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 December, 2024

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): ☐

INCORPORATION BY REFERENCE

This report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form S-8 (Registration Numbers 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883, 333-228576, 333-254101, 333-261550, 333-270088, 333-277519 and 333-281916) and Form F-3 (Registration Numbers 333-209336 and 333-282196) of Ascendis Pharma A/S (the "Company") (including any prospectuses forming a part of such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

On December 12, 2024, the Company announced that the U.S. Food & Drug Administration ("FDA") has accepted for review its supplemental Biologics License Application ("sBLA") in adult growth hormone deficiency ("GHD") for TransCon hGH (lonapegsomatropin-tcgd; marketed as SKYTROFA® for pediatric GHD). The FDA set a Prescription Drug User Fee Act ("PDUFA") goal date of July 27, 2025.

The sBLA submission is based on results from foresiGHt, a Phase 3 randomized, parallel-arm, placebo-controlled (double-blind) and active-controlled (open-label) trial that compared the efficacy and safety of weekly TransCon hGH with weekly placebo and daily human growth hormone ("hGH") in adults with GHD. The trial evaluated 259 adults with GHD aged 23 to 80 years old, randomized 1:1:1, titrated to receive a target fixed dose of TransCon hGH, placebo, or daily hGH based on age and oral estrogen intake with approximately equivalent hGH mg/week for TransCon hGH and daily hGH. TransCon hGH demonstrated superiority on its primary efficacy and key secondary efficacy endpoints at Week 38, with TransCon hGH-treated participants showing a statistically significant reduction from baseline in trunk fat and increase in total body lean mass at Week 38 compared to placebo. In the trial, TransCon hGH was generally safe and well tolerated, with no discontinuations related to study drug and with comparable safety and tolerability to daily hGH treatment.

Forward-Looking Statements

This report contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report 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 the PDUFA goal date for SKYTROFA. 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' prospectus supplement filed on September 20, 2024 and Ascendis' current and future reports filed with, or submitted to, the U.S. Securities and Exchange Commission ("SEC"), including its Annual Report on Form 20-F filed with the SEC on February 7, 2024. 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.

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: December 12, 2024

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