
**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 July, 2021

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 and 333-254101) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 July 6, 2021, the Company announced it has reached the target enrollment in the phase 3 PaTHway Trial, a trial evaluating the safety, tolerability, and efficacy of TransCon PTH (“palopegteriparatide”) in addition to providing a comprehensive global clinical program update. The Company anticipates announcing top-line results from the PaTHway Trial in the first quarter of 2022. The PaTHway Trial is a phase 3, randomized, double-blind, placebo-controlled trial in North America and Europe evaluating the safety, tolerability, and efficacy of palopegteriparatide in adults with hypoparathyroidism (“HP”). The primary efficacy endpoint is the proportion of subjects with albumin-adjusted serum calcium within the normal range, and independent from active vitamin D and therapeutic doses of calcium (≤ 600 mg/day) at 26 weeks. If successful, the Company expects to submit a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) in mid-2022 and subsequently submit a Marketing Authorisation Application (“MAA”) to the European Medicines Agency.

The Company also announced the Japanese Pharmaceuticals and Medical Devices Agency (“PMDA”) acceptance of the clinical trial notification for the PaTHway Japan Trial, a single-arm, phase 3 trial of palopegteriparatide in a minimum of 12 Japanese subjects with HP. Subjects will start with an 18 µg dose of palopegteriparatide and be followed over a 26-week period during which they will be titrated to an optimal dose. In addition, the Japanese Ministry of Health, Labor and Welfare (the “MHLW”) granted Orphan Drug Designation (“ODD”) to palopegteriparatide for the treatment of HP. In Japan, ODD is granted to therapies intended for use in less than 50,000 patients in Japan and for which significant unmet medical need exists. The designation is granted by the MHLW based on the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

In Greater China, VISEN Pharmaceuticals recently announced that they obtained the Investigational New Drug approval from the Center for Drug Evaluation of the National Medical Products Administration for the phase 3 China clinical trial (the “PaTHway China Trial”) of TransCon PTH on June 1, 2021 and is soon expected to initiate the study of TransCon PTH in patients with HP in China. The design of the PaTHway China Trial mirrors the design of the PaTHway Trial.

All subjects from phase 3 PaTHway trials in North America, Europe, Japan and Greater China will be eligible to enter into open-label extensions to collect long-term follow-up data.

Palopegteriparatide was granted ODD from the FDA in June 2018 and from the European Commission in October 2020.

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 expected timing of reporting PaTHway top-line data and, if successful, the expected timing of a submission of an NDA and MAA for TransCon PTH, and (ii) the eligibility of subjects from the phase 3 PaTHway trial in North America, Europe, Japan and Greater China to enter into open-label extensions to collect long-term follow-up data. 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: unforeseen safety or efficacy results in its TransCon PTH or other development programs; unforeseen

expenses related to the development and potential commercialization of its TransCon PTH or other development programs, selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its TransCon PTH or other development programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; dependence on third party manufacturers to supply study drug for planned clinical studies; Ascendis' ability to obtain additional funding, if needed, to support its business activities and the effects on its business from the worldwide COVID-19 pandemic. 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 March 10, 2021 and Ascendis' other future reports filed with, or submitted to, the SEC. Forward-looking statements do not reflect the potential impact of any future in-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.

Date: July 6, 2021

Ascendis Pharma A/S

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