



Ascendis Pharma Reports Second Quarter 2024 Financial Results

September 3, 2024 at 5:04 PM EDT

- *YORVIPATH approved by U.S. Food & Drug Administration (FDA) as the first and only treatment of hypoparathyroidism in adults*
 - *TransCon CNP (navepegritide) pivotal ApproaCH Trial topline results expected in the coming weeks*
- *SKYTROFA Q2 revenue of €26 million – 134% year-over-year volume growth offset by negative adjustment of €27 million, resetting market access for continued growth*
 - *Revising full year 2024 SKYTROFA revenue outlook to €220 - €240 million*
 - *Conference call today at 4:30 pm ET*

COPENHAGEN, Denmark, Sept. 03, 2024 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the second quarter ended June 30, 2024, and provided a business update.

"The recent FDA approval of YORVIPATH demonstrates why our unrelenting focus on helping patients suffering from hypoparathyroidism and other serious diseases with considerable unmet need is so important for Ascendis," said Jan Mikkelsen, Ascendis Pharma's President and Chief Executive Officer. "Already, two out of our three Endocrine Rare Disease TransCon product candidates have been approved by the FDA and European Commission. Our first, SKYTROFA, has achieved U.S. market value leadership, and, we believe, now with broader market access, remains well positioned to reach blockbuster status in the U.S. alone. Looking forward, we are preparing for our second U.S. launch with YORVIPATH and are on track to report pivotal data in the coming weeks for our third TransCon product candidate, TransCon CNP."

Select Highlights & Anticipated 2024 Milestones

- **TransCon hGH:**
(lonapegsomatropin, marketed as SKYTROFA)
 - SKYTROFA revenue for the second quarter of 2024 totaled €26.2 million, a 27% year-over-year decrease compared to €35.9 million during the same period in 2023. 134% year-over-year volume growth was offset by the cost associated with broader market access for SKYTROFA which also resulted in a negative adjustment to prior period sales deductions of €27.1 million, where €19.5 million and €7.6 million were attributable to the three months ended March 31, 2024, and periods prior to January 1, 2024, respectively.
 - SKYTROFA revenue for the first half of 2024 totaled €91.2 million, a 35% year-over-year increase compared to €67.4 million during the same period of 2023. 159% year-over-year volume growth was offset by the cost associated with broader market access for SKYTROFA which also resulted in a negative adjustment to prior period sales deductions of €7.6 million, which were attributable to periods prior to January 1, 2024.
 - On track to submit a supplemental Biologics License Application to the FDA for adult growth hormone deficiency in the third quarter of 2024.
 - Topline results from Phase 2 New InsiGHTS Trial in Turner syndrome expected in the fourth quarter of 2024.
- **TransCon PTH:**
(palopegteriparatide, marketed as YORVIPATH)
 - Received U.S. FDA approval for TransCon PTH, under the brand name YORVIPATH, for the treatment of hypoparathyroidism in adults.
 - Completing manufacturing of commercial product for the U.S. market and anticipate initial supply will be available in the first quarter of 2025. The Company is in dialogue with the FDA about commercialization of existing manufactured product, which if agreed, could be introduced in the U.S. in the fourth quarter of 2024.
 - Second quarter YORVIPATH revenue totaled €5.2 million, reflecting the first full quarter of commercial launch in Germany and Austria as well initial revenue in International Markets. Initial revenue in France expected starting in the fourth quarter of 2024.

- TransCon CNP
(navepegritide)
 - Topline data from pivotal ApproaCH Trial expected in the coming weeks, and, if successful, plan to submit a New Drug Application to FDA for children with achondroplasia (age 2-11 years) in the first quarter of 2025.
 - Plan to complete enrollment in the combination TransCon hGH and TransCon CNP COACH trial of children with achondroplasia (ages 2-11 years) during the third quarter of 2024; topline Week 26 data expected in the second quarter of 2025.
 - Expect to initiate teACH, a Phase 2 trial in adolescents with achondroplasia, in the fourth quarter of 2024.
- Oncology Programs
 - Presented new and updated results from the ongoing Phase 1/2 IL-Believe Trial of TransCon IL-2 βγ in a poster presentation at ASCO 2024. As of the April 16, 2024, data cutoff, 40% of efficacy-evaluable patients (2 out of 5) in the initial cohort of patients with anti-PD-1 refractory melanoma treated with TransCon IL-2 βγ in combination with TransCon TLR7/8 Agonist exhibited confirmed clinical responses with no new safety signals.
 - Initial results from the Phase 2 dose expansion cohort of the IL-Believe Trial of TransCon IL-2 βγ in combination with chemotherapy in platinum-resistant ovarian cancer (PROC) will be presented later this month at the European Society for Medical Oncology (ESMO) 2024 Congress in Barcelona, Spain.
- Financial Update and Outlook Based on Current Plans
 - As of June 30, 2024, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €259 million, compared to €399 million as of December 31, 2023.
 - Full year 2024 SKYTROFA revenue expected to be €220 million to €240 million.
 - Expect total operating expenses (SG&A and R&D) to be approximately €600 million for 2024.
 - Pending launch timing of YORVIPATH in the U.S., expect to be operating cash flow breakeven on a quarterly basis in 2024 or 2025
 - Subsequent to the quarter end, entered into a \$150 million capped synthetic royalty funding agreement with Royalty Pharma relating to net sales of YORVIPATH in the United States. More information on this funding can be found in a separate press release issued today and available [here](#) on the Investors & News section of the Ascendis Pharma website.

Second Quarter 2024 Financial Results

Total revenue for the second quarter of 2024 was €36.0 million, compared to €47.4 million during the same period for 2023. Results in the quarter were primarily impacted by a negative adjustment to prior periods' estimates and assumptions for sales deductions of €27.1 million, where €19.5 million and €7.6 million were attributable to the three months ended March 31, 2024, and periods prior to January 1, 2024, respectively. This was partially offset by increased demand for SKYTROFA in the U.S. and revenue contribution from YORVIPATH. In addition, non-product revenue was €4.6 million in the second quarter of 2024, compared to €11.5 million during the same period for 2023.

Total Revenue (In EUR'000s)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue from external customers				
Commercial sale of products	31,389	35,895	97,888	67,446
Licenses	869	589	25,639	1,203
Other	3,740	10,909	8,365	12,333
Total revenue from external customers	35,998	47,393	131,892	80,982

Research and development (R&D) costs for the second quarter of 2024 were €83.5 million, compared to €105.0 million during the same period in 2023. The decline was largely tied to lower external development costs for TransCon TLR 7/8 Agonist and lower costs for TransCon PTH, as well as lower employee costs as a result of the Eyconis spin-off.

Selling, general, and administrative (SG&A) expenses for the second quarter of 2024 were €74.3 million, compared to €70.3 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 second quarter of 2024 were €157.8 million compared to €175.3 million during the same period in 2023.

Net finance income for the second quarter of 2024 was €29.4 million compared to a net finance income of €26.4 million during the same period in 2023.

For the second quarter of 2024, Ascendis Pharma reported a net loss of €109.4 million, or €1.91 per share (basic and diluted) compared to a net loss of €121.4 million, or €2.16 per share (basic and diluted) for the same period in 2023.

As of June 30, 2024, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €258.7 million compared to €399.4 million as of December 31, 2023. As of June 30, 2024, Ascendis Pharma had 58,231,484 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 second 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 timing of topline results from the ApproaCH Trial, (ii) Ascendis' expectations regarding full year 2024 SKYTROFA revenue, (iii) Ascendis' expectations regarding SKYTROFAs potential to reach blockbuster status, (iv) Ascendis' plan to submit a supplemental Biologics License Application for SKYTROFA for adult growth hormone deficiency in the third quarter of 2024, (v) the timing of topline results from the Phase 2 trial of TransCon hGH in Turner syndrome, (vi) Ascendis' plan to submit a New Drug Application for TransCon CNP for children with achondroplasia, (vii) Ascendis' expectations regarding completing manufacturing of YORVIPATH commercial product for the U.S. market and the timing of initial supply, (viii) dialogue with FDA regarding commercialization of existing YORVIPATH manufactured product and, if agreed, the potential timing of introduction, (ix) Ascendis' expectations regarding initial revenue in France from YORVIPATH, (x) Ascendis' plan to complete enrollment in the COACH Trial, (xi) the timing of topline Week 26 data from the COACH Trial, (xii) the timing of initiating the teACH Phase 2 trial in adolescents, (xiii) Ascendis' plan to present initial results from the Phase 2 dose expansion cohort of the IL-Believe Trial, (xiv) Ascendis' expectations regarding its total operating expenses for 2024, (xv) Ascendis' expectation to be operating cash flow breakeven on a quarterly basis in 2024 or 2025, (xvi) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated biopharma company, and (xvii) 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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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
June 30,

Six Months Ended
June 30,

	2024	2023	2024	2023
Consolidated Statement of Profit or Loss				
Revenue	35,998	47,393	131,892	80,982
Cost of sales	11,465	12,929	19,034	17,551
Gross profit	24,533	34,464	112,858	63,431
Research and development costs	83,478	105,021	154,165	211,134
Selling, general and administrative expenses	74,312	70,281	141,095	136,820
Operating profit/(loss)	(133,257)	(140,838)	(182,402)	(284,523)
Share of profit/(loss) of associate	(5,322)	(7,451)	(11,118)	(8,677)
Finance income	49,052	35,761	14,395	80,374
Finance expenses	19,624	9,334	58,553	18,652
Profit/(loss) before tax	(109,151)	(121,862)	(237,678)	(231,478)
Income taxes/(expenses)	(229)	429	(2,737)	(868)
Net profit/(loss) for the period	(109,380)	(121,433)	(240,415)	(232,346)
Attributable to owners of the Company	(109,380)	(121,433)	(240,415)	(232,346)
Basic and diluted earnings/(loss) per share	€ (1.91)	€ (2.16)	€ (4.21)	€ (4.14)
Number of shares used for calculation (basic and diluted)	57,345,613	56,218,257	57,114,435	56,155,441

(EUR'000)

Consolidated Statement of Comprehensive Income or (Loss)				
Net profit/(loss) for the period	(109,380)	(121,433)	(240,415)	(232,346)
<i>Items that may be reclassified subsequently to profit or loss:</i>				
Exchange differences on translating foreign operations	15	(1,016)	78	(1,803)
Other comprehensive income/(loss) for the period, net of tax	15	(1,016)	78	(1,803)
Total comprehensive income/(loss) for the period, net of tax	(109,365)	(122,449)	(240,337)	(234,149)
Attributable to owners of the Company	(109,365)	(122,449)	(240,337)	(234,149)

Ascendis Pharma A/S

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

Assets

Non-current assets

	June 30, 2024	December 31, 2023
Intangible assets	4,186	4,419
Property, plant and equipment	104,041	110,634
Investment in associates	20,564	5,686
Other receivables	2,186	2,127
	130,977	122,866

Current assets

Inventories	251,199	208,931
Trade receivables	49,163	35,874
Income tax receivables	1,841	802
Other receivables	29,679	19,097
Prepayments	36,743	38,578
Marketable securities	—	7,275
Cash and cash equivalents	258,696	392,164
	627,321	702,721
Total assets	758,298	825,587

Equity and liabilities

Equity

Share capital	7,819	7,749
Distributable equity	(328,952)	(153,446)
Total equity	(321,133)	(145,697)

Non-current liabilities

Borrowings	219,052	222,996
Contract liabilities	5,000	5,949
Deferred tax liabilities	7,644	5,830
	231,696	234,775

Current liabilities**Convertible notes, matures in April 2028**

Borrowings	432,190	407,095
Derivative liabilities	159,059	143,296
	591,249	550,391

Other current liabilities

Borrowings	21,397	14,174
Contract liabilities	1,293	1,184
Trade payables and accrued expenses	99,527	94,566
Other liabilities	26,411	41,176
Income tax payables	1,090	2,299
Provisions	106,768	32,719
	256,486	186,118

	847,735	736,509
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Total liabilities	1,079,431	971,284
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Total equity and liabilities	758,298	825,587
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Source: Ascendis Pharma