

PRESS RELEASE

Ascendis Pharma Reports Full Year 2022 Results

- *TransCon™ PTH PDUFA date of April 30, 2023, for adults with hypoparathyroidism; European MAA decision expected in the fourth quarter of 2023*
- *Expanding TransCon hGH geographic reach with planned launch in Germany in the third quarter of 2023; Phase 3 data in adult GHD indication expected in the fourth quarter of 2023*
- *Initiated Phase 2b ApproaCH Trial for TransCon CNP in achondroplasia; expected to complete enrollment in the second quarter of 2023*
- *SKYTROFA® U.S. revenue grew to €17.1 million in the fourth quarter of 2022, providing a foundation for growth in 2023 and beyond*
 - *Conference call today at 4:30 pm ET*

COPENHAGEN, Denmark, February 16, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the full year ended December 31, 2022 and provided a business update.

“Our unique TransCon technology platform and algorithm for product innovation enables us to address major unmet medical needs with a diverse, growing pipeline of highly differentiated product candidates,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “With our demonstrated ability to take a product from concept through approval and launch, we will continue to focus on building long term value for patients and other stakeholders, establishing Ascendis Pharma as a leading sustainable, profitable biopharma company.”

Select Highlights & Anticipated 2023 Milestones

- TransCon hGH:
 - First European SKYTROFA (lonapegsomatropin) commercial launch in Germany on track for the third quarter of 2023.
 - In the third quarter of 2023, we anticipate completing enrollment in New InsiGHTS, a four-armed Phase 2 trial designed to investigate the safety, tolerability, and efficacy of different dose levels of TransCon hGH in patients with Turner Syndrome.
 - We expect Phase 3 topline results from foresiGHt in adult growth hormone deficiency in the fourth quarter of 2023.
 - Fourth quarter 2022 SKYTROFA (lonapegsomatropin-tcgd) U.S. revenue grew to €17.1 million.

	Q1-2022	Q2-2022	Q3-2022	Q4-2022	2022
SKYTROFA revenue (millions)	€ 1.9	€ 4.4	€ 12.3	€ 17.1	€ 35.7

- TransCon PTH:
 - U.S. FDA Priority Review continues for use in adult patients with hypoparathyroidism, with a PDUFA date of April 30, 2023. If approved, U.S. commercial launch expected by the end of the second quarter of 2023.
 - European Commission decision on MAA anticipated during the fourth quarter of 2023. If approved, first European country launch expected in early 2024.
 - In anticipation of U.S. and EU approvals, commercial, medical affairs, product supply and other teams continue launch readiness activities.
 - Phase 3 PaTHway Japan trial achieved its primary objectives; topline results consistent with North American and EU trials.
 - Enrollment opened in January 2023 for U.S. Expanded Access Program.
- TransCon CNP:
 - Announced positive topline data from the Phase 2 ACcomplisH Trial, with results in children with achondroplasia down to 2 years of age; as of February 14, 2023 all 57 patients currently remain in the trial with treatment duration up to 3 years.
 - During the second quarter of 2023, we expect to complete enrollment in ApproaCH, a global randomized, double-blind, placebo-controlled Phase 2b trial in children ages 2–11 years with achondroplasia. The trial targets enrollment of ~80 patients.
 - During the third quarter of 2023, we plan to submit an IND or similar in children under the age of two years with achondroplasia.
- TransCon TLR7/8 Agonist:
 - Reported topline data and recommended Phase 2 dose from the dose escalation portion of the Phase 1/2 transcendIT-101 Trial. Early signs of clinical activity were observed in patients receiving TransCon TLR7/8 Agonist as monotherapy or in combination with pembrolizumab.
 - Enrollment in the dose expansion phase of transcendIT-101 continues, with a focus on investigating TransCon TLR7/8 Agonist in combination with pembrolizumab in four different cancer types.
- TransCon IL-2 β/γ :
 - The Phase 1/2 IL- β elieye Trial evaluating TransCon IL-2 β/γ monotherapy in patients with locally advanced or metastatic solid tumors continues to enroll patients. Results from monotherapy dose escalation are expected during the first quarter of 2023. Dose escalation combination therapy results expected during the third quarter of 2023.
 - Preparing to initiate β elieye-IT-201, a randomized Phase 2 trial of TransCon IL-2 β/γ and TLR7/8 combination therapies, in the second quarter of 2023.
- TransCon RBZ:
 - Ophthalmology selected as the third therapeutic area; TransCon RBZ (ranibizumab) selected as the first investigational pipeline candidate, designed for higher efficacy with 6-month dosing intervals.

- Ended the fourth quarter of 2022 with cash, cash equivalents, and marketable securities totaling €742.9 million.

Full-Year 2022 Financial Results

Total revenue for 2022 was €51.2 million compared to €7.8 million in 2021. Revenue for 2022 include SKYTROFA U.S. revenue, and license, clinical supply and services provided to third parties, primarily VISEN Pharmaceuticals. Revenue in 2022 benefited from a full-year contribution of SKYTROFA U.S. revenue of €35.7 million compared to €0.9 million in 2021.

Research and development (R&D) costs for 2022 were €379.6 million compared to €295.9 million in 2021. The higher R&D costs in 2022 reflect a one-time reversal of pre-launch inventories in 2021, following the U.S. FDA approval of SKYTROFA in August 2021. In addition, higher R&D costs in 2022 reflect 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 2022 were €221.2 million compared to €160.2 million 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 €17.7 million in 2022, compared to a net gain of €12.0 million in 2021. For 2021, the net profit of associate included a non-cash gain of €42.3 million as a result of a financing round in VISEN.

Net finance income was €1.7 million in 2022 compared to a net finance income of €55.8 million in 2021.

For the full year 2022, Ascendis Pharma reported a net loss of €583.2 million, or €10.40 per share (basic and diluted) compared to a net loss of €383.6 million, or €7.00 per share (basic and diluted) for the same period in 2021.

As of December 31, 2022, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €742.9 million compared to €789.6 million as of December 31, 2021. As of December 31, 2022, Ascendis Pharma had 57,152,295 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 full year 2022 financial results.

Those who would like to participate may access the live webcast [here](#), or register in advance for the teleconference [here](#). The link to the live webcast will also be available on the Investors & News section of the Ascendis Pharma website at <https://investors.ascendispharma.com>. A replay of the webcast will be available on this section of our website 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, Berlin and Munich, 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) Ascendis' PDUFA date of April 30, 2023 with respect to the FDA's Priority Review of TransCon PTH, (ii) the timing of the European MAA decision for TransCon PTH; (iii) the expected launch of TransCon hGH in Germany; (iv) the timing and announcement of Phase 3 data in new adult GHD indication; (v) the ability of Ascendis' TransCon platform and algorithm for product innovation to address major unmet medical needs with a diverse, growing pipeline of highly differentiated product candidates; (vi) the timing and announcement of top-line results from the foresiGHt Trial and the Phase 1/2 IL-βelieye Trial; (vii) the timing of completion of patient enrollment in the New InsiGHTS Trial, Phase 2b ApproaCH Trial, dose expansion phase of the Phase 1/2 transcendIT-101 Trial and the Phase 1/2 IL-βelieye Trial; (viii) the expected commercial launch of TransCon PTH in the U.S. and EU; (ix) the expected submission of an IND for TransCon CNP; (x) Ascendis' intent to initiate the βelieye -IT-201 trial of TransCon IL-2β/γ and TLR7/8 combination therapy, (xi) TransCon RBZ's ability to reduce the intravitreal treatment burden for patients; (xii) Ascendis' ability to apply its TransCon platform to build a leading, fully integrated global biopharma company, and (xiii) 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 Ascendis' products and product candidates, if approved, for commercial sales in the U.S. and other study drug for clinical studies; unforeseen safety or efficacy results in its oncology and ophthalmology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to commercialization of Ascendis' products and product candidates, if approved, in the U.S. and EU, the co-pay program and the further development of Ascendis' products and product candidates; expenses related to the development and potential commercialization of its oncology and ophthalmology programs, TransCon hGH, TransCon PTH and TransCon CNP or other programs; unforeseen selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its oncology and ophthalmology programs, TransCon hGH, TransCon PTH and TransCon CNP or other 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)

	Year ended December 31,	
	2022	2021
Revenue	51,174	7,778
Cost of sales	12,137	3,523
Gross profit	39,037	4,255
Research and development costs	379,624	295,867
Selling, general and administrative expenses	221,227	160,180
Operating profit / (loss)	(561,814)	(451,792)
Share of profit / (loss) of associate	(17,697)	12,041
Finance income	52,181	59,718
Finance expenses	50,487	3,911
Profit / (loss) before tax	(577,817)	(383,944)
Tax on profit / (loss) for the year	(5,377)	367
Net profit / (loss) for the year	(583,194)	(383,577)
Attributable to owners of the Company	(583,194)	(383,577)
Basic and diluted earnings / (loss) per share	€ (10.40)	€ (7.00)
Number of shares used for calculation (basic and diluted)	56,071,793	54,771,763
Net profit / (loss) for the year	(583,194)	(383,577)
Other comprehensive income / (loss)		
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange differences on translating foreign operations	(327)	3,855
Other comprehensive income / (loss) for the year, net of tax	(327)	3,855
Total comprehensive income / (loss) for the year, net of tax	(583,521)	(379,722)
Attributable to owners of the Company	(583,521)	(379,722)

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

	December 31, 2022	December 31, 2021
Assets		
Non-current assets		
Intangible assets	4,828	5,272
Property, plant and equipment	129,095	126,049
Investment in associate	22,932	38,345
Other receivables	1,920	1,808
Marketable securities	7,492	107,561
	166,267	279,035
Current assets		
Inventories	130,673	75,405
Trade receivables	11,910	2,200
Income tax receivable	883	893
Other receivables	12,833	20,093
Prepayments	31,717	25,231
Marketable securities	290,688	235,797
Cash and cash equivalents	444,767	446,267
	923,471	805,886
Total assets	1,089,738	1,084,921
Equity and liabilities		
Equity		
Share capital	7,675	7,646
Distributable equity	255,673	875,989
Total equity	263,348	883,635
Non-current liabilities		
Borrowings	482,956	97,966
Derivative liabilities	157,950	-
Contract liabilities	14,213	2,964
	655,119	100,930
Current liabilities		
Borrowings	25,421	6,995
Contract liabilities	-	2,601
Trade payables and accrued expenses	101,032	59,417
Other liabilities	31,989	29,952
Income tax payables	5,490	198
Provisions	7,339	1,193
	171,271	100,356
Total liabilities	826,390	201,286
Total equity and liabilities	1,089,738	1,084,921

Investor Contacts:

Tim Lee

Ascendis Pharma

+1 (650) 374-6343

tlee@ascendispharma.com

ir@ascendispharma.com

Patti Bank

ICR Westwicke

+1 (415) 513-1284

patti.bank@westwicke.com

Media Contact:

Melinda Baker

Ascendis Pharma

+1 (650) 709-8875

media@ascendispharma.com