UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO SECTION 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2023

Commission File Number: 001-36815

Ascendis Pharma A/S
(Exact Name of Registrant as Specified in Its Charter)

Tuborg Boulevard 12
DK-2900 Hellerup
Denmark
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Furnished as an exhibit to this Report on Form 6-K is a press release reporting the financial results of Ascendis Pharma A/S for the fiscal quarter ended June 30, 2023.

Exhibits

Exhibit No.	Description
99.1	Press Release dated September 5, 2023.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Ascendis Pharma A/S

Date: September 5, 2023

By: /s/ Michael Wolff Jensen
Michael Wolff Jensen
Executive Vice President, Chief Legal Officer

PRESS RELEASE

Ascendis Pharma Reports Second Quarter 2023 Financial Results

– Expect to resubmit NDA to FDA for TransCon™ PTH in October 2023; EC decision on MAA for TransCon PTH expected during the fourth quarter of 2023

– U.S. and EU regulatory authorities endorsed ApproaCH as a pivotal Phase 3 trial of TransCon CNP in children with achondroplasia; enrollment completed, and topline results expected in second half of 2024

– Raising full year 2023 U.S. SKYTROFA® revenue expectations to €165 - €170 million*

– Conference call today at 4:30 pm ET

COPENHAGEN, Denmark, September 5, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the second quarter ended June 30, 2023 and provided business updates.

"We have built a fully integrated Endocrinology Rare Disease franchise with a growing commercial reach and are on our way to achieving our Vision 3x3, including regulatory approval for three differentiated product candidates by 2025," said Jan Mikkelsen, Ascendis Pharma's President and Chief Executive Officer. "With a proven U.S. and expanding global commercial infrastructure positioned to capture the multi-billion-dollar opportunities that each represents, coupled with an R&D engine for label expansion and future innovation for new patient populations, Ascendis has many routes to realize long-term profitability and sustainability."

Corporate Highlights

- TransCon hGH (marketed in the U.S. as SKYTROFA):
  - Second quarter 2023 SKYTROFA revenue totaled €36 million, and the Company is increasing full year 2023 U.S. SKYTROFA revenue expectations from €150 - €160 million to €165 - €170 million.
  - Second quarter 2023 SKYTROFA revenue included a negative adjustment to provision for estimated sales rebates related to sales from prior periods of €2.1 million as a result of expanding payer coverage and a negative foreign currency impact of €0.6 million compared to the first quarter of 2023, due to a weaker U.S. dollar.

	Q2-2022	Q3-2022	Q4-2022	Q1-2023	Q2-2023
SKYTROFA revenue (millions)	€ 4.4	€ 12.3	€ 17.1	€ 31.6	€ 35.9

- Based on reported revenues, SKYTROFA was the leading U.S. growth hormone product in the second quarter, with a market share of less than 10% of treated U.S. pediatric GHD patients.
- First commercial launch of SKYTROFA in the EU expected in September in Germany.
- Received FDA approval of Lonza as a high-capacity drug substance manufacturing site to support worldwide demand of SKYTROFA. Expect EU approval in first half of 2024.
- Topline results from Phase 3 foresiGHt Trial in adult growth hormone deficiency investigating the metabolic impact of TransCon hGH expected in the fourth quarter of 2023, opening up the first label expansion opportunity.

- TransCon PTH:
  - In June 2023, the Company requested a Type A meeting with FDA and submitted an updated control strategy. The Company's Type A meeting was held with FDA in late August based on the Agency's availability. Following a constructive Type A meeting, the Company submitted additional information to FDA supporting the updated control strategy. Ascendis believes the materials submitted to FDA combined with the Type A meeting discussions will position the Company to resubmit the NDA for TransCon PTH for adults with hypoparathyroidism in October 2023.
  - Remain on track for European Commission decision on Marketing Authorisation Application (MAA) for TransCon PTH during the fourth quarter of 2023. If approved, first country launch planned in Germany in early 2024.
  - New post hoc analysis showed TransCon PTH-treated patients demonstrated substantial increases in estimated glomerular filtration rate (eGFR), indicating improved kidney function. More information on this analysis can be found in a separate press release issued today and available here on the Investors & News section of the Ascendis Pharma website.
  - 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.
  - The U.S. Expanded Access Program and German Compassionate Use Program continue to be open for enrollment of eligible patients.
- TransCon CNP:
  - U.S. and EU regulatory agencies have endorsed ApproaCH, a global randomized, double-blind, placebo-controlled trial in children ages 2–11 years with achondroplasia, as a pivotal Phase 3 trial. Enrollment is complete and topline results are expected in the second half of 2024.
  - All 57 patients remain in the 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.
- TransCon TLR7/8 Agonist:
  - Enrollment continues in the Phase 2 portion of transcendIT-101 at the recommended Phase 2 dose (RP2D) in four indication-specific cohorts. Topline/interim analysis from Phase 2 dose-expansion cohorts expected in 2024.

- TransCon IL-2 b/g:
    - Completed Phase 1 dose escalation in combination with pembrolizumab in the Phase 1/2 IL-Believe Trial with a total of 21 patients enrolled. RP2D was determined at 120 µg/kg IV every three weeks. No dose-limiting toxicity, vascular leak syndrome, or grade 3 or 4 cytokine release syndrome was observed at any dose level evaluated.
    - Enrollment initiated in the Phase 2 portion in indication-specific cohorts, with expected topline/interim analysis from Phase 2 dose-expansion cohorts expected in 2024.
- Expanding leadership in long-acting prodrug technologies with new TransCon technology carrier platform to unlock large market opportunities where high volume and low-cost manufacturing is required.
    - Proof-of-principle demonstrated for GLP-1 analogs (semaglutide), with data supporting potential best-in-class weekly and monthly administration profiles. More information on the pre-clinical data can be found in a presentation here on the Investors & News section of the Ascendis Pharma website.
- Ended the second quarter of 2023 with cash, cash equivalents, and marketable securities totaling €431.1 million.
- Subsequent to the quarter end, entered into a $150 million capped synthetic royalty funding agreement with Royalty Pharma. 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 2023 Financial Results

Total revenue for the second quarter of 2023 was €47.4 million compared to €6.2 million during the same period in 2022. The increase was primarily attributable to higher SKYTROFA revenue of €35.9 million compared to €4.4 million in the same period last year.

Research and development (R&D) costs for the second quarter were €105.0 million compared to €90.4 million during the same period in 2022. This increase was primarily due to higher development costs for Ascendis Pharma Oncology programs (TransCon IL-2 ß/g and TransCon TLR7/8 Agonist), 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 second quarter were €70.3 million compared to €56.6 million during the same period in 2022. This increase was primarily due to higher external commercial expenses related to SKYTROFA, pre-launch activities for SKYTROFA outside the U.S., global 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 €26.4 million in the second quarter compared to €61.7 million in the same period in 2022.

For the second quarter of 2023, Ascendis Pharma reported a net loss of €121.4 million, or €2.16 per share (basic and diluted) compared to a net loss of €81.3 million, or €1.46 per share (basic and diluted) for the same period in 2022.

As of June 30, 2023, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling €431.1 million compared to €742.9 million as of December 31, 2022. As of June 30, 2023, Ascendis Pharma had 57,335,496 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 second 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 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, Berlin and Munich) and the United States (Palo Alto and Redwood City, California, and Princeton, New Jersey). 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) Ascendis' plan to resubmit an NDA for TransCon PTH in October 2023; (ii) the timing and results of the EC decision on the TransCon PTH MAA; (iii) the timing of topline results of the ApproaCH trial; (iv) Ascendis' expectations regarding 2023 SKYTROFA revenues in the United States; (v) Ascendis' ability to achieve its Vision 3x3; (vi) Ascendis' expectations regarding regulatory approval for three independent product candidates by 2025; (vii) Ascendis' ability to capture the opportunities presented by its product candidates and realize long-term profitability and sustainability; (viii) Ascendis' SKYTROFA revenue expectations; (ix) Ascendis' expectations regarding the launch of SKYTROFA in Germany; (x) Ascendis' expectations regarding EU approval at Lonza for a high-capacity drug substance manufacturing site; (xi) the timing of Topline results from Phase 3 foresiGHt trial and the potential for the first label expansion opportunity; (xii) Ascendis' expectations regarding the launch of TransCon PTH in Germany; (xiii) the timing of topline results from the ApproaCH trial; (xiv) the timing of one-year follow-up data from the OLE portion of the Phase 2 ACcomplisH trials; (xv) the timing of topline/interim analysis from Phase 2 dose-expansion cohorts of transcendIT-101 and IL-Believe trials; (xvi) the ability of the new TransCon technology carrier platform to unlock large market opportunities where high volume and low-cost manufacturing is required; (xvii) the potential best-in-class weekly and monthly administration profiles of Ascendis' new TransCon technology carrier platform; (xviii) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated global biopharma company; and (xix) 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.

Ascendis, Ascendis Pharma, the Ascendis Pharma logo, the company logo, TransCon, and SKYTROFA® are trademarks owned by the Ascendis Pharma group. © September 2023 Ascendis Pharma A/S.

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,	
	2023	2022	2023	2022
Revenue	47,393	6,160	80,982	12,988
Cost of sales	12,929	1,086	17,551	5,332
Gross profit	**34,464**	**5,074**	**63,431**	**7,656**
Research and development costs	105,021	90,383	211,134	173,576
Selling, general and administrative expenses	70,281	56,584	136,820	104,002
Operating profit / (loss)	**(140,838)**	**(141,893)**	**(284,523)**	**(269,922)**
Share of profit / (loss) of associate	(7,451)	(1,166)	(8,677)	(6,039)
Finance income	35,761	71,127	80,374	84,171
Finance expenses	9,334	9,434	18,652	14,833
Profit / (loss) before tax	**(121,862)**	**(81,366)**	**(231,478)**	**(206,623)**
Income taxes (expenses)	429	47	(868)	(195)
Net profit / (loss) for the period	**(121,433)**	**(81,319)**	**(232,346)**	**(206,818)**
Attributable to owners of the Company	(121,433)	(81,319)	(232,346)	(206,818)
Basic and diluted earnings / (loss) per share	€ (2.16)	€ (1.46)	€ (4.14)	€ (3.68)
Number of shares used for calculation (basic and diluted)	56,218,257	55,805,486	56,155,441	56,260,248
Net profit / (loss) for the period	**(121,433)**	**(81,319)**	**(232,346)**	**(206,818)**
Other comprehensive income / (loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations	(1,016)	(757)	(1,803)	(332)
Other comprehensive income / (loss) for the period, net of tax	**(1,016)**	**(757)**	**(1,803)**	**(332)**
Total comprehensive income / (loss) for the period, net of tax	**(122,449)**	**(82,076)**	**(234,149)**	**(207,150)**
Attributable to owners of the Company	(122,449)	(82,076)	(234,149)	(207,150)

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

	June 30, 2023	December 31, 2022
Assets		
Non-current assets		
Intangible assets	4,606	4,828
Property, plant and equipment	125,362	129,095
Investment in associate	14,111	22,932
Other receivables	2,066	1,920
Marketable securities	—	7,492
	146,145	**166,267**
Current assets		
Inventories	167,919	130,673
Trade receivables	20,212	11,910
Income tax receivable	1,360	883
Other receivables	14,127	12,833
Prepayments	42,958	31,717
Marketable securities	36,880	290,688
Cash and cash equivalents	394,222	444,767
	677,678	**923,471**
Total assets	**823,823**	**1,089,738**
Equity and liabilities		
Equity		
Share capital	7,699	7,675
Distributable equity	57,142	255,673
Total equity	**64,841**	**263,348**
Non-current liabilities		
Borrowings	479,374	482,956
Derivative liabilities	86,385	157,950
Contract liabilities	949	14,213
	566,708	**655,119**
Current liabilities		
Borrowings	26,564	25,421
Contract liabilities	4,146	—
Trade payables and accrued expenses	122,120	101,032
Other liabilities	22,860	31,989
Income tax payables	5,773	5,490
Provisions	10,811	7,339
	192,274	**171,271**
Total liabilities	**758,982**	**826,390**
Total equity and liabilities	**823,823**	**1,089,738**

Investor Contacts:
Tim Lee
Ascendis Pharma
+1 (650) 374-6343
tle@ascendispharma.com
ir@ascendispharma.com

Patti Bank
ICR Westwicke
+1 (415) 513-1284
patti.bank@westwicke.com

Media Contact:
Melinda Baker
Ascendis Pharma
+1 (650) 709-8875
media@ascendispharma.com

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