

**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 8, 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 February 8, 2016, Organovo Holdings, Inc. (the “Company”) issued a press release announcing financial results for the third quarter of its fiscal year, which period ended December 31, 2015. 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 8, 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: February 8, 2016

/s/ Keith Murphy

Keith Murphy

Chief Executive Officer and President

Exhibit Index

Exhibit

No. Description

99.1 Press Release, dated February 8, 2016.



Investor Contact:

Press Contact:

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

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

ORGANOVO ANNOUNCES FISCAL THIRD-QUARTER RESULTS; COMPANY UPDATES FULL-YEAR FISCAL 2016 OUTLOOK AND AFFIRMS LONG-RANGE GUIDANCE

SAN DIEGO, Ca. – February 8, 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 third quarter of 2016, updated its full-year fiscal 2016 outlook and affirmed its long-range guidance. Net loss was \$10.5 million, or \$0.11 per share, for the fiscal third quarter of 2016, as compared to \$7.0 million, or \$0.09 per share, for the fiscal third quarter of 2015.

Organovo reported fiscal third-quarter total revenue of \$0.3 million, which consisted primarily of product and service revenue. Total revenue increased 112 percent versus the comparable period of fiscal 2015 and 9 percent versus the fiscal second quarter of 2016. Product and service revenue, which primarily represents revenue from the exVive3D™ Human Liver Tissue research service and product, increased by \$0.2 million from the year-ago period. The Company commercially released the exVive3D Human Liver Tissue in November 2014.

“We have solid fundamentals and excellent long-term growth prospects supporting our core business,” said Keith Murphy, CEO, Organovo. “Our leadership in the 3D bioprinting space is grounded in serving attractive and growing markets with critical unmet needs, a competitive landscape in which our first mover advantage allows us to offer strongly differentiated cutting-edge services, and a growing, world-class IP portfolio. Our technology platform is flexible and is being leveraged to target multiple revenue streams in the preclinical safety, efficacy and disease modeling and therapeutic tissue markets.”

Murphy continued, “During the quarter, we found that recent data from methotrexate exposure in our exVive3D Liver serves as compelling additional differentiation for our target customers. We expect these results to drive more rapid adoption going forward. Overall, our customers are pleased with the scientific results we’re providing as evidenced by the solid pace of repeat agreements, and we expect this momentum to build now that we have dedicated sale resources across the U.S. and Europe. We updated our fiscal 2016 outlook to reflect an improved net cash utilization rate as we capitalize on operating efficiencies from the thoughtful deployment of our capital resources. In addition, we see a shift in timing for revenue recognition from previously disclosed contract bookings for our commercial liver tissue product. To be more specific, our adjusted guidance for revenue recognition indicates that certain milestones from a large customer are now anticipated in early fiscal 2017 rather than late fiscal 2016, reflecting the need for this customer to finalize aspects of its work plan. There is no change in the total revenue that we expect to recognize from this agreement, only a change in the timing of revenue recognition.”

Murphy concluded, “As fiscal 2016 winds down, we continue to make progress in key strategic areas. The development of our kidney tissue product is on track as we move past functional validation and take the necessary steps for commercialization later this year. We’re also advancing with business development initiatives in the drug discovery and therapeutic tissue spaces, and expect to achieve important objectives in the next 12 months. We’re executing against the key scientific and operating targets that will drive our future success.”

Organovo Business Highlights

Revenue

- Product and service revenue was \$0.3 million, up 111 percent from the prior-year period, largely driven by customer contracts for the Company's exVive3D Human Liver Tissue research services.

Operating Expenses

- Selling, general and administrative expenses increased 60 percent from the prior-year period to \$6.2 million, primarily due to higher non-cash share-based compensation expense and employee costs related to sales and administrative staffing.
- Research and development costs grew 42 percent year-over-year to \$4.6 million, reflecting increased employee related costs and lab supplies.

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⁽¹⁾ during the period was \$6.8 million. The Company's net cash utilization for the nine months ended December 31, 2015 was \$23.3 million.
- Working capital was \$65.2 million to end the fiscal third quarter compared to \$46.8 million in the prior-year quarter.

Fiscal-Year 2016 Outlook

The Company updated its full-year fiscal 2016 outlook for revenue recognized from previously disclosed contract bookings for its commercial liver tissue product and net cash utilization. The Company now expects:

- In fiscal 2016, to recognize between \$0.7 million and \$0.9 million of its previously reported approximately \$2 million in contract bookings for its exVive3D Human Liver Tissue for the period from April 1, 2014 to June 9, 2015. The Company had already recognized approximately \$0.3 million from these contract bookings in fiscal 2015. Organovo anticipates that additional revenue from these contract bookings will be recognized in fiscal 2017. In addition, revenue from new contracts signed after June 9, 2015, as well as revenue from grants and collaborations, will continue to be recognized during the remainder of fiscal 2016.
 - Net cash utilization of between \$32 million and \$34 million for fiscal-year 2016. The Company had a cash and cash equivalents balance of \$70.0 million for its fiscal third quarter ended December 31, 2015.
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	Fiscal-Year 2016 Outlook (November 2015)	Fiscal-Year 2016 Outlook (February 2016)
Total Revenue Recognized From Previously Reported Contract Bookings	\$1.2 million - \$1.4 million	\$0.7 million - \$0.9 million
Net Cash Utilization	\$32 million - \$36 million	\$32 million - \$34 million

Long-Range Outlook

The Company affirmed its long-range outlook for potential revenue from its liver tissue product and initiation of commercial contracting for its kidney 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).
- Initiation of commercial contracting for its kidney tissue product in the calendar third quarter of 2016.

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 Monday, February 8, 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 5006379. 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 Monday, February 8, 2016 through Monday, February 15, 2016 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 5006379, 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 medical research and practice. 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; and 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. 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, 2015 and its Quarterly Report on Form 10-Q filed with the SEC on February 8, 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.
Condensed Consolidated Balance Sheets
(in thousands except share data)

	December 31, 2015	March 31, 2015
	(Unaudited)	(Audited)
Assets		
Current Assets		
Cash and cash equivalents	\$ 70,026	\$ 50,142
Accounts receivable	165	—
Inventory	71	66
Prepaid expenses and other current assets	483	1,054
Total current assets	70,745	51,262
Fixed assets, net	3,560	2,042
Restricted cash	79	79
Other assets, net	152	106
Total assets	<u>\$ 74,536</u>	<u>\$ 53,489</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 466	\$ 1,387
Accrued expenses	2,494	2,257
Deferred rent	1,079	759
Deferred revenue	1,444	227
Capital lease obligation	—	5
Warrant liabilities	14	126
Total current liabilities	5,497	4,761
Deferred revenue, net of current portion	—	32
Total liabilities	\$ 5,497	\$ 4,793
Commitments and Contingencies		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 92,413,951 and 81,536,724 shares issued and outstanding at December 31, 2015 and March 31, 2015, respectively	92	82
Additional paid-in capital	221,445	170,909
Accumulated deficit	(152,498)	(122,295)
Total stockholders' equity	69,039	48,696
Total Liabilities and Stockholders' Equity	<u>\$ 74,536</u>	<u>\$ 53,489</u>

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

	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014	Nine Months Ended December 31, 2015	Nine Months Ended December 31, 2014
Revenues				
Product and service	\$ 293	\$ 139	\$ 689	\$ 139
Collaborations	25	7	58	121
Grants	10	9	188	44
Total Revenues	328	155	935	304
Selling, general, and administrative expenses	6,212	3,878	17,680	13,350
Research and development expenses	4,586	3,238	13,467	9,281
Loss from Operations	(10,470)	(6,961)	(30,212)	(22,327)
Other Income (Expense)				
Change in fair value of warrant liabilities	2	(40)	(27)	24
Loss on disposals of fixed assets	—	—	—	(3)
Interest income	13	8	39	22
Total Other Income (Expense)	15	(32)	12	43
Income Tax Expense	—	—	(3)	—
Net Loss	\$ (10,455)	\$ (6,993)	\$ (30,203)	\$ (22,284)
Net loss per common share—basic and diluted	\$ (0.11)	\$ (0.09)	\$ (0.34)	\$ (0.28)
Weighted average shares used in computing net loss per common share—basic and diluted	92,396,358	80,491,120	90,026,158	79,225,692

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

	Nine Months Ended December 31, 2015	Nine Months Ended December 31, 2014
Cash Flows From Operating Activities		
Net loss	\$ (30,203)	\$ (22,284)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	3
Depreciation and amortization	560	334
Change in fair value of warrant liabilities	27	(24)
Stock-based compensation	7,049	5,215
Amortization of warrants issued for services	(99)	556
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(165)	—
Inventory	(5)	(6)
Prepaid expenses and other assets	553	318
Accounts payable	(921)	169
Accrued expenses	237	1,206
Deferred rent	(54)	254
Deferred revenue	1,185	268
Net cash used in operating activities	(21,836)	(13,991)
Cash Flows From Investing Activities		
Purchases of fixed assets	(1,711)	(867)
Proceeds from disposals of fixed assets	14	—
Purchases of intangible assets	(35)	—
Net cash used in investing activities	(1,732)	(867)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	43,137	16,512
Proceeds from exercise of stock options	320	213
Principal payments on capital lease obligations	(5)	(7)
Net cash provided by financing activities	43,452	16,718
Net Increase in Cash and Cash Equivalents	19,884	1,860
Cash and Cash Equivalents at Beginning of Period	50,142	48,167
Cash and Cash Equivalents at End of Period	\$ 70,026	\$ 50,027
Supplemental Disclosure of Cash Flow Information:		
Interest	\$ —	\$ —
Income Taxes	\$ 3	\$ —