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September 4, 2020

U.S. Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Mail Stop 4546 Washington, D.C. 20549

Attn: Mr. David Burton Ms. Mary Mast Mr. Alan Campbell Ms. Christine Westbrook

Re: Orphazyme A/S Amendment No. 1 to Draft Registration Statement on Form F-1 Submitted August 5, 2020 CIK No. 0001764791

Ladies and Gentlemen:

On behalf of our client, Orphazyme A/S (the "*Company*"), we are responding to the comments (the "*Comments*") of the staff (the "*Staff*") of the Securities and Exchange Commission (the "*Commission*") contained in its letter dated August 20, 2020 (the "*Comment Letter*"), relating to the above referenced Amendment No.1 to the Draft Registration Statement on Form F-1 (the "*Draft Registration Statement*"). In response to the Comments set forth in the Comment Letter, the Company has revised the Draft Registration Statement and is filing via EDGAR a revised version of the Registration Statement (the "*Registration Statement*") with this response letter.

Set forth below are the Company's responses to the Comments. The numbering of the paragraphs below corresponds to the numbering of the Comments, which for your convenience we have incorporated into this response letter. Page references in the text of this response letter correspond to the page numbers of the Registration Statement. Capitalized terms used but not defined herein are used herein as defined in the Registration Statement.

<u>Prospectus Summary</u> <u>Overview, page 1</u>

1. We note your response to prior comment 3 and re-issue in part. Please revise your statements regarding your belief that arimoclomol has an acceptable safety profile to remove any implication that your product candidate is safe. We will not object to disclosure indicating, if accurate, that arimoclomol has been well-tolerated in clinical trials.

VIA EDGAR



We further note that you continue to refer to the observation of the "clinically meaningful results" and "clinically meaningful benefits" of arimoclomol. It is inappropriate for you to state or imply that your product candidates are effective or are likely to be found effective. Please remove such statements from your document. You may present clinical trial end points and objective data result from your clinical trials with concluding that the results establish efficacy.

## **Response to Comment 1**

### In response to the Staff's comment, the Company has revised the disclosure throughout the Registration Statement as requested.

## Management's Discussion and Analysis of Financial Condition and Results of Operations Asset Purchase Agreement with CytRx, page 79

2. Please update your description of the Asset Purchase Agreement with CytRx to describe the non-royalty licensing fee in Section 2.14 of the agreement. Please quantify the nonroyalty licensing fee percentage at a range of no greater than 10 percentage points.

#### **Response to Comment 2**

The Company acknowledges the Staff's comment and respectfully advises the Staff that the non-royalty licensing fee in Section 2.14 of the agreement was only applicable if the Company would have entered into a license agreement during a specified period of time following the Closing Date (as defined in the agreement). The Company confirms that it did not enter into such a license agreement during the applicable period of time, and therefore, the non-royalty licensing fee is inapplicable. Accordingly, the Company believes that the non-royalty licensing fee is not a material term of the agreement that would require disclosure.

## Business, page 115

3. We note your updated disclosure in your descriptions of your clinical trials of arimoclomol for ALS and sIBM with respect to the observance of increased transaminases. Please update your disclosure to discuss the potential risks to your product candidate development, including risks related to clinical trial subjects and to regulatory approval, if transaminase elevations in trial subjects are determined to be related to arimoclomol as further data becomes available.

## **Response to Comment 3**

In response to the Staff's comment, the Company has revised page 23 of the Registration Statement as requested.



Sales and Marketing, page 120

4. We note your disclosure regarding your entry into U.S. distribution and specialist pharmacy partnerships. Please describe the material terms of the agreements underlying these partnerships.

## **Response to Comment 4**

In response to the Staff's comment, the Company has revised page 138 of the Registration Statement. The Company advises the Staff, as set forth in the revised disclosure, while the Company expects to enter into agreements with a third-party logistics firm and a specialty pharmacy, the Company does not have any material agreements in place currently with such parties.

\* \* \* \*

# Cooley

Please direct any questions or comments concerning the Registration Statement or this response letter to either the undersigned at (212) 479-6495, Alison Haggerty at (212) 479-6596 or Divakar Gupta at (212) 479-6474.

Very truly yours,

/s/ Josh Kaufman

Josh Kaufman

cc: Kim Stratton, Orphazyme A/S Anders Vadsholt, Orphazyme A/S Alison Haggerty, Cooley LLP Divakar Gupta, Cooley LLP Mark Ballantyne, Cooley LLP Ilir Mujalovic, Shearman & Sterling LLP