
**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, 2020

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 and 333-216883) and Form F-3 (Registration Numbers 333-209336, 333-211511, 333-216882, 333-223134 and 333-225284) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 29, 2020, the Company announced preliminary six-month results from the open-label extension (OLE) portion of PaTH Forward, a global phase 2 trial evaluating the safety, tolerability and efficacy of TransCon PTH in adult subjects with hypoparathyroidism (HP).

TransCon PTH is an investigational long-acting prodrug of parathyroid hormone (PTH) in development as a once-daily hormone replacement therapy for adult hypoparathyroidism designed to replace PTH at physiologic levels for 24 hours each day and addresses both short-term symptoms and long-term complications of HP. Fifty-nine subjects participated in the phase 2 PaTH Forward Trial and continued in the OLE, where they all received a customized maintenance dose of TransCon PTH (6 to 30 µg) with a ready-to-use, room temperature, prefilled pen injector. One subject randomized to placebo withdrew after completing the four-week double-blinded fixed-dose period for reasons unrelated to safety or efficacy of the study drug. All of the other 58 subjects remained on TransCon PTH at the time of the six month data cutoff.

IND Amendment Filed for Phase 3 PaTHway Trial

The company submitted an amendment to its investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) to initiate the U.S. sites of the PaTHway phase 3 clinical trial evaluating the safety, tolerability and efficacy of TransCon PTH in adults with HP following discussions with FDA and European regulatory authorities. The company expects to file the clinical trial applications for the European region later this year. The double-blind, placebo-controlled trial is expected to enroll approximately 76 subjects at sites in North America and Europe in order to obtain 68 evaluable subjects.

The primary composite endpoint of the PaTHway Trial at 26 weeks is the proportion of subjects with (1) serum calcium in the normal range, (2) independence from active vitamin D, and (3) taking £600 mg/day of calcium supplements.

Preliminary OLE Results of PaTH Forward Trial at 6 Months

Preliminary six-month results from the PaTH Forward OLE demonstrated:

- 91 percent of all subjects eliminated standard of care (defined as (1) off active vitamin D and (2) £500 mg per day of calcium supplements), including 76 percent who eliminated all supplements.
- 86 percent of all subjects normalized or reduced by 50 percent 24-hour urine calcium.
- 71 percent of all subjects achieved a response on the composite endpoint of (1) serum calcium in the normal range, (2) independence from active vitamin D, (3) taking £500 mg/day of calcium supplements, and (4) 24-hour urine calcium in the normal range or 50 percent reduction from baseline, including 74 percent of subjects who were randomized to TransCon PTH.
- All mean summary and subdomain SF-36® Health Survey scores normalized despite all mean scores starting below norms at baseline including subjects randomized to placebo who switched to TransCon PTH group at week 4. Importantly, subjects randomized to TransCon PTH demonstrated continued improvements from week 4 to month 6.
- All doses of TransCon PTH were well-tolerated, and no treatment-related serious or severe adverse events were observed at any point. No subjects had PTH treatment-emergent adverse events related to hyper- or hypocalcemia leading to emergency visit, urgent care visit, or hospitalization.
- Adherence to daily injections of TransCon PTH was 99.7 percent.

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) Ascendis' expectation to enroll approximately 76 subjects in the PaTHway phase 3 clinical trial at sites in North America and Europe, (ii) Ascendis' ability to apply its platform technology to build a leading, fully integrated biopharma company, (iii) Ascendis' product pipeline and expansion into additional therapeutic areas and (iv) Ascendis' expectations regarding its ability to utilize its TransCon technologies to create new and potentially best-in-class therapies. 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 oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to the development and potential commercialization of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs, selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP 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 of 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' prospectus supplement filed on July 9, 2020 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 April 3, 2020. 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.

Ascendis Pharma A/S

Date: September 29, 2020

By: /s/ Michael Wolff Jensen

Michael Wolff Jensen

Chairman and Senior Vice President, Chief Legal Officer