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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 19, 2020

ORGANOVO HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Commission File Number: 001-35996

Delaware	**27-1488943**
(State or other jurisdiction of incorporation)	**(I.R.S. Employer Identification No.)**

440 Stevens Avenue, Suite 200
Solana Beach, CA 92075
(Address of principal executive offices, including zip code)

(858) 224-1000

(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☒ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	**(Trading symbol(s))**	**(Name of each exchange on which registered)**
Common Stock, $0.001 par value	**ONVO**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

Supplemental Disclosures

As previously disclosed, on December 13, 2019, Organovo Holdings, Inc. (the "Company" or "Organovo") entered into an Agreement and Plan of Merger and Reorganization, as amended (the "Merger Agreement"), with Tarveda Therapeutics, Inc. ("Tarveda"). Upon the terms and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, including approval of the transaction by Organovo's stockholders and Tarveda's stockholders, Opal Merger Sub, a wholly-owned subsidiary of Organovo ("Merger Sub"), will merge with and into Tarveda, with Tarveda becoming a wholly-owned subsidiary of Organovo and the surviving corporation of the merger (the "Merger"). On February 24, 2020, Organovo filed a definitive proxy statement/prospectus/information statement (the "Definitive Proxy Statement"), as such may be supplemented from time to time, with the Securities and Exchange Commission (the "SEC") with respect to the special meeting of Organovo's stockholders scheduled to be held on March 26, 2020 (the "Organovo Special Meeting").

Supplemental Disclosures to Definitive Proxy Statement

The additional disclosures in this Current Report on Form 8-K supplement the disclosures contained in the Definitive Proxy Statement and should be read in conjunction with the Definitive Proxy Statement, which in turn should be read in its entirety. To the extent that information in this Current Report on Form 8-K differs from or updates information contained in the Definitive Proxy Statement, the information in this Current Report on Form 8-K shall supersede or supplement the information in the Definitive Proxy Statement. All page references in the information below are to pages in the Definitive Proxy Statement, and all defined and capitalized terms used below shall have the meanings ascribed to such terms in the Definitive Proxy Statement. Paragraph references used herein refer to the Definitive Proxy Statement before any additions or deletions resulting from the information set forth below. Without admitting in any way that the disclosures below are material or otherwise required by law, Organovo and Tarveda make the following supplemental disclosures:

The disclosure under the heading "*The Merger – Background of the Merger – Potential Strategic Alternatives*" is hereby supplemented by inserting the following disclosure as a new paragraph immediately following the end of the first paragraph on page 98 of the Definitive Proxy Statement:

Organovo's form confidentiality and standstill agreement contained a one-year standstill period and a provision, known as a "don't ask, don't waive" provision, prohibiting potential bidders from requesting, privately or publicly, that Organovo agree to waive or amend the standstill restrictions so as to allow the potential bidder to make another bid during the standstill period. If requested by potential bidders during negotiations, however, Organovo did agree to amend the terms of its form confidentiality and standstill agreement to either delete the "don't ask, don't waive" provision or to add language that caused the standstill period to automatically terminate upon the occurrence of certain events, including but not limited to, the Company's announcement that it had entered into the Merger Agreement. Four of the 51 companies who signed confidentiality and standstill agreements with Organovo requested an amendment to the "don't ask, don't waive" provision or the term of the standstill period, and Organovo agreed to amend its form of confidentiality and standstill agreement for each of these four parties. After signing the Merger Agreement, Organovo has not, and does not plan to, interpret the confidentiality and standstill agreements it signed to preclude any bidder from requesting to be relieved of its standstill obligations for the sole purpose of making a Superior Offer as the term is described in the Merger Agreement.

The disclosure under the bulleted sub-heading *"The Merger – Background of the Merger – History of Strategic Alternatives Discussions and Significant Corporate Events – Tarveda*" on page 109 is hereby supplemented by adding the following disclosure immediately prior to the first full sentence on page 110:

To support its expectations regarding Tarveda's opportunity to progress to clinical data read-outs with the combined organization's anticipated cash at closing, the Organovo special committee reviewed the projections Tarveda provided regarding the total operating expenses it expected incur to support its product development plans for calendar year 2020, which forecasted total quarterly operating expenses of approximately $5.0-6.0 million a quarter in 2020. The Organovo special committee also considered Tarveda's estimate that the combined cash of the company would be sufficient to fund its development plans and operations into the second half of 2021.

* * *

SEC Investigation

On March 4, 2020, Organovo received a letter from the SEC indicating that it had initiated an investigation of the Company and attaching a subpoena seeking information and documents for the period from January 1, 2017 to the present, relating to, among other things, disclosures to investors regarding the efficacy and/or tissue duration of the Company's liver therapeutic program and products, the Company's communications with the FDA, and purchases or sales of Company stock by the Company's officers and directors. The Company intends to cooperate with the SEC's investigation.

Tarveda Press Release

On March 19, 2020, Tarveda issued a press release announcing that it has entered into a licensing agreement with SciClone Pharmaceuticals for PEN-866, the initial clinical program from Tarveda's HSP90 binding miniature drug conjugate platform. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Forward-Looking Statements

This communication contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended) concerning Organovo and Tarveda, the proposed merger, and Tarveda's business and product development plans. These statements discuss goals, intentions and expectations as to future plans, results of operations and financial condition, and are based on current beliefs of the management of Organovo and Tarveda. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the proposed merger are not satisfied, including the failure to obtain stockholder approval for the merger and the related proposals in a timely manner or at all; uncertainties as to the timing of the consummation of the proposed merger and the ability of each of Organovo and Tarveda to consummate the transaction; risks related to Organovo's continued listing on The Nasdaq Capital Market until closing of the proposed merger and the ability of the combined company to maintain its listing if the transaction is consummated; risks related to the ability of Organovo and Tarveda to correctly estimate their respective operating expenses, the expenses associated with the proposed merger and their net cash as of the closing of the transaction; the risk that as a result of adjustments to the exchange ratio, Organovo stockholders and Tarveda stockholders could own more or less of the combined company than is currently anticipated; unexpected costs, charges or expenses resulting from the proposed merger; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed merger; Tarveda has incurred significant net losses since inception and anticipates that it will continue to incur substantial net losses for the foreseeable future and may never achieve or maintain profitability; even after completion of the merger, Tarveda will require substantial additional funding to finance its operations and product development plans; Tarveda is early in its development efforts and its lead drug candidates, PEN-866 and PEN-221 are still in early stage clinical development and there is no assurance that Tarveda will successfully complete late stage clinical trials or ever obtain regulatory approval for any drug candidate; Tarveda's approach to the discovery and development of *Pentarin* miniature drug conjugates, including using its HSP90 binding miniature drug conjugate platform, is based on novel technologies that are unproven and may not result in marketable products; and other factors discussed in the risk factors included in the Definitive Proxy Statement, and its most recent Current Reports on Form 8-K filed with the SEC. In addition, the forward-looking statements included in this communication represent Organovo's and Tarveda's views as of the date hereof. Organovo and Tarveda anticipate that subsequent events and developments will cause their respective views to change. However, while Organovo and Tarveda may elect to update these forward-looking statements at some point in the future, Organovo and Tarveda specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing Organovo's or Tarveda's views as of any date subsequent to the date hereof.

Important Information and Where to Find It

This communication may be deemed to be solicitation material in respect to the proposed transaction between Organovo and Tarveda. On February 24, 2020, Organovo initially filed the Definitive Proxy Statement with the SEC. Organovo mailed the Definitive Proxy Statement to its stockholders on or about February 26, 2020. Each party may file other documents with the SEC in connection with the proposed merger. BEFORE MAKING ANY VOTING OR INVESTMENT DECISION, INVESTORS AND STOCKHOLDERS ARE URGED TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT ORGANOVO, TARVEDA THE PROPOSED MERGER AND RELATED MATTERS. Investors and stockholders may obtain, free of charge, copies of the Definitive Proxy Statement and any other documents filed by Organovo with the SEC in connection with the proposed transactions at the SEC's website (http://www.sec.gov) and on the investor relations section of Organovo's website at ir.organovo.com. Investors and stockholders are urged to read the Definitive Proxy Statement and the other relevant materials before making any voting or investment decision with respect to the proposed merger and the related proposals.

Non-Solicitation

This communication does not constitute an offer to sell or solicitation of an offer to buy any securities, nor will there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction.

Participants in the Solicitation

Organovo and its directors and executive officers and Tarveda and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Organovo in connection with the proposed Merger. Information regarding the special interests of the Organovo and Tarveda directors and executive officers in the proposed Merger is included in the Definitive Proxy Statement. Additional information regarding the directors and executive officers of Organovo is included in Organovo's definitive proxy statement on Schedule 14A relating to the 2019 Annual Meeting of Stockholders, filed with the SEC on July 26, 2019. These documents are available free of charge from the sources indicated above.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Tarveda Therapeutics, Inc. dated March 19, 2020.

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 hereunto duly authorized.

ORGANOVO HOLDINGS, INC.

Date: March 20, 2020

/s/ Taylor Crouch

Taylor Crouch
Chief Executive Officer and President

Exhibit 99.1

Tarveda Therapeutics and SciClone Pharmaceuticals International Establish Licensing Agreement for PEN-866 in Greater China

SciClone granted exclusive license to co-develop and commercialize PEN-866 upon approval in the Greater China Region

Watertown, MA, **March 19, 2020** – Tarveda Therapeutics, Inc. ("Tarveda"), a clinical stage biopharmaceutical company developing a new class of potent and selective precision oncology medicines, which it refers to as Pentarin® miniature drug conjugates, for the treatment of patients with various solid tumor malignancies, and SciClone Pharmaceuticals International Ltd., ("SciClone") today announced that they have entered into a licensing agreement for PEN-866, the initial clinical program from Tarveda's HSP90 binding miniature drug conjugate platform, which is designed to bind to the activated form of Heat Shock Protein 90 (HSP90) to accumulate and release its potent topoisomerase 1 inhibitor (SN-38) payload in solid tumors.

Under the terms of the agreement, SciClone will obtain exclusive licensing rights to co-develop and commercialize PEN-866 in the Greater China territory, including mainland China, Hong Kong, Macau and Taiwan. SciClone will be responsible for development, product registration and commercialization in these territories. Per the agreement, SciClone will pay Tarveda an upfront payment of U.S. $4 million with the right to make a future equity investment in Tarveda of up to U.S. $5 million. Tarveda will be eligible to receive up to $75 million in aggregate development, approval and commercial sales milestone payments. Tarveda is also eligible to receive royalties based on sales in the Greater China territory. Shanghai Yafo Capital Asset Management Co., Ltd acted as banking and financial advisor on this transaction for Tarveda.

"We are excited to partner with SciClone, a leading specialty pharmaceutical company with valuable experience developing and commercializing oncology and infectious disease products in Greater China that shares our dedication to advancing PEN-866," said Drew Fromkin, President and Chief Executive Officer of Tarveda. "We have completed Phase 1 clinical trials for PEN-866 and look forward to working closely with SciClone as PEN-866 moves into the later phases of its development. With SciClone's experienced team and broad knowledge related to bringing drugs to commercialization in the Greater China region, we are confident that we have found an excellent partner to help advance PEN-866 in China."

"Tarveda's HSP90 binding miniature drug conjugate platform offers a promising approach to the development of precision oncology medicines," said Hong Zhao, President and Chief Executive Officer of SciClone. "We are pleased to partner with the Tarveda team to develop and commercialize PEN-866, the first clinical program from Tarveda's HSP90 binding miniature drug conjugate platform, in the Greater China region."

PEN-866 is a miniature drug conjugate that preferentially binds to the activated form of HSP90 in solid tumors and is linked to the topoisomerase 1 inhibitor (SN-38), a potent anti-cancer payload. PEN-866 is designed to accumulate and be retained in tumors. As the SN-38 payload is cleaved in the tumor over time, the sustained release of SN-38 in the tumor results in prolonged DNA damage and tumor regressions as demonstrated in multiple patient-derived and other xenograft tumor models. PEN-866 has recently completed the Phase 1, all-comers, dose escalation and safety portion of its Phase 1/2a clinical trial. PEN-866 is the first miniature drug conjugate from Tarveda's HSP90 binding drug conjugate platform.

Non-Solicitation

This communication does not constitute an offer to sell or solicitation of an offer to buy any securities, nor will there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction.

Important Information and Where to Find It

This communication may be deemed to be solicitation material in respect of the proposed transaction between Organovo Holdings, Inc. ("Organovo") and Tarveda. In connection with the proposed transaction, Organovo has filed relevant materials with the SEC, including a registration statement on Form S-4 that contains a proxy statement/prospectus/information statement, which was declared effective on February 24, 2020. BEFORE MAKING ANY VOTING OR INVESTMENT DECISION, INVESTORS AND STOCKHOLDERS ARE URGED TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTIONS. Stockholders may obtain, free of charge, copies of the definitive proxy statement and any other documents filed by Organovo with the SEC in connection with the proposed transactions at the SEC's website (http://www.sec.gov) and at Organovo's website (www.organovo.com).

Organovo and its directors and executive officers and Tarveda and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Organovo in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger is included in the proxy statement/prospectus/information statement referred to above. Additional information regarding the directors and executive officers of Organovo is included in Organovo's Definitive Proxy Statement on Schedule 14A relating to the 2019 Annual Meeting of Stockholders, filed with the SEC on July 26, 2019. This document is available free of charge at the SEC website (www.sec.gov) or at Organovo's website (www.organovo.com).

About Tarveda Therapeutics®, Inc.

Tarveda Therapeutics is a clinical stage biopharmaceutical company developing a new class of potent and selective precision oncology medicines, which it refers to as Pentarin® miniature drug conjugates, for the treatment of patients with various solid tumor malignancies. Tarveda's Pentarin miniature drug conjugates are designed to take the best properties of both small molecule drugs and antibody drug conjugates to form a miniature drug conjugate able to penetrate into solid tumors, selectively bind to the desired tumor targets and accumulate the anti-cancer payloads directly in tumor cells. The anti-cancer payload is retained in tumor and then released over time causing the anti-cancer payload to become active in the tumor.

Tarveda currently has two Pentarin miniature drug conjugates in clinical trials. Its first clinical program, PEN-866, is the initial candidate from its Heat Shock Protein 90 (HSP90) binding miniature drug conjugate platform. HSP90 is a molecular chaperone that is highly activated in the harsh tumor environment across a wide range of solid tumor cancers, but which remains relatively dormant in normal tissue. Tarveda's binding moieties of its HSP90 binding miniature drug conjugates have been shown to bind with high affinity to HSP90, which is frequently activated and overexpressed in solid tumor cells. PEN-866 has completed its Phase 1 dose escalation portion of its "all comers" trial in various types of solid tumors. In addition to PEN-866, Tarveda is developing additional miniature drug conjugates on its HSP90 binding miniature drug conjugate platform to target other promising anti-cancer payloads such as kinase inhibitors and radioisotopes to solid tumors. Tarveda's second clinical program, PEN-221, is a Pentarin miniature drug conjugate currently in clinical evaluation for the treatment of patients with solid tumors expressing somatostatin receptor 2, or SSTR2, on the cell surface as is seen in neuroendocrine tumors and small cell lung cancer. PEN-221 is currently progressing through its Phase 2a trial. For more information regarding Tarveda, go to: https://www.tarvedatx.com/.

About SciClone Pharmaceuticals International Ltd.

SciClone Pharmaceuticals is a private-owned specialty pharmaceutical company with a substantial commercial business in Greater China and a product portfolio focusing oncology and infectious diseases. SciClone is dedicated to improving patients' health by providing top-tier healthcare products and services with global standards of care. SciClone's proprietary lead product, ZADAXIN® (Thymalfasin), is approved in over 30 countries and may be used for the treatment of certain cancers, hepatitis, and as a vaccine adjuvant, according to the local regulatory approvals. In addition, SciClone currently market a number of oncology products as commercial partner for Baxter, Pfizer and Boston Scientific in China. The Company also have a robust product pipeline aiming to address the unmet needs in severe and specialized disease areas, especially oncology. For more information regarding to SciClone, go to: http://www.sciclone.com/.

Forward Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are “forward-looking statements,” including those relating to future events. In some cases, you can identify forward-looking statements by terminology such as “may,” “might,” “will,” “should,” “expect,” “plan,” “anticipate,” “project,” “believe,” “estimate,” “predict,” “potential,” “intend” or “continue,” the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include statements about the clinical activity of PEN-866, any additional equity investment by SciClone, or the receipt of future milestones and royalties from SciClone. Although Tarveda believes that it has a reasonable basis for forward-looking statements contained herein, they are based on current expectations about future events affecting Tarveda and are subject to risks, uncertainties and factors relating to its operations and business environment, all of which are difficult to predict and many of which are beyond its control. These risk factors include those risks associated with developing pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, and other risks applicable to clinical-stage biopharmaceutical companies, such as whether or not PEN-866 will be approved and whether Tarveda will receive any development or commercial milestones or royalties under the SciClone agreement. These risks may cause actual results to differ materially from those expressed or implied by forward-looking statements in this press release. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Tarveda does not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under applicable securities law.

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