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 June, 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): ☐

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 and 333-270088) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 June 17, 2023, the Company reported one-year (Week 52) data from its ongoing Phase 3 PaTHway Trial of TransCon PTH in adults with hypoparathyroidism. The data showed that treatment with TransCon PTH resulted in sustained improvements through Week 52, as well as safety and tolerability similar to that reported for the initial 26-week blinded portion of the trial. The data were presented by Bart Clarke, M.D., endocrinologist and Professor of Medicine at the Mayo Clinic (Rochester, MN), during ENDO 2023, the annual meeting of the Endocrine Society being held in Chicago.

Methods

PaTHway is a Phase 3 trial of TransCon PTH with a placebo (PBO)-controlled 26-week blinded portion and a 156-week open-label extension (OLE) portion, designed to evaluate the long-term efficacy and safety of TransCon PTH as a potential hormone therapy for those diagnosed with hypoparathyroidism. Results through Week 52 (26 weeks blinded + 26 weeks OLE) were reported at ENDO 2023. Of the 82 study participants dosed, 79 completed blinded treatment and entered the OLE, and 78 (59 TransCon PTH/TransCon PTH, 19 PBO/TransCon PTH) completed Week 52.

Week 52 Highlights

- 95% of patients in the OLE (74 out of 78) achieved independence from conventional therapy (defined as no active vitamin D and calcium supplements of <600mg/day), and none required active vitamin D.
- At Week 52, 81% of participants treated with TransCon PTH achieved both normal serum calcium and independence from conventional therapy.
- With TransCon PTH treatment, mean albumin-adjusted serum calcium levels were maintained within the normal range (8.3–10.6 mg/dL) through Week 52 of the OLE (8.9 mg/dL at Week 52).
- Patient-reported scores on the Hypoparathyroidism Patient Experience Scale (HPES) and SF-36 Health Survey showed sustained improvements in disease-related physical and cognitive symptoms, as well as physical functioning and daily life, starting at the first scheduled follow up after randomization or switching from placebo and sustained through Week 52.
- Bone mineral density (BMD) Z-scores continued to trend toward age- and sex-matched norms with 52 weeks of TransCon PTH treatment.
- TransCon PTH normalized 24-hour urine calcium through Week 52, regardless of initial randomization (placebo or TransCon PTH).
- TransCon PTH continued to be well-tolerated in the Phase 3 open-label extension, with no new safety signal identified. Most TEAEs were mild or moderate (Grades 1-2) and none reported during the open-label extension through Week 52 led to discontinuation of the study drug or trial.

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. 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 its 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, and 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.

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: June 20, 2023

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