
**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 August, 2021

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):

Furnished as an exhibit to this Report on Form 6-K is a press release reporting the Company's financial results for the fiscal quarter ended June 30, 2021.

Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release dated August 25, 2021. |

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.

Date: August 25, 2021

Ascendis Pharma A/S

By: /s/ Michael Wolff Jensen

Michael Wolff Jensen

Senior Vice President, Chief Legal Officer



Ascendis Pharma A/S Reports Second Quarter 2021 Financial Results

– Announced U.S. Food and Drug Administration Approval of SKYTROFA® (lonapegsomatropin-tcgd), the First Once-weekly Treatment for Pediatric Growth Hormone Deficiency –

– Exceeded target enrollment in Phase 3 PaTHway Trial for TransCon PTH (palopegteriparatide) in adults with hypoparathyroidism (HP); top-line results expected in Q1 2022 –

– Initiated combination therapy arm in transcendIT-101; TransCon TLR7/8 Agonist used in combination with a check point inhibitor (CPI) –

– Conference call today at 4:30 p.m. Eastern Time –

COPENHAGEN, Denmark, August 25, 2021/ Globe Newswire/ – Ascendis Pharma A/S (Nasdaq: ASND), a biopharmaceutical company that utilizes its innovative TransCon™ technologies to potentially create new treatments that make a meaningful difference in patients’ lives, today announced financial results for the second quarter ended June 30, 2021.

“We are actively preparing for the U.S. commercial launch of SKYTROFA for the treatment of children with GHD, which is now the first FDA-approved once-weekly treatment for pediatric GHD. SKYTROFA is also the first FDA-approved product utilizing our innovative TransCon technology. Our pivotal heiGHt Trial demonstrated that once-weekly TransCon hGH increased annualized height velocity in treatment-naïve subjects at 52 weeks compared to a daily growth hormone with comparable safety and tolerability,” said Jan Mikkelsen, Ascendis Pharma’s President and Chief Executive Officer. “We see this approval as the first step in creating a market leading product and building a fully integrated global biopharmaceutical company guided by our values of patients, science, and passion.”

Company Highlights & Progress

- TransCon hGH (lonapegsomatropin)
 - TransCon hGH is now FDA approved in the U.S. under the brand name SKYTROFA. Continued preparation for commercial launch for the treatment of pediatric patients with GHD in the U.S.
 - European Commission decision on the company’s Marketing Authorisation Application (MAA) for the treatment of pediatric patients with GHD is anticipated in the fourth quarter of 2021.
 - Ongoing enrollment in the foresiGHt Trial, a global phase 3 trial in adults with GHD, and the riGHt Trial, a phase 3 trial in Japan in pediatric patients with GHD.
 - Patient follow-up continues in enliGHten, a multi-center phase 3, long-term open-label trial investigating safety and efficacy of SKYTROFA in pediatric patients with GHD.
 - Comprehensive results from the heiGHt Trial recently published on-line in the *Journal of Clinical Endocrinology & Metabolism*, an official journal of the Endocrine Society.

- TransCon PTH (palopegteriparatide)
 - Exceeded target enrollment in the PaTHway Trial, a phase 3 trial evaluating the safety, tolerability, and efficacy of palopegteriparatide in adult subjects with hypoparathyroidism with similar demographics as enrolled in the phase 2 trial including broad representation of different non-surgical disease etiologies and leading influential clinical sites balanced between North America and Europe.
 - On track to announce 84-week top line results from the open label extension (OLE) portion of the PaTH Forward Trial in the fourth quarter of 2021. Continued strong long-term subject retention with 58 out of the 59 randomized subjects continuing in the OLE portion of the trial as of August 23, 2021.
 - Clinical trial notification for the PaTHway Japan Trial was accepted by the Japanese Pharmaceuticals and Medical Device Agency. The single-arm, phase 3 study will enroll a minimum of 12 Japanese subjects with HP.
 - Received Orphan Drug Designation (ODD) from the Japanese Ministry of Health, Labor and Welfare.
 - VISEN Pharmaceuticals (VISEN) obtained investigational new drug (IND) approval to initiate the phase 3 PaTHway China Trial.
- TransCon CNP
 - Continued execution in the ongoing phase 2 ACcomplisH Trial and ACcomplisH China Trial to evaluate the safety and efficacy of TransCon CNP in children ages two to ten years with achondroplasia.
 - Clinical program update planned for the fourth quarter of 2021.
- TransCon TLR7/8 Agonist
 - Initiated combination therapy arm in transcendIT-101 with TLR7/8 Agonist and a CPI.
- TransCon IL-2 β /g
 - IND filing on track for this quarter.
- Ended the second quarter of 2021 with cash, cash equivalents and marketable securities totaling €641.3 million.

Second Quarter 2021 Financial Results

For the second quarter, Ascendis Pharma reported a net loss of €134.4 million, or €2.50 per share (basic and diluted) compared to a net loss of €94.9 million, or €1.97 per share (basic and diluted) for the same period in 2020.

Revenue for the second quarter was €1.0 million compared to €1.4 million in the same quarter of 2020. The decrease was due to a lower amount of license revenue being recognized, partly offset by higher sale of clinical supplies and services to VISEN and recognition of revenue from services rendered to another collaboration partner.

Research and development (R&D) costs for the second quarter were €83.3 million compared to €63.6 million during the same period in 2020. Higher R&D costs in 2021 reflect an increase in external development costs of the company's product candidates and an increase in personnel-related costs.

Selling, general and administrative expenses for the second quarter were €35.3 million compared to €20.8 million during the same period in 2020. The increase is primarily due to higher personnel-related costs and an increase in IT costs.

Net loss of associate for the second quarter was €4.8 million compared to a net loss of €1.9 million in the same quarter of 2020. The net loss of associate represents our share of the net result from VISEN.

As of June 30, 2021, Ascendis Pharma had cash, cash equivalents and marketable securities of €641.3 million compared to €771.1 million as of March 31, 2021. As of June 30, 2021, Ascendis Pharma had 53,900,990 ordinary shares outstanding.

Conference Call Details

| | |
|--------------------------------|-------------------------------------|
| Date | Wednesday, August 25, 2021 |
| Time | 4:30 p.m. ET/1:30 p.m. Pacific Time |
| Dial In (U.S.) | 844-290-3904 |
| Dial In (International) | 574-990-1036 |
| Access Code | 8553236 |

A live webcast of the conference call will be available on the Investors and News section of the Ascendis Pharma website at www.ascendispharma.com. A webcast replay will be available on this website shortly after conclusion of the event for 30 days.

About Ascendis Pharma's Pipeline

Ascendis Pharma currently has three product candidates in clinical development in rare endocrine diseases and one oncology product candidate in clinical development:

- TransCon hGH (lonapegsomatropin-tcgd), an investigational long-acting prodrug of somatropin (human growth hormone or hGH) that releases somatropin with the identical amino acid sequence and size as daily growth hormone, is designed as a once-weekly treatment for GHD and is approved for pediatric GHD by the U.S. Food and Drug Administration and under review by the European Medicines Agency.
- TransCon PTH (palopegteriparatide), an investigational long-acting prodrug of parathyroid hormone (PTH) in phase 3 development as a once-daily replacement therapy for adults with hypoparathyroidism designed to replace PTH at physiologic levels for 24 hours, and address both short-term symptoms and long-term complications of the disease.
- TransCon CNP, an investigational long-acting prodrug of C-type natriuretic peptide (CNP) in phase 2 development as a therapy for children with achondroplasia (ACH), the most common form of dwarfism, for which there is no FDA-approved treatment. TransCon CNP is designed to provide continuous exposure of CNP at safe, therapeutic levels via a single, weekly subcutaneous dose.
- TransCon TLR7/8 Agonist is an investigational long-acting prodrug of resiquimod, a small molecule agonist of Toll-like receptors (TLR) 7 and 8. Administered as an intratumoral injection, TransCon TLR7/8 Agonist is designed to provide sustained activation of intratumoral antigen presenting cells driving tumor antigen presentation and induction of immune stimulatory cytokines in the tumor.
- TransCon IL-2 β /g is an investigational long-acting prodrug of IL-2 β /g designed for optimized IL-2R β /g bias and potency, combined with low Cmax and long exposure.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated biopharma company focused on making a meaningful difference in patients' lives. Guided by its core values of patients, science and passion, the company utilizes its TransCon technologies to create new and potentially best-in-class therapies.

Ascendis Pharma currently has a pipeline of multiple independent endocrinology rare disease and oncology product candidates in development. The company continues to expand into additional therapeutic areas to address unmet patient needs.

Ascendis is headquartered in Copenhagen, Denmark, with additional facilities in Heidelberg and Berlin, Germany, in Palo Alto and Redwood City, California, and in Princeton, New Jersey.

Please visit www.ascendispharma.com (for global information) or www.ascendispharma.us (for U.S. information).

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) Ascendis' expectations regarding the U.S. commercial launch of SKYTROFA, (ii) Ascendis' planned IND submission for TransCon IL-2 β /y in the third quarter of 2021, (iii) Ascendis' expectations regarding the European Commission's decision on its Marketing Authorisation Application in the fourth quarter of 2021, (iv) Ascendis' expectations regarding the announcement of top line results from the OLE portion of the PaTH Forward Trial in the fourth quarter of 2021, (v) Ascendis' expectations regarding the announcement of top line results from the PaTHway Trial in the first quarter of 2022, (vi) Ascendis' ability to apply its platform technology to build a leading, fully integrated biopharma company, (vii) Ascendis' product pipeline and expansion into additional therapeutic areas and (viii) Ascendis' expectations regarding its ability to utilize its TransCon technologies to create new and potentially best-in-class therapies. 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 to supply SKYTROFA, the SKYTROFA® Auto-Injector and other study drug for commercial sales and clinical studies; unforeseen safety or efficacy results in its oncology programs, SKYTROFA, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to commercialization of SKYTROFA and the further development of SKYTROFA, expenses related to the development and potential commercialization of its oncology programs, TransCon PTH and TransCon CNP or other development programs, selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its oncology programs, SKYTROFA, TransCon PTH and TransCon CNP or other development programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; dependence on third party manufacturers to supply study drug for planned clinical studies; 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. 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 10, 2021 and Ascendis' other future reports filed with, or submitted to, the SEC. Forward-looking statements do not reflect the potential impact of any future in-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.

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FINANCIAL TABLES FOLLOW

Ascendis Pharma A/S

Consolidated Statements of Profit or Loss and Comprehensive Income / (loss)

(In EUR'000s, except share and per share data)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|------------------------------------|-----------------|----------------------------------|------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue | 1,022 | 1,436 | 1,767 | 3,661 |
| Research and development costs | (83,306) | (63,578) | (171,455) | (121,093) |
| Selling, general and administrative expenses | (35,345) | (20,805) | (72,591) | (38,720) |
| Operating profit / (loss) | (117,629) | (82,947) | (242,279) | (156,152) |
| Share of profit / (loss) of associate | (4,817) | (1,885) | 23,289 | (3,400) |
| Finance income | 145 | 86 | 23,268 | 1,996 |
| Finance expenses | (12,141) | (10,292) | (1,703) | (876) |
| Profit / (loss) before tax | (134,442) | (95,038) | (197,425) | (158,432) |
| Tax on profit / (loss) for the period | 68 | 106 | 259 | 183 |
| Net profit / (loss) for the period | (134,374) | (94,932) | (197,166) | (158,249) |
| Attributable to owners of the Company | (134,374) | (94,932) | (197,166) | (158,249) |
| Basic and diluted earnings / (loss) per share | € (2.50) | € (1.97) | € (3.66) | € (3.29) |
| Number of shares used for calculation (basic and diluted) | 53,848,166 | 48,207,661 | 53,804,300 | 48,096,749 |
| Net profit / (loss) for the period | (134,374) | (94,932) | (197,166) | (158,249) |
| Other comprehensive income / (loss) | | | | |
| <i>Items that may be reclassified subsequently to profit or loss:</i> | | | | |
| Exchange differences on translating foreign operations | 77 | (147) | 1,765 | (61) |
| Other comprehensive income / (loss) for the period, net of tax | 77 | (147) | 1,765 | (61) |
| Total comprehensive income / (loss) for the period, net of tax | (134,297) | (95,079) | (195,401) | (158,310) |
| Attributable to owners of the Company | (134,297) | (95,079) | (195,401) | (158,310) |

Ascendis Pharma A/S
Consolidated Statements of Financial Position
(In EUR'000s)

| | June 30, 2021 | December 31, 2020 |
|-------------------------------------|------------------|----------------------|
| Assets | | |
| Non-current assets | | |
| Intangible assets | 5,495 | 5,717 |
| Property, plant and equipment | 123,924 | 108,112 |
| Investment in associate | 45,783 | 9,176 |
| Deposits | 1,702 | 1,375 |
| Marketable securities | 90,693 | 115,280 |
| | 267,597 | 239,660 |
| Current assets | | |
| Trade receivables | 394 | 387 |
| Other receivables | 11,398 | 6,957 |
| Prepayments | 21,826 | 13,994 |
| Marketable securities | 166,094 | 134,278 |
| Cash and cash equivalents | 384,539 | 584,517 |
| | 584,251 | 740,133 |
| Total assets | 851,848 | 979,793 |
| Equity and liabilities | | |
| Equity | | |
| Share capital | 7,237 | 7,217 |
| Distributable equity | 680,250 | 831,494 |
| Total equity | 687,487 | 838,711 |
| Non-current liabilities | | |
| Lease liabilities | 94,059 | 85,116 |
| Other liabilities | — | 3,162 |
| | 94,059 | 88,278 |
| Current liabilities | | |
| Lease liabilities | 6,950 | 6,859 |
| Contract liabilities | 145 | 363 |
| Trade payables and accrued expenses | 44,207 | 21,897 |
| Other payables | 18,623 | 23,384 |
| Income taxes payable | 377 | 301 |
| | 70,302 | 52,804 |
| Total liabilities | 164,361 | 141,082 |
| Total equity and liabilities | 851,848 | 979,793 |

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