Organovo and Tarveda Therapeutics Announce Definitive Merger Agreement

December 16, 2019

Combined company to operate as Tarveda Therapeutics upon closing of merger

Transaction to advance Tarveda’s proprietary Pentarin® miniature drug conjugates including its two clinical programs for the treatment of solid tumor malignancies

Companies to host conference call today at 8:30 AM ET

SAN DIEGO & WATERTOWN, Mass.--(BUSINESS WIRE)--Dec. 16, 2019-- Organovo Holdings, Inc. ("Organovo") (Nasdaq: ONVO) and Tarveda Therapeutics, Inc. ("Tarveda"), a privately-held, clinical stage biopharmaceutical company developing a new class of potent and selective precision oncology medicines, which it refers to as Pentarin miniature drug conjugates, today announced that they have entered into a definitive merger agreement under which Tarveda would merge with a wholly-owned subsidiary of Organovo in an all-stock transaction. Upon completion of the merger, the merged company would operate under the name Tarveda Therapeutics, Inc. and trade on the Nasdaq Stock Market LLC under the ticker symbol “TVDA.”

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20191216005228/en/

Tarveda is primarily focused on the development of its pipeline of Pentarin miniature drug conjugates designed to selectively accumulate and retain anti-cancer payloads in solid tumor malignancies. Following the closing of the merger, Tarveda intends to continue to focus on advancing its two clinical stage oncology programs, PEN-866 and PEN-221, and on further development of novel conjugates from its proprietary miniature drug conjugate platform. At the closing of the merger, it is estimated that the combined company will have approximately $35 million of cash on hand that is expected to provide sufficient funding into the second half of 2021 to achieve key upcoming clinical data milestones on both clinical programs.

“At the conclusion of a comprehensive and thorough review of strategic alternatives, we are extremely pleased to announce this transaction with Tarveda, which we believe is in the best interest for our stockholders,” said Taylor J. Crouch, President and Chief Executive Officer, Organovo. “Tarveda is advancing an innovative pipeline of clinical stage cancer therapies derived from the company’s proprietary miniature drug conjugate platform. Tarveda is supported by a strong syndicate of investors including Novo A/S, Versant Ventures and ND Capital (NanoDimension) and a highly seasoned management team with prior public company experience.”

“Our growing portfolio of miniature drug conjugates has the potential to represent much needed new treatment options for patients with solid tumor malignancies,” said Drew Fromkin, President and Chief Executive Officer of Tarveda. “We are encouraged by the activity and tolerability demonstrated in Phase 1 human studies of our two clinical programs, PEN-866 and PEN-221. Our Pentarin miniature drug conjugates are designed to incorporate the best properties of small molecule drugs and antibody drug conjugates to form miniature drug conjugates that are effective at rapidly and deeply penetrating solid tumors while minimizing damage to healthy tissue. We are excited about this merger with Organovo and believe that this is the right point in Tarveda’s trajectory to move forward as a publicly traded company given several upcoming clinical data milestones that we expect to be achieved in 2020 and 2021.”

Tarveda expects the merger to provide the capital required to advance its two lead programs through the next set of clinical milestones and to generate novel conjugates from its Heat Shock Protein 90 (HSP90) binding miniature drug conjugate platform. PEN-866, the initial clinical program from Tarveda’s HSP90 binding miniature drug conjugate platform, is designed to bind to the activated form of HSP90 in solid tumors to accumulate and retain its potent topoisomerase 1 inhibitor (SN-38) payload. PEN-866 is completing the Phase 1 dose escalation and safety portion of its “all comers” trial in various types of solid tumors and has shown to be well tolerated and demonstrated early clinical activity in heavily treated, advanced patients with a range of solid tumor malignancies. Beginning in early 2020, it is expected that PEN-866 will be evaluated in a Phase 2a study both as a single agent and as a combination therapy across a range of solid tumors that are sensitive to topoisomerase 1 inhibitors. PEN-221 is a miniature drug conjugate in clinical evaluation for the treatment of patients with solid tumors expressing somatostatin receptor 2 (SSTR2) on the cell surface and is linked to the potent tubulin inhibitor payload, DM1. In a Phase 1 study, PEN-221 was well tolerated and demonstrated early clinical activity. PEN-221 is currently being evaluated in a Phase 2a study for the treatment of patients with neuroendocrine tumors and small cell lung cancer.

About the Proposed Merger

Under the terms of the merger, it is anticipated that Tarveda stockholders will own approximately 75% of the combined company and current Organovo stockholders will own approximately 25% of the combined company on a fully-diluted basis. The exchange ratio is based on valuation assumptions for both companies subject to potential adjustments for certain financial metrics prior to the completion of the merger.

The transaction has been approved by the boards of directors of both companies. The merger is anticipated to close in the first quarter of 2020, subject to the approval of Organovo and Tarveda stockholders as well as other customary closing conditions.

Roth Capital Partners served as financial advisor, and Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP served as legal counsel to Organovo. Canaccord Genuity served as financial advisor, and Cooley LLP served as legal counsel, to Tarveda.

Management and Organization

Following the merger, the combined company will be led by the current Tarveda management team, including Drew Fromkin as President, Chief
Executive Officer and Chairman; Jeffrey D. Bloss, M.D., Chief Medical Officer; Brian Roberts, Chief Financial Officer; Mark Bilodeau, Ph.D., Chief Scientific Officer; and Sudhakar Kadiyala Ph.D., Executive Vice President, Strategy.

The Board of Directors of the combined company will be comprised of eight directors, including six directors to be named by Tarveda and two directors to be named by Organovo. The corporate headquarters will be located in Watertown, MA.

Conference Call

Organovo and Tarveda will host a conference call at 8:30 a.m. ET on December 16, 2019, to discuss the proposed transaction. The conference call may be accessed by dialing (866) 405-4577 (domestic) or (602) 563-8680 (international) and using the conference ID 3679123. To help ensure the conference call begins in a timely manner, please dial in five minutes prior to the scheduled start time. The conference call will also be simultaneously webcast at http://www.organovo.com.

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 and Tarveda. In connection with the proposed transaction, Organovo intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement/prospectus/information statement. BEFORE MAKING ANY VOTING OR INVESTMENT DECISION, INVESTORS AND STOCKHOLDERS ARE URGED TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL 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.

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 will be 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.

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 currently has two Pentarin® miniature drug conjugates in clinical trials. Its first clinical program, PEN-866, is its 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. PEN-866 is currently completing its Phase 1 dose escalation portion of its “all comers” trial of various types of solid tumors and is anticipating conclusion of this Phase 1 dose escalation study in the first quarter of 2020. 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 such as neuroendocrine tumors and small cell lung cancer. PEN-221 is a proprietary asset discovered in-house and is currently progressing through its Phase 2a trial. For more information regarding Tarveda, go to: http://www.tarvedatx.com.

About Organovo

Organovo has been a pioneer in the development of 3-D bioprinted tissues comprised of human cells. After Organovo concluded that it had not generated decisive scientific data supporting the prolonged functionality and therapeutic benefit of its lead therapeutic liver tissue candidate, Organovo implemented a restructuring plan to significantly reduce expenses in order to focus on evaluating strategic alternatives, while retaining certain key management, IP, licenses, collaborations, and proprietary equipment.

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 transaction and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Organovo and Tarveda, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as “may,” “will,” “should,” “would,” “expect,” “anticipate,” “plan,” “likely,” “believe,” “estimate,” “project,” “intend,” and other similar expressions. 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 that 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 transaction are not satisfied, including the failure to obtain stockholder approval for the transaction in a timely manner or at all; uncertainties as to the timing of the consummation of the transaction and the ability of each of Organovo and Tarveda to consummate the transaction; risks related to Organovo’s continuing listing on the Nasdaq Global Market or Nasdaq Capital Market until closing of the proposed transaction; risks related to Organovo’s ability to correctly estimate its operating expenses, its expenses associated with the transaction and its 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; competitive responses to the transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; legislative, regulatory, political and economic developments; the combined company’s expected cash
position at the closing of the proposed merger and other factors discussed in the risk factors included in Organovo's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC. Risks and uncertainties related to Tarveda that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to the future operations and success of the combined company, including with respect to the continued development of Tarveda's product pipeline; the nature, strategy and focus of the combined company; the success, cost and timing of the combined company’s product development activities, studies and clinical trials, the success of competing products that are or become available, the combined company's ability to obtain FDA approval for and commercialize its product candidates; the executive and board structure of the combined company; the location of the combined company's corporate headquarters; the combined company having sufficient resources to advance its pipeline; the impact of government laws and regulations; Tarveda's ability to protect its intellectual property position; and the combined company's estimates regarding future revenue, expenses, capital requirements and need for additional financing following the proposed transaction. In addition, the forward-looking statements included in this press release 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.

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Source: Organovo Holdings, Inc. and Tarveda Therapeutics, Inc.

Organovo:
Taylor Crouch
858 779 2494
info@organovo.com

Tarveda:
Amanda Houlihan
MacDougall
781 235 3060
ahoulihan@macbiocom.com