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 May, 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, 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 May 31, 2023, the Company will host an investor meeting highlighting the latest developments in the Company's Oncology programs, including clinical data updates and a review of clinical development strategy for the Company's two immuno-oncology product candidates, TransCon TLR7/8 Agonist and TransCon IL-2 ß/g. Both are designed to recruit innate and adaptive components of the immune system to maximize anti-cancer activity while reducing dose-limiting toxicities.

Meeting highlights include:

TransCon IL-2 ß/g program update from the Phase 1/2 IL-Believe Trial

- Phase 1 monotherapy dose escalation complete; 25 heavily pre-treated patients enrolled (median of 4 prior lines of systemic therapies).
- 120 µg/kg IV every three weeks selected as monotherapy recommended Phase 2 dose (RP2D).
- Eight monotherapy patients dosed at RP2D; of the three efficacy evaluable patients to date, one partial response in a metastatic colorectal cancer patient, and one stable disease in a renal cell carcinoma patient (data cut April 28, 2023).
- At RP2D, TransCon IL-2 ß/g was generally well-tolerated with no DLT observed, no vascular leak syndrome and no grade 3 or 4 cytokine release syndrome.
- As designed, the non-alpha TransCon IL-2 ß/g expanded local and systemic cytotoxic immune effector cells (CD8+ T and NK cells) without clear effect on T_{regs} and eosinophils.
- RP2D for combination therapy with checkpoint inhibitor dose escalation data expected in the third quarter of 2023 and will be presented at a scientific congress in the fourth quarter.
- Enrollment continues in indication-specific cohorts for the Phase 2 portion of the IL-Believe trial.

TransCon TLR7/8 Agonist program update from the Phase 1/2 transcendIT-101 Trial

- Additional follow-up indicates further clinical activity in patients receiving TransCon TLR7/8 Agonist as monotherapy or in combination with pembrolizumab. Results supporting selection of RP2D from transcendIT-101 were first reported at SITC 2022 last November.
- Preliminary results showed that TransCon TLR7/8 Agonist was well-tolerated both as a monotherapy and in combination with pembrolizumab.
- Enrollment continues in the Phase 2 portion of transcendIT-101 at the RP2D of 0.5 mg/lesion for up to two lesions, which is being evaluated in four indication-specific cohorts.

TransCon IL-2 ß/g is an investigational long-acting prodrug with sustained release of an IL-2Rß/g-selective analog (IL-2 ß/g) designed to address the known limitations of interleukin-2 (IL-2) cancer immunotherapy through prolonged activation of IL-2Rß/g with low C_{max}.

TransCon TLR7/8 Agonist is an investigational long-acting prodrug designed to provide sustained, localized release over weeks of resiquimod (a potent immune response modifier with clinically demonstrated anti-tumor activity) with low systemic exposure.

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 the timing of dose escalation combination therapy data from the Phase 1/2 IL-Believe trial and its presentation at a scientific congress. 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, and 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: May 31, 2023

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