# 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 March, 2022**

**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 and 333-261550) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 March 13, 2022, the Company announced that top-line data from the randomized, double-blind, placebo-controlled portion of its Phase 3 PaTHway Trial of TransCon PTH in adults with hypoparathyroidism demonstrated statistically significant improvement with TransCon PTH compared to control on the primary composite endpoint and all key secondary endpoints. The primary endpoint – defined as serum calcium levels in the normal range (8.3–10.6 mg/dL) and independence from conventional therapy (active vitamin D and >600 mg/day of calcium supplements) with no increase in prescribed study drug within the 4 weeks prior to the Week 26 visit – was achieved by 78.7% of TransCon PTH-treated patients (48 of 61), compared to 4.8% for patients (1 of 21) in control group (p-value <0.0001).

**Highlights of the Phase 3 PaTHway Trial Top-Line Data**

The PaTHway Trial is a Phase 3 double-blind, placebo-controlled trial of 82 dosed adults with chronic hypoparathyroidism randomized 3:1 (TransCon PTH:placebo).

**Primary Composite Endpoint:**

- 78.7% of TransCon PTH-treated patients (48 of 61) achieved serum calcium levels in the normal range (8.3–10.6 mg/dL) and independence from therapeutic levels of conventional therapy, compared to 4.8% for patients (1 of 21) in control group (p-value = <0.0001).

**Key Pre-Specified Secondary Endpoints:**

- Statistically significant decrease in patient-reported, disease-specific physical and cognitive symptoms compared to patients in control group, as shown on Hypoparathyroidism Patient Experience Scales ("HPES") Symptom-Physical domain scores (p-value = 0.0038) and HPES Symptom-Cognitive domain scores (p-value = 0.0055).
- Statistically significant reduction in patient-reported disease impact compared to patients in control group, as shown on HPES Impact-Physical Functioning domain scores (p-value = 0.0046) and HPES Impact-Daily Life domain scores (p-value = 0.0061).
- Statistically significant improvements in patient-reported physical functioning compared to patients in control group, as shown on the SF-36v2® survey Physical Functioning subscale (p-value = 0.0347).

**Selected other analyses:**

- At Week 26, 95% of TransCon PTH-treated patients were able to discontinue conventional treatments with therapeutic levels of calcium supplements and active vitamin D.
- PaTHway patients had low levels of bone turnover at baseline. TransCon PTH-treated patients demonstrated increased levels of bone turnover markers at Week 26.

**Safety summary:**

- TransCon PTH was generally well tolerated, with no discontinuations related to study drug. Three patients discontinued during the treatment period – 2 from the placebo arm and 1 from the TransCon PTH arm.
- 82% of TransCon PTH patients and 100% of patients in control group reported treatment-emergent adverse events ("TEAEs"), the majority of which were Grade 1, 2 in severity.
- One serious related TEAE in the TransCon PTH arm was reported due to a dosing error.
- One death in the TransCon PTH arm was assessed as unrelated to study drug.
- TransCon PTH-treated patients showed a mean decrease in 24-hour urine calcium excretion into the normal range, from 390 mg/24 hours down to 220 mg/24 hours. Despite a higher mean serum calcium at Week 26, there was a significantly greater decrease in mean 24-hour urine calcium for TransCon PTH-treated patients compared to patients in control group.

Following an initial blinded study period of 26 weeks, for which top-line data are reported here, all 79 patients completing the blinded period opted to receive treatment with TransCon PTH in the ongoing open-label extension portion of the study for up to 3 years (156 weeks). As of March 13, 2022, all 79 patients continued in the open label extension portion of the PaTHway Trial.

Ascendis plans to submit a New Drug Application ("NDA") to the U.S. Food & Drug Administration for TransCon PTH for adults with hypoparathyroidism during the third quarter of 2022 and a Marketing Authorisation Application ("MAA") to the European Medicines Agency during the fourth quarter of 2022. Top-line results for the Phase 3 PaTHway Japan Trial are expected in the third quarter of 2022. In addition, Ascendis plans to initiate a clinical trial of TransCon PTH in pediatric hypoparathyroidism during the fourth quarter of 2022.

***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' plans to submit an NDA and MAA for TransCon PTH, (ii) the expected timing of top-line results for the Phase 3 Pathway Japan Trial, and (iii) Ascendis' plans to initiate a clinical trial of TransCon PTH in pediatric patients with hypoparathyroidism. 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 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 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 2, 2022 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: March 14, 2022

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