# 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, 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):

Furnished as an exhibit to this Report on Form 6-K is a press release reporting the financial results of Ascendis Pharma A/S for the fiscal quarter ended June 30, 2022.

# Exhibits

Exhibit<br/>No.Description99.1Press Release dated August 10, 2022.

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

By: /s/ Michael Wolff Jensen

Michael Wolff Jensen Senior Vice President, Chief Legal Officer

Date: August 10, 2022



# PRESS RELEASE

### Ascendis Pharma A/S Reports Second Quarter 2022 Financial Results

- U.S. regulatory submission for TransCon PTH, designed to be the first parathyroid hormone replacement therapy, on track for Q3 2022; EU submission planned for Q4 2022

- SKYTROFA revenue continued to double quarter-to-quarter, reaching €4.4 million in the second quarter

- With anticipated growth in U.S. revenues and approximately  $\in 1$  billion of cash, cash equivalents, and marketable securities on hand, Ascendis is positioned to fulfill Vision 3x3 and become cash flow positive

- Conference call today at 4:30 pm ET

**COPENHAGEN, Denmark, August 10, 2022 (GLOBE NEWSWIRE)** – Ascendis Pharma A/S (Nasdaq: ASND) today announced financial results for the second quarter ended June 30, 2022, and provided a business update.

"Our anticipated launch of TransCon PTH in the U.S. next year, combined with our progress towards making SKYTROFA the leading product in a growing growth hormone market, moves us closer to fulfilling our Vision 3x3 and becoming a sustainable, profitable, leading biopharma company," said Jan Mikkelsen, Ascendis Pharma's President and Chief Executive Officer.

#### **Company Highlights & Progress**

- TransCon hGH:
  - SKYTROFA revenue continued to double quarter-to-quarter, reaching €4.4 million in the second quarter.

U.S. SKYTROFA Launch Metrics	Q4-2021	Q1-2022	Q2-2022
SKYTROFA revenue (millions)	€ 0.9	€ 1.9	€ 4.4
Cumulative number of new patient SKYTROFA prescriptions	369	976	1,707
Total number of prescribers to date	139	349	505
Percent of prescribers to date who have written prescriptions for more than one			
patient	42%	46%	53%
% of U.S. lives covered*	34%	45%	57%

\* Per MMIT - data accessed on July 15, 2022

- In June 2022, submitted a trial protocol to the FDA to evaluate TransCon hGH in Turner Syndrome.
- The foresiGHt Trial in adult GHD on track to complete enrollment by the end of 2022.
- Enrollment in the riGHt Trial, a Phase 3 trial in Japan for pediatric GHD, is expected to complete by the end of 2022.
- Commercial launch of TransCon hGH planned for Europe in mid-2023.
- TransCon PTH:
  - Following pre-NDA meeting with the FDA, on track to submit regulatory filing in the U.S. during the third quarter of 2022, with expected U.S. launch in mid-2023.
  - EU MAA submission planned during the fourth quarter of 2022.
  - After more than two years of treatment in the open-label extension portion of the Phase 2 PaTH Forward Trial, 57 out of 59 original subjects continue in the open label extension portion of the trial as of June 30, 2022.
  - In the Phase 3 PaTHway Trial, 79 out of 79 patients completed one-year follow-up; 78 out of 79 patients continue in the open-label extension portion of the trial as of June 30, 2022.
- TransCon CNP:
  - Top-line data from the ACcomplisH Trial, a Phase 2 randomized, double-blind, placebo-controlled clinical trial in North America, Europe, and Oceania in children ages 2-10 years with achondroplasia expected in the fourth quarter of 2022.
  - Planned fourth-quarter regulatory submissions for a new global randomized, double-blind, placebo-controlled Phase 2b trial of TransCon CNP in children down to 2 years of age with achondroplasia.
- TransCon TLR7/8 Agonist:
  - Enrollment continues in transcendIT-101, a Phase 1/2 trial of TransCon TLR7/8 Agonist with or without a checkpoint inhibitor in patients with advanced or metastatic solid tumors who have failed prior lines of therapy.
  - transcendIT-101 monotherapy and combo-therapy dose escalation top-line data are expected during the third quarter of 2022.
- TransCon IL-2 β/g:
  - The Phase 1/2 IL-Beliege Trial evaluating TransCon IL-2 B/g monotherapy in patients with locally advanced or metastatic solid tumors continues to enroll patients. The Phase 1/2 IL-Beliege Trial top-line data are expected in the fourth quarter of 2022.
  - During the second quarter of 2022, dosed first patient in combination checkpoint inhibitor and TransCon IL-2 ß/g dose-escalation arm of the IL-Beliege Trial.
- TransCon TLR7/8 Agonist and TransCon IL-2 ß/g Combination Therapy:
  - Plan to submit an IND or similar for Phase 2 cohort expansion for TransCon TLR7/8 Agonist and TransCon IL-2 ß/g during the fourth quarter of 2022.
- Board of Directors to nominate Bill Fairey, and Siham Imani, both leaders in pharmaceutical commercialization, as new independent board members. The Board of Directors will call into an Extraordinary General Meeting to take place first half of September 2022.

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• Ended the second quarter of 2022 with cash, cash equivalents, and marketable securities totaling €995 million.

#### Second Quarter 2022 Financial Results

Total revenue for the second quarter was  $\notin 6.2$  million compared to  $\notin 1.0$  million in the same quarter of 2021. Revenue included U.S. revenue from SKYTROFA, as well as license, clinical supply and services provided to third parties, primarily VISEN Pharmaceuticals. The increase in revenue compared to the same period the prior year was primarily attributable to the  $\notin 4.4$  million commercial revenue from SKYTROFA (lonapegsomatropintcgd) in the second quarter following U.S. commercial launch in October 2021.

Research and development (R&D) costs for the second quarter were  $\notin$ 90.4 million compared to  $\notin$ 83.3 million during the same period in 2021, reflecting primarily higher employee costs resulting from an increase in the number of R&D related personnel.

Selling, general, and administrative (SG&A) expenses for the second quarter were  $\in$  56.6 million compared to  $\in$  35.3 million during the same period in 2021. Higher SG&A expenses were primarily due to an increase in commercial and administrative personnel following the launch of SKYTROFA.

Our share of net loss of associate was €1.2 million in the second quarter, compared to a net loss of €4.8 million during the same period in 2021.

Net finance income was €61.7 million in the second quarter compared to a net finance expense of €12.0 million in the same period in 2021.

For the second quarter of 2022, Ascendis Pharma reported a net loss of  $\in$ 81.3 million, or  $\in$ 1.46 per share (basic and diluted) compared to a net loss of  $\in$ 134.4 million, or  $\in$ 2.50 per share (basic and diluted) for the same period in 2021.

As of June 30, 2022, Ascendis Pharma had cash, cash equivalents, and marketable securities totaling  $\notin$  994.9 million compared to  $\notin$  789.6 million as of December 31, 2021. As of June 30, 2022, Ascendis Pharma had 56,965,058 ordinary shares outstanding.

#### **Conference Call and Webcast Information**

Ascendis Pharma will host a conference call and webcast today at 4:30 pm Eastern Time (ET) to discuss its second quarter 2022 financial results.

Those who would like to listen to the live webcast can access it through the following <u>link</u>. To access the live teleconference, register online <u>here</u>. Participants are encouraged to register at least 15 minutes prior to the call.

A replay of the webcast will be available on the Investors & News section of the Ascendis Pharma website at <u>https://investors.ascendispharma.com</u> shortly after conclusion of the event for 30 days.

#### About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated, global biopharmaceutical company focused on making a meaningful difference in patients' lives. Guided by its core values of patients, science and passion, the company uses its TransCon technologies to create new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark, and has additional facilities in Heidelberg and Berlin, Germany; Palo Alto and Redwood City, California; and Princeton, New Jersey. Please visit www.ascendispharma.com to learn more.

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#### **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 timing of top-line results from the ACcomplisH Trial, the transcendIT-101 Trial and the Phase 1/2 IL-Beliege Trial, (ii) the timing of completion of patient enrollment in the foresiGHt Trial and the riGHt Trial, (iii) Ascendis' expectations regarding the strength of 2022, the growth of U.S. revenues and its ability to fulfill Vision 3x3 and become cash flow positive, (iv) whether Ascendis is able to become a sustainable, profitable, leading biopharma company, (v) the expected launch of TransCon PTH in the U.S. in 2023, (vi) the expected launch of TransCon hGH in Europe in 2023, (vii) Ascendis' expectations regarding the timing of its regulatory submissions, applications, protocols, clinical trials and the results thereof, (viii) Ascendis' expectations regarding the potential for TransCon PTH to become the first parathyroid replacement therapy, (ix) Ascendis' ability to make SKYTROFA the leading product in the growth hormone market, (x) Ascendis' ability to apply its platform technology to build a leading, fully integrated biopharma company, (xi) Ascendis' use of its TransCon technologies to create new and potentially best-in-class therapies and (xii) Ascendis' intent to nominate Bill Fairey and Siham Imani to its Board of Directors and the timing of the Extraordinary General Meeting. 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 and distributors to supply TransCon hGH and the SKYTROFA® Auto-Injector for commercial sales in the U.S. and other study drug for clinical studies; unforeseen safety or efficacy results in its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to commercialization of TransCon hGH in the U.S., the co-pay program and the further development of TransCon hGH; expenses related to the development and potential commercialization of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its oncology programs, TransCon hGH, 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 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.

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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,	
	2022	2021	2022	2021
Revenue	6,160	1,022	12,988	1,767
Cost of sales	1,086		5,332	
Gross profit / (loss)	5,074	1,022	7,656	1,767
Research and development costs	90,383	83,306	173,576	171,455
Selling, general and administrative expenses	56,584	35,345	104,002	72,591
Operating profit / (loss)	(141,893)	(117,629)	(269,922)	(242,279)
Share of profit / (loss) of associate	(1,166)	(4,817)	(6,039)	23,289
Finance income	71,127	145	84,171	23,268
Finance expenses	9,434	12,141	14,833	1,703
Profit / (loss) before tax	(81,366)	(134,442)	(206,623)	(197,425)
Tax on profit / (loss) for the period	47	68	(195)	259
Net profit / (loss) for the period	(81,319)	(134,374)	(206,818)	(197,166)
Attributable to owners of the Company	(81,319)	(134,374)	(206,818)	(197,166)
Basic and diluted earnings / (loss) per share	€ (1.46)	€ (2.50)	€ (3.68)	€ (3.66)
Number of shares used for calculation (basic and diluted)	55,805,486	53,848,166	56,260,248	53,804,300
Net profit / (loss) for the period	(81,319)	(134,374)	(206,818)	(197,166)
Other comprehensive income / (loss)				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations	(757)	77	(332)	1,765
Other comprehensive income / (loss) for the period, net of tax	(757)	77	(332)	1,765
Total comprehensive income / (loss) for the period, net of tax	(82,076)	(134,297)	(207,150)	(195,401)
Attributable to owners of the Company	(82,076)	(134,297)	(207,150)	(195,401)

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

	June 30, 2022	December 31, 2021
Assets		
Non-current assets		
Intangible assets	5,050	5,272
Property, plant and equipment	133,224	126,049
Investment in associate	34,905	38,345
Other receivables	1,836	1,808
Marketable securities	39,721	107,561
	214,736	279,035
Current assets		
Inventories	101,322	75,405
Trade receivables	4,369	2,200
Income tax receivable	1,128	893
Other receivables	15,055	20,093
Prepayments	35,067	25,231
Marketable securities	282,767	235,797
Cash and cash equivalents	672,387	446,267
	1,112,095	805,886
Total assets	1,326,831	1,084,921
Equity and liabilities		
Equity		
Share capital	7,649	7,646
Distributable equity	600,193	875,989
Total equity	607,842	883,635
Non-current liabilities		
Borrowings	498,130	97,966
Derivative liabilities	102,031	
Contract liabilities	3,700	2,964
	603,861	100,930
Current liabilities		
Borrowings	14,079	6,995
Contract liabilities		2,601
Trade payables and accrued expenses	74,984	59,417
Other liabilities	20,957	29,952
Income taxes payable	90	198
Provisions	5,018	1,193
	115,128	100,356
Total liabilities	718,989	201,286
Total equity and liabilities	1,326,831	1,084,921

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