

PRESS RELEASE

Ascendis Pharma Reports Third Quarter 2022 Financial Results

- SKYTROFA® U.S. revenue more than doubled quarter-to-quarter again, reaching €12.3 million in the third quarter
 - FDA accepted for Priority Review TransCon™ PTH NDA in adult patients with hypoparathyroidism; target action PDUFA date is April 30, 2023
- Announced selection of Phase 2 recommended dose of TransCon TLR7/8 Agonist; first-in-human data accepted for oral presentation at SITC 2022
 - Conference call today at 4:30 pm ET

COPENHAGEN, Denmark, November 2, 2022 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the third quarter ended September 30, 2022 and provided a business update.

“With our improved commercial execution and emphasis on SKYTROFA’s unique patient-focused product strengths, I believe we are advancing our goal to build SKYTROFA into the leading brand and expand the pediatric growth hormone market,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “With our expanding global commercial activities, potential U.S. approval of TransCon PTH in April 2023, and new data expected in achondroplasia and oncology, I am confident in our ability to deliver multiple high-value products to drive long-term sustainable growth.”

Select Highlights

- TransCon hGH:
 - SKYTROFA® (lonapegsomatropin-tcgd) U.S. revenue more than doubled quarter-to-quarter again to €12.3 million in the third quarter. As of September 30, 2022, the cumulative number of new patient prescriptions increased to over 2,400.
 - On track to complete enrollment in the global Phase 3 foresiGHt Trial in adult growth hormone deficiency (GHD) during the fourth quarter of 2022.
 - Endocrinology Rare Disease commercial center for Germany planned in Munich; Skytrofa® (lonapegsomatropin) launch in Germany expected mid-2023.
- TransCon PTH:
 - U.S. FDA accepted for Priority Review NDA submission in adult patients with hypoparathyroidism; PDUFA target action date is April 30, 2023.
 - MAA submission to EMA on track for the fourth quarter of 2022.

- Topline results from Phase 3 PaTHway Japan Trial expected during fourth quarter of 2022.
- After more than two years of treatment, 57 out of 59 patients continue in the open-label extension portion of the Phase 2 PaTH Forward Trial as of September 30, 2022.
- In the Phase 3 PaTHway Trial, 79 out of 79 patients completed one-year follow-up; 77 out of 79 patients continue in the open-label extension portion of the trial as of September 30, 2022.
- TransCon CNP:
 - Topline and initial open-label extension data from ACcomplisH, a Phase 2 randomized, double-blind, placebo-controlled clinical trial in children ages 2-10 years with achondroplasia, expected during the fourth quarter of 2022; 57 out of 57 patients continue in the open-label portion of the trial as of September 30, 2022.
 - Submitted protocol to initiate ApproaCH, a new global randomized, double-blind, placebo-controlled Phase 2b trial in children ages 2-11 years with achondroplasia. The trial is expected to enroll approximately 80 patients.
- TransCon TLR7/8 Agonist:
 - Completed the dose-escalation portion and announced selection of recommended Phase 2 dose in transcendIT-101. Topline data accepted for oral presentation at SITC 2022, the annual meeting of the Society for Immunotherapy of Cancer being held in Boston November 8-12.
 - The next phase of transcendIT-101 will evaluate the recommended Phase 2 dose of investigational TransCon TLR7/8 Agonist in combination with pembrolizumab in patients in four different indication-specific cohorts: head and neck squamous cell carcinoma (HNSCC); other human papillomavirus (HPV)-associated cancers; melanoma; and cutaneous squamous cell carcinoma (cSCC).
- TransCon IL-2 β/γ :
 - The Phase 1/2 IL- β elieye Trial evaluating investigational TransCon IL-2 β/γ monotherapy in patients with locally advanced or metastatic solid tumors continues to enroll patients. The Phase 1/2 IL- β elieye Trial topline data from monotherapy dose escalation are expected during the fourth quarter of 2022.
- Ended the third quarter of 2022 with cash, cash equivalents, and marketable securities totaling €935 million.

Third Quarter 2022 Financial Results

Total revenue for the third quarter was €15.3 million compared to €1.1 million in the same quarter of 2021. Revenue included U.S. revenue from SKYTROFA, as well as license, clinical supply and services provided to third parties, primarily VISEN Pharmaceuticals. The increase in revenue compared to the same period last year was primarily attributable to the €12.3 million commercial revenue from SKYTROFA.

Research and development (R&D) costs for the third quarter were €97.4 million compared to €58.8 million during the same period in 2021. Lower R&D costs in the third quarter of 2021 reflect a one-time €53.7 million reversal of pre-launch inventories, which had previously been recognized as research and development costs. The third quarter 2022 R&D costs also reflect the manufacturing of pre-launch inventories for TransCon PTH and an increase in employee and other costs attributable to organizational growth.

Selling, general, and administrative (SG&A) expenses for the third quarter were €60.7 million compared to €39.3 million during the same period in 2021. Higher SG&A expenses were primarily due to an increase in commercial and administrative personnel following the launch of SKYTROFA in the U.S. and preparation for future product launches.

Our share of net loss of associate was €3.7 million in the third quarter, compared to a net loss of €3.9 million during the same period in 2021.

Net finance loss was €20.9 million in the third quarter compared to a net finance income of €20.4 million in the same period in 2021.

For the third quarter of 2022, Ascendis Pharma reported a net loss of €169.0 million, or €3.03 per share (basic and diluted) compared to a net loss of €80.3 million, or €1.47 per share (basic and diluted) for the same period in 2021.

As of September 30, 2022, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €935.1 million compared to €789.6 million as of December 31, 2021. As of September 30, 2022, Ascendis Pharma had 57,027,240 ordinary shares outstanding.

Conference Call and Webcast Information

Ascendis Pharma will host a conference call and webcast today at 4:30 pm Eastern Time (ET) to discuss its third quarter 2022 financial results.

Those who would like to listen to the live webcast can access it through the following link [here](#). To access the live teleconference, register online [here](#). Participants are encouraged to register at least 15 minutes prior to the call.

A replay of the webcast will be available on the Investors & News section of the Ascendis Pharma website at <https://investors.ascendispharma.com> shortly after conclusion of the event for 30 days.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative TransCon platform to build a leading, fully integrated, global 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 timing and announcement of top-line results from the PaTHway Japan Trial, ACcomplisH Trial, the transcendIT-101 Trial and the Phase 1/2 IL-βelieye Trial, (ii) the timing of completion of patient enrollment in the foresiGHt Trial, ApproaCH Trial and the IL-βelieye Trial, (iii) Ascendis' ability to deliver multiple high-value products and drive long-term sustainable growth, (iv) the expected launch of TransCon PTH in the U.S. in 2023, (v) the expected launch of TransCon hGH in Europe in 2023, (vi) Ascendis' expectations regarding the timing of its regulatory approvals, submissions, applications, protocols, clinical trials and the results thereof, (vii) Ascendis' ability to make SKYTROFA the leading brand and expand the growth hormone market, (viii)

Ascendis' ability to apply its TransCon platform to build a leading, fully integrated global biopharma company, and (ix) 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 and the SKYTROFA[®] Auto-Injector for commercial sales in the U.S. and other study drug for 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 TransCon hGH 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; unforeseen 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; the impact of international economic, political, legal, compliance, social and business factors, including inflation, and the effects on its business from the worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia. 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 2, 2022 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)

	<u>Three Months ended September 30,</u>		<u>Nine Months ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenue	15,290	1,113	28,278	2,881
Cost of sales	1,693	-	7,025	-
Gross profit / (loss)	13,597	1,113	21,253	2,881
Research and development costs	97,431	58,761	271,006	230,216
Selling, general and administrative expenses	60,671	39,284	164,675	111,876
Operating profit / (loss)	(144,505)	(96,932)	(414,428)	(339,211)
Share of profit / (loss) of associate	(3,696)	(3,855)	(9,736)	19,434
Finance income	20,326	21,321	73,797	44,589
Finance expenses	41,247	877	25,381	2,580
Profit / (loss) before tax	(169,122)	(80,343)	(375,748)	(277,768)
Tax on profit / (loss) for the period	167	(5)	(28)	253
Net profit / (loss) for the period	(168,955)	(80,348)	(375,776)	(277,515)
Attributable to owners of the Company	(168,955)	(80,348)	(375,776)	(277,515)
Basic and diluted earnings / (loss) per share	€ (3.03)	€ (1.47)	€ (6.70)	€ (5.13)
Number of shares used for calculation (basic and diluted)	55,831,561	54,639,597	56,115,782	54,085,793
Net profit / (loss) for the period	(168,955)	(80,348)	(375,776)	(277,515)
Other comprehensive income / (loss)				
<i>Items that may be reclassified subsequently to profit or loss:</i>				
Exchange differences on translating foreign operations	(2,207)	1,016	(2,538)	2,781
Other comprehensive income / (loss) for the period, net of tax	(2,207)	1,016	(2,538)	2,781
Total comprehensive income / (loss) for the period, net of tax	(171,162)	(79,332)	(378,314)	(274,734)
Attributable to owners of the Company	(171,162)	(79,332)	(378,314)	(274,734)

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

	September 30, 2022	December 31, 2021
Assets		
Non-current assets		
Intangible assets	4,939	5,272
Property, plant and equipment	139,345	126,049
Investment in associate	32,001	38,345
Other receivables	1,895	1,808
Marketable securities	15,338	107,561
	193,518	279,035
Current assets		
Inventories	103,975	75,405
Trade receivables	6,655	2,200
Income tax receivable	1,630	893
Other receivables	13,264	20,093
Prepayments	34,568	25,231
Marketable securities	311,480	235,797
Cash and cash equivalents	608,330	446,267
	1,079,902	805,886
Total assets	1,273,420	1,084,921
Equity and liabilities		
Equity		
Share capital	7,658	7,646
Distributable equity	443,894	875,989
Total equity	451,552	883,635
Non-current liabilities		
Borrowings	533,145	97,966
Derivative liabilities	132,731	-
Contract liabilities	13,154	2,964
	679,030	100,930
Current liabilities		
Borrowings	20,096	6,995
Contract liabilities	3,137	2,601
Trade payables and accrued expenses	86,102	59,417
Other liabilities	26,578	29,952
Income taxes payable	126	198
Provisions	6,799	1,193
	142,838	100,356
Total liabilities	821,868	201,286
Total equity and liabilities	1,273,420	1,084,921

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