



Ascendis Pharma Reports Third Quarter 2024 Financial Results

November 14, 2024 at 4:01 PM EST

– YORVIPATH launching in U.S. with product availability expected mid-January 2025; ex-U.S. YORVIPATH revenue of €8.5 million in Q3

– TransCon CNP NDA submission for achondroplasia planned for Q1 2025 followed by MAA submission planned for Q3 2025

– SKYTROFA Q3 revenue of €47.2 million – 60%+ year-over-year volume growth offset by current and prior period sales deductions

– Full year 2024 SKYTROFA revenue excluding sales deductions related to prior years expected to be €200 - €220 million, and full year 2024 operating expenses of approximately €600 million

– Novo Nordisk collaboration for the development of product candidates in metabolic and cardiovascular diseases, including a once-monthly GLP-1 receptor agonist, signed last week, seeking to close before the end of 2024

– Conference call today at 4:30 pm ET

COPENHAGEN, Denmark, Nov. 14, 2024 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the third quarter ended September 30, 2024, and provided a business update.

“2024 has been another transformative year for Ascendis. Now, all three of our three endocrinology rare disease programs have delivered clinically differentiated pivotal data, each demonstrating potential ability to address major unmet medical needs and the potential for each to achieve blockbuster status. We are ready and very excited about launching YORVIPATH in the U.S. with product availability expected in mid-January of 2025,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “In addition, our new partnership with Novo Nordisk highlights our ability to extend the success of our TransCon platform and positions Ascendis to benefit patients and capture significant value in this large, high volume therapeutic areas.”

Select Highlights & Anticipated 2024 Milestones

- TransCon hGH:
(lonapegsomatropin, marketed as SKYTROFA)
 - SKYTROFA revenue for the third quarter of 2024 totaled €47.2 million compared to €47.0 million during the same period in 2023. Volume growth was offset by higher sales deductions and a negative adjustment to prior period sales deductions of €2.5 million.
 - SKYTROFA revenue for the first nine months of 2024 totaled €138.5 million, a 21% year-over-year increase compared to €114.4 million during the same period of 2023. Volume growth was partially offset by higher sales deductions. In addition, sales deductions attributable to periods prior to January 1, 2024 totaled €9.3 million.
 - Submitted U.S. Food & Drug Administration (FDA) supplemental Biologics License Application for TransCon hGH for the treatment of adults with growth hormone deficiency.
 - Topline results from Phase 2 New InsiGHTS Trial in Turner syndrome expected in the fourth quarter of 2024.
 - Expect to initiate a basket trial evaluating SKYTROFA in other established daily growth hormone indications in the first half of 2025.
- TransCon PTH:
(palopegteriparatide, marketed as YORVIPATH)
 - YORVIPATH launching in U.S. with our expanded U.S. field teams engaging with health care providers, our Ascendis Signature Access Program accepting prescriptions and enrolling patients starting in December in preparation for product availability in mid-January 2025
 - Third quarter YORVIPATH revenue outside the U.S. totaled €8.5 million, a sequential quarter-over-quarter revenue increase of more than 60%, reflecting growing physician and patient demand with now over 600 patients on treatment, partially offset by accruals reflecting the end of the free pricing period in the third quarter. Final pricing in Germany is expected to be completed next year.
- TransCon CNP
(navepegritide)
 - Announced positive topline data from pivotal ApproaCH Trial with children with achondroplasia (ages 2-11 years)

treated with once-weekly TransCon CNP.

- Plan to submit New Drug Application (NDA) to the FDA for TransCon CNP for the treatment of children with achondroplasia during the first quarter of 2025 and a Marketing Authorisation Application (MAA) for the treatment of children with achondroplasia to the European Medicines Agency during the third quarter of 2025.
- Expect topline Week 26 data from COACH, the combination TransCon hGH and TransCon CNP trial of children with achondroplasia (ages 2-11 years) in the second quarter of 2025.
- Oncology Programs
 - Presented first results from platinum-resistant ovarian cancer (PROC) cohort of the Phase 1/2 IL-Believe Trial at ESMO 2024. Initial data suggest clinical activity in heavily pre-treated PROC patients and that TransCon IL-2 β/γ in combination with chemotherapy was generally well-tolerated.
 - Recently, we closed enrollment to dose expansion cohorts involving TransCon TLR7/8 Agonist in the transcendIT-101 and IL Believe trials to prioritize our efforts on TransCon IL-2 β/γ .
- Strategic Collaboration
 - In November, granted Novo Nordisk A/S an exclusive, multi-product, worldwide license to the TransCon technology platform to develop, manufacture and commercialize Novo Nordisk proprietary products in metabolic diseases and a product-by-product exclusive license in cardiovascular diseases. The lead program in the collaboration is a once-monthly GLP-1 receptor agonist product candidate that will initially target obesity and type 2 diabetes.
 - For the lead program, Ascendis will be eligible to receive total payments of up to \$285 million in upfront, development, and regulatory milestone payments, plus sales-based milestone payments and escalating tiered, mid-single digit royalties on global net sales.
 - Novo Nordisk will be responsible for Ascendis' early development costs as well as for clinical development, regulatory, commercial manufacturing, and commercialization activities.
- Financial Update and Outlook Based on Current Plans
 - As of September 30, 2024, Ascendis Pharma had cash, cash equivalents, and marketable securities, totaling €626 million, compared to €399 million as of December 31, 2023.
 - Full year 2024 SKYTROFA revenue excluding sales deductions related to prior years expected to be €200 - €220 million.
 - Expect total operating expenses (SG&A and R&D) to be approximately €600 million for 2024.

Third Quarter 2024 Financial Results

Total revenue for the third quarter of 2024 was €57.8 million, compared to €48.0 million during the same period for 2023. The year-over-year increase in total revenue was primarily attributable to revenue contribution of €8.5 million from YORVIPATH following commercial launch in the first quarter of 2024. Non-product revenue was €2.1 million in the third quarter of 2024, compared to €1.1 million for the same period for 2023.

Total Revenue (In EUR'000s)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue from external customers				
Commercial sale of products	55,710	46,968	153,598	114,414
Licenses	851	571	26,490	1,774
Other	1,272	495	9,637	12,828
Total revenue from external customers	57,833	48,034	189,725	129,016

Research and development (R&D) costs for the third quarter of 2024 were €73.5 million, compared to €111.4 million during the same period in 2023. The decline was largely tied to lower external development costs across for TransCon hGH, TransCon PTH, and TransCon CNP as well as the Eyonis spin-off.

Selling, general, and administrative (SG&A) expenses for the third quarter of 2024 were €69.8 million, compared to €63.6 million during the same period in 2023. The increase was primarily due to higher employee costs, including the impact from commercial expansion.

Total operating expenses for the third quarter of 2024 were €143.4 million compared to €175.1 million during the same period in 2023.

Net finance income for the third quarter of 2024 was €2.9 million compared to a net finance expense of €20.4 million during the same period in 2023. The change was primarily tied the impact of currency fluctuations.

For the third quarter of 2024, Ascendis Pharma reported a net loss of €99.2 million, or €1.72 per share (basic and diluted) compared to a net loss of €162.2 million, or €2.88 per share (basic and diluted) for the same period in 2023.

As of September 30, 2024, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €625.5 million compared to €399.4 million as of December 31, 2023. As of September 30, 2024, Ascendis Pharma had 60,642,144 ordinary shares outstanding, including 881,730 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 third quarter 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 U.S. launch of YORVIPATH; (ii) the timing of NDA and MAA submissions for TransCon CNP; (iii) projections for full year 2024 SKYTROFA revenue and operating expenses; (iv) the closing of the Novo Nordisk collaboration; (v) the ability of Ascendis' three endocrinology rare disease programs to address major unmet medical needs and achieve blockbuster status; (vi) Ascendis' ability to extend the success of its TransCon platform and capture significant value in the areas of metabolic and cardiovascular disease; (vii) the timing of topline results from Phase 2 New InSiGHTS Trial in Turner syndrome; (viii) the initiation of a basket trial evaluating SKYTROFA in other daily growth hormone indications; (ix) the timing by which the Ascendis Signature Access Program will begin accepting prescriptions and enrolling patients; (x) the timing of final YORVIPATH pricing in Germany; (xi) the timing of topline Week 26 data from COACH, the combination TransCon hGH and TransCon CNP trial of children with achondroplasia; (xii) Ascendis' revenues from the Novo Nordisk collaboration; (xiii) Novo Nordisk's responsibilities under the collaboration; (xiv) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated biopharma company, and (xv) 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 7, 2024, 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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Investor Contacts:

Scott Smith

Ascendis Pharma

ir@ascendispharma.com

Patti Bank

Media Contact:

Melinda Baker

Ascendis Pharma

+1 (650) 709-8875

media@ascendispharma.com

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Consolidated Statement of Profit or (Loss)				
Revenue	57,833	48,034	189,725	129,016
Cost of sales	11,201	7,388	30,235	24,938
Gross profit	46,632	40,646	159,490	104,078
Research and development costs	73,544	111,439	227,708	322,573
Selling, general and administrative expenses	69,831	63,614	210,928	200,435
Operating profit/(loss)	(96,743)	(134,407)	(279,146)	(418,930)
Share of profit/(loss) of associate	(4,367)	(6,794)	(15,485)	(15,471)
Finance income	28,279	4,142	29,262	76,985
Finance expenses	25,347	24,519	70,488	35,640
Profit/(loss) before tax	(98,178)	(161,578)	(335,857)	(393,056)
Income taxes/(expenses)	(1,020)	(645)	(3,758)	(1,513)
Net profit/(loss) for the period	(99,198)	(162,223)	(339,615)	(394,569)
Attributable to owners of the Company	(99,198)	(162,223)	(339,615)	(394,569)
Basic and diluted earnings/(loss) per share	€ (1.72)	€ (2.88)	€ (5.93)	€ (7.02)
Number of shares used for calculation (basic and diluted)	57,535,349	56,272,698	57,255,764	56,194,956

Consolidated Statement of Comprehensive Income or (Loss)

Net profit/(loss) for the period	(99,198)	(162,223)	(339,615)	(394,569)
<i>Items that may be reclassified subsequently to profit or (loss):</i>				
Exchange differences on translating foreign operations	154	571	232	(1,232)
Other comprehensive income/(loss) for the period, net of tax	154	571	232	(1,232)
Total comprehensive income/(loss) for the period, net of tax	(99,044)	(161,652)	(339,383)	(395,801)
Attributable to owners of the Company	(99,044)	(161,652)	(339,383)	(395,801)

Ascendis Pharma A/S

Consolidated Statements of Financial Position
(In EUR'000s)

	September 30, 2024	December 31, 2023
Assets		
Non-current assets		
Intangible assets	4,106	4,419
Property, plant and equipment	97,522	110,634
Investment in associates	16,213	5,686
Other receivables	2,202	2,127

	<u>120,043</u>	<u>122,866</u>
Current assets		
Inventories	265,433	208,931
Trade receivables	33,098	35,874
Income tax receivables	1,995	802
Other receivables	15,259	19,097
Prepayments	32,440	38,578
Marketable securities	—	7,275
Cash and cash equivalents	625,515	392,164
	<u>973,740</u>	<u>702,721</u>
Total assets	<u>1,093,783</u>	<u>825,587</u>
Equity and liabilities		
Equity		
Share capital	8,143	7,749
Distributable equity	(105,463)	(153,446)
Total equity	<u>(97,320)</u>	<u>(145,697)</u>
Non-current liabilities		
Borrowings	338,930	222,996
Contract liabilities	5,000	5,949
Deferred tax liabilities	8,716	5,830
	<u>352,646</u>	<u>234,775</u>
Current liabilities		
Convertible notes, matures in April 2028		
Borrowings	422,064	407,095
Derivative liabilities	168,346	143,296
	<u>590,410</u>	<u>550,391</u>
Other current liabilities		
Borrowings	27,668	14,174
Contract liabilities	1,586	1,184
Trade payables and accrued expenses	75,268	94,566
Other liabilities	42,241	41,176
Income tax payables	1,016	2,299
Provisions	100,268	32,719
	<u>248,047</u>	<u>186,118</u>
	<u>838,457</u>	<u>736,509</u>
Total liabilities	<u>1,191,103</u>	<u>971,284</u>
Total equity and liabilities	<u>1,093,783</u>	<u>825,587</u>



Source: Ascendis Pharma