

**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): May 22, 2019

ORGANOVO HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Commission File Number: 001-35996

Delaware
(State or other jurisdiction
of incorporation)

27-1488943
(I.R.S. Employer
Identification No.)

**6275 Nancy Ridge Dr.,
San Diego, California 92121**
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	ONVO	The NASDAQ Stock Market (NASDAQ Global Market)

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 2.02 Results of Operations and Financial Condition.

On May 22, 2019, Organovo Holdings, Inc. (the “Company”) issued a press release announcing its preliminary financial results for its fiscal fourth quarter ended March 31, 2019 and for the fiscal year ended March 31, 2019. A copy of the Company’s press release is attached as Exhibit 99.1 to this report and incorporated by reference.

The information in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d)

<u>Exhibit No.</u>	<u>Exhibits</u>
99.1	Press Release, dated May 22, 2019.

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.

Date: May 22, 2019 _____

ORGANOVO HOLDINGS, INC.

/s/ Taylor Crouch _____

Taylor Crouch

Chief Executive Officer and President



Investor & Press Contact:

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ORGANOVO UPDATES KEY CLINICAL DEVELOPMENT GOALS; COMPANY REPORTS PRELIMINARY FISCAL FOURTH-QUARTER 2019 RESULTS

- *Pre-Investigational New Drug (“IND”) meeting with the FDA expected to be held in calendar 2020*
- *Submit first IND in calendar 2021*

SAN DIEGO – May 22, 2019 – Organovo Holdings, Inc. (NASDAQ:ONVO) (“Organovo”), a biotechnology company pioneering the development of 3D bioprinted tissues aimed at treating a range of serious adult and pediatric liver diseases, today updated its key clinical development goals and reported its preliminary fiscal fourth-quarter 2019 financial results.

“We have determined that we need to conduct additional preclinical studies, optimize our manufacturing processes, and most importantly to generate decisive scientific data regarding the prolonged functionality and therapeutic benefits of our liver tissue patch,” said Taylor J. Crouch, CEO, Organovo. “As a result, our preclinical development will be extended into calendar 2020, and consequently we also now expect to have our pre-IND meeting with the FDA in calendar 2020, rather than the latter part of this calendar year. This change in our timeline also pushes the start of our IND-enabling studies back, with our revised plan now supporting an IND submission and the start of first-in-human trials in calendar 2021. Accordingly, we intend to devote substantially all of our financial and operating resources to meet these critical timelines.”

Crouch continued, “The most recent data we’ve generated from a much larger group of animal studies provides differing results from what we observed in our earlier pilot studies. We continue to see statistically meaningful reduction in toxic globules in the Alpha-1-antitrypsin

animal models over a three-month period. However, in these and other animal models, we are also seeing evidence of shorter tissue duration than we observed in previous studies, as measured by human protein output and the quantity of hepatocytes. We'll continue to examine all aspects of our manufacturing process, with the goal of improving the durability and optimizing the functionality of our tissues."

Crouch concluded, "At the same time, we've had good progress in other critical elements of our development program. We've explored alternate placement and implantation strategies and have shown the ability to apply multiple tissue patches of varying sizes to the animals using different adhesion methods. In addition, we've initiated early work with larger NovoTissues® to focus on surgical approaches for human implantation. We've also successfully engrafted our therapeutic tissue onto a fibrotic animal liver, an important step in evaluating the patch's versatility as we consider end-stage liver disease indications. From a safety perspective, although definitive IND-enabling toxicology studies have not been performed yet, no adverse effects have been detected to date on liver enzymes or histology in over 500 animals treated with our liver patches. Finally, we have reviewed our operational capabilities to prepare our Chemistry Manufacturing and Controls plan. Assuming successful outcomes of our additional preclinical studies, we plan to move forward with our objective to implement clinical scale manufacturing and quality processes in advance of our first-in-human trials. These achievements and challenges are natural parts of the innovation process for novel cell-based therapies."

Key Clinical Development Goals & Outlook

- The Company believes its healthy therapeutic liver tissue patch has the potential to treat a broad range of liver disease indications. Its initial Phase I trial is expected to target patients with end-stage liver disease, and subject to favorable outcomes in that trial, Organovo intends to explore the benefits of its NovoTissues® in one or more inborn errors of metabolism disease areas such as Alpha-1 antitrypsin deficiency. The Company may also study its product as a bridge-to-transplant. All of these diseases represent high unmet need areas where Organovo believes its liver patches may provide a meaningful benefit to patients.
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- Organovo expects to hold a pre-IND meeting with the FDA in calendar 2020 for its lead program with the intent to begin IND-enabling studies in the second half of calendar 2020.
- Organovo expects to file for its first IND in calendar 2021.
- As of March 31, 2019, the Company had a cash and cash equivalents balance of \$36.5 million. Organovo expects a net cash utilization⁽¹⁾ rate of \$20.0 million to \$22.0 million in fiscal 2020, and believes it has sufficient funds, along with the continued usage of its at-the-market (“ATM”) facility, to meet its operating and capital requirements through its forecasted IND submission in calendar 2021.

Other Developments

- Organovo began its evaluation of surgical implantation techniques for its liver therapeutic tissue in large animals at a leading academic institution.
- Organovo commenced a collaboration with Professor Melissa Little at the Murdoch Childrens Research Institute, The Royal Children’s Hospital, Melbourne, Australia and Ton Rabelink at Universiteit Leiden, Leiden, Netherlands to develop a 3D bioprinted stem cell-based therapeutic tissue for treating end-stage renal disease.
- The Company also continued to partner with leading academic institutions conducting proof-of-concept studies in 3D bioprinted tissue research areas including the retina, vasculature and musculoskeletal applications.

Preliminary Fiscal Fourth-Quarter 2019 Financial Results (Unaudited)

- Net loss was \$7.0 million, a \$0.5 million improvement over the year-ago period, as total costs and expenses declined 10 percent to \$7.8 million, primarily due to lower employee costs.
 - Net cash utilization was \$5.1 million, an improvement from \$5.7 million in the prior-year quarter.
 - Total revenue was \$0.7 million, a 38 percent decrease from the year-ago period, primarily driven by lower products and services revenue.
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- During the fiscal fourth quarter, the Company generated net proceeds of approximately \$6.3 million from the issuance of 6.1 million shares of common stock in ATM offerings at a weighted average price of \$1.04 per share.

Definitions & Supplemental Financial Measures

- (1) In addition to disclosing financial results that are determined in accordance with U.S. GAAP, the Company provides net cash utilization as a supplemental measure to help investors evaluate the Company's fundamental operational performance. The Company defines net cash utilization as the net decrease in cash and cash equivalents during the reporting period less proceeds from the sale of common stock and the exercise of warrants and stock options during the reporting period. Net cash utilization is an operational measure that should be considered as additional financial information regarding our operations. This operational measure should not be considered without also considering our results prepared in accordance with U.S. GAAP, and should not be considered as a substitute for, or superior to, our U.S. GAAP results. The Company believes net cash utilization is a relevant and useful operational measure because it provides information regarding our cash utilization rate. Management uses net cash utilization to manage the business, including in preparing its annual operating budget, financial projections and compensation plans. The Company believes that net cash utilization is also useful to investors because similar measures are frequently used by securities analysts, investors and other interested parties in their evaluation of companies in similar industries. However, there is no standardized measurement of net cash utilization, and net cash utilization as the Company presents it may not be comparable with similarly titled operational measures used by other companies. Due to these limitations, the Company's management does not view net cash utilization in isolation but also uses other measurements, such as cash used in operating activities and revenues to measure operating performance.

Conference Call Information

As previously announced, the Company will host a conference call to discuss its results at 5:00 p.m. ET on Wednesday, May 22, 2019. Callers should dial (888) 317-6003 (U.S. only) or (412) 317-6061 (from outside the U.S.) to access the call. The conference call ID is 6755803.

The conference call will also be simultaneously webcast on Organovo's Investor Relations webpage at www.organovo.com. A replay of the conference call will be available beginning Wednesday, May 22, 2019 through Wednesday, May 29, 2019 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10130958, for an audio replay of the conference call.

About Organovo Holdings, Inc.

Organovo is a biotech platform company that has developed a leadership position with its revolutionary ability to 3D bioprint tissues with human functionality. The Company is pursuing IND-track programs to develop its NovoTissues® to address a number of serious unmet medical needs, initially focusing on liver disease. Organovo's program for Alpha-1-antitrypsin deficiency received orphan drug designation from the FDA in 2017. The Company is also providing access to its ExVive™ *in vitro* tissue platform to facilitate high value drug discovery and development collaborations. Organovo's wholly-owned subsidiary, Samsara Sciences, provides the Company and its clients with high quality human liver cells for research applications. Organovo is changing the shape of life science research and transforming medical care. Learn more at www.organovo.com.

Forward-Looking Statements

*Any statements contained in this press release that do not describe historical facts constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements regarding the potential benefits and therapeutic uses of the Company's therapeutic liver tissue, including the benefits of an orphan designation; the Company's expectations regarding the FDA regulatory pathway and anticipated timelines for its regulatory filings; the Company's ability to successfully complete additional preclinical studies, improve its manufacturing processes and demonstrate the prolonged functionality and therapeutic benefits of its therapeutic liver tissue; the Company's ability to implement clinical scale manufacturing and quality processes; the Company's ability to meet market demand; the Company's ability to fund its future operations and business plans; and acceptance of its disease modeling and other *in vitro* tissue platforms. The factors that could cause the Company's actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the possibility that the final results of the Company's earlier preclinical studies may be different from the Company's later preclinical studies and may not support further clinical development of its therapeutic tissues, or*

that the results of the Company's preclinical studies may be different from the results of its clinical trials; the Company may not successfully complete the required preclinical and clinical trials required to obtain regulatory approval for its therapeutic tissues on a timely basis or at all; the novelty of the therapeutic approach and risks relating to its adoption rate by clinicians; the complexity of the manufacturing process and the effort involved in developing GTP and GMP facilities; the nascence of the industry and the lack of experienced GMP manufacturing organizations for bioprinting tissues; risks relating to the Company's ability to successfully scale up from research to clinical tissue patches; risks relating to the Company's reliance on a single supplier for clinical grade organs, including that the Company may not be able to obtain sufficient raw materials to meet clinical or commercial demand for its therapeutic products; risks that competitive products may adversely impact the market opportunity for the Company's therapeutic tissue candidates; the Company's ability to develop, market and sell products and services based on its technology; the expected benefits and efficacy of the Company's products, services and technology; the Company's ability to successfully complete studies and provide the technical information required to support market acceptance of its disease modeling and other in vitro tissue products, services and technology, on a timely basis or at all; the Company's ability to raise sufficient funds to support its business plan and ongoing operations; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies, including its use of third party distributors; and the Company's ability to recognize deferred revenue. These and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on May 31, 2018. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

This press release contains certain unaudited financial results for the Company's fiscal year and fourth quarter ended March 31, 2019. These unaudited results may change as a result of further review by the Company's management and its independent auditors. The completion of the audit of our financial results for fiscal 2019 could result in changes to the unaudited financial results presented in this press release and may identify issues related to the effectiveness of the Company's internal controls over financial reporting. Final fiscal fourth quarter and annual results will be provided in the Company's annual report to the SEC on Form 10-K.

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