

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

January 19, 2020

Craig Kussman Chief Financial Officer Organovo Holdings, Inc. 440 Stevens Avenue, Suite 200 Solana Beach, California 92075

> Re: Organovo Holdings, Inc. Registration Statement on Form S-4 Filed December 23, 2019 File No. 333-235683

Dear Mr. Kussman:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form S-4

Even after completion of the Merger, Tarveda will require substantial additional funding to finance its operations, page 41

1. We note your disclosure here that Tarveda believes that the \$13.6 million of gross proceeds from the December private placement of its Series 1 preferred stock and recapitalization, the anticipated cash that Organovo will have on its balance sheet at the effective time of the Merger, together with its existing cash and cash equivalents as of September 30, 2019, will fund the combined organization's current operating plans through at least the next 18 months from the anticipated effective time of the Merger. Please reconcile this disclosure with the statement on page 211 that Tarveda expects that its existing cash and cash equivalents, including \$13.6 million of gross proceeds from the

Craig Kussman Organovo Holdings, Inc. January 19, 2020 Page 2

December 2019 equity financing, will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through September 2020.

Background of the Merger, page 96

- 2. We note your disclosure of certain discussions regarding potential strategic alternatives that predated both the August 2019 announcement that Organovo would be pursuing strategic alternatives and the strategic alternative process conducted by Roth. Please disclose how these discussions were initiated with the various parties.
- 3. Please identify the members of the Special Committee of the Organovo board of directors that was formed to evaluate strategic alternatives and establish the material terms of the transaction with Tarveda.
- 4. We note your disclosure that of the 27 companies that submitted non-binding indications of interest, eight were invited to present to the Organovo board of directors. Please revise to disclose the material terms of the bids from those eight companies and why the special committee selected those eight companies. We also note your disclosure that Organovo discussed and negotiated term sheets for a potential strategic transaction with four life sciences companies. Please revise this section to disclose how the material terms of the transaction were negotiated with those four companies, including how the deal value, pricing mechanism, exchange ratio and ownership split were negotiated. Please also disclose what led the special committee to select Tarveda's offer over the other three parties.
- 5. Please supplementally provide us with copies of all materials prepared by Roth and shared with your board of directors and their representatives, including copies of all board books and all transcripts and summaries, that were material to the board's decision to approve the Merger Agreement.

Summary of Material Financial Analysis, page 121

6. With respect to the analyses where Roth selected certain companies for purposes of comparison, please disclose whether any companies meeting the selection criteria were excluded from the analyses, and if so, why they were excluded.

Organovo Business

Intellectual Property, page 182

7. With respect to Organovo's material patents and patent applications, please disclose the foreign jurisdictions where you own or license patents and where you have pending patent applications.

Craig Kussman Organovo Holdings, Inc. January 19, 2020 Page 3

Tarveda Business, page 184

8. We note several references to "improved efficacy" in the charts and graphs in this section. Please revise your disclosure to remove these statements as determinations of efficacy are solely within the authority of the FDA.

Tarveda's Product Pipeline, page 189

- 9. We note that your pipeline table includes three programs in the discovery stage. Please provide us your analysis as to why you believe these programs are material enough to be included in your pipeline table.
- 10. Please include a column for each of Phase 1, Phase 2 and Phase 3 in your product pipeline table.

Madrigal Pharmaceuticals, Inc. License Agreement, page 193

11. Please disclose the aggregate future potential milestone payments under the agreement and the royalty term.

Intellectual Property, page 195

12. With respect to Tarveda's material patents and patent applications, please disclose the type of patent protection and the applicable foreign jurisdictions.

Loan and Security Agreement with Oxford, page 222

13. We note your disclosure that the 2019 Oxford Loan contains customary negative covenants limiting Tarveda's ability to consummate mergers such as the one currently contemplated. Please revise your disclosure to indicate whether you require Oxford's consent to consummate the merger, and, if so, whether such consent has been obtained.

<u>Unaudited Pro Forma Combined Financial Information</u> Unaudited Pro Forma Condensed Combined Balance Sheet, page 252

14. We note that you accumulate several pro forma merger adjustments to equity and show only the cumulative amount of the adjustments. So that we, and investors, may better understand your accounting and the impact of each adjustment, please quantify the amount of each adjustment separately either on the pro forma balance sheet or as part of your footnote disclosure in Note 4.

Principal Stockholders of Organovo, page 271

15. Please revise your disclosure to identify the natural person or persons who have voting and investment control of the shares held by ARK Investment Management, LLC.

Craig Kussman Organovo Holdings, Inc. January 19, 2020 Page 4

Incorporation of Certain Documents by Reference, page 282

16. We note that you have incorporated by reference certain information about the registrant. It appears that you are not S-3 eligible and are, therefore, ineligible to incorporate by reference certain information that Form S-4 requires. Refer to General Instruction B.1 of Form S-4. Please provide an analysis as to your eligibility, or revise to include the disclosure required by Item 14 of Form S-4.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Julie Sherman at 202-551-3640 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmento at 202-551-3798 or Mary Beth Breslin at 202-551-3625 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Jeffrey C. Thacker, Esq.