## **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 June 2021

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): $\Box$		

#### RISK FACTORS

The following risk factors should be read in conjunction with, and amend and supplement, those included in the Annual Report on Form 20-F filed by Orphazyme A/S (the "Company") on March 2, 2021 (the "Form 20-F"). Investing in the Company's American Depositary Shares representing its ordinary shares ("ADSs") and its ordinary shares involves a high degree of risk. You should carefully consider the risks described below, and all other information contained in or incorporated by reference in the Form 20-F, before making an investment decision regarding the company's securities. The terms "we," "us" and "our" refer to the Company.

#### The trading price of our equity securities may be volatile due to factors beyond our control.

The market prices of the ordinary shares or ADSs and shares has been, and may continue to be, volatile due to many factors, some of which may be beyond our control. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ordinary shares or ADSs or shares at or above the price originally paid for the security. The market price for the ordinary shares or ADSs and shares may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- the release of new data from the clinical trials of arimoclomol;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments:
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- commentary by investors on the prospects for our business, the ordinary shares or ADSs on the internet, including blogs, articles and message board, and/or social media and resulting in trading of our ordinary shares or ADSs;
- unusual trading in our ordinary shares or ADSs or securities derivative thereof, including pursuant to naked, or uncovered, short positions or "short squeezes;"
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- currency fluctuations;
- ordinary share price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- uncertainty caused by and the unprecedented nature of the current COVID-19 pandemic;
- issuances or sales of the ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

These and other market and industry factors have caused and may continue to cause the market price and demand for the ordinary shares or ADSs to fluctuate substantially, regardless of our actual operating performance. This volatility may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. For example, ADSs on Nasdaq US have since June 10, 2021 experienced extreme volatility in price and trading volume. We are not aware of any material change in our clinical development programs, financial condition or results of operations that would explain such price volatility or trading volume that has occurred since June 10, 2021. Investors who purchase ADS or ordinary shares may lose a significant portion of their investments if the price of such securities subsequently declines.

Information available in public media that is published by third parties, including blogs, articles, message boards and social and other media may include statements not attributable to us and may not be reliable or accurate.

We have received, and may continue to receive, a high degree of media coverage that is published or otherwise disseminated by third parties, including blogs, articles, message boards and social and other media. This includes coverage that is not attributable to statements made by our directors, officers or employees. You should read carefully, evaluate and rely only on the information contained in this Report on Form 6-K, our Annual Report on Form 20-F and such other reports that we file with the SEC from time to time in determining whether to purchase our ADSs or ordinary shares. Information provided by third parties may not be reliable or accurate and could materially impact the trading price of our ADSs and/or ordinary shares, which could cause losses to your investments in our securities.

#### **INCORPORATION BY REFERENCE**

This Report on Form 6-K (the "Report") and Exhibit 99.1 to this Report are hereby expressly incorporated by reference into the registrant's registration statements on Form S-8 (File nos. 333-249407 and 333-255661) 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**

Exhibit	Description	
99.1	Company announcement dated June 11, 2021	

## **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.

Date: June 11, 2021

## Orphazyme A/S

By: /s/ Anders Vadsholt

Name Anders Vadsholt Title: Chief Financial Officer

### Orphazyme A/S Company announcement

No. 15/2021

Company Registration No. 32266355

Copenhagen – June 11, 2021 - Orphazyme A/S (ORPHA.CO; ORPH), a late-stage biopharmaceutical company pioneering the heat shock protein response for the treatment of rare diseases, today announced that American Depositary Shares (ADSs) representing its ordinary shares on Nasdaq US have since June 10, 2021 experienced extreme volatility in price and trading volume. The company is not aware of any material change in its clinical development programs, financial condition or results of operations that would explain such price volatility or trading volume that has occurred since June 10, 2021. Investors who purchase the company's ADS or shares may lose a significant portion of their investments if the price of such securities subsequently declines.

Orphazyme's applications for arimoclomol (to be branded MIPLYFFA<sup>TM</sup>)<sup>1</sup> for Niemann-Pick disease type C (NPC) are under priority review with the U.S. Food and Drug Administration, with an expected PDUFA action date of June 17 2021, as well as with the European Medicines Agency, with an opinion from the Committee for Medicinal Products for Human Use (CHMP) expected later this year.

## For additional information, please contact:

#### Orphazyme A/S

Copenhagen: Anders Vadsholt, CFO, +45 28989055

Chicago: Molly Carey Poarch, Global Media, +1-773-770-6888

#### **About Orphazyme A/S**

Orphazyme is a late-stage biopharmaceutical company pioneering the heat shock protein response for the treatment of rare diseases. The company is harnessing amplification of heat shock proteins (or HSPs) to develop and commercialize novel therapeutics for diseases caused by protein misfolding, protein aggregation, and lysosomal dysfunction, including lysosomal storage diseases. Arimoclomol, the company's lead candidate, is in clinical development for Niemann-Pick disease type C (NPC) and Gaucher disease. Orphazyme is headquartered in Denmark and has operations in the U.S. and Switzerland. Orphazyme's shares are listed on Nasdaq U.S. (ORPH) and Nasdaq Copenhagen (ORPHA.CO).

#### **About arimoclomol**

Arimoclomol is an investigational drug candidate that amplifies the production of heat shock proteins (HSPs). HSPs can rescue defective misfolded proteins, clear protein aggregates, 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 is in clinical development for NPC and Gaucher disease. Arimoclomol has received orphan drug designation (ODD) for NPC in the US and EU. Arimoclomol has received fast-track designation (FTD) from the U.S. Food and Drug Administration (FDA) for NPC. In addition, arimoclomol has received breakthrough therapy designation (BTD) and rare-pediatric disease designation (RPDD) from the FDA for NPC. Arimoclomol is an investigational treatment and has not been approved by the FDA.

#### Forward-looking statement

This company announcement may contain certain forward-looking statements, including in respect of the expected PDUFA action date of June 17 2021 for arimoclomol for the treatment of NPC, the potential U.S. approval of arimoclomol in June and the opinion from the Committee for Medicinal Products for Human Use (CHMP) later this year. 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," "can have," "likely," "should," "would," "could", and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control 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. 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.