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): ☐

Ascendis Pharma A/S (the "Company") is hereby furnishing as Exhibit 99.1 the attached presentation relating to the Company's top-line data from the randomized, double-blind, placebo-controlled, dose-escalation trial portion of its Phase 2 ACcomplisH Trial of TransCon CNP in children with achondroplasia aged 2 to 10 years old.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the presentation is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing or furnishing of other reports or documents with the SEC or through other public disclosures.

Exhibit

99.1 Company Presentation.

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

TransCon™ CNP
ACcomplisH Trial Topline Results

November 14, 2022

TransCon CNP is an investigational product candidate.
For investor communication only. Not for use in product promotion.
Not for further distribution.

Cautionary Note on Forward-Looking Statements

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, such as statements regarding our prospective product candidates; clinical trial results; the expected timing of future clinical trial results; the scope, progress, results and costs of developing our product candidates or any other future product candidates; timing and likelihood of success; plans and objectives of management for future operations; and future results of current and anticipated products and product candidates are forward-looking statements. These forward-looking statements are based on our current expectations and beliefs, as well as assumptions concerning future events. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the results discussed in the forward-looking statements. These risks, uncertainties and other factors are more fully described in our reports filed with or submitted to the Securities and Exchange Commission, including, without limitation, our most recent Annual Report on Form 20-F filed with the SEC on March 2, 2022 particularly in the sections titled "Risk Factors" and "Operating and Financial Review and Prospects." In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

Any forward-looking statement made by us in this presentation speaks only as of the date of this presentation and represents our estimates and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these statements publicly, whether as a result of new information, future events, changed circumstances or otherwise after the date of this presentation.

This presentation concerns product candidates that are or have been under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration, European Medicines Agency or other foreign regulatory authorities. These product candidates are currently limited by U.S. Federal law to investigational use, and no representations are made as to their safety or effectiveness for the purposes for which they are being investigated.

Executive Summary

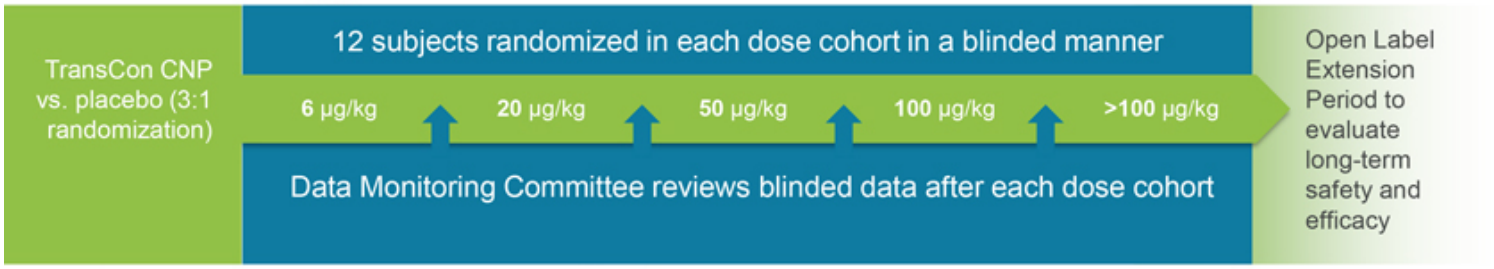
- In the Phase 2 ACcomplisH Trial in children with achondroplasia aged 2-10, once-weekly TransCon CNP demonstrated the potential to meet patient and caregiver needs for a safe, effective, tolerable, and convenient treatment
- The primary endpoint, annualized height velocity (AHV) at Week 52, demonstrated superiority of TransCon CNP at 100 µg/kg/week compared to placebo (p=0.0218)
- TransCon CNP was generally well tolerated with low frequency of injection site reactions; all 57 randomized children continued, with the longest treatment duration beyond two years
- Data showed robust and consistent results in prespecified analyses across age groups and dose levels, supporting continued development at the selected dose of 100 µg/kg/week

ANCOVA model. Data on file, Ascendis Pharma 2022.

TransCon CNP: Phase 2 Trial Design

ACcomplisH TRIAL

Up to 60 children (ages 2–10 years) with achondroplasia



Primary Endpoint

- Annualized height velocity

Key Secondary/Additional Endpoints

- Change in body proportionality
- Patient reported outcome (PRO) measures
- Exploratory biomarkers evaluated

ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04085523?term=ACcomplisH&draw=2&rank=5. Accessed 05/23/2021.

ascendis pharma

Demographics and Baseline Characteristics

	TransCon CNP 6 µg/kg/week n=10	TransCon CNP 20 µg/kg/week n=11	TransCon CNP 50 µg/kg/week n=10	TransCon CNP 100 µg/kg/week n=11	Total TransCon CNP n=42	Total Placebo n=15
Age (years)						
Mean (SD)	6.5 (2.6)	6.3 (2.9)	5.2 (3.0)	5.8 (2.6)	6.0 (2.7)	5.9 (3.1)
Median (Min, Max)	6.8 (2.3, 10.7)	7.3 (2.7, 11.0)	4.7 (2.1, 10.1)	5.4 (2.1, 9.9)	5.6 (2.1, 11.0)	4.9 (2.4, 11.0)
Age Group (years) – n (%)						
< 5 years	3 (30.0)	5 (45.5)	5 (50.0)	3 (27.3)	16 (38.1)	8 (53.3)
≥ 5 years	7 (70.0)	6 (54.5)	5 (50.0)	8 (72.7)	26 (61.9)	7 (46.7)
Sex – n (%)						
Female	7 (70.0)	3 (27.3)	3 (30.0)	6 (54.5)	19 (45.2)	5 (33.3)
Male	3 (30.0)	8 (72.7)	7 (70.0)	5 (45.5)	23 (54.8)	10 (66.7)
Race – n (%)						
White	8 (80.0)	10 (90.9)	8 (80.0)	10 (90.9)	36 (85.7)	12 (80.0)
Other	2 (20.0)	1 (9.1)	2 (20.0)	1 (9.1)	6 (14.3)	3 (20.0)

5 | Data on file, Ascendis Pharma 2022.

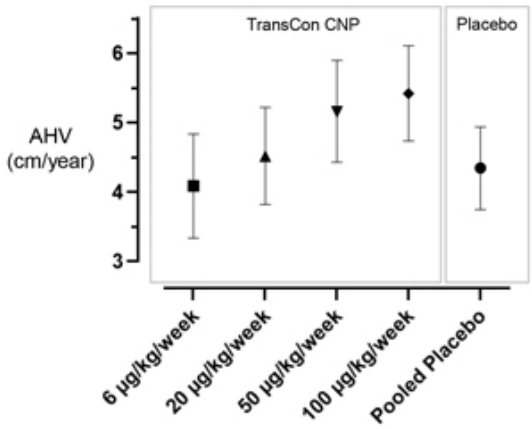
Demographics and Baseline Characteristics (continued)

	TransCon CNP 6 µg/kg/week n=10	TransCon CNP 20 µg/kg/week n=11	TransCon CNP 50 µg/kg/week n=10	TransCon CNP 100 µg/kg/week n=11	Total TransCon CNP n=42	Total Placebo n=15
Height (cm)						
Mean (SD)	90.63 (8.97)	92.29 (12.10)	86.61 (12.97)	89.23 (12.82)	89.74 (11.61)	90.85 (14.92)
Median (Min, Max)	90.25 (73.70, 101.77)	93.70 (78.20, 111.17)	84.70 (72.10, 105.87)	90.23 (69.40, 111.53)	90.08 (69.40, 111.53)	89.70 (70.47, 113.37)
Height SDS*						
Mean (SD)	-5.45 (1.05)	-4.87 (0.67)	-4.85 (0.80)	-4.92 (0.83)	-5.02 (0.85)	-4.85 (0.96)
Median (Min, Max)	-5.80 (-6.56, -3.92)	-4.66 (-6.15, -4.10)	-5.14 (-6.03, -3.66)	-4.64 (-6.16, -3.74)	-5.12 (-6.56, -3.66)	-4.69 (-6.73, -3.32)
Height SDS, ACH-Specific**						
Mean (SD)	-0.20 (0.70)	0.28 (0.68)	0.21 (0.67)	0.11 (0.77)	0.11 (0.70)	0.43 (0.91)
Median (Min, Max)	-0.36 (-1.31, 0.66)	0.28 (-0.89, 1.21)	0.09 (-0.55, 1.46)	0.02 (-1.16, 1.33)	0.02 (-1.31, 1.46)	0.65 (-1.18, 2.08)

* CDC 2000 Stature-for-Age Charts, https://www.cdc.gov/growthcharts/data_tables.htm, accessed 13 Nov 2022.
** Hoover-Fong JE, Schulze KJ, Alade AY, et al. Growth in achondroplasia including stature, weight, weight-for-height and head circumference from CLARITY. *Orphanet J Rare Dis*. 2021;16(1):522.

TransCon CNP 100 µg/kg/week Demonstrated Superiority in AHV Compared to Placebo

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



TransCon CNP demonstrated a dose-response in AHV across the four dose groups

ANCOVA model.

Comparable AHV Across Age Groups

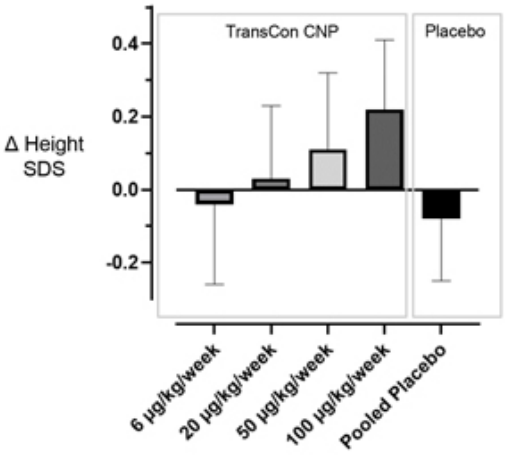
Treatment Group (TransCon CNP Dose Levels or Placebo)	Age <5 years old	Age ≥5 years old
	AHV (cm/year), n LS Mean, [95% CI]	AHV (cm/year), n LS Mean, [95% CI]
6 µg/kg/week	4.31, n=3 [2.52, 6.10]	3.79, n=7 [2.87, 4.71]
20 µg/kg/week	4.72, n=5 [3.30, 6.15]	4.29, n=6 [3.43, 5.15]
50 µg/kg/week	5.07, n=5 [3.62, 6.52]	5.33, n=5 [4.39, 6.26]
100 µg/kg/week	5.95, n=3 [4.03, 7.87]	5.12, n=8 [4.35, 5.90]
Pooled Placebo	4.53, n=8 [3.43, 5.63]	4.29, n=7 [3.44, 5.14]

Consistent dose-dependent treatment effect across age groups

ANCOVA model.

TransCon CNP 100 µg/kg/week Demonstrated Superiority in Change in ACH-Specific Height SDS Compared to Placebo

Treatment Group (TransCon CNP Dose Levels or Placebo)	Δ Height SDS*, n LS Mean [95% CI]	p-value (TransCon CNP vs. Pooled Placebo)
6 µg/kg/week	-0.04, n=10 [-0.26, 0.17]	0.8207
20 µg/kg/week	0.03, n=11 [-0.17, 0.23]	0.4107
50 µg/kg/week	0.11, n=10 [-0.10, 0.32]	0.1660
100 µg/kg/week	0.22, n=11 [0.02, 0.41]	0.0283
Pooled Placebo	-0.08, n=15 [-0.25, 0.10]	NA



TransCon CNP demonstrated a dose-dependent improvement in ACH-specific height SDS across all dose groups

* Hoover-Fong JE, Schulze KJ, Alade AY, et al. Growth in achondroplasia including stature, weight, weight-for-height and head circumference from CLARITY. *Orphanet J Rare Dis*. 2021;16(1):522. ANCOVA model

Safety Results Summary (Double-Blind Period)

- TransCon CNP was generally well tolerated, with no discontinuations
  - Frequency of TEAEs in each dose group was similar to placebo
- No serious AEs (SAEs) related to treatment were reported
  - Two unrelated SAEs were reported (febrile convulsion and viral infection)
- 95% of TransCon CNP patients and 93% of placebo patients reported TEAEs
  - 95% of TransCon CNP TEAEs were assessed as mild (Grade 1) in severity
- Injections were generally well tolerated with low frequency of injection site reactions
- No reported events of symptomatic hypotension
- For body proportionality, induced growth was proportional across all groups at Week 52

Observed safety results support continued development of TransCon CNP for children with achondroplasia

TEAE : Treatment emergent adverse event

Data on file, Ascendis Pharma 2022.

Overview of TEAEs (Double-Blind Period)

	TransCon CNP 6 µg/kg/week (n=10)	TransCon CNP 20 µg/kg/week (n=11)	TransCon CNP 50 µg/kg/week (n=10)	TransCon CNP 100 µg/kg/week (n=11)	Total Placebo (n=15)
Subjects with TEAEs*	9 (90.0)	11 (100.0)	10 (100.0)	10 (90.9)	14 (93.3)
Grade 1 (mild)	9 (90.0)	11 (100.0)	10 (100.0)	9 (81.8)	14 (93.3)
Grade 2 (moderate)	3 (30.0)	3 (27.3)	3 (30.0)	1 (9.1)	5 (33.3)
Serious TEAEs	1 (10.0)	0	1 (10.0)	0	0
Treatment-Related TEAEs	3 (30.0)	2 (18.2)	3 (30.0)	2 (18.2)	5 (33.3)
Achondroplasia-Related TEAEs**	3 (30.0)	4 (36.4)	5 (50.0)	1 (9.1)	9 (60.0)

* No reported Grade 3 (severe) or Grade 4 (life-threatening) TEAEs.
**Adverse events reported by investigator as related to underlying disease.

Treatment-Related Adverse Events (Double-Blind Period)

	TransCon CNP 6 µg/kg/week (n=10)	TransCon CNP 20 µg/kg/week (n=11)	TransCon CNP 50 µg/kg/week (n=10)	TransCon CNP 100 µg/kg/week (n=11)	Total Placebo (n=15)
Subjects with at Least One Treatment-Related TEAE	3 (30.0)	2 (18.2)	3 (30.0)	2 (18.2)	5 (33.3)
Injection site reactions (ISRs)*	2 (20.0)	1 (9.1)	3 (30.0)	2 (18.2)	2 (13.3)
Abdominal pain upper	0	1 (9.1)	0	0	0
Overdose	0	0	0	0	1 (6.7)
Dizziness	0	0	0	0	1 (6.7)
Sleep terror	0	0	0	0	1 (6.7)
Urticaria	1 (10.0)	0	0	0	0

Injections were generally well tolerated with low frequency of injection site reactions
11 mild ISRs (in 8 patients) out of >2,000 injections

* Injection site reactions includes preferred terms of Injection site reaction, Injection site pain, Injection site erythema, Injection site discolouration, Injection site haemorrhage, and Injection site swelling.

Data on file, Ascendis Pharma 2022.

Open Label Extension (OLE) Efficacy and Safety Results*

- 57 of 57 patients completed the blinded period of ACcomplisH and continued in the OLE on 100 µg/kg/week with 100% retention
- Patients treated ≥6 months at 100 µg/kg/week in the blinded or OLE period demonstrated a consistent and sustained response with mean AHV of 5.39 cm/year (n=40)
- TransCon CNP continued to be well tolerated in the OLE period with safety results consistent with those observed in the blinded period for all patients

Open-label extension data confirms target product profile for once-weekly TransCon CNP 100 µg/kg/week

* Preliminary ACcomplisH Trial live database snapshot as of October 27, 2022.

Next Steps

- IND submitted for ApproaCH, a global Phase 2b trial in 80 children with achondroplasia aged 2-11; enrollment targeted for completion in early 2023
  - TransCon CNP 100 µg/kg/week vs. Placebo (2:1)
- End of Phase 2 meetings with FDA and EMA planned
- Plan to file IND or similar for TransCon CNP in infants (age 0-2)
- Plan to file IND or similar for a combination trial with TransCon hGH and TransCon CNP
- Expand global reach with finalizing trial in China* and initiating trial in Japan

* Conducted by VISEN Pharmaceuticals.

Thank you

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