# 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, 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): $\Box$

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):  $\Box$ 

#### 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, 333-261550 and 333-270088) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 September 5, 2023, the Company announced new post hoc analysis showing adults with hypoparathyroidism treated with TransCon PTH demonstrated substantial improvement in estimated glomerular filtration rate (eGFR), suggesting improved kidney function. TransCon PTH (palopegteriparatide) is an investigational prodrug of parathyroid hormone (PTH 1-34) administered once daily designed to provide sustained release of active PTH within the physiological range for 24 hours per day in adult patients with hypoparathyroidism.

In the Phase 3 PaTHway Trial, mean baseline eGFR was 67.3 and 72.7 mL/min/1.73m² for subjects randomized to TransCon PTH and placebo, respectively. At Week 26, patients treated with TransCon PTH experienced a mean increase in eGFR of 7.9 mL/min/1.73m² compared to baseline (p<0.0001) while those on placebo experienced a mean decrease in eGFR of -1.9 mL/min/1.73m² compared to baseline (p=0.3468). By Week 52, patients treated with TransCon PTH, including those crossing over from placebo, experienced a mean increase in eGFR of 8.9 mL/min/1.73m² compared to baseline (p<0.0001). The improvement at Week 52 was even greater, with patients with eGFR <60 at baseline, the threshold for kidney dysfunction, experiencing a mean increase in eGFR of 11.5 mL/min/1.73m².

### PaTHway: eGFR Change from Baseline by eGFR Group

	Baseline		Week 26		Week 52	
Study Arm	eGFR (mL/min/1.73m²)	N	Mean (p value)	N	Mean (p value)	
TransCon PTH / TransCon PTH	eGFR < 60	19	+11.4 (p=0.0002)	19	+11.5 (p=0.0003)	
	eGFR ≥ 60	41	+6.3 (p=0.0002)	40	+8.2 (p <0.0001)	
	All	60	+7.9 (p< 0.0001)	59	+9.3 (p<0.0001)	
Placebo (first 26 weeks) / TransCon PTH*	eGFR < 60	4	+0.05 (p=0.9877)	4	+11.7 (p=0.0018)	
	eGFR ≥ 60	15	-2.4 (p=0.3280)	15	+6.5 (p=0.0199)	
	All	19	-1.9 (p=0.3468)	19	+7.6 (p=0.0014)	

eGFR (an assessment of kidney filtering capacity) was calculated by the trial's central lab using the Modification of Diet in Renal Disease Study Group (MDRD) equation (Levey, Ann Intern Med 2006).

Among subjects with baseline eGFR  $< 60 \text{ mL/min/m}^2$  (considered the threshold for impaired kidney function), approximately 50% were able to improve their eGFR to > 60 mL/min with TransCon PTH therapy.

<sup>\*</sup> Patients in the placebo arm switched to TransCon PTH following the Week 26 visit.

	eGFR < 60 at Baseline (n)	Number of Responders* (n, %) Week 26	Number of Responders* (n, %) Week 52
TransCon PTH / TransCon PTH	n=19	n=12	n=10
		63%	53%
Placebo (first 26 weeks) / TransCon PTH**	n=4	n=0	n=3
		0%	75%
Total PaTHway Trial	n=23	n=12	n=13
		52%	57%

eGFR based on central lab data using the MDRD Study Group formula.

- \* Responders defined as moving from eGFR < 60 to eGFR  $\geq$  60. Units in (mL/min/1.73m<sup>2</sup>).
- \*\* Patients in the placebo arm switched to TransCon PTH following the Week 26 visit.

### 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) TransCon PTH's ability to provide sustained release of active PTH within the physiological range for 24 hours per day in adult patients with hypoparathyroidism, and (ii) the potential of TransCon PTH to improve kidney function. 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; unforeseen 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, the effects on its business from the worldwide COVID-19 pandemic and ongoing conflicts such as that 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 February 16, 2023 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: September 5, 2023

By: /s/ Michael Wolff Jensen

Michael Wolff Jensen Executive Vice President, Chief Legal Officer