

---

**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 4, 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))
- 
-

**Item 2.02 Results of Operations and Financial Condition**

On August 4, 2016, 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, 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 August 4, 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: August 4, 2016

/s/ Keith Murphy

Keith Murphy

Chief Executive Officer and President

---

## Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated August 4, 2016.



*Investor Contact:*  
Steve Kunschabo  
Organovo Holdings, Inc.  
+1 (858) 224-1092  
[skunschabo@organovo.com](mailto:skunschabo@organovo.com)

*Press Contact:*  
Jessica Yingling  
Little Dog Communications  
+1 (858) 480-2411  
[jessica@litldog.com](mailto:jessica@litldog.com)

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

SAN DIEGO – August 4, 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 first quarter of 2017 and affirmed its full-year fiscal 2017 and long-range outlook. Net loss was \$8.8 million, or \$0.09 per share, for the fiscal first quarter of 2017, as compared to \$8.5 million, or \$0.10 per share, for the fiscal first quarter of 2016.

Organovo reported fiscal first-quarter total revenue of \$0.9 million, which consisted largely of product and service revenue<sup>(1)</sup>. Total revenue increased 191 percent versus the comparable period of fiscal 2016 and 63 percent versus the fiscal fourth quarter of 2016. Collaborations revenue<sup>(2)</sup>, which primarily represents revenue from the Company’s research agreements with L’Oreal USA and Merck & Co., increased by \$0.2 million from the year-ago period.

“We’re off to a strong start in fiscal 2017, nearly tripling our total revenue year-over-year in the first quarter and affirming our guidance across the board,” said Keith Murphy, CEO, Organovo. “We continue to see solid adoption of our tissue research services, with an increase in new customers across the healthcare and biotechnology space signing agreements during the last few months. We’ve also recently added two global Top 25 pharma customers, bringing our total to seven with this important and influential group, and are benefiting from a high percentage of repeat orders from our established customer base. Many of our new customers now work with us under master service agreements, rather than signing up for just a single order or transaction. We believe this framework supports repeat business and fosters our ability to become a standard part of customers’ toolkits for their drug discovery workflow.”

Murphy continued, “We’re on track to commercialize our second tissue, the kidney proximal tubule, at the end of September. We’re pleased with the momentum of our early access program for kidney tissue research services, having recently signed our first customer orders, with significant interest from additional biopharmaceutical companies to study the effects of drug exposure using our kidney model. Kidney is a natural expansion of our preclinical solutions portfolio, showcasing the power and versatility of our technology platform.”

---

Murphy concluded, “Our long-term plan is sustained by reaching attractive and growing markets with critical unmet needs, extending our position as first mover in the 3D bioprinting space, and capitalizing on our technology leadership to grow our product and service offerings.”

## **Organovo Business Highlights**

### **Revenue**

- Product and service revenue was \$0.7 million, up 222 percent from the prior-year period, largely driven by an increase in customer contracts for the Company’s tissue research services.
- Collaborations revenue totaled \$0.2 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 total expenses related to manufacturing and delivering its product and service revenues.
- Research and development costs grew 7 percent year-over-year to \$4.4 million, driven by increased employee related costs and lab supplies.
- Selling, general and administrative expenses increased 9 percent from the prior-year period to \$5.1 million, primarily due to higher employee related costs and non-cash share-based compensation expense.

### **Liquidity & Capital Resources**

- The Company ended the fiscal first quarter with a cash and cash equivalents balance of \$53.5 million. Organovo’s net cash utilization<sup>(3)</sup> during the period was \$8.6 million.
- Working capital was \$52.0 million to end the fiscal first quarter compared to \$81.8 million in the prior-year quarter.

## **Fiscal-Year 2017 Outlook**

The Company affirmed its full-year fiscal 2017 outlook for total revenue, net cash utilization and initiation of commercial contracting for its kidney tissue product. The Company continues to expect:

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

### **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).

### **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 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, August 4, 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 2415344. 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, August 4, 2016 through Thursday, August 11, 2016 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 2415344, 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 initial product is 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, 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](http://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. 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.*

---

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

	<b>Three Months Ended</b>	
	<b>June 30, 2016</b>	<b>June 30, 2015</b>
<b>Revenues</b>		
Products and services	\$ 674	\$ 209
Collaborations	213	14
Grants	4	83
	891	306
<b>Total Revenues</b>		
Cost of revenues	168	-
Research and development expenses	4,444	4,142
Selling, general, and administrative expenses	5,056	4,622
	9,668	8,764
<b>Total Costs and Expenses</b>		
<b>Loss from Operations</b>	(8,777)	(8,458)
<b>Other Income (Expense)</b>		
Change in fair value of warrant liabilities	(5)	(38)
Gain (loss) on fixed asset disposals		
Interest expense	-	-
Interest income	37	8
	32	(30)
<b>Total Other Income (Expense)</b>		
<b>Income Tax Expense</b>	(22)	(3)
<b>Net Loss</b>	\$ (8,767)	\$ (8,491)
Net loss per common share-basic and diluted	\$ (0.09)	\$ (0.10)
Weighted average shares used in computing net loss per common share-basic and diluted	92,391,964	82,993,966

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

	<b>June 30, 2016</b>	<b>March 31, 2016</b>
	<b>Unaudited</b>	<b>Audited</b>
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	53,538	62,091
Grant receivable	-	-
Accounts receivable	103	259
Inventory, net	512	334
Prepaid expenses and other current assets	1,028	968
Total current assets	55,181	63,652
Fixed assets, net	3,456	3,711
Restricted cash	79	79
Other assets, net	131	134
Total assets	58,847	67,576
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	481	787
Accrued expenses	1,715	2,450
Deferred rent	140	139
Deferred revenue	791	1,110
Current portion of capital lease	-	-
Accrued interest payable	-	-
Convertible notes payable, current portion	-	-
Warrant liabilities	9	4
Total current liabilities	3,136	4,490
Deferred rent, net of current portion	868	905
Capital lease obligation, net of current portion	-	-
Warrant liabilities	-	-
Convertible notes payable, long-term portion	-	-
Total liabilities	4,004	5,395
<b>Commitments and contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 92,389,730 and 92,391,989 shares issued and outstanding at June 30, 2016 and March 31, 2016, respectively	92	92
Additional paid-in capital	224,388	222,959
Accumulated deficit	(169,637)	(160,870)
Total stockholders' equity	54,843	62,181
<b>Total Liabilities and Stockholders' Equity</b>	<b>58,847</b>	<b>67,576</b>

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

	<b>Three months ended</b>	
	<b>June 30, 2016</b>	<b>June 30, 2015</b>
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (8,767)	\$ (8,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	251	135
Change in fair value of warrant liabilities	5	38
Stock-based compensation	1,429	1,780
Amortization of warrants issued for services	-	(95)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	156	(132)
Inventory	(178)	(3)
Prepaid expenses and other assets	(41)	256
Accounts payable	(306)	(357)
Accrued expenses	(735)	(611)
Deferred rent	(36)	(8)
Deferred revenue	(319)	1,193
<b>Net cash used in operating activities</b>	<b>(8,541)</b>	<b>(6,295)</b>
<b>Cash Flows From Investing Activities</b>		
Purchases of fixed assets	(12)	(1,135)
<b>Net cash used in investing activities</b>	<b>(12)</b>	<b>(1,135)</b>
<b>Cash Flows From Financing Activities</b>		
Proceeds from issuance of common stock and exercise of warrants, net	-	43,214
Proceeds from exercise of stock options	-	77
Principal payments on capital lease obligations	-	(3)
<b>Net cash provided by financing activities</b>	<b>-</b>	<b>43,288</b>
<b>Net Increase (Decrease) in Cash and Cash Equivalents</b>	<b>(8,553)</b>	<b>35,858</b>
<b>Cash and Cash Equivalents at Beginning of Period</b>	<b>62,091</b>	<b>50,142</b>
<b>Cash and Cash Equivalents at End of Period</b>	<b>\$ 53,538</b>	<b>\$ 86,000</b>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Interest	\$ -	\$ -
Income Taxes	\$ (22)	\$ (3)