

**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): June 9, 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 June 9, 2016, Organovo Holdings, Inc. (the “Company”) issued a press release announcing financial results for its fourth quarter and fiscal year ended March 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 June 9, 2016.

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**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: June 9, 2016

/s/ Keith Murphy

Keith Murphy

Chief Executive Officer and President

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## Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated June 9, 2016.

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## **ORGANOVO ANNOUNCES FISCAL FOURTH-QUARTER AND FULL-YEAR 2016 RESULTS; COMPANY ISSUES FULL-YEAR FISCAL 2017 OUTLOOK**

SAN DIEGO – June 9, 2016 – Organovo Holdings, Inc. (NYSE MKT: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 fourth quarter of 2016, issued its full-year fiscal 2017 outlook and affirmed its long-range guidance. Net loss was \$8.4 million, or \$0.09 per share, for the fiscal fourth quarter of 2016, as compared to \$7.8 million, or \$0.10 per share, for the fiscal fourth quarter of 2015.

Organovo reported fiscal fourth-quarter total revenue of \$0.5 million, which consisted primarily of collaborations and product and service revenue. Total revenue increased 105 percent versus the comparable period of fiscal 2015 and 67 percent versus the fiscal third quarter of 2016. Collaborations revenue, which primarily represents revenue from the Company’s research agreements with L’Oreal USA and Merck & Co., increased by \$0.4 million from the year-ago period.

“Fiscal 2016 was a rewarding year for Organovo, as we achieved many of our key operating and scientific targets,” said Keith Murphy, CEO, Organovo. “We issued our outlook today for fiscal 2017 total revenue, which reflects meaningful growth as we drive customer adoption of our liver product and reach important milestones in our research collaborations and partnerships. We also continue to penetrate the global Top 25 pharmaceutical space, having recently added one new customer to bring our total to five with this leading group. Repeat agreements remain strong, as evidenced by the fact that we’re now on a third contract with one of our earliest global Top 25 pharma customers.”

Murphy continued, “As we look ahead to fiscal 2017, we’re focused on a few key objectives including accelerated liver tissue revenue growth, initiation of commercial contracting for our kidney product, advancement of our skin model with L’Oreal and sharing preliminary results from our work with multiple tissue types in the therapeutic tissues space. Specifically, we’re

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moving from functional validation to a customer ‘early-access’ program with our kidney product, and are seeing strong interest from about a dozen potential customers. In all, we’re expanding our product portfolio and diversifying our revenue profile in the preclinical safety and efficacy and disease modeling markets.”

Murphy concluded, “Our ability to grow in fiscal 2017 and beyond is rooted in serving attractive and growing markets with critical unmet needs, our leadership position in the 3D bioprinting space and an exceptional IP portfolio around our technology platform and scientific work. We’re poised to change the shape of life science research and transform medical care.”

### **Full-Year Fiscal 2016 Organovo Business Highlights**

For the full year, Organovo reported net loss of \$38.6 million, or \$0.43 per share, as compared to net loss of \$30.1 million, or \$0.38 per share, for fiscal 2015. The Company reported fiscal 2016 total revenue of \$1.5 million, which was up 160% from the year-ago period. Total revenue included \$0.8 million of product and service revenue and \$0.7 million of revenue related to collaborations and grants.

### **Fourth-Quarter Organovo Business Highlights**

#### **Revenue**

- Product and service revenue was \$0.1 million, down 33 percent from the prior-year period, largely driven by the timing of revenue recognition for the Company’s exVive3D Human Liver Tissue research services contracts. As the Company previously stated, certain milestones for revenue recognition from a large customer are expected in early fiscal 2017 rather than late fiscal 2016, reflecting the need for this customer to finalize aspects of its work plan.
- Collaborations revenue totaled \$0.4 million, primarily supported by a milestone achievement from the Company’s agreement with L’Oreal USA to develop the skin tissue model.

#### **Operating Expenses**

- Selling, general and administrative expenses decreased 3 percent from the prior-year period to \$4.4 million, primarily due to lower employee related costs and non-cash share-based compensation expense.
  - Research and development costs grew 25 percent year-over-year to \$4.5 million, reflecting increased employee related costs and lab supplies.
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## Liquidity & Capital Resources

- The Company ended the fiscal fourth quarter with a cash and cash equivalents balance of \$62.1 million. Organovo's net cash utilization(1) during the period was \$7.9 million. The Company's net cash utilization for the full-year fiscal 2016 was \$31.5 million, lower than the expected net cash utilization rate of between \$32 million and \$34 million.
- Working capital was \$59.2 million to end the fiscal fourth quarter compared to \$46.5 million in the prior-year quarter.

## Fiscal-Year 2017 Outlook

The Company issued its full-year fiscal 2017 outlook for total revenue, net cash utilization and initiating of commercial contracting for its kidney tissue product. The Company expects:

- Total revenue of between \$4 million and \$6 million for fiscal-year 2017. Fiscal 2016 total revenue was \$1.5 million.
- Net cash utilization of between \$32.5 million and \$36.5 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.
- Initiation of commercial contracting for its kidney tissue product in the calendar third quarter of 2016.

	<b>Fiscal-Year 2017 Outlook (June 2016)</b>
<b>Fiscal-Year 2017 Total Revenue</b>	\$4 million - \$6 million
<b>Net Cash Utilization</b>	\$32.5 million - \$36.5 million
<b>Initiation of Commercial Contracting for Kidney Tissue</b>	Calendar Third Quarter of 2016

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## Long-Range Outlook

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

- As it penetrates the toxicology market, Organovo's exVive3D Human Liver Tissue and 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).

## Net Cash Utilization Definition

- (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 change in the amount of cash and cash equivalents at the beginning of the reporting period as compared to the end of the reporting period, excluding financing activities (which would include proceeds from the sale of common stock and the exercise of warrants and stock options). Net cash utilization is an operational measure that should be considered in addition to our results prepared in accordance with U.S. GAAP. This operational measure should not be considered as a substitute for, or superior to, 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, June 9, 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 2570234. The conference call will also be simultaneously webcast on Organovo's Investor Relations webpage at [www.organovo.com](http://www.organovo.com). A replay of the conference call will be available beginning Thursday, June 9, 2016 through Thursday, June 16, 2016 at Organovo's Investor Relations webpage.

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Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 2570234, 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 disease models through internal development and in collaboration with pharmaceutical and academic 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 recently launched its initial product of the planned exVive3D portfolio offering, the exVive3D Human Liver Tissue for use in toxicology and other preclinical drug testing. Additional products are in development, with the anticipated release of the exVive3D Human Kidney Tissue scheduled for the third quarter of calendar year 2016. 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, and numerous other media outlets. Organovo is changing the shape of life science research and transforming medical care. Learn more at [www.organovo.com](http://www.organovo.com).

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## **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. 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. 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.**  
**Consolidated Statements of Operations**  
(in thousands)

	Year Ended March 31, 2016	Year Ended March 31, 2015
<b>Revenues</b>		
Product and service	\$ 806	\$ 314
Collaborations	486	134
Grants	191	123
<b>Total Revenues</b>	1,483	571
Selling, general, and administrative expenses	22,118	17,947
Research and development expenses	18,008	12,921
Operating Expenses	40,126	30,868
<b>Loss from Operations</b>	(38,643)	(30,297)
<b>Other Income (Expense)</b>		
Change in fair value of warrant liabilities	(17)	196
Loss on disposals of fixed assets	-	(12)
Interest expense	-	(1)
Interest income	88	32
<b>Total Other Income (Expense)</b>	71	215
<b>Income Tax Expense</b>	(3)	-
<b>Net Loss</b>	\$ (38,575)	\$ (30,082)

**Organovo Holdings, Inc.**  
**Consolidated Balance Sheets**  
(in thousands)

	March 31, 2016	March 31, 2015
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	62,091	50,142
Accounts receivable	259	-
Inventory	334	66
Prepaid expenses and other current assets	968	1,054
<b>Total current assets</b>	<b>63,652</b>	<b>51,262</b>
Fixed assets, net	3,711	2,042
Restricted cash	79	79
Other assets, net	134	106
<b>Total assets</b>	<b>\$ 67,576</b>	<b>\$ 53,489</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 787	\$ 1,387
Accrued expenses	2,450	2,257
Deferred rent	139	759
Deferred revenue	1,110	227
Current portion of capital lease	-	5
Warrant liabilities	4	126
<b>Total current liabilities</b>	<b>4,490</b>	<b>4,761</b>
Deferred revenue, net of current portion	-	32
Deferred rent, net of current portion	905	-
<b>Total liabilities</b>	<b>\$ 5,395</b>	<b>\$ 4,793</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock	92	82
Additional paid-in capital	222,959	170,909
Accumulated deficit	(160,870)	(122,295)
<b>Total stockholders' equity</b>	<b>62,181</b>	<b>48,696</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 67,576</b>	<b>\$ 53,489</b>

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

	Year Ended March 31, 2016	Year Ended March 31, 2015
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (38,575)	\$ (30,082)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	-	12
Depreciation and amortization	815	472
Change in fair value of warrant liabilities	17	(196)
Expense associated with warrant modification	-	-
Stock-based compensation	8,556	7,020
Amortization of warrants issued for services	(92)	557
Increase (decrease) in cash resulting from changes in:		
Grants receivable	-	-
Accounts receivable	(259)	-
Inventory	(268)	(3)
Prepaid expenses and other assets	83	(389)
Accounts payable	(600)	1,061
Accrued expenses	193	1,435
Deferred rent	(89)	270
Deferred revenue	851	242
<b>Net cash used in operating activities</b>	<b>(29,368)</b>	<b>(19,601)</b>
<b>Cash Flows From Investing Activities</b>		
Deposits released from restriction (restricted cash deposits)	-	-
Purchases of fixed assets	(2,114)	(1,517)
Proceeds from disposals of fixed assets	14	-
Purchases of intangible assets	(35)	-
<b>Net cash used in investing activities</b>	<b>(2,135)</b>	<b>(1,517)</b>
<b>Cash Flows From Financing Activities</b>		
Proceeds from issuance of common stock and exercise of warrants, net	43,137	22,752
Proceeds from exercise of stock options	320	351
Principal payments on capital lease obligations	(5)	(10)
Deferred financing costs	-	-
<b>Net cash provided by financing activities</b>	<b>43,452</b>	<b>23,093</b>
<b>Net Increase in Cash and Cash Equivalents</b>	<b>11,949</b>	<b>1,975</b>
<b>Cash and Cash Equivalents at Beginning of Period</b>	<b>50,142</b>	<b>48,167</b>
<b>Cash and Cash Equivalents at End of Period</b>	<b>\$ 62,091</b>	<b>\$ 50,142</b>

**Organovo Holdings, Inc.**  
**Consolidated Statements of Operations**  
(in thousands)

	Three Months Ended March 31, 2016	Three Months Ended March 31, 2015
<b>Revenues</b>		
Product and service	\$ 117	\$ 175
Collaborations	427	13
Grants	4	79
<b>Total Revenues</b>	548	267
Selling, general, and administrative expenses	4,438	4,597
Research and development expenses	4,542	3,641
Operating Expenses	8,980	8,238
<b>Loss from Operations</b>	(8,432)	(7,971)
<b>Other Income (Expense)</b>		
Change in fair value of warrant liabilities	10	172
Loss on disposals of fixed assets	-	(9)
Interest expense	-	-
Interest income	50	10
<b>Total Other Income (Expense)</b>	60	173
<b>Income Tax Expense</b>	-	-
<b>Net Loss</b>	\$ (8,372)	\$ (7,798)