## **UNITED STATES SECURITIES** AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 6-K

### REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of March 2022

Commission File Number: 001-39545

# Orphazyme A/S (Translation of registrant's name into English)

Ole Maaløes Vej 3, DK-2200 Copenhagen N Denmark (Address of principal executive office)
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): $\Box$
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): $\Box$
INCORPORATION BY REFERENCE
This Report on Form 6-K (the "Report") and Exhibit 99.1 to this Report shall be deemed to be incorporated by reference into the registration statements of Orphazyme A/S (the "Company") on Form S-8 (File nos. 333-249407 and 333-255661) and Form F-3 (File no. 333-260283) and to be a part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently furnished.

#### **EXHIBIT LIST**

ExhibitDescription99.1Company announcement dated March 22, 2022

# SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### Orphazyme A/S

Date: March 22, 2022 By: /s/ Anders Vadsholt

Name Anders Vadsholt
Title: Chief Executive Officer
and Chief Financial Officer

Orphazyme A/S Company announcement No. 13/2022

Inside information

Ole Maaløes Vej 3, DK-2200 Copenhagen N

www.orphazyme.com

Company Registration No. 32266355

#### Orphazyme announces withdrawal of European Marketing Authorisation Application for arimoclomol for the treatment of Niemann-Pick disease type C

- Decision to withdraw the European Marketing Authorisation Application comes ahead of scheduled final vote on the application later this month
- Orphazyme intends to request Type C Meeting with the U.S. Food and Drug Administration to discuss potential pathway for resubmission of the New Drug Application for arimoclomol for Niemann-Pick disease type C

Copenhagen, Denmark, March 22, 2022 – Orphazyme A/S (ORPHA.CO; ORPH) ("Orphazyme" or the "Company"), a late-stage biopharmaceutical company, announces that, following the receipt of the negative Trend Vote by the Committee for Medicinal Products for Human Use (CHMP) as announced on February 23, 2022 (please see company announcement no. 07/2022), the Company has decided to withdraw its European Marketing Authorisation Application (MAA) for arimoclomol for the treatment of Niemann-Pick disease Type C (NPC) ahead of a final vote and opinion by the CHMP on the MAA scheduled for later this month.

"Today's decision to withdraw the MAA enables us to consider the best possible path forward for arimoclomol," commented Orphazyme Chief Executive Officer, Anders Vadsholt. "NPC is an ultra-rare neurodegenerative disease with a high unmet medical need, and we want to explore options for arimoclomol in this indication, to deliver on our commitment to patients with this devastating disease.

Orphazyme is currently under an in-court restructuring and has reduced its workforce by approximately 50% to reduce costs as it seeks to explore whether a basis can be established for all or part of the Company's operations to continue, including a sale of all or parts of the Company's assets. At this stage it is uncertain whether a solution can be found, and further update will be provided

As part of the pursuit of a regulatory pathway in the U.S., the Company continues to work towards resubmission of the Company's New Drug Application for arimoclomol to the U.S. Food and Drug Administration (FDA) and plans to request a Type C Meeting in Q2 2022.

#### For additional information, please contact

#### Orphazyme A/S

Anders Vadsholt, Chief Executive Officer and Chief Financial Officer

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Orphazyme is a late-stage biopharmaceutical company developing arimoclomol for Niemann-Pick disease type C (NPC). Orphazyme is headquartered in Denmark and has operations in Switzerland. ADSs representing Orphazyme's shares are listed on Nasdaq U.S. (ORPH) and its shares are listed on Nasdaq Copenhagen (ORPHA).

Animoclomol is an investigational drug candidate that amplifies the production of heat shock proteins (HSPs). HSPs can rescue defective misfolded proteins and improve the function of lysosomes. Arimoclomol is administered orally, and has now been studied in 10 Phase 1, four Phase 2, and three pivotal Phase 2/3 trials. Arimoclomol has received Orphan Drug Designation (ODD) for NPC in the US and EU. Arimoclomol has received Fast-Track Designation (FTD), Breakthrough Therapy Designation (BTD), and Rare Pediatric Disease Designation (RPDD) from the U.S. Food and Drug Administration (FDA) for NPC. On June 17, 2021, Orphazyme received a Complete Response Letter from the FDA regarding its New Drug Application for arimoclomol for the treatment of NPC. The Company plans to request a Type C Meeting with the FDA in Q2 2022. Org22, the EMA Committee for Medicinal Products for Human Use (CHMP) issued a negative Trend Vote on the Marketing Authorization Application (MAA) for arimoclomol in NPC filed with the European Medicines Agency (EMA). The Company has subsequently decided to withdraw its MAA.

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#### Forward-looking statement

Forward-looking statement
This company announcement may contain certain forward-looking statements under the U.S. Private Securities Litigation Reform Act of 1995 and otherwise, including forward-looking statements about the U.S. regulatory process for the potential approval of arimoclomol by the FDA. Although the Company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this company announcement about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by, or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "could," and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties that could cause the Company's actual results, performance, or achievements to be materially different from the expected results, performance, or achievements expressed or implied by such forward-looking statements, including the risks and uncertainties that are described in the Risk Factors section of the Company's Report on Form 20-F for the year ended December 31, 2020 filed with the U.S. Securities and Exchange Commission (SEC) on March 2, 2021, the Company's Report on Form 6-K filed with the SEC on June 11, 2021, and other filings Orphazyme makes with the SEC from time to time. These documents are available on the "investors & Media" section of Orphazyme's website at www.orphazyme.com. Except as required by law, the Company assumes no obligation to update these forward-looking statements, publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.