Ascendis Pharma Reports Fourth Quarter and Full Year 2024 Financial Results

February 12, 2025 at 4:01 PM EST

– Strong early U.S. YORVIPATH® launch with 908 prescriptions as of Feb. 7, 2025; YORVIPATH full year 2024 revenue of €28.7 million

– Following pre-NDA meeting with FDA, on track to submit TransCon ™CNP NDA for achondroplasia in children in Q1 2025, followed by MAA in Q3 2025

– SKYTROFA® full year 2024 revenue was ~€202 million, excluding sales deductions related to prior years, (€197.0 million plus ~€5 million of sales deductions related to prior years)

– Total 2024 operating expenses of €598 million

– Conference call today at 4:30 pm ET

COPENHAGEN, Denmark, Feb. 12, 2025 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the fourth quarter and full year ended December 31, 2024, and provided a business update.

“Having achieved pivotal milestones in 2024, Ascendis is positioned to continue strong revenue growth in 2025 and beyond,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “We believe YORVIPATH is well on its way to establishing itself as the new global standard for the treatment of hypoparathyroidism in adults. SKYTROFA has achieved a leading position in value in the U.S. growth hormone market. And for TransCon CNP, we have a clear path to submit our NDA and MAA as a differentiated treatment of achondroplasia in children. Together with a strong cash balance and established partnerships, I am confident in our ability to become a leading global biopharmaceutical company with multiple blockbuster products and a strong engine for future innovation.”

Select 2024 Highlights & Anticipated 2025 Milestones

- TransCon hGH
  (lonapegsomatropin, marketed as SKYTROFA)
  - SKYTROFA fourth quarter 2024 revenue excluding a positive impact due to reversal of €4.6 million of sales deductions related to prior years was ~€54 million (fourth quarter reported 2024 SKYTROFA revenue of €58.5 million).
  - SKYTROFA full year 2024 revenue excluding €4.7 million of sales deductions related to prior years was ~€202 million (full year reported 2024 SKYTROFA revenue of €197.0 million).
  - Prescription Drug User Fee Act (PDUFA) goal date of July 27, 2025, for FDA review of supplemental BLA for the treatment of adults with growth hormone deficiency; pending approval, U.S. commercial launch planned in the fourth quarter of 2025.
  - During the third quarter of 2025, plan to submit an Investigational New Drug (IND) application or similar for a basket trial evaluating TransCon hGH in additional indications.
- TransCon PTH
  (palopegteriparatide, marketed as YORVIPATH)
  - YORVIPATH revenue for the fourth quarter of 2024 totaled €13.6 million and €28.7 million for the full year 2024, as previously announced.
  - Strong start to U.S. YORVIPATH launch, with 908 prescriptions as of Feb. 7, 2025, and 539 unique prescribing health care providers.
  - Expect commercial launch in at least five additional Europe Direct countries in 2025.
  - Eight International Markets exclusive distribution agreements signed covering 50+ countries.
- TransCon CNP
  (navepegritide)
  - Following pre-NDA meeting with FDA, on track to submit New Drug Application (NDA) for the treatment of achondroplasia in children during the first quarter of 2025, and to submit Marketing Authorisation Application (MAA) to the European Medicines Agency during the third quarter of 2025.
  - Presented new data demonstrating additional benefits beyond linear growth, with significant improvements in leg bowing (a common complication in achondroplasia) observed with TransCon CNP compared to worsening observed with placebo in pivotal ApproaCH Trial.
  - During the fourth quarter of 2025, plan to submit an IND or similar for the treatment of hypochondroplasia.
- TransCon hGH / TransCon CNP Combination Treatment
  - Topline Week 26 results from Phase 2 COACH Trial (TransCon CNP in combination with TransCon hGH) in

children with achondroplasia expected in the second quarter of 2025.

- Oncology Program
  - Clinical development of TransCon IL-2 β/γ continues, including ongoing investigation of clinical activity in platinum-resistant ovarian cancer (PROC).
- Financial Update
  - December 31, 2024, cash and cash equivalents totaling €559.5 million.
  - Subsequent to the year end, in January 2025, received $100 million related to the Exclusive License Agreement with Novo Nordisk announced last year. Including the $100 million upfront payment, cash at the end of 2024 would have totaled €655 million.

Fourth Quarter and Full Year 2024 Financial Results

Total revenue for the fourth quarter of 2024 was €173.9 million, compared to €137.7 million during the same period for 2023. The increase was primarily attributable to the upfront fee of $100 million from Novo Nordisk and the EU launch of YORVIPATH.

Total revenue for 2024 was €363.6 million compared to €266.7 million in 2023. The increase was primarily attributable to the upfront fee of $100 million from Novo Nordisk and greater commercial product revenue. Non-product revenue was €137.9 million in 2024, compared to €88.1 million in 2023.

Total Revenue
(In EUR'000s)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	**2023**	**2024**	**2023**
Revenue from external customers				
Commercial products	72,130	64,249	225,728	178,663
Licenses	95,853	64,304	122,343	66,077
Other	5,933	9,150	15,570	21,978
Total revenue from external customers	**173,916**	**137,703**	**363,641**	**266,718**

Commercial Product Revenue
(In EUR'000s)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	**2023**	**2024**	**2023**
Revenue from commercial products				
SKYTROFA®	58,546	64,249	197,001	178,663
YORVIPATH®	13,584	—	28,727	—
Total revenue from commercial products	**72,130**	**64,249**	**225,728**	**178,663**

Research and development (R&D) costs for the fourth quarter of 2024 were €79.3 million, compared to €90.9 million during the same period in 2023. The decline was largely due to lower external development costs for TransCon hGH and TransCon PTH, as well as the Eyconis spin-off. R&D costs for 2024 were €307.0 million compared to €413.5 million in 2023. The lower R&D costs in 2024 was driven primarily by a decrease in external program development costs as well as the Eyconis spin-off.

Selling, general, and administrative (SG&A) expenses for the fourth quarter of 2024 were €80.2 million, compared to €64.0 million during the same period in 2023. The increase was due to higher employee costs, including the impact from global commercial expansion, and higher external commercial costs. SG&A expenses for 2024 were €291.1 million compared to €264.4 million in 2023. Higher SG&A expenses were primarily due to higher employee related expenses and other general and administrative expenses attributable to organizational growth in support of launch of YORVIPATH in Europe and the U.S.

Total operating expenses for the fourth quarter of 2024 were €159.5 million compared to €154.9 million during the same period in 2023. Total operating expenses for 2024 were €598.1 million compared to €677.9 million in 2023.

Net finance expenses were €33.2 million in the fourth quarter compared to €41.6 million in the same period in 2023. Net finance expenses for 2024 were €74.4 million compared to €0.2 million in 2023. The full year net finance expense increase was driven primarily by non-cash items.

For the fourth quarter of 2024, Ascendis Pharma reported a net loss of €38.5 million, or €0.64 per share (basic and diluted) compared to a net loss of €86.9 million, or €1.54 per share (basic and diluted) for the same period in 2023. For the full year 2024, Ascendis Pharma reported a net loss of €378.1 million, or €6.53 per share (basic and diluted) compared to a net loss of €481.4 million, or €8.55 per share (basic and diluted) in 2023.

As of December 31, 2024, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €559.5 million compared to €399.4 million as of December 31, 2023. Subsequent to the year end, we received the $100 million upfront payment from Novo Nordisk which was received in January 2025. As of December 31, 2024, Ascendis Pharma had 60,689,487 ordinary shares outstanding, including 845,887 ordinary shares represented by ADSs held by the company.

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 fourth quarter and full year 2024 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 the Ascendis Pharma 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 biopharma company focused on making a meaningful difference in patients' lives. Guided by its core values of Patients, Science, and Passion, Ascendis uses its TransCon technologies to create new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark and has additional facilities in Europe and the United States. Please visit 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 NDA, MAA and IND submissions for TransCon CNP; (ii) Ascendis' ability to continue strong revenue growth in 2025 and beyond; (iii) YORVIPATH's ability to become the new global standard for the treatment of hypoparathyroidism in adults; (iv) Ascendis' ability to become a leading global biopharmaceutical company with multiple blockbuster products and a strong engine for future innovation; (v) the PDUFA goal date for FDA review of SKYTROFA's supplemental BLA for the treatment of adults with growth hormone deficiency and Ascendis' plans for a U.S. commercial launch in the fourth quarter of 2025, if approved; (vi) Ascendis' plan to submit an IND application or similar for a basket trial evaluating TransCon hGH in additional indications; (vii) Ascendis' expectations with respect to the commercial launch of TransCon PTH in additional countries; (viii) the timing of topline Week 26 data from Phase 2 COACH Trial, the combination TransCon hGH and TransCon CNP trial; (ix) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated biopharma company, and (x) 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. 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 12, 2025, 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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NEW AND AMENDED IFRS ACCOUTING STANDARDS AND INTERPRETATIONS

The Company has applied amendments to paragraphs 69 to 76 of IAS 1, "Presentation of Financial Statements," which was effective for annual reporting periods beginning on or after January 1, 2024, and must be applied retrospectively. The amendments to IAS 1 specify the requirements for classifying liabilities as current or non-current. Refer to Note 2 in the financial statements of Ascendis' Annual Report on Form 20-F for further details.

FINANCIAL TABLES FOLLOW

Ascendis Pharma A/S
Consolidated Statements of Profit or (Loss) and Other Comprehensive Income or (Loss)
(In EUR'000s, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	**2023**	**2024**	**2023**
Consolidated Statement of Profit or (Loss)				
Revenue	173,916	137,703	363,641	266,718
Cost of sales	14,023	19,457	44,258	44,395
Gross profit	**159,893**	**118,246**	**319,383**	**222,323**
Research and development costs	79,294	90,881	307,004	413,454

Selling, general, and administrative expenses	80,216	63,975	291,142	264,410
Operating profit/(loss)	**383**	**(36,610)**	**(278,763)**	**(455,541)**
Share of profit/(loss) of associates	(4,575)	(2,924)	(20,060)	(18,395)
Finance income	26,233	22,727	25,609	43,857
Finance expenses	59,425	64,280	100,027	44,065
Profit/(loss) before tax	**(37,384)**	**(81,087)**	**(373,241)**	**(474,144)**
Income taxes (expenses)	(1,085)	(5,791)	(4,843)	(7,303)
Net profit/(loss) for the period	**(38,469)**	**(86,878)**	**(378,084)**	**(481,447)**
Attributable to owners of the Company	(38,469)	(86,878)	(378,084)	(481,447)
Basic and diluted earnings/(loss) per share	€ (0.64)	€ (1.54)	€ (6.53)	€ (8.55)
Number of shares used for calculation (basic and diluted)	59,785,166	56,560,368	57,891,570	56,287,060

Consolidated Statement of Comprehensive Income or (Loss)				
Net profit/(loss) for the period	**(38,469)**	**(86,878)**	**(378,084)**	**(481,447)**
Other comprehensive income/(loss)				
Items that may be reclassified subsequently to profit or (loss):				
Exchange differences on translating foreign operations	830	(1,498)	1,062	(2,731)
Other comprehensive income/(loss) for the period, net of tax	**830**	**(1,498)**	**1,062**	**(2,731)**
Total comprehensive income/(loss) for the period, net of tax	**(37,639)**	**(88,376)**	**(377,022)**	**(484,178)**
Attributable to owners of the Company	(37,639)	(88,376)	(377,022)	(484,178)

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

	December 31, 2024	December 31, 2023 (Restated)*	January 1, 2023 (Restated)*
Assets			
Non-current assets			
Intangible assets	4,028	4,419	4,828
Property, plant and equipment	98,714	110,634	129,095
Investments in associates	13,575	5,686	22,932
Other receivables	2,317	2,127	1,920
Marketable securities	—	—	7,492
	118,634	**122,866**	**166,267**
Current assets			
Inventories	295,609	208,931	130,673
Trade receivables	166,280	35,874	11,910
Income tax receivables	1,775	802	883
Other receivables	9,385	19,097	12,833
Prepayments	28,269	38,578	31,717
Marketable securities	—	7,275	290,688
Cash and cash equivalents	559,543	392,164	444,767
	1,060,861	**702,721**	**923,471**
Total assets	**1,179,495**	**825,587**	**1,089,738**
Equity and liabilities			
Equity			
Share capital	8,149	7,749	7,675
Distributable equity	(113,855)	(153,446)	255,673
Total equity	**(105,706)**	**(145,697)**	**263,348**
Non-current liabilities			
Borrowings	365,080	222,996	95,400
Contract liabilities	5,000	5,949	14,213
Deferred tax liabilities	7,258	5,830	—
	377,338	**234,775**	**109,613**

Current liabilities			
Convertible notes, matures in April 2028			
Borrowings	458,207	407,095	399,186
Derivative liabilities	150,670	143,296	157,950
	608,877	**550,391**	**557,136**
Other current liabilities			
Borrowings	33,329	14,174	13,791
Contract liabilities	936	1,184	—
Trade payables and accrued expenses	96,394	94,566	101,032
Other liabilities	67,956	41,176	31,989
Income tax payables	1,222	2,299	5,490
Provisions	99,149	32,719	7,339
	298,986	**186,118**	**159,641**
	907,863	**736,509**	**716,777**
Total liabilities	**1,285,201**	**971,284**	**826,390**
Total equity and liabilities	**1,179,495**	**825,587**	**1,089,738**

*Restatement relates to adoption of amendments to IAS 1 “Presentation of Financial Statements.”
Refer to Note 2 in the financial statements of Ascendis’ Annual Report on Form 20-F for further details.

Source: Ascendis Pharma