

**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): October 11, 2016

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))
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Item 2.02 Results of Operations and Financial Condition.

On October 11, 2016, Organovo Holdings, Inc. (the “Company”) issued a press release to announce select preliminary results for the fiscal second quarter of 2017, to update its full-year fiscal 2017 outlook and to affirm its long-range outlook. A copy of this press release is furnished as Exhibit 99.1 hereto.

Item 7.01 Regulation FD Disclosure.

The information disclosed under Item 2.02 is also intended to be disclosed under this Item 7.01 and is incorporated herein by reference.

The information furnished in Items 2.02 and 7.01 to this Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

<u>(d)</u>	<u>Exhibits</u>
99.1	Press Release, dated October 11, 2016.

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: October 11, 2016

/s/ Keith Murphy

Keith Murphy

Chief Executive Officer and President

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated October 11, 2016

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ORGANOVO ANNOUNCES SELECT PRELIMINARY SECOND-QUARTER 2017 RESULTS; COMPANY UPDATES FULL-YEAR FISCAL 2017 OUTLOOK

SAN DIEGO – October 11, 2016 – Organovo Holdings, Inc. (NASDAQ:ONVO) (“Organovo”), a three-dimensional biology company focused on delivering scientific and medical breakthroughs using its 3D bioprinting technology, today reported preliminary unaudited revenue and net cash utilization results for the fiscal second quarter of 2017 and updated its full-year fiscal 2017 outlook. The Company expects to release full fiscal second-quarter financial results on November 3, 2016.

Organovo’s preliminary fiscal second quarter total revenue was approximately \$1.4 million, consisting largely of product and service revenue(1). This result reflects a 357 percent increase in total revenue versus the comparable period of fiscal 2016 and a 54 percent increase versus the fiscal first quarter of 2017.

Selected Organovo Financial Highlights

Revenue

- Product and service revenue was approximately \$1.0 million, up 400 percent from the prior-year period, largely driven by an increase in customer contracts for the Company’s tissue research services.
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- Collaborations and grant revenue(2) totaled approximately \$0.4 million, primarily supported by a milestone achievement from the Company’s agreement with Merck & Co. to develop multiple custom tissue models.

Liquidity & Capital Resources

- The Company’s preliminary cash and cash equivalents balance was approximately \$51.7 million as of the end of the fiscal second quarter, which compares to \$53.5 million for the fiscal first quarter. Organovo’s preliminary net cash utilization(3) during the period was approximately \$6.8 million. During the fiscal second quarter, the Company generated net proceeds of approximately \$4.5 million from the issuance of 997,181 shares of common stock in at-the-market (“ATM”) offerings at a weighted average price of \$4.67 per share and approximately \$0.5 million from the exercise of stock options and warrants.

Fiscal-Year 2017 Outlook

The Company updated its full-year fiscal 2017 outlook for total revenue and net cash utilization. The Company now expects:

- Total revenue of between \$4.5 million and \$6.2 million for fiscal-year 2017. Fiscal 2016 total revenue was \$1.5 million.
- Net cash utilization of between \$31.0 million and \$34.0 million for fiscal-year 2017. The Company had a cash and cash equivalents balance of \$62.1 million for its fiscal year ended March 31, 2016.

	Fiscal-Year 2017 Outlook (August 2016)	Fiscal-Year 2017 Outlook (October 2016)
Fiscal-Year 2017 Total Revenue	\$4 million - \$6 million	\$4.5 million - \$6.2 million
Net Cash Utilization	\$32.5 million - \$36.5 million	\$31.0 million - \$34.0 million

Long-Range Outlook

The Company affirmed its long-range outlook for potential revenue from its liver and kidney tissue products. The Company continues to expect:

- As it penetrates the toxicology market, Organovo's ExVive™ Human Liver Tissue service will grow into the tens of millions in annual revenue, and has \$100 million+ revenue potential in the future (inside of a total addressable market of over \$1 billion).
- As it penetrates the toxicology market, Organovo's ExVive Human Kidney Tissue service will grow into the tens of millions in annual revenue, and has \$100 million+ revenue potential in the future (inside of a total addressable market of over \$2 billion).

Definitions & Supplemental Financial Measures

- (1) Product and service revenue includes tissue research service agreements and product sales, including product sales from the Company's wholly-owned subsidiary, Samsara Sciences Inc.
 - (2) Collaborations revenue consists of license and collaboration agreements that contain multiple elements, which may include non-refundable up-front fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any.
 - (3) 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 (which was (\$1.8 million) during the second quarter of fiscal 2017) less proceeds from the sale of common stock and the exercise of warrants and stock options during the reporting period (which was \$5.0 million during the second quarter of fiscal 2017). 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
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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.

About Organovo Holdings, Inc.

Organovo designs and creates functional, three-dimensional human tissues for use in medical research and therapeutic applications. The Company develops 3D human tissue models through internal development and in collaboration with pharmaceutical, academic and other partners. Organovo's 3D human tissues have the potential to accelerate the drug discovery process, enabling treatments to be developed faster and at lower cost. The Company's ExVive Human Liver and Kidney Tissues are used in toxicology and other preclinical drug testing. The Company also actively conducts early research on specific tissues for therapeutic use in direct surgical applications. In addition to numerous scientific publications, the Company's technology has been featured in The Wall Street Journal, Time Magazine, The Economist, Forbes, and numerous other media outlets. 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 Company's select

preliminary financial results for the second quarter of fiscal year 2017, the Company's fiscal year 2017 outlook and the Company's long-range outlook. The Company's select quarterly financial results for the second quarter of fiscal year 2017 are preliminary and subject to adjustments in the ongoing review by the Company and its external auditors. 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 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 market acceptance of the Company's products and services; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies; the Company's ability to successfully complete the contracts and recognize the revenue represented by the contracts included in its previously reported total contract bookings; the Company's ability to secure additional contracted collaborative relationships; the risk of further adjustments to the Company's select preliminary financial results; and the Company's ability to meet its fiscal year 2017 outlook and/or its long-range outlook. 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 June 9, 2016 and its Quarterly Report on Form 10-Q filed with the SEC on August 4, 2016. 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. ###