

ASCENDIS PHARMA A/S

FORM 6-K

(Report of Foreign Issuer Pursuant to Rule 13a-16 or 15d-16)

Filed 09/26/17 for the Period Ending 09/26/17

Telephone	45 70 22 22 44
CIK	0001612042
Symbol	ASND
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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, 2017

Commission File Number: 001-36815

Ascendis Pharma A/S

(Exact Name of Registrant as Specified in Its Charter)

Tuborg Boulevard 5
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 and 333-216883) and Form F-3 (Registration Numbers 333-209336, 333-211511 and 333-216882) 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

The Company has dosed subjects in a phase 1 trial of TransCon PTH, a long-acting prodrug of parathyroid hormone (“PTH”) in development for the treatment of hypoparathyroidism. The phase 1 clinical trial of TransCon PTH is a randomized, single and multiple ascending dose trial to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of TransCon PTH in healthy adults. The primary objective of the trial is to assess the safety and tolerability of single and 10 multiple daily doses of TransCon PTH in healthy adults. Secondary objectives of the trial are to evaluate the pharmacodynamics (serum Calcium, down regulation of endogenous PTH(1-84), and bone markers) and pharmacokinetics following single and multiple daily doses of TransCon PTH, assess whether TransCon PTH treatment reduces urine calcium excretion, and determine the incidence of anti-PTH and anti-polyethylene glycol antibodies. If the phase 1 clinical trial is successful, the Company expects that a phase 3 clinical trial of TransCon PTH would have a starting dose range selected from the phase 1 clinical trial and titrated for each subject in the initial period of the trial.

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 the Company's future operations, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to the Company's expectations regarding (i) its phase 1 clinical trial of TransCon PTH and (ii) a potential phase 3 clinical trial for TransCon PTH. The Company 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 the Company makes, including the following: unforeseen safety or efficacy results in its TransCon PTH program; unforeseen expenses related to the development of TransCon PTH; delays in the development of TransCon PTH related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen issues; dependence on third party manufacturers to supply trial drug for planned clinical studies; and the Company's ability to obtain additional funding, if needed, to support its business activities. 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 the Company's business in general, see the Company's current and future reports filed with, or submitted to, the U.S. Securities and Exchange Commission (“SEC”), including its Annual Report on Form 20-F filed with the SEC on March 22, 2017. Forward-looking statements do not reflect the potential impact of any future in-licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments that the Company may enter into or make. The Company 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 26, 2017

By: /s/ Michael Wolff Jensen

Michael Wolff Jensen
Senior Vice President, General Counsel