

**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): February 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))
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Item 2.02 Results of Operations and Financial Condition

On February 9, 2017, Organovo Holdings, Inc. (the “Company”) issued a press release announcing financial results for its third quarter ended December 31, 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

(d)	Exhibits
99.1	Press Release, dated February 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: February 9, 2017

/s/ Keith Murphy

Keith Murphy

Chief Executive Officer and President

Exhibit Index

Exhibit

No. Description

99.1 Press Release, dated February 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 THIRD-QUARTER 2017 RESULTS; COMPANY UPDATES FULL-YEAR FISCAL 2017 TOTAL REVENUE OUTLOOK

SAN DIEGO – February 9, 2017 – 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 third quarter of 2017 and updated its full-year fiscal 2017 outlook for total revenue. Net loss was \$9.6 million, or \$0.09 per share, for the fiscal third quarter of 2017, as compared to \$10.5 million, or \$0.11 per share, for the fiscal third quarter of 2016.

Organovo reported fiscal third-quarter total revenue of \$1.2 million, which consisted largely of product and service revenue(1). Total revenue increased 251 percent versus the comparable period of fiscal 2016.

“We grew total revenue at a strong year-over-year pace during the fiscal third quarter, showing continued uptake of our tissue research services,” said Keith Murphy, CEO, Organovo. “We recognized revenue from six new customers and seven repeat customers during the period, demonstrating market penetration and solid repeat business. We also added one global Top 25 pharma customer to our roster, bringing our total to eleven with this key group.”

Murphy continued, “We’re revising our total revenue guidance for fiscal 2017 because of a change in the timing of customer orders due to specific customer requests for additional validation studies related to certain use cases and for qualification of an additional cell source. We expect to successfully complete the additional scientific studies required to address these issues, and don’t anticipate these items will have a long-term impact on customer adoption. The required studies will delay a portion of our forecasted revenue into fiscal 2018. We’re working diligently with our customers to complete the technical work and to unlock both existing backlog and prospective orders, and look ahead with confidence to continued growth in our pipeline. In addition, our internal liver validation data now includes successful identification of toxicity for two out of three proprietary compounds that were classic preclinical misses for one of our Top 10 pharma customers. This hit rate is consistent with our overall testing success and further demonstrates significantly increased predictive power for our customers.”

Murphy concluded, “During the fiscal third quarter, we also announced our 3D bioprinted human liver as the first candidate in our therapeutic tissues portfolio and presented early data showing survival and sustained functionality of this tissue when implanted into animal models at the Tissue Engineering & Regenerative Medicine International Society Conference (TERMIS). We expect to optimize the final tissue design and are embarking on pre-GLP safety and efficacy studies that will take us through the next 18 months. Based on our path forward, we now expect to target an IND submission with the liver tissue during the calendar year 2020.”

Organovo Business Highlights

Revenue

- Product and service revenue was \$0.7 million, up 139 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 \$0.2 million, reflecting the Company’s expenses related to manufacturing and delivering its product and service revenues.
- Research and development costs increased 10 percent year-over-year to \$5.0 million, primarily due to increased employee related and lab supplies costs.
- Selling, general and administrative expenses decreased 11 percent from the prior-year period to \$5.5 million, reflecting lower non-cash shared-based compensation expense, partially offset by higher employee related costs.

Liquidity & Capital Resources

- The Company ended the fiscal third quarter with a cash and cash equivalents balance of \$70.0 million. Organovo’s net cash utilization⁽³⁾ during the period was \$7.7 million. The Company’s net cash utilization for the nine months ended December 31, 2016 was \$23.1 million.
 - Working capital was \$67.5 million to end the fiscal third quarter compared to \$65.2 million in the prior-year quarter.
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Fiscal-Year 2017 Outlook

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

- Total revenue of between \$3.7 million and \$4.5 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 (November 2016)	Fiscal-Year 2017 Outlook (February 2017)
Fiscal-Year 2017 Total Revenue	\$4.5 million - \$6.2 million	\$3.7 million - \$4.5 million
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).
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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 cash utilization as the net decrease in cash and cash equivalents during the reporting period (which was an increase of \$18.3 million during the third 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 \$26.0 million during the third 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.
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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, February 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 1376489. 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, February 9, 2017 through Thursday, February 16, 2016 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10100036, 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 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 February 9, 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.

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Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Loss
(in thousands except for share data)

	Three Months Ended December 31, 2016	Three Months Ended December 31, 2015	Nine Months Ended December 31, 2016	Nine Months Ended December 31, 2015
Revenues				
Products and services	\$ 699	\$ 293	\$ 2,396	\$ 689
Collaborations	443	\$ 25	1,001	58
Grants	9	\$ 10	21	188
Total Revenues	1,151	328	3,418	935
Cost of revenues	212	-	773	-
Research and development expenses	5,024	4,586	14,012	13,467
Selling, general, and administrative expenses	5,546	6,212	16,520	17,680
Total Costs and Expenses	10,782	10,798	31,305	31,147
Loss from Operations	(9,631)	(10,470)	(27,887)	(30,212)
Other Income (Expense)				
Change in fair value of warrant liabilities	1	2	(4)	(27)
Interest income	50	13	124	39
Total Other Income (Expense)	51	15	120	12
Income Tax Expense	(1)	-	(23)	(3)
Net Loss	\$ (9,581)	\$ (10,455)	\$ (27,790)	\$ (30,203)
Currency Translation Adjustment	(3)	-	(10)	-
Comprehensive Loss	\$ (9,584)	\$ (10,455)	\$ (27,800)	\$ (30,203)
Net loss per common share-basic and diluted	\$ (0.09)	\$ (0.11)	\$ (0.29)	\$ (0.34)
Weighted average shares used in computing net loss per common share-basic and diluted	101,174,734	92,396,358	95,595,640	90,026,158

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

	December 31, 2016	March 31, 2016
	Unaudited	Audited
Assets		
Current Assets		
Cash and cash equivalents	69,996	62,091
Grant receivable	-	-
Accounts receivable	1,030	259
Inventory, net	328	334
Prepaid expenses and other current assets	589	968
	71,943	63,652
Total current assets		
Fixed assets, net	3,937	3,711
Restricted cash	127	79
Other assets, net	124	134
	76,131	67,576
Total assets		
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	722	787
Accrued expenses	2,936	2,450
Deferred rent	155	139
Deferred revenue	620	1,110
Current portion of capital lease	-	-
Accrued interest payable	-	-
Convertible notes payable, current portion	-	-
Warrant liabilities	8	4
	4,441	4,490
Total current liabilities		
Deferred rent, net of current portion	786	905
	5,227	5,395
Total liabilities		
Commitments and Contingencies		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 104,095,729 and 92,391,989 shares issued and outstanding at December 31, 2016 and March 31, 2016, respectively	104	92
Additional paid-in capital	259,470	222,959
Accumulated deficit	(188,660)	(160,870)
Unrealized gain (loss) on foreign currency revaluation	(10)	-
	70,904	62,181
Total stockholders' equity		
Total Liabilities and Stockholders' Equity	76,131	67,576

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

	Nine Months Ended December 31, 2016	Nine Months Ended December 31, 2015
Cash Flows From Operating Activities		
Net loss	\$ (27,790)	\$ (30,203)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	824	560
Change in fair value of warrant liabilities	4	27
Stock-based compensation	5,540	7,049
Amortization of warrants issued for services	-	(99)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(771)	(165)
Inventory	6	(5)
Prepaid expenses and other assets	400	553
Accounts payable	(65)	(921)
Accrued expenses	486	237
Deferred rent	(103)	(54)
Deferred revenue	(490)	1,185
Net cash used in operating activities	(21,959)	(21,836)
Cash Flows From Investing Activities		
Restricted cash deposits	(48)	-
Purchases of fixed assets	(1,061)	(1,711)
Proceeds from disposals of fixed assets	-	14
Purchases of intangible assets	-	(35)
Net cash used in investing activities	(1,109)	(1,732)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	30,401	43,137
Proceeds from exercise of stock options	582	320
Principal payments on capital lease obligations	-	(5)
Net cash provided by financing activities	30,983	43,452
Effect of currency exchange rate changes on cash and cash equivalents	(10)	-
Net Increase (Decrease) in Cash and Cash Equivalents	7,905	19,884
Cash and Cash Equivalents at Beginning of Period	62,091	50,142
Cash and Cash Equivalents at End of Period	\$ 69,996	\$ 70,026
Supplemental Disclosure of Cash Flow Information:		
Interest	\$ -	\$ -
Income taxes paid	\$ 23	\$ 3