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 October, 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such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 October 3, 2022, the Company announced completion of the dose-escalation portion and recommendation of the Phase 2 dose in transcendIT-101, a Phase 1/2 clinical trial to evaluate the safety and efficacy of TransCon TLR7/8 Agonist in locally advanced or metastatic solid tumors, alone or in combination with pembrolizumab. TransCon TLR7/8 Agonist is a novel investigational product candidate designed for sustained, localized release of resiquimod (a potent immune-response modifier with clinically demonstrated anti-tumor activity) with low systemic exposure. The abstract for the dose-escalation topline data was accepted for an oral presentation at SITC 2022, the annual meeting of the Society for Immunotherapy of Cancer being held November 8-12 in Boston.

All patients in the dose escalation portion of the trial had advanced or metastatic solid-tumors and had progressed on prior treatments. In the next phase of the trial, the recommended Phase 2 dose of TransCon TLR7/8 Agonist will be evaluated in four cohorts focused on cancers where increased Toll-like receptor (TLR) activity has potential to improve adaptive immune activation and host defense against cancers. The cohorts include head and neck squamous-cell carcinoma (HNSCC); other HPV-associated cancers; melanoma; and cutaneous squamous cell carcinoma (cSCC). In this portion of the study, all participants will be treated every three weeks with intratumoral TransCon TLR7/8 Agonist in combination with intravenous pembrolizumab. Limits on prior lines of therapy vary by cohort.

Later this year, Ascendis will initiate a clinical investigation of TransCon TLR7/8 Agonist intratumoral treatment in combination with TransCon IL-2 ß/g, the company's product candidate designed for systemic activation of tumor-antigen specific cytotoxic cells.

Forward-Looking Statements

This press release 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 (i) the potential for TransCon TLR7/8 Agonist offer sustained, localized release of resiquimod with low systemic drug exposure, (ii) Ascendis' plans and expectations with respect to future phases of the transcendIT-101 trial, (iii) Ascendis' plans to initiate a clinical investigation of TransCon TLR7/8 Agonist intratumoral treatment in combination with TransCon IL-2 ß/g later this year, and (iv) the potential for TransCon IL-2 ß/g to provide systemic activation of tumor-antigen specific cytotoxic cells. 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' of its development programs; unforeseen selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its development 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 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: October 3, 2022

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