

## PRESS RELEASE

### Ascendis Pharma Reports Third Quarter 2023 Financial Results

- European Commission decision for TransCon™ PTH expected this month; if approved, first European Union launch planned in Germany in January 2024
  - TransCon PTH NDA resubmission to FDA expected before mid-November
- Completed enrollment in the Phase 3 ApproaCH Trial; initiated TransCon CNP infant trial in the third quarter 2023; expect to initiate combination trial of TransCon CNP and TransCon hGH in the fourth quarter 2023
- SKYTROFA Q3 revenue of €47.0 million, increasing full year 2023 SKYTROFA revenue expectations to €170 – €175 million
  - Conference call today at 4:30 pm ET

**COPENHAGEN, Denmark, November 7, 2023 (GLOBE NEWSWIRE)** – Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the third quarter ended September 30, 2023 and provided business updates.

“This quarter marks an important milestone for Ascendis on our path to become a leading, sustainable biopharma company, where we began our journey to extend our SKYTROFA U.S. market value leadership globally with our first EU product launch in Germany,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “Expected approval in the EU for our second product, TransCon PTH, this month demonstrates the value of following our algorithm for product innovation.”

#### Corporate Highlights

- TransCon hGH (marketed in the U.S. and EU as SKYTROFA):
  - Third quarter 2023 SKYTROFA revenue totaled €47.0 million, a 31% sequential increase. Increased full year 2023 SKYTROFA revenue expectations from €165 – €170 million to €170 – €175 million.

	Q3-2022	Q4-2022	Q1-2023	Q2-2023	Q3-2023
SKYTROFA revenue (millions)	€12.3	€17.1	€31.6	€35.9	€47.0

- Announced results from enliGHten, the Company’s open-label extension trial evaluating the long-term safety and efficacy of TransCon hGH for children and adolescents with growth hormone deficiency (GHD), demonstrating the long-term safety and efficacy of TransCon hGH in patients treated up to six years, with the majority of children meeting or exceeding average parental height SDS at time of treatment completion or last visit.

- Topline results from Phase 3 foresiGHt Trial in adult growth hormone deficiency expected in the fourth quarter of 2023, potentially opening a new label expansion opportunity.
- TransCon PTH:
  - On September 14, 2023, the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the approval of TransCon PTH (palopegteriparatide) as a parathyroid hormone replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism. Final European Commission decision is expected this month. If approved, the first launch is planned in Germany, leveraging the Company’s existing SKYTROFA commercial infrastructure, in January 2024.
  - In the U.S., expect to resubmit NDA for TransCon PTH for adults with hypoparathyroidism to the FDA before mid-November.
  - Presented 52-week data from Phase 3 PaTHway Trial demonstrating that skeletal dynamics of patients with chronic hypoparathyroidism trended toward a new steady state closer to age-appropriate norms with continued use of TransCon PTH. Results confirm trends previously reported in the Phase 2 PaTH Forward Trial.
  - As of September 30, 2023, 145 out of 154 participants continue in the open-label extension (OLE) portions of the Phase 2 PaTH Forward, Phase 3 PaTHway, and PaTHway Japan trials.
- TransCon CNP:
  - Completed enrollment in ApproaCH, a Phase 3, global randomized, double-blind, placebo-controlled trial in children ages 2–11 years with achondroplasia. Topline results are expected in the second half of 2024.
  - Filed an Investigational New Drug (IND) amendment with the FDA to initiate reACHin, a Phase 2, multicenter, double-blind, randomized, placebo-controlled trial, designed to evaluate the safety, tolerability, and efficacy of 100 µg/kg of TransCon CNP once-weekly for 52 weeks in infants aged 0 to < 2 years with achondroplasia.
  - One-year follow-up data from AComplisH OLE expected in the fourth quarter of 2023.
  - During the fourth quarter of 2023, the Company expects to file an IND amendment or similar for COACH, a combination trial evaluating TransCon CNP and TransCon hGH in children with achondroplasia. The Company believes that this combination therapy may provide greater annualized height velocity than CNP alone, and at the same time, address the comorbidities of achondroplasia.
- TransCon IL-2 β/γ:
  - Reported new data from ongoing Phase 1/2 IL-Believe Trial demonstrating clinical activity of TransCon IL-2 β/γ as monotherapy or in combination with a checkpoint inhibitor. Of three small-cell lung cancer patients treated in the combination portion of the trial who had previously progressed on checkpoint inhibitors, a partial response (confirmed) and a complete response (unconfirmed, treatment ongoing) were observed to date.

- Enrollment continues in the Phase 2 portion in indication-specific cohorts; first patient dosed with TransCon IL-2  $\beta/\gamma$  and TransCon TLR7/8 Agonist in combination. Initial data from indication-specific cohorts expected in the second half of 2024.
- TransCon TLR7/8 Agonist:
  - Enrollment continues in Phase 2 portion of transcendIT-101, a Phase 1/2 trial to evaluate TransCon TLR7/8 Agonist as monotherapy or in combination with pembrolizumab in dose escalation and dose expansion. Initial data expected in the second half of 2024.
- Ended the third quarter of 2023 with cash, cash equivalents, and marketable securities totaling €455.4 million.

### **Third Quarter 2023 Financial Results**

Total revenue for the third quarter of 2023 was €48.0 million compared to €15.3 million during the same period in 2022. The increase was primarily attributable to higher SKYTROFA revenue of €47.0 million compared to €12.3 million in the same period last year.

Research and development (R&D) costs for the third quarter were €111.4 million compared to €97.4 million during the same period in 2022. This increase was primarily due to higher development costs for the Oncology and Ophthalmology programs, increasing clinical trial activities for TransCon CNP, and higher employee-related costs, and was partly offset by lower development costs for TransCon hGH.

Selling, general, and administrative (SG&A) expenses for the third quarter were €63.6 million compared to €60.7 million during the same period in 2022. This increase was primarily due to higher employee related expenses and other expenses attributable to organizational growth.

Net finance expenses were €20.4 million in the third quarter compared to €20.9 million in the same period in 2022.

For the third quarter of 2023, Ascendis Pharma reported a net loss of €162.2 million, or €2.88 per share (basic and diluted) compared to a net loss of €169.0 million, or €3.03 per share (basic and diluted) for the same period in 2022.

As of September 30, 2023, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €455.4 million compared to €742.9 million as of December 31, 2022. As of September 30, 2023, Ascendis Pharma had 57,656,568 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 2023 financial results.

To participate in the call, please dial (800) 445-7795 (domestic) or +1 (785) 424-1699 (international), and reference passcode ASNDQ323. 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 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 Germany (Heidelberg and Munich) and the United States (Palo Alto and Redwood City, California, and Princeton, New Jersey). Please visit [ascendispharma.com](https://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 of the European Commission decision for TransCon PTH and the potential approval of TransCon PTH in the EU; (ii) Ascendis' plan to resubmit an NDA for TransCon PTH before mid-November; (iii) Ascendis' plans to launch TransCon PTH, if approved, in Germany in January 2024; (iv) Ascendis' expectations regarding the initiation of its combination trial of TransCon CNP and TransCon hGH; (v) Ascendis' expectations regarding 2023 SKYTROFA revenues; (vi) Ascendis' ability to become a leading, sustainable biopharma company; (vii) Ascendis' ability to extend its SKYTROFA U.S. market value leadership globally; (viii) the timing of Topline results from Phase 3 foresiGHt trial and the potential for a label expansion opportunity; (ix) the timing of topline results from the ApproaCH trial; (x) the timing of one-year follow-up data from the OLE portion of the ACcomplisH trial; (xi) Ascendis' plan to file an IND amendment or similar for COACH; (xii) the ability for a combination therapy of TransCon CNP and TransCon hGH to provide greater annualized height velocity than CNP alone and address the comorbidities of achondroplasia; (xiii) the timing of initial data from indication-specific cohorts in the Phase 2 portion of the Phase 1/2 IL-Believe Trial; (xiv) the timing of initial data from the Phase 2 portion of transcendIT-101; (xv) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated global biopharma company; and (xvi) 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, distributors and service providers for Ascendis' products and product candidates; unforeseen safety or efficacy results in Ascendis' development programs or on-market products; unforeseen expenses related to commercialization of any approved Ascendis products; unforeseen expenses related to Ascendis' development programs; unforeseen selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; 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, the effects on its business from the worldwide COVID-19 pandemic and ongoing conflicts such as that 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 February 16, 2023 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>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Revenue	48,034	15,290	129,016	28,278
Cost of sales	7,388	1,693	24,938	7,025
<b>Gross profit</b>	<b>40,646</b>	<b>13,597</b>	<b>104,078</b>	<b>21,253</b>
Research and development costs	111,439	97,431	322,573	271,006
Selling, general and administrative expenses	63,614	60,671	200,435	164,675
<b>Operating profit / (loss)</b>	<b>(134,407)</b>	<b>(144,505)</b>	<b>(418,930)</b>	<b>(414,428)</b>
Share of profit / (loss) of associate	(6,794)	(3,696)	(15,471)	(9,736)
Finance income	4,142	20,326	76,985	73,797
Finance expenses	24,519	41,247	35,640	25,381
<b>Profit / (loss) before tax</b>	<b>(161,578)</b>	<b>(169,122)</b>	<b>(393,056)</b>	<b>(375,748)</b>
Income taxes (expenses)	(645)	167	(1,513)	(28)
<b>Net profit / (loss) for the period</b>	<b>(162,223)</b>	<b>(168,955)</b>	<b>(394,569)</b>	<b>(375,776)</b>
Attributable to owners of the Company	(162,223)	(168,955)	(394,569)	(375,776)
Basic and diluted earnings / (loss) per share	€ (2.88)	€ (3.03)	€ (7.02)	€ (6.70)
Number of shares used for calculation (basic and diluted)	56,272,698	55,831,561	56,194,956	56,115,782
<b>Net profit / (loss) for the period</b>	<b>(162,223)</b>	<b>(168,955)</b>	<b>(394,569)</b>	<b>(375,776)</b>
<b>Other comprehensive income / (loss)</b>				
<i>Items that may be reclassified subsequently to profit or loss:</i>				
Exchange differences on translating foreign operations	571	(2,207)	(1,232)	(2,538)
<b>Other comprehensive income / (loss) for the period, net of tax</b>	<b>571</b>	<b>(2,207)</b>	<b>(1,232)</b>	<b>(2,538)</b>
<b>Total comprehensive income / (loss) for the period, net of tax</b>	<b>(161,652)</b>	<b>(171,162)</b>	<b>(395,801)</b>	<b>(378,314)</b>
Attributable to owners of the Company	(161,652)	(171,162)	(395,801)	(378,314)

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

	<b>September 30,</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	4,495	4,828
Property, plant and equipment	125,535	129,095
Investment in associate	8,116	22,932
Other receivables	2,142	1,920
Marketable securities	-	7,492
	<b>140,288</b>	<b>166,267</b>
<b>Current assets</b>		
Inventories	189,132	130,673
Trade receivables	26,794	11,910
Income tax receivables	1,644	883
Other receivables	21,595	12,833
Prepayments	38,327	31,717
Marketable securities	14,165	290,688
Cash and cash equivalents	441,268	444,767
	<b>732,925</b>	<b>923,471</b>
<b>Total assets</b>	<b>873,213</b>	<b>1,089,738</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	7,742	7,675
Distributable equity	(81,175)	255,673
<b>Total equity</b>	<b>(73,433)</b>	<b>263,348</b>
<b>Non-current liabilities</b>		
Borrowings	549,483	387,555
Lease liabilities	90,103	95,401
Derivative liabilities	93,353	157,950
Contract liabilities	949	14,213
	<b>733,888</b>	<b>655,119</b>
<b>Current liabilities</b>		
Borrowings	11,824	11,630
Lease liabilities	14,433	13,791
Contract liabilities	4,030	-
Trade payables and accrued expenses	121,552	101,032
Other liabilities	33,660	31,989
Income tax payables	6,478	5,490
Provisions	20,781	7,339
	<b>212,758</b>	<b>171,271</b>
<b>Total liabilities</b>	<b>946,646</b>	<b>826,390</b>
<b>Total equity and liabilities</b>	<b>873,213</b>	<b>1,089,738</b>