

## PRESS RELEASE

### Ascendis Pharma Reports First Quarter 2023 Financial Results

- Focused on bringing TransCon™ PTH to the U.S. and EU markets as soon as possible
- 145 of 154 clinical trial participants continue treatment with TransCon PTH for up to 3 years, and U.S. Expanded Access Program continues to enroll new patients
- SKYTROFA®\* revenue reached €31.6 million in the first quarter of 2023; Ascendis expects full-year 2023 SKYTROFA revenue of €150 - €160 million
- Company to hold Oncology program update on Wednesday, May 31 in New York City
  - Conference call today at 4:30 pm ET

**COPENHAGEN, Denmark, April 27, 2023 (GLOBE NEWSWIRE)** – Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the first quarter ended March 31, 2023 and provided a business update.

“Based on our clinical experience with TransCon PTH to date, we have seen the improvement in the lives of many patients living with hypoparathyroidism and we are committed to working with regulatory authorities in the U.S. and EU to bring it to market as soon as possible,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “We are managing our business to achieve our goal of reaching cash flow breakeven without the need for additional dilutive equity financing, supported by our first approved product, SKYTROFA, which is now accelerating to U.S. market value leadership. With advances across our portfolio and a focus on cost control, we remain on track to achieve Vision 3x3 to become a sustainable, profitable leading biopharma company.”

#### Select Highlights & Anticipated 2023 Milestones

- TransCon hGH:
    - First quarter 2023 SKYTROFA revenue grew to €31.6 million, including a negative foreign currency impact of €1.4 million compared to the previous quarter.
- |                             | Q1-2022 | Q2-2022 | Q3-2022 | Q4-2022 | Q1-2023 |
|-----------------------------|---------|---------|---------|---------|---------|
| SKYTROFA revenue (millions) | €1.9    | €4.4    | €12.3   | €17.1   | €31.6   |
- SKYTROFA commercial launch in Germany on track for the third quarter of 2023.
  - Expect topline results from Phase 3 foresiGHt trial in adult growth hormone deficiency in the fourth quarter of 2023.
- TransCon PTH:
    - Committed to working with the FDA to address any NDA deficiencies.

- 145 of 154 clinical trial participants continue treatment with TransCon PTH for up to 3 years, and U.S. Expanded Access Program continues to enroll new patients.
- Submitted application to initiate an early access program in Germany during the second quarter of 2023. If approved, expect to enroll first patient during the second quarter of 2023.
- Anticipate European Commission decision on MAA during the fourth quarter of 2023. If approved, first launch planned in Germany in early 2024.
- TransCon CNP:
  - As of March 31, 2023, all 57 patients remain in the open-label extension (OLE) portion of the Phase 2 ACcomplisH trial with treatment duration up to 3 years. One-year follow-up data from OLE expected in the fourth quarter of 2023.
  - Expect to complete target enrollment of ~80 patients in ApproaCH, a global randomized, double-blind, placebo-controlled Phase 2b trial in children ages 2–11 years with achondroplasia, during the second quarter of 2023.
- TransCon TLR7/8 Agonist:
  - Enrollment in the dose expansion portion of the Phase 1/2 transcendIT-101 trial continues, with a focus on investigating TransCon TLR7/8 Agonist in combination with pembrolizumab in four different cancer types.
- TransCon IL-2  $\beta/\gamma$ :
  - Initial monotherapy dose escalation data from the ongoing Phase 1/2 IL-Believe trial of TransCon IL-2  $\beta/\gamma$  alone or in combination with pembrolizumab will be published online at ASCO 2023. Dose escalation combination therapy results expected during the third quarter of 2023.
  - Preparing to initiate Believe-IT-201, a randomized Phase 2 trial of TransCon IL-2  $\beta/\gamma$  and TLR7/8 combination therapies, in the second quarter of 2023.
- Ended the first quarter of 2023 with cash, cash equivalents, and marketable securities totaling €585.7 million.

### **First Quarter 2023 Financial Results**

Total revenue for the first quarter of 2023 was €33.6 million compared to €6.8 million during the same period in 2022. The increase was primarily attributable to higher SKYTROFA revenue of €31.6 million compared to €1.9 million in the same period last year.

Research and development (R&D) costs for the first quarter were €106.1 million compared to €83.2 million during the same period in 2022. This increase was primarily due to higher development costs for Ascendis Pharma oncology programs, TransCon IL-2  $\beta/\gamma$  and TransCon TLR7/8, reflecting the advancement of these product candidates.

Selling, general, and administrative (SG&A) expenses for the first quarter were €66.5 million compared to €47.4 million during the same period in 2022. This increase was primarily due to higher external commercial expenses related to SKYTROFA and to pre-launch activities for TransCon PTH, higher employee related expenses, and an increase in other general and administrative expenses attributable to organizational growth.

Net finance income was €35.3 million in the first quarter compared to €7.6 million in the same period in 2022.

For the first quarter of 2023, Ascendis Pharma reported a net loss of €110.9 million, or €1.98 per share (basic and diluted) compared to a net loss of €125.5 million, or €2.21 per share (basic and diluted) for the same period in 2022.

As of March 31, 2023, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €585.7 million compared to €742.9 million as of December 31, 2022. As of March 31, 2023, Ascendis Pharma had 57,328,548 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 first quarter 2023 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 technology 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](http://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' ability to bring TransCon PTH to U.S. and EU markets as soon as possible; (ii) Ascendis' expectations regarding 2023 SKYTROFA revenues; (iii) Ascendis' intent to work with regulatory authorities in the U.S. and EU to bring TransCon PTH to market as soon as possible; (iv) Ascendis' ability to achieve cash flow breakeven without the need for additional dilutive equity financing; (v) Ascendis' expectations regarding SKYTROFA's acceleration to market value leadership; (vi) Ascendis' ability to achieve Vision 3x3 to become a sustainable, profitable leading biopharma company; (vii) the expected launch of SKYTROFA in Germany in the third quarter of 2023; (viii) the timing of topline results from Phase 3 foresiGHT trial in adult growth hormone deficiency; (ix) Ascendis' ability to work with the FDA to address any NDA deficiencies; (x) the timing of enrollment of the first patient in an early access program in Germany; (xi) the timing of the EU MAA decision for TransCon PTH; (xii) the expected launch of TransCon PTH in Germany in 2024; (xiii) the timing of announcement of one-year follow-up data from the OLE portion of the ACcompish trial; (xiv) the timing of enrollment of patients in the ApproaCH trial; (xv) the publishing

of monotherapy dose escalation data from the ongoing Phase 1/2 IL-Believe trial of TransCon IL-2  $\beta/\gamma$ ; (xvi) the timing of dose escalation combination therapy results from the Phase 1/2 IL-Believe trial; (xvii) Ascendis' intent to initiate the Believe-IT-201 trial of TransCon IL-2 $\beta/\gamma$  and TLR7/8 combination therapies; (xviii) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated global biopharma company, and (xx) 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 its 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, and 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 March 31,</u>	
	<u>2023</u>	<u>2022</u>
Revenue	33,589	6,828
Cost of sales	4,621	4,246
<b>Gross profit</b>	<b>28,968</b>	<b>2,582</b>
Research and development costs	106,114	83,193
Selling, general and administrative expenses	66,539	47,418
<b>Operating profit / (loss)</b>	<b>(143,685)</b>	<b>(128,029)</b>
Share of profit / (loss) of associate	(1,227)	(4,873)
Finance income	45,135	13,044
Finance expenses	9,840	5,399
<b>Profit / (loss) before tax</b>	<b>(109,617)</b>	<b>(125,257)</b>
Income taxes (expenses)	(1,297)	(241)
<b>Net profit / (loss) for the period</b>	<b>(110,914)</b>	<b>(125,498)</b>
Attributable to owners of the Company	(110,914)	(125,498)
Basic and diluted earnings / (loss) per share	€ (1.98)	€ (2.21)
Number of shares used for calculation (basic and diluted)	56,091,927	56,720,063
<b>Net profit / (loss) for the period</b>	<b>(110,914)</b>	<b>(125,498)</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	(787)	425
<b>Other comprehensive income / (loss) for the period, net of tax</b>	<b>(787)</b>	<b>425</b>
<b>Total comprehensive income / (loss) for the period, net of tax</b>	<b>(111,701)</b>	<b>(125,073)</b>
Attributable to owners of the Company	(111,701)	(125,073)

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

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	4,717	4,828
Property, plant and equipment	127,762	129,095
Investment in associate	21,966	22,932
Other receivables	1,984	1,920
Marketable securities	-	7,492
	<b>156,429</b>	<b>166,267</b>
<b>Current assets</b>		
Inventories	150,850	130,673
Trade receivables	16,121	11,910
Income tax receivable	1,064	883
Other receivables	17,375	12,833
Prepayments	38,694	31,717
Marketable securities	84,460	290,688
Cash and cash equivalents	501,281	444,767
	<b>809,845</b>	<b>923,471</b>
<b>Total assets</b>	<b>966,274</b>	<b>1,089,738</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	7,698	7,675
Distributable equity	159,503	255,673
<b>Total equity</b>	<b>167,201</b>	<b>263,348</b>
<b>Non-current liabilities</b>		
Borrowings	479,988	482,956
Derivative liabilities	116,768	157,950
Contract liabilities	3,956	14,213
	<b>600,712</b>	<b>655,119</b>
<b>Current liabilities</b>		
Borrowings	25,393	25,421
Contract liabilities	10,000	-
Trade payables and accrued expenses	131,438	101,032
Other liabilities	15,503	31,989
Income taxes payable	6,873	5,490
Provisions	9,154	7,339
	<b>198,361</b>	<b>171,271</b>
<b>Total liabilities</b>	<b>799,073</b>	<b>826,390</b>
<b>Total equity and liabilities</b>	<b>966,274</b>	<b>1,089,738</b>

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*\* Registered in the U.S. as SKYTROFA<sup>®</sup> (longapegsomatropin-tcgd) and in the EU as SKYTROFA<sup>®</sup> (lonapegsomatropin). SKYTROFA<sup>®</sup> is not marketed in the EU.*