



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

July 27, 2020

Kim Stratton
Chief Executive Officer
Orphazyme A/S
Ole Maaløes Vej 3, DK-2200
Copenhagen N
Denmark

Re: Orphazyme A/S
Draft Registration Statement on Form F-1
Submitted June 30, 2020
CIK No. 0001764791

Dear Ms. Stratton:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1 submitted June 30, 2020

Cover page

1. We note your disclosure on the prospectus cover page that the last reported sale price of your ordinary shares on the Nasdaq Copenhagen A/S was DKK ____ per ordinary share, equivalent to \$ ____ per ADS. You may use the most recent home market trading price, converted to U.S. dollars at the most recent exchange rate, assuming the U.S. IPO price will be substantially similar to the home market trading price. If you expect that the U.S. IPO price will not be substantially similar as the home market trading price, please disclose on the prospectus cover page a bona fide price range of the offered securities. If you intend to price the securities based on the Nasdaq Copenhagen price, you may

disclose a percentage range based on that price (for example, 10% of the home market price) within which you intend to price the securities. Please refer to the instructions to Item 501(b)(3) of Regulation S-K which require bona fide pricing information for offerings by companies not subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act. Please also tell us whether the offering is conditioned upon approval of your ADS's to trade on the Nasdaq Global Market and if it is not, please revise your cover page to clarify this fact.

Market and Industry Data, page iii

2. Your statements that (i) you have not independently verified third party publications and studies and (ii) no independent source has verified your internal research and definition of market and industry may imply an inappropriate disclaimer of responsibility with respect to the third party information and your own research. Please either delete these statements or specifically state that you are liable for such information.

Prospectus Summary

Overview, page 1

3. We note your disclosure that you have "seen positive efficacy results" in your Phase 2 clinical trials for Amyotrophic Lateral Sclerosis (ALS), Sporadic Inclusion Body Myositis (sIBM) and Gaucher disease as well as your statement that you have not observed "major safety concerns." Safety and efficacy are determinations that are solely within the authority of the U.S. Food and Drug Administration (FDA) or similar foreign regulators. You may present clinical trial end points and objective data resulting from trials without concluding efficacy and you may state that your product candidates have been well tolerated, if accurate. Please revise these and similar statements here and throughout the document, including, as examples only, references to "clinically meaningful results," "evidence of the efficacy and safety profile arimoclomol" and "acceptable safety profile of arimoclomol."
4. We note your references to your ongoing clinical trials of arimoclomol for the treatment of ALS and sIBM as "registrational." Please tell us whether you expect your respective ongoing trials to be the last clinical trial necessary in order to support marketing approval. Address in your response the basis for such expectation. We note also your reference to advancing arimoclomol to "pivotal-stage" clinical development for the treatment of neurological Gaucher disease. Such characterization does not appear appropriate given that results from your Phase 2 trial in this indication did not meet the trial's primary endpoint, as discussed on page 105. Please tell us the basis for such characterization. Additionally, your statement on page 4 that arimoclomol was well-tolerated in your Phase 2 trial for the treatment of Gaucher disease does not appear supportable based on your disclosure of the incidence of serious adverse events (SAEs) across doses on page 106. Please revise your disclosure to remove this characterization.

5. Please clarify in the Summary that the FDA's accelerated approval pathway may not lead to a faster development process or regulatory review and does not increase the likelihood that a product candidate will receive approval.

Risks Associated with our Business, page 5

6. Please expand your disclosure in the sixth bullet point to highlight the risks associated with your limited trial populations to date, as referenced on page 18. Please also expand your disclosure in the third to last bullet point to highlight the risk that you are dependent on orphan drug exclusivity, as referenced on page 21.

Implications of Being an Emerging Growth Company, page 7

7. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Use of Proceeds, page 71

8. We note your disclosure that you intend to use the proceeds of this offering to (i) seek regulatory approval and fund the commercial launch of arimoclomol for the treatment of NPC and (ii) advance the clinical development of arimoclomol for the treatment of ALS, sIBM and neurological Gaucher disease. Please specify what amounts will be allocated to each of your programs and specify how far in the development of each of your projects you expect to reach with the proceeds of the offering. If any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of other funds needed for each specified purpose and the sources. Refer to Item 3.C.1 of Form 20-F.

Business, page 90

9. We note that your disclosure on page 15 indicates that a QTc clinical trial to support your NDA for NPC has been delayed due to COVID-19, which may delay FDA approval for NPC. Please update your Business section to include a discussion of this trial, including its endpoints, and the potential effects of the delay on regulatory approval.

Clinical Trials of Arimoclomol for the Treatment of NPC, page 103

10. Please expand your disclosure regarding the safety findings from your Phase 2/3 clinical trial of arimoclomol for NPC to disclose what proportion of the adverse events related to arimoclomol were determined to be treatment-related. Please also expand your discussion of this trial and the open-label extension clinical trial to discuss whether any SAEs were determined to be treatment-related. Please quantify and describe any treatment-related SAEs and SAEs the investigator could not determine were not treatment related.

Overview of Gaucher disease, page 104

11. Please disclose how common each of Gaucher Type 1, Gaucher Type 2 and Gaucher Type 3 are among all cases of Gaucher disease or explain why this information would not be material.

Clinical Trials of Arimoclomol for the Treatment of Gaucher Disease, page 106

12. Please expand your discussion of the Phase 2 clinical trial of arimoclomol for the treatment of Gaucher disease and the open-label extension trial to discuss whether any of the other SAEs observed in the trial were determined to be treatment-related or possibly related to treatment. Please quantify and describe any of these additional treatment-related SAEs and SAEs the investigator could not determine were not treatment related. Please also explain the significance of the increase in transaminases that was observed in the one patient that discontinued treatment.

Trial 20100758, page 111

13. Please update your disclosure to explain the significance of the hazard ratio findings in Trial 20100758.

Manufacturing, page 117

14. We note that your disclosure on page 19 of the prospectus indicates that your CMO will need to install and obtain approval for specialized equipment for the manufacture of arimoclomol. Please update your Manufacturing section to include a discussion of the installation of this equipment along with any anticipated effects on the timing of regulatory approvals or commercial launch.

Material Agreements, page 120

15. Please revise the descriptions of each of your agreements to disclose the aggregate amount of all payments made under each agreement to date. We note that in the description of the CytRx, you state that the royalty rate for products which are prescribed for the treatment or prevention of ALS or stroke is in the low double-digits. Please revise the disclosure to quantify the rate at a range of no greater than 10 percentage points per tier.

Please also disclose when the sIBM royalty provision expires in your description of the license agreement with University of Kansas and UCL Business PLC.

We note your disclosure that the licenses granted to you under the agreements with (i) the University of Miami and (ii) the University of Kansas and UCL Business PLC are subject to the rights of the U.S. government. Please revise your disclosure to further explain what rights the U.S. government has to the licenses granted under these agreements, including whether the U.S. government has rights to any of your product candidates based on these provisions.

Principal Shareholders, page 161

16. Please identify the natural persons who are the beneficial owners of the shares held by the 5% or greater shareholders identified in your table.

Notes to the Consolidated Financial Statements

3.1 Intangible Assets

CytRx Asset Purchase Agreement, page F-24

17. Please tell us your consideration of disclosing the amounts and triggering points of each of the milestones payable under the CytRx agreement pursuant to paragraphs 84-92 of IAS 37.

4.7 Significant Events After the Reporting Period, page F-39

18. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. In this respect we note that on February 7, 2020 you completed an offering of 7,032,937 shares at a price of DKK 106 per share which was determined by your Board of Directors. Please tell us how that price per share compares to the traded value of the company's stock on the Nasdaq Copenhagen at the date of the transaction. Also, please tell us if the shares were issued to related parties.

You may contact David Burton at 202-551-3626 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at 202-551-4224 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Joshua A. Kaufman, Esq.