

**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): November 3, 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 November 3, 2016, Organovo Holdings, Inc. (the “Company”) issued a press release announcing financial results for its second quarter and fiscal year ended September 30, 2016. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished in this Item 2.02 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. The information in this Item 2.02 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

<u>(d)</u>	<u>Exhibits</u>
99.1	Press Release, dated November 3, 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: November 3, 2016

/s/ Keith Murphy

Keith Murphy

Chief Executive Officer and President

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated November 3, 2016.

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ORGANOVO ANNOUNCES FISCAL SECOND-QUARTER 2017 RESULTS; COMPANY AFFIRMS FULL-YEAR FISCAL 2017 AND LONG-RANGE OUTLOOK

SAN DIEGO – November 3, 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 financial results for the fiscal second quarter of 2017 and affirmed its full-year fiscal 2017 and long-range outlook. Net loss was \$9.4 million, or \$0.10 per share, for the fiscal second quarter of 2017, as compared to \$11.3 million, or \$0.12 per share, for the fiscal second quarter of 2016.

Organovo reported fiscal second-quarter total revenue of \$1.4 million, which consisted largely of product and service revenue⁽¹⁾. Total revenue increased 358 percent versus the comparable period of fiscal 2016 and 54 percent versus the fiscal first quarter of 2017.

“The first half of fiscal 2017 represents a meaningful inflection point in our growth trajectory, as we more than doubled our product and service revenue when compared to all of fiscal 2016,” said Keith Murphy, CEO, Organovo. “We also affirmed our recently increased total revenue guidance, supported by solid adoption of our tissue research services. We are penetrating the global Top 25 pharma segment at a rapid clip, having recently added three customers to bring our total to ten with this group, and continue to see good momentum with biopharmaceutical companies of all sizes.”

Murphy continued, “With just two months behind us since commercialization, we’re pleased with the early traction of our kidney tissue. We’ve signed multiple orders, including with two global Top 25 pharma customers, bringing to market an advanced way to investigate kidney toxicity of new drug candidates. Kidney is a natural expansion of our preclinical solutions portfolio, showcasing the power and versatility of our technology platform.”

Murphy concluded, “As we look to the second half of our fiscal year, we’re focused on a few key targets including expanding our liver tissue revenue, scaling our kidney tissue offering, business development initiatives in the drug discovery space and advancing bioprinted human liver as the first candidate in our therapeutic tissue portfolio.”

Organovo Business Highlights

Revenue

- Product and service revenue was \$1.0 million, up 449 percent from the prior-year period, largely driven by an increase in customer contracts for the Company's tissue research services.
- Collaborations and grant revenue totaled \$0.4 million, primarily supported by a milestone achievement from the Company's agreement with Merck & Co. to develop multiple custom tissue models.

Operating Expenses

- Cost of revenues was \$0.4 million, reflecting the Company's expenses related to manufacturing and delivering its product and service revenues.
- Research and development costs declined 4 percent year-over-year to \$4.5 million, driven largely by a decrease in the use of outsourced professional services, partially offset by higher employee related costs due to increased staffing.
- Selling, general and administrative expenses decreased 14 percent from the prior-year period to \$5.9 million, primarily due to lower compensation expense related to non-recurring separation and payroll costs for two former executives, partially offset by higher employee related costs from increased staffing.

Liquidity & Capital Resources

- The Company ended the fiscal second quarter with a cash and cash equivalents balance of \$51.7 million. Organovo's net cash utilization⁽³⁾ during the period was \$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.
 - Working capital was \$49.5 million to end the fiscal second quarter compared to \$72.3 million in the prior-year quarter.
 - On October 25, 2016, the Company closed the issuance and sale of 10,065,000 shares of common stock at a price to the public of \$2.75 per share. The net proceeds to the Company from the sale were approximately \$25,600,000, after deducting underwriting discounts and commissions and estimated expenses payable by the Company.
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Fiscal-Year 2017 Outlook

The Company affirmed its full-year fiscal 2017 outlook for total revenue and net cash utilization. The Company continues to expect:

- 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 (October 2016)	Fiscal-Year 2017 Outlook (November 2016)
Fiscal-Year 2017 Total Revenue	\$4.5 million - \$6.2 million	Affirmed
Net Cash Utilization	\$31.0 million - \$34.0 million	Affirmed

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) Collaboration 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
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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 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 Thursday, November 3, 2016. 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 9089780. 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 Thursday, November 3, 2016 through Thursday, November 10, 2016 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 9089780, 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 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 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 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 November 3, 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. ###

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

	Three Months Ended		Six Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues				
Products and services	\$ 1,023	\$ 187	\$ 1,697	\$ 396
Collaborations	345	19	557	33
Grants	8	95	12	178
Total Revenues	<u>1,376</u>	<u>301</u>	<u>2,266</u>	<u>607</u>
Cost of revenues	393	-	561	-
Research and development expenses	4,544	4,739	8,987	8,881
Selling, general, and administrative expenses	5,918	6,846	10,974	11,468
Total Costs and Expenses	<u>10,855</u>	<u>11,585</u>	<u>20,522</u>	<u>20,349</u>
Loss from Operations	<u>(9,479)</u>	<u>(11,284)</u>	<u>(18,256)</u>	<u>(19,742)</u>
Other Income (Expense)				
Change in fair value of warrant liabilities	-	9	(5)	(28)
Interest income	37	18	74	25
Total Other Income (Expense)	37	27	69	(3)
Income Tax Expense	-	-	(22)	(3)
Net Loss	<u>\$ (9,442)</u>	<u>\$ (11,257)</u>	<u>\$ (18,209)</u>	<u>\$ (19,748)</u>
Currency Translation Adjustment	(7)	-	(7)	-
Comprehensive Loss	<u>\$ (9,449)</u>	<u>\$ (11,257)</u>	<u>\$ (18,216)</u>	<u>\$ (19,748)</u>
Net loss per common share-basic and diluted	\$ (0.10)	\$ (0.12)	\$ (0.20)	\$ (0.23)
Weighted average shares used in computing net loss per common share-basic and diluted	93,185,400	92,385,150	92,790,850	87,715,217

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

	September 30, 2016 Unaudited	March 31, 2016 Audited
Assets		
Current Assets		
Cash and cash equivalents	\$ 51,723	\$ 62,091
Accounts receivable	606	259
Inventory, net	445	334
Prepaid expenses and other current assets	908	968
Total current assets	53,682	63,652
Fixed assets, net	3,647	3,711
Restricted cash	79	79
Other assets, net	128	134
Total assets	57,536	67,576
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	754	787
Accrued expenses	2,831	2,450
Deferred rent	147	139
Deferred revenue	479	1,110
Warrant liabilities	9	4
Total current liabilities	4,220	4,490
Deferred rent, net of current portion	829	905
Total liabilities	5,049	5,395
Commitments and contingencies		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 93,750,862 and 92,391,989 shares issued and outstanding at September 30, 2016 and March 31, 2016, respectively	94	92
Additional paid-in capital	231,479	222,959
Accumulated deficit	(179,079)	(160,870)
Unrealized gain (loss) on foreign currency revaluation	(7)	-
Total stockholders' equity	52,487	62,181
Total Liabilities and Stockholders' Equity	\$ 57,536	\$ 67,576

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

	Six Months Ended	
	September 30, 2016	September 30, 2015
Cash Flows From Operating Activities		
Net loss	\$ (18,209)	\$ (19,748)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	502	324
Change in fair value of warrant liabilities	5	28
Stock-based compensation	3,522	3,952
Amortization of warrants issued for services	-	(105)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(347)	(180)
Inventory	(111)	(2)
Prepaid expenses and other assets	80	337
Accounts payable	(33)	(820)
Accrued expenses	381	164
Deferred rent	(68)	(21)
Deferred revenue	(631)	1,150
Net cash used in operating activities	<u>(14,909)</u>	<u>(14,921)</u>
Cash Flows From Investing Activities		
Purchases of fixed assets	(452)	(1,550)
Proceeds from disposals of fixed assets	-	14
Purchases of intangible assets	-	(35)
Net cash used in investing activities	<u>(452)</u>	<u>(1,571)</u>
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	4,500	43,137
Proceeds from exercise of stock options	500	81
Principal payments on capital lease obligations	-	(5)
Net cash provided by financing activities	<u>5,000</u>	<u>43,213</u>
Effect of currency exchange rate changes on cash and cash equivalents	<u>(7)</u>	<u>-</u>
Net Increase (Decrease) in Cash and Cash Equivalents	(10,368)	26,721
Cash and Cash Equivalents at Beginning of Period	62,091	50,142
Cash and Cash Equivalents at End of Period	\$ 51,723	\$ 76,863
Supplemental Disclosure of Cash Flow Information:		
Interest	\$ -	\$ -
Income Taxes	\$ 22	\$ 3