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 April, 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 333-203040, 333-210810, 333-211512, 333-213412, 333-214843, 333-216883, 333-228576, 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" or "Ascendis") (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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 April 3, 2023, the Company announced that the U.S. Food & Drug Administration ("FDA") has notified the Company that, as part of their ongoing review, the FDA has identified deficiencies in the Company's New Drug Application ("NDA") for TransCon PTH (palopegteriparatide) in hypoparathyroidism that at this time precludes them from holding further discussions about labeling and post-marketing requirements/commitments. The deficiencies were not disclosed in the letter. The FDA also stated that this does not reflect their final regulatory decision on the Company's application.

To date, 145 out of 154 clinical trial participants continue to be treated with TransCon PTH in Phase 2 and Phase 3 clinical trial open label extensions, including 57 patients in the Phase 2 PaTH Forward Trial (> 3 years), 76 in the Phase 3 PaTHway Trial (> 2 years), and 12 in the Phase 3 PaTHway Japan (> 1 year). In these studies, TransCon PTH has been generally well tolerated, with no discontinuations related to study drug.

In December 2022, the FDA allowed Ascendis to initiate a U.S. EAP for TransCon PTH for eligible adults with hypoparathyroidism previously treated with parathyroid hormone. This EAP, which remains open for enrollment, allows U.S. physicians to request access to investigational TransCon PTH for their eligible patients.

In Europe, as expected, Ascendis has received the comprehensive Day 120 response from the European Medicines Agency. The Company remains on track for a European Commission decision on the Marketing Authorisation Application for TransCon PTH during the fourth quarter of 2023. If approved, Ascendis expects its first European country launch in early 2024. Ascendis expects to submit an application for an EAP in Germany and open it for enrollment in the second quarter of this year.

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 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 and results of a European Commission decision on the Marketing Authorisation Application for TransCon PTH, (ii) Ascendis' expectations regarding the timing of potential commercial launch of TransCon PTH in Europe, and (iii) Ascendis' expectations regarding an EAP in Germany. 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; 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 the ongoing conflict 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: April 3, 2023

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