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, 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 333-228576, 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883, 333-254101, 333-261550, 333-270088, 333-277519 and 333-281916) and Form F-3 (Registration Numbers 333-209336, 333-211511, 333-216882, 333-223134, 333-225284, and 333-256571) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 September 16, 2024, the Company announced topline data from the pivotal double-blind placebo-controlled ApproaCH Trial of TransCon CNP (navepegritide), which included 84 children with achondroplasia (ages 2-11 years) randomized 2:1 (TransCon CNP:placebo). TransCon CNP is an investigational prodrug of C-type natriuretic peptide (CNP) administered once weekly and designed to provide sustained release and continuous exposure of active CNP. In the trial, children treated with once-weekly TransCon CNP demonstrated annualized growth velocity (AGV) superior to placebo. TransCon CNP also demonstrated statistically significant improvements in other growth parameters, including height Z-score and change from baseline AGV.

Highlights of the ApproaCH Trial Topline Data

Primary Endpoint

- For the primary endpoint of AGV at Week 52, children treated with TransCon CNP (n=57) demonstrated an LS mean AGV of 5.89 cm/year compared to 4.41 cm/year in the placebo arm (n=27), an LS mean difference of 1.49 cm/year ($p<0.0001$).
- Sub-group analyses:
  - Children aged 2 to <5 years treated with TransCon CNP (n=21) demonstrated an LS mean AGV at Week 52 of 6.07 cm/year compared to 5.06 cm/year in the placebo arm (n=10), an LS mean difference of 1.02 cm/year ($p=0.0084$).
  - Children aged 5-11 years treated with TransCon CNP (n=36) demonstrated an LS mean AGV at Week 52 of 5.79 cm/year compared to 4.02 cm/year in the placebo arm (n=17), an LS mean difference of 1.78 cm/year ($p<0.0001$).

AGV Change from Baseline

- Children aged 2 to <5 years, treated with TransCon CNP (n=19) demonstrated a change from baseline AGV at Week 52 of 1.57 cm/year compared to 0.43 cm/year in the placebo arm (n=10), an LS mean difference of 1.15 cm/year ($p=0.0047$).
- Children aged 5-11 years, treated with TransCon CNP (n=35) demonstrated a change from baseline AGV at Week 52 of 2.29 cm/year compared to 0.52 cm/year in the placebo arm (n=17), an LS mean difference of 1.78 cm/year ($p<0.0001$).

Secondary Endpoints

- For the secondary endpoint of change in ACH Height Z-score, children treated with TransCon CNP (n=57) demonstrated an LS mean change from baseline ACH Height Z-score of 0.30 compared to 0.01 in the placebo arm (n=27), an LS mean difference of 0.28 ($p<0.0001$).
- For the secondary endpoint of change in CDC Height Z-score, children treated with TransCon CNP (n=55) demonstrated an LS mean change from baseline CDC Height Z-score of 0.15 compared to -0.15 in the placebo arm (n=27), an LS mean difference of 0.30 ($p=0.0003$).

Selected Other Endpoints

- In the total trial population, treatment with TransCon CNP resulted in numerical improvements in health-related quality of life compared to placebo as measured in several Achondroplasia Child Experience Measure (ACEM) domains.

- Predefined sub-group analyses of ACEM-Physical Functioning demonstrated potential treatment effect, supported by muscle functionality test results.
- At baseline, parents of children generally reported lower burden of health-related quality of life (HRQoL) compared to the ACcomplisH Trial.
    - For children with HRQoL burden at baseline, a potential treatment effect was observed across several HRQoL domains of the ACEM measures.

Safety Summary

- TransCon CNP continues to show a safety profile comparable to placebo and was generally well-tolerated, with generally mild treatment-emergent adverse events (TEAEs), no evidence of hypotensive effect, and a low frequency of injection site reactions (0.41 events per patient year), all mild.
- No adverse events (AEs) led to discontinuation of TransCon CNP or withdrawal from the trial and no serious adverse events (SAEs) were assessed as related to TransCon CNP.

As of today, all 82 children who completed the double-blind period are continuing in the open-label extension of the ApproaCH Trial.

Ascendis plans to submit a New Drug Application (NDA) to the U.S. Food & Drug Administration 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.

ApproaCH is a pivotal, multicenter, randomized, double-blind, placebo-controlled trial of once-weekly TransCon CNP versus placebo in 84 children with achondroplasia ages 2-11 years old. Patients were randomized 2:1 to receive TransCon CNP or placebo for 52 weeks at the 100µg/kg/week dose in the double-blind period, after which all participants could choose to receive TransCon CNP in an ongoing open-label extension at the 100µg/kg/week dose.

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 (i) the potential treatment effects of TransCon CNP and (ii) Ascendis' timing for submission of certain regulatory filings related to TransCon CNP. 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.

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 16, 2024

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