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 January, 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 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") (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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 January 8, 2023, the Company announced that it will provide an update on its Vision 3x3 strategic roadmap and planned 2023 key corporate milestones at the 41st Annual J.P. Morgan Health Conference. Details of the update are outlined below.

Key Updates

- TransCon hGH:
    - During the fourth quarter, 2022, the Company completed recruitment into the Phase 3 foresiGHt Trial in adult growth hormone deficiency (GHD). Topline results from foresiGHt are expected in the fourth quarter of 2023.
    - During the third quarter of 2023, the Company anticipates completing enrollment in New InsiGHTS, a Phase 2 trial evaluating the safety and efficacy of TransCon hGH in patients with Turner Syndrome.
    - First European SKYTROFA® (lonapegsomatropin) commercial launch planned in Germany for the third quarter of 2023.
    - SKYTROFA® (lonapegsomatropin-tcgd) U.S preliminary, unaudited fourth quarter 2022 revenue is expected to be approximately €17.1 million. This includes an estimated negative foreign currency translation impact of €0.4 million, compared to a benefit of €0.5 million in the third quarter of 2022.
- TransCon PTH:
    - Phase 3 PaTHway Japan trial achieved its primary objectives; topline results consistent with North American and EU trials.
    - FDA Priority Review continues for use in adult patients with hypoparathyroidism, with an April 30, 2023 PDUFA date; if approved, U.S. commercial launch planned in the second quarter of 2023.
    - Enrollment opened in January 2023 for U.S. Expanded Access Program (EAP).
    - European Commission decision anticipated during the fourth quarter of 2023; if approved, EU commercial launch planned shortly thereafter.
    - Once-weekly TransCon PTH in preclinical development for patients on stable daily TransCon PTH dose.
- TransCon CNP:
    - First-ever randomized, double-blind, placebo-controlled Phase 2 trial (ACcomplisH) suggests a potential for safety, efficacy, tolerability, and convenience in children with achondroplasia as young as two years of age; all 57 patients currently remain in the trial with treatment duration up to 3 years.
    - During the second quarter of 2023, the Company expects to complete enrollment in ApproaCH, a global randomized, double-blind, placebo-controlled Phase 2b trial in children ages 2–11 years with achondroplasia. The trial targets enrollment of ~80 patients.
    - During the third quarter of 2023, the Company expects to submit an IND or similar in children under the age of two years with achondroplasia.
- TransCon TLR7/8 Agonist:

- Reported topline data from the dose escalation portion of the Phase 1/2 transcendIT-101 Trial at SITC 2022. Early signs of clinical activity were observed in patients receiving TransCon TLR7/8 Agonist as monotherapy or in combination with pembrolizumab.
- Enrollment in transcendIT-101 continues with dose expansion focused on investigating TransCon TLR7/8 Agonist in combination with pembrolizumab in four cancer types.

- TransCon IL-2 ß/g:
  - The Phase 1/2 IL-ßeliege Trial evaluating TransCon IL-2 ß/g monotherapy in patients with locally advanced or metastatic solid tumors continues to enroll patients. Results from monotherapy dose escalation are expected during the first quarter of 2023.

- Ophthalmology selected as the third therapeutic area:
  - In vivo data demonstrates, TransCon Hydrogel Platform supports continuous local drug release over at least 6 months supporting twice yearly administration.
  - TransCon RBZ (ranibizumab) selected as the first product candidate.

Forward-Looking Statements

This press release 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 expected regulatory approval and launch of TransCon PTH in 2023, (ii) the timing and announcement of top-line results from the foresiGHt Trial and the Phase 1/2 IL-ßeliege Trial, (iii) the timing of completion of patient enrollment in the New InsiGHTS Trial and the ApproaCH Trial (iv) Ascendis' PDUFA date of April 30, 2023 with respect to the FDA's Priority Review of TransCon PTH, (v) the expected launch of TransCon hGH in Europe in 2023, (vi) Ascendis' unaudited preliminary financial information for the fiscal year ended December 31, 2022, (vii) Ascendis' expectations regarding the timing of its regulatory approvals, submissions, applications, protocols, clinical trials and the results thereof, (viii) Ascendis' ability to apply its TransCon platform to build a leading, fully integrated global biopharma company, and (ix) Ascendis' use of 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: dependence on third party manufacturers and distributors to supply TransCon hGH and the SKYTROFA® Auto-Injector for commercial sales in the U.S. and other study drug for clinical studies; unforeseen safety or efficacy results in its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to commercialization of TransCon hGH in the U.S., the co-pay program and the further development of TransCon hGH; expenses related to the development and potential commercialization of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen 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; 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 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. The preliminary financial information set forth in this press release is subject to the completion of Ascendis' audit process and is subject to change. The estimated preliminary results included in this press release should not be viewed as a substitute for Ascendis' annual financial statements prepared in accordance with International Financial Reporting Standards. 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: January 9, 2023

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