

**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): August 9, 2017

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))

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 August 9, 2017, Organovo Holdings, Inc. (the “Company”) issued a press release announcing financial results for the first quarter of its fiscal year, which period ended June 30, 2017. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished in this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act of 1934 or otherwise subject to the liabilities of that Section and shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission (the “SEC”).

Item 9.01 Financial Statements and Exhibits

(d)

<u>Exhibit No.</u>	<u>Exhibits</u>
--------------------	-----------------

99.1	Press Release, dated August 9, 2017.
------	--------------------------------------

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: August 9, 2017

/s/ Taylor Crouch

Taylor Crouch

Chief Executive Officer and President

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated August 9, 2017.

*Investor Contact:*

Steve Kunszabo
Organovo Holdings, Inc.
+1 (858) 224-1092
skunszabo@organovo.com

Press Contact:

Jessica Yingling
Little Dog Communications
+1 (858) 480-2411
jessica@litldog.com

ORGANOVO ANNOUNCES FISCAL FIRST-QUARTER 2018 RESULTS; COMPANY AFFIRMS FULL-YEAR FISCAL 2018 OUTLOOK

SAN DIEGO – August 9, 2017 – Organovo Holdings, Inc. (NASDAQ:ONVO) (“Organovo”) today reported financial results for the fiscal first quarter of 2018 and affirmed its full-year fiscal 2018 outlook. Organovo reported fiscal first-quarter total revenue of \$1.0 million, which consisted largely of product and service revenue(1). Total revenue increased 11 percent versus the comparable period of fiscal 2017. Net loss was \$10.1 million, or \$0.10 per share, for the fiscal first quarter of 2018, as compared to \$8.8 million, or \$0.09 per share, for the fiscal first quarter of 2017. Negative Adjusted EBITDA(2) for the first quarter was \$7.5 million, as compared to \$7.1 million for the prior-year period.

“We’re tracking to our plan through the first quarter of fiscal 2018, delivering total revenue that was in-line with our outlook and affirming our guidance across the board,” said Taylor J. Crouch, CEO, Organovo. “We continued to see a healthy balance of new sales and repeat business during the period, with nearly 70% of orders for tissue research services coming from existing clients as we more deeply engage our customers. Demand for compound screening in disease models is growing, with new applications frequently emerging as clients seek novel solutions in their drug discovery workflow. Beyond recognized areas such as liver fibrosis and non-alcoholic steatohepatitis (“NASH”), recent exploratory applications include Hepatitis B and RNA therapeutics. These are all good leading indicators of broader adoption as we seek to move customers to routine use of our solutions.”

Crouch continued, “In the therapeutics space, we continue to successfully achieve key objectives as we advance our liver therapeutic tissue. Our bioprinted liver tissues are now thriving 90 days post-implantation in animal models, triple the duration of our earliest preclinical studies. Importantly, we’ve continued to observe strong synthetic function and meaningful improvement in liver health for treated animals. During fiscal 2018, we’ll continue to conduct pre-GLP studies in small animal disease models for our target indications and take preliminary steps to seek orphan designation in the U.S.”

Crouch concluded, “Our long-term plan remains founded on targeting attractive and growing markets with critical unmet needs, extending our first mover advantage, and capitalizing on our technology leadership to grow our product and service offerings.”

First-Quarter Organovo Business Highlights

Revenue

- Product and service revenue was \$0.9 million, up 40 percent from the prior-year period, largely driven by an increase in customer contracts for the Company’s tissue research services.

Operating Expenses

- Cost of revenues was \$0.3 million, an increase of 79 percent from the prior-year period, reflecting a gain in product and service revenue.
 - Research and development costs increased 13 percent year-over-year to \$5.0 million, primarily due to increased materials and outside services costs related to the Company’s ongoing validation studies.
 - Selling, general and administrative expenses increased 16 percent from the prior-year period to \$5.9 million, reflecting higher non-cash stock-based compensation and employee related expense.
-

Liquidity & Capital Resources

- The Company ended the fiscal first quarter with a cash and cash equivalents balance of \$55.0 million.
- During the fiscal first quarter, the Company generated net proceeds of approximately \$3.0 million from the issuance of 1,139,489 shares of common stock in at-the-market (“ATM”) offerings at a weighted average price of \$2.69 per share.
- Working capital was \$54.2 million to end the fiscal first quarter compared to \$52.0 million in the prior-year quarter.

Fiscal-Year 2018 Outlook

The Company affirmed its full-year fiscal 2018 outlook for total revenue and negative Adjusted EBITDA. The Company continues to expect:

- Total revenue of between \$6.0 million and \$8.5 million for fiscal-year 2018. Fiscal 2017 total revenue was \$4.2 million.
- Negative Adjusted EBITDA of between \$29.0 million and \$31.0 million for fiscal-year 2018. Fiscal 2017 negative Adjusted EBITDA was \$29.8 million.

	Fiscal-Year 2018 Outlook (June 2017)	Fiscal-Year 2018 Outlook (August 2017)
Fiscal-Year 2018 Total Revenue	\$6.0 million - \$8.5 million	Affirmed
Fiscal-Year 2018 Negative Adjusted EBITDA	\$29.0 million - \$31.0 million	Affirmed

A reconciliation of non-GAAP negative Adjusted EBITDA, as forecasted for fiscal 2018, to the closest corresponding GAAP measure, net loss, is not available without unreasonable efforts on a forward-looking basis due to the high variability and low visibility of certain charges that may impact our GAAP results on a forward-looking basis, such as the measures and effects of share-based compensation.

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) In addition to disclosing financial results that are determined in accordance with U.S. GAAP, the Company provides Adjusted EBITDA which is a non-GAAP financial measure, as a supplemental measure to help investors evaluate the Company's fundamental operational performance. Adjusted EBITDA represents earnings before interest, income taxes, depreciation and amortization, share-based compensation expenses and CEO transition costs. Adjusted EBITDA does not represent, and should not be considered, an alternative to U.S. GAAP measurements such as net income or loss. By eliminating interest, income taxes, depreciation and amortization, share-based compensation expenses and CEO transition costs, the Company believes the result is a useful measure across time in evaluating its fundamental core operating performance. Management also uses Adjusted EBITDA to manage the business, including in preparing its annual operating budget, financial projections and compensation plans. The Company believes that Adjusted EBITDA 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 Adjusted EBITDA, and Adjusted EBITDA as the Company presents it may not be comparable with similarly titled non-GAAP financial measures used by other companies. Since Adjusted EBITDA does not account for certain expenses, its utility as a measure of the Company's operating performance has material limitations. Due to these limitations, the Company's management does not view Adjusted EBITDA in isolation, but also uses other measurements, such as net income or loss and revenues to measure operating performance. Please refer to the
-

schedule below for a reconciliation of consolidated GAAP net income to Adjusted EBITDA for the fiscal quarters ended June 30, 2017 and 2016.

Organovo Holdings, Inc.
Supplemental Reconciliation of GAAP Net Income to Adjusted EBITDA
(in thousands)

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016
GAAP net loss	\$ (10,102)	\$ (8,767)
Interest expense	-	-
Interest income	(98)	(37)
Income taxes	-	22
Depreciation and amortization	326	251
Share-based compensation	2,052	1,429
CEO transition costs	305	-
Adjusted EBITDA	\$ (7,517)	\$ (7,102)

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, August 9, 2017. 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 4567146. 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, August 9, 2017 through Tuesday, August 15, 2017 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10110045, for an audio replay of the conference call.

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. 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 Company's ability to successfully complete studies and provide the technical information required to support market acceptance of its products, services and technology, on a timely basis or at all; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies, including its use of third party distributors; 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 and secure additional contracted collaborative relationships; the final results of the Company's preclinical studies may be different from the Company's studies or interim preclinical data results and may not support further clinical development of its therapeutic tissues; 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; and the Company's ability to meet its fiscal year 2018 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 7, 2017. 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.

###

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands except share and per share data)

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016
Revenues		
Products and services	\$ 944	\$ 674
Collaborations and licenses	46	213
Grants	-	4
Total Revenues	<u>990</u>	<u>891</u>
Cost of revenues	301	168
Research and development expenses	5,033	4,444
Selling, general, and administrative expenses	5,856	5,056
Total Costs and Expenses	<u>11,190</u>	<u>9,668</u>
Loss from Operations	<u>(10,200)</u>	<u>(8,777)</u>
Other Income (Expense)		
Change in fair value of warrant liabilities	-	(5)
Interest income	98	37
Total Other Income (Expense)	<u>98</u>	<u>32</u>
Income Tax Expense	<u>-</u>	<u>(22)</u>
Net Loss	<u>\$ (10,102)</u>	<u>\$ (8,767)</u>
Currency Translation Adjustment	<u>\$ (11)</u>	<u>\$ -</u>
Comprehensive Loss	<u>\$ (10,113)</u>	<u>\$ (8,767)</u>
Net loss per common share-basic and diluted	\$ (0.10)	\$ (0.09)
Weighted average shares used in computing net loss per common share-basic and diluted	104,689,391	92,391,964

Organovo Holdings, Inc.
Condensed Consolidated Balance Sheets
(in thousands except for share data)

	June 30, 2017	March 31, 2017
	Unaudited	Audited
Assets		
Current Assets		
Cash and cash equivalents	\$ 54,974	\$ 62,751
Accounts receivable	772	647
Inventory, net	461	550
Prepaid expenses and other current assets	1,661	1,144
Total current assets	57,868	65,092
Fixed assets, net	3,528	3,840
Restricted cash	127	127
Other assets, net	189	121
Total assets	61,712	69,180
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	558	\$ 1,171
Accrued expenses	2,111	4,101
Deferred rent	165	157
Deferred revenue	854	582
Total current liabilities	3,688	6,011
Deferred revenue, net of current portion	48	58
Deferred rent, net of current portion	707	749
Total liabilities	4,443	6,818
Commitments and contingencies (Note 4)		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 105,724,320 and 104,551,466 shares issued and outstanding at June 30, 2017 and March 31, 2017, respectively	106	104
Additional paid-in capital	266,593	261,586
Accumulated deficit	(209,419)	(199,317)
Accumulated unrealized gain (loss) on foreign currency revaluation	(11)	(11)
Total stockholders' equity	57,269	62,362
Total Liabilities and Stockholders' Equity	61,712	69,180

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016
Cash Flows From Operating Activities		
Net loss	\$ (10,102)	\$ (8,767)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	326	251
Change in fair value of warrant liabilities	-	5
Stock-based compensation	2,052	1,429
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(125)	156
Inventory	89	(178)
Prepaid expenses and other assets	(518)	(41)
Accounts payable	(613)	(306)
Accrued expenses	(1,990)	(735)
Deferred rent	(34)	(36)
Deferred revenue	262	(319)
Net cash used in operating activities	(10,653)	(8,541)
Cash Flows From Investing Activities		
Purchases of fixed assets	(11)	(12)
Purchases of intangible assets	(70)	-
Net cash used in investing activities	(81)	(12)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	2,957	-
Net cash provided by financing activities	2,957	-
Net Increase (Decrease) in Cash and Cash Equivalents	(7,777)	(8,553)
Cash and Cash Equivalents at Beginning of Period	62,751	62,091
Cash and Cash Equivalents at End of Period	\$ 54,974	\$ 53,538
Supplemental Disclosure of Cash Flow Information:		
Interest	\$ -	\$ -
Income Taxes paid	\$ -	\$ 22