH
 - Completed enrollment in the Phase 3 PaTHway Trial of TransCon PTH in adults with hypoparathyroidism, with topline results expected in Q1 2022.
 - 58 subjects continue in the PaTH Forward Trial open-label extension as of November 7, 2021, with 84-week topline results expected in Q4 2021.
 - Enrollment continues in the PaTHway Japan Trial, a single-arm Phase 3 trial of TransCon PTH designed to enroll a minimum of 12 adult Japanese subjects.
- TransCon CNP
 - Continued execution in the ongoing Phase 2 ACcomplish Trial and ACcomplish China Trial (through VISEN Pharmaceuticals) to evaluate the safety and efficacy of TransCon CNP in children ages 2-10 years with achondroplasia.
- TransCon TLR7/8 Agonist
 - Patient enrollment continues in transcendIT-101, a Phase 1/2 study of TransCon TLR7/8 Agonist with or without pembrolizumab in patients with advanced or metastatic solid tumors.
 - Presenting new non-clinical data at this week’s SITC 2021 (Society for Immunotherapy of Cancer’s 36th annual meeting) in Washington D.C.
- TransCon IL-2 β/γ
 - Initiated IL βelieve (“I’ll Believe”) Trial, a Phase 1/2 clinical trial to evaluate TransCon IL-2 β/γ in patients with advanced cancer.
- Ended the third quarter of 2021 with cash, cash equivalents and marketable securities totaling €929.9 million.
- Completed a successful public offering of American Depositary Shares raising net proceeds of approximately \$436 million.
- Completed \$25 million share repurchase program of Ascendis’ American Depositary Shares in connection with the Company’s planned share-based incentive program. In total, 154,837 shares were repurchased with a weighted average

purchase price of \$161.43.

- Virtual R&D update on Ascendis' pipeline planned for mid-December.

Third Quarter 2021 Financial Results

For the third quarter, Ascendis Pharma reported a net loss of €80.3 million, or €1.47 per share (basic and diluted) compared to a net loss of €121.7 million, or €2.31 per share (basic and diluted) for the same period in 2020.

Revenue for the third quarter was €1.1 million compared to €2.8 million in the same quarter of 2020. The decrease was due to lower sale of clinical supplies to VISEN Pharmaceuticals compared to the same period last year.

Research and development (R&D) costs for the third quarter were €58.8 million compared to €64.1 million during the same period in 2020. The decline in R&D costs in 2021 reflect a one-time reversal of pre-launch inventories, which had been recognized as research and development costs in current and previous periods. The reversal of pre-launch inventories followed the U.S. FDA approval of SKYTROFA (lonapegsomatropin-tcgd) on August 25, 2021.

Selling, general and administrative expenses for the third quarter were €39.3 million compared to €17.5 million during the same period in 2020. The increase is primarily due to higher personnel-related and IT costs.

Net loss of associate for the third quarter was €3.9 million compared to a net loss of €3.1 million in the same quarter of 2020. The net loss of associate represents our share of the net result from VISEN Pharmaceuticals.

As of September 30, 2021, Ascendis Pharma had cash, cash equivalents and marketable securities of €929.9 million compared to €641.3 million as of June 30, 2021. As of September 30, 2021, Ascendis Pharma had 56,877,723 ordinary shares outstanding.

Conference Call Details

Date	Wednesday, November 10, 2021
Time	4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time
Dial In (U.S.)	1 844-290-3904
Dial In (International)	+1 574-990-1036
Access Code	2357838

A live webcast of the conference call will be available on the Investors & News section of the Ascendis Pharma website at <https://ascendispharma.com>. A webcast replay will be available on the site shortly after conclusion of the event and will stay available 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 uses its TransCon technologies to create new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark, and has additional facilities in Heidelberg and Berlin, Germany; Palo Alto and Redwood City, California; and Princeton, New Jersey. Please visit www.ascendispharma.com to learn more.

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 Ascendis' 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) the expected timing of topline results from the Phase 3 Phase 3 PaTHway Trial and 84-week topline results from Phase 2 PaTH Forward Trial, (ii) Ascendis' belief that the FDA-approval for a TransCon product validates its technology platform, product innovation algorithm, and product development capabilities, (iii) the anticipated timing of a decision from the European Commission on Ascendis' Marketing Authorisation Application, for TransCon hGH in pediatric GHD, (iv) Ascendis' ability to apply its platform technology to build a leading, fully integrated biopharma company, and (v) Ascendis' use of its TransCon technologies to create new and potentially best-in-class therapies. Ascendis 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 Ascendis makes, including the following: dependence on third party manufacturers and distributors to supply TransCon hGH, the SKYTROFA[®] Auto-Injector and other study drug for commercial sales in the U.S. and clinical studies; unforeseen safety or efficacy results in its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to commercialization of lonapegsomatropin-tcgd in the U.S., the co-pay program, and the further development of TransCon hGH, expenses related to the development and potential commercialization of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs, selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its oncology programs, 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; Ascendis' ability to obtain additional funding, if needed, to support its business activities and the effects on its business from the worldwide COVID-19 pandemic. 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 Ascendis' business in general, see Ascendis' Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 10, 2021 and Ascendis' other future reports filed with, or submitted to, the SEC. Forward-looking statements do not reflect the potential impact of any future licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments that Ascendis may enter into or make. Ascendis does 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
Consolidated Statements of Profit or Loss and
Comprehensive Income / (loss)
(In EUR'000s, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	1,113	2,757	2,881	6,418
Research and development costs	(58,761)	(64,059)	(230,216)	(185,152)
Selling, general and administrative expenses	(39,284)	(17,523)	(111,876)	(56,243)
Operating profit / (loss)	(96,932)	(78,825)	(339,211)	(234,977)
Share of profit / (loss) of associate	(3,855)	(3,101)	19,434	(6,501)
Finance income	21,321	136	44,589	1,677
Finance expenses	(877)	(39,970)	(2,580)	(40,391)
Profit / (loss) before tax	(80,343)	(121,760)	(277,768)	(280,192)
Tax on profit / (loss) for the period	(5)	19	253	202
Net profit / (loss) for the period	(80,348)	(121,741)	(277,515)	(279,990)
Attributable to owners of the Company	(80,348)	(121,741)	(277,515)	(279,990)
Basic and diluted earnings / (loss) per share	€ (1.47)	€ (2.31)	€ (5.13)	€ (5.64)
Number of shares used for calculation (basic and diluted)	54,639,597	52,715,204	54,085,793	49,647,471
Net profit / (loss) for the period	(80,348)	(121,741)	(277,515)	(279,990)
Other comprehensive income / (loss)				
<i>Items that may be reclassified subsequently to profit or loss:</i>				
Exchange differences on translating foreign operations	1,016	(75)	2,781	(136)
Other comprehensive income / (loss) for the period, net of tax	1,016	(75)	2,781	(136)
Total comprehensive income / (loss) for the period, net of tax	(79,332)	(121,816)	(274,734)	(280,126)
Attributable to owners of the Company	(79,332)	(121,816)	(274,734)	(280,126)

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

	September 30,	December 31,
	2021	2020
Assets		
Non-current assets		
Intangible assets	5,384	5,717
Property, plant and equipment	126,295	108,112
Investment in associate	43,639	9,176
Deposits	1,713	1,375
Marketable securities	71,614	115,280
	248,645	239,660
Current assets		
Inventories	55,270	-
Trade receivables	533	387
Other receivables	20,258	6,957

Prepayments	22,239	13,994
Marketable securities	165,347	134,278
Cash and cash equivalents	692,941	584,517
	956,588	740,133
Total assets	1,205,233	979,793
Equity and liabilities		
Equity		
Share capital	7,638	7,217
Distributable equity	985,924	831,494
Total equity	993,562	838,711
Non-current liabilities		
Lease liabilities	95,553	85,116
Other liabilities	-	3,162
	95,553	88,278
Current liabilities		
Lease liabilities	6,748	6,859
Contract liabilities	36	363
Trade payables and accrued expenses	76,471	21,897
Other payables	32,362	23,384
Income taxes payable	501	301
	116,118	52,804
Total liabilities	211,671	141,082
Total equity and liabilities	1,205,233	979,793

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