
**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 November, 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 November 13, 2022, the Company announced topline results from the ACcomplisH Trial, its Phase 2 randomized, double-blind, placebo-controlled, dose-escalation trial evaluating the safety and efficacy of once-weekly TransCon CNP compared to placebo in children with achondroplasia aged 2 to 10 years old. TransCon CNP is an investigational long-acting prodrug of C-type natriuretic peptide (CNP), designed to provide continuous exposure of CNP at safe, therapeutic levels via a single, weekly subcutaneous dose.

The ACcomplisH Trial evaluated 57 children with achondroplasia aged 2 to 10 years old, randomized in a 3:1 ratio to receive either sequential ascending doses of once-weekly TransCon CNP or placebo for 52 weeks. All 57 randomized children completed the blinded portion of ACcomplisH and are currently continuing in the open label extension (OLE) at the 100 µg/kg/week dose.

The trial met its primary objectives, demonstrating that TransCon CNP at 100 µg/kg/week was superior to placebo on the primary efficacy endpoint of AHV at 52 weeks.

Key data include:

TransCon CNP Dose Group (n)	AHV (cm/year) LS Mean [95% CI]	p-value (TransCon CNP vs. Pooled Placebo)
6 µg/kg/week (n=10)	4.09 [3.34, 4.84]	0.6004
20 µg/kg/week (n=11)	4.52 , [3.82, 5.22]	0.7022
50 µg/kg/week (n=10)	5.16 [4.43, 5.90]	0.0849
100 µg/kg/week (n=11)	5.42 [4.74, 6.11]	0.0218
Pooled Placebo (n=15)	4.35 [3.75, 4.94]	NA

Additional highlights:

- TransCon CNP demonstrated a consistent dose-response in AHV across the four dose groups.
- Mean improvements in AHV for TransCon CNP-treated patients were consistent across age groups <5 years and ≥5 years, with dose response established.
- TransCon CNP at 100 µg/kg/week demonstrated superiority in change in ACH-specific height SDS compared to placebo.
- TransCon CNP was generally safe and well tolerated, with no discontinuations.

- No serious AEs (SAEs) related to treatment were reported; two unrelated SAEs were reported.
- Injections were generally well tolerated with low frequency of injection site reactions (ISRs):
 - 11 mild ISRs (in 8 patients) out of >2,000 injections.
- Patients treated ≥ 6 months at 100 $\mu\text{g}/\text{kg}/\text{week}$ in the blinded or OLE period demonstrated a consistent and sustained response, with mean AHV of 5.39 cm/year (n=40).

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 TransCon CNP's ability to provide continuous exposure of CNP at safe, therapeutic levels via a single, weekly subcutaneous dose. 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 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: November 14, 2022

By: /s/ Michael Wolff Jensen

Michael Wolff Jensen

Senior Vice President, Chief Legal Officer