# Cooley

Josh Kaufman	
(212) 479-6495	
josh.kaufman@cooley.com	

September 23, 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. Alan Campbell Ms. Christine Westbrook Mr. David Burton Ms. Mary Mast

Re: Orphazyme A/S Amendment No. 1 to Registration Statement on Form F-1 Filed September 21, 2020 File No. 333-248607

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 September 22, 2020 (the "*Comment Letter*"), relating to the above referenced Amendment No. 1 to the Registration Statement on Form F-1 (the "*Registration Statement*"). In response to the Comments set forth in the Comment Letter, the Company has revised the Registration Statement and is filing via EDGAR Amendment No. 2 to the Registration Statement (the "*Amended 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 Amended Registration Statement. Capitalized terms used but not defined herein are used herein as defined in the Amended Registration Statement.

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

1. We note your disclosure on page 22 that the U.S. Food and Drug Administration (FDA) has identified to you potential review issues that you will need to address before obtaining FDA approval of arimoclomol for the treatment of Niemann-Pick disease Type C. Please

VIA EDGAR



September 23, 2020 Page 2

place your selected disclosure in appropriate context by describing the potential review issues.

#### **Response to Comment 1**

In response to the Staff's comment, the Company has revised pages 1, 22 and 106 of the Amended Registration Statement as requested. The Company respectfully notes that the FDA has not conveyed specific review issues to the Company; rather, in the letter related to the acceptance of the NDA, the FDA simply indicated that, as is standard practice, it has identified potential review issues that the Company may need to address before obtaining FDA approval.

#### Use of Proceeds, page 80

2. We refer to comment 8 in our letter dated July 27, 2020. Please specify how far in the development of each of your programs 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.

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

In response to the Staff's comment, the Company has revised page 80 of the Amended Registration Statement as requested. The Company also intends to convey the same incremental information to investors by means of a free writing prospectus, which the Company plans to file with the Commission today.

### **Exhibits**

3. Please have counsel file a revised Exhibit 5.1 opinion that does not include the assumptions set forth in Section 2.d. Refer to Staff Legal Bulletin No. 19, Section II.B.3.a.

## **Response to Comment 3**

In response to the Staff's comment, the Amended Registration Statement includes a revised Exhibit 5.1 opinion of Gorrissen Federspiel Advokatpartnerselskab that does not include the assumptions set forth in Section 2.d of the prior Exhibit 5.1 opinion.

\* \* \* \*

## Cooley

Please direct any questions or comments concerning the Amended Registration Statement or this response letter to either the undersigned at (212) 479-6495.

Very truly yours,

/s/ Josh Kaufman

Josh Kaufman

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