



Organovo Announces Fiscal Fourth-Quarter and Full-Year 2017 Results; Company Issues Full-Year Fiscal 2018 Outlook

June 7, 2017

SAN DIEGO, June 07, 2017 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo") today reported financial results for the fiscal fourth quarter of 2017 and issued its full-year fiscal 2018 outlook. Organovo reported fiscal fourth-quarter total revenue of \$0.8 million, which consisted largely of product and service revenue⁽¹⁾. Total revenue increased 48 percent versus the comparable period of fiscal 2016. Net loss was \$10.7 million, or \$0.10 per share, for the fiscal fourth quarter of 2017, as compared to \$8.4 million, or \$0.09 per share, for the fiscal fourth quarter of 2016.

"Fiscal 2017 was a year of significant commercial progress for Organovo, as we grew total revenue 185% and achieved many important scientific targets," said Taylor J. Crouch, CEO, Organovo. "We issued our outlook today for fiscal 2018 total revenue, which represents a robust increase in sales led by growth in tissue research services. In addition to our established work in the toxicology space, we're seeing strong customer demand for compound screening in disease models, including key areas such as liver fibrosis and non-alcoholic steatohepatitis ("NASH"). With 30% of the developed world now living with progressive fatty liver disease, I believe our work and capabilities will become critical to understanding the effects of new drugs in realistically modeled patient populations."

Crouch continued, "I've joined Organovo during a transformational time in its history. The leading indicators of broader customer acceptance are taking shape. A key component of customer adoption remains the breadth of our ongoing validation work. I'm excited to share that we've now studied 46 compounds and accurately characterized the safety profile in a high percentage of the cases based on clinical correlation. It's important to remember that these cases included preclinical misses and approved drugs where cell and animal models did not provide an adequate safety signal. We'll not only focus on growing our library of core validation work over the long-term, but as we shared last quarter, we'll continue supporting immediate customer needs related to optimized utilization and new applications."

Crouch concluded, "As we look ahead to fiscal 2018, our core business infrastructure is at a sufficient level to support anticipated customer demand and revenue producing opportunities. We're focused on a precise set of goals to enable our rapid growth. First, we expect to capitalize on future adoption of our liver and kidney tissue research services. Ongoing validation work and business development execution with new customers will be the cornerstones for achieving this objective, while also moving existing clients quickly to repeat orders on the path to routine use of our solutions. Second, we plan to advance our liver therapeutic tissue through preclinical studies with the goal of locking down our final tissue design and conducting successful animal disease model studies over the next 12 months. With each incremental success against these objectives, we're changing how drugs are developed and ultimately impacting patient outcomes where critical unmet needs exist."

Full-Year Fiscal 2017 Organovo Business Highlights

For the full year, the Company reported total revenue of \$4.2 million, which was up 185% from the year-ago period. Total revenue included \$3.2 million of product and service revenue and \$1.0 million of revenue related to collaborations⁽²⁾. Organovo reported fiscal 2017 net loss of \$38.4 million, or \$0.39 per share, as compared to net loss of \$38.6 million, or \$0.43 per share, for fiscal 2016.

Fourth-Quarter Organovo Business Highlights

Revenue

- Product and service revenue was \$0.8 million, up \$0.7 million from the prior-year period, largely driven by an increase in customer contracts for the Company's tissue research services.

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 22 percent year-over-year to \$5.5 million, primarily due to increased employee related, scientific validation work and lab supplies costs.
- Selling, general and administrative expenses gained 30 percent from the prior-year period to \$5.8 million, reflecting higher employee related and outside professional services costs.

Liquidity & Capital Resources

- The Company ended the fiscal fourth quarter with a cash and cash equivalents balance of \$62.8 million. Organovo's net cash utilization⁽³⁾ during the period was \$7.5 million. The Company's net cash utilization for the full-year fiscal 2017 was \$30.6 million, lower than the expected net cash utilization rate of between \$31.0 million and \$34.0 million.
- Working capital was \$59.1 million to end the fiscal fourth quarter compared to \$59.2 million in the prior-year quarter.

Fiscal-Year 2018 Outlook

The Company issued its full-year fiscal 2018 outlook for total revenue and negative Adjusted EBITDA⁽⁴⁾. The Company expects:

- Total revenue of between \$6.0 million and \$8.5 million for fiscal-year 2018. Fiscal 2017 total revenue was \$4.2 million.
- Negative Adjusted EBITDA of between \$29.0 million and \$31.0 million for fiscal-year 2018. Fiscal 2017 negative Adjusted EBITDA was \$29.8 million.

**Fiscal-Year 2018 Outlook
(June 2017)**

Fiscal-Year 2018 Total Revenue	\$6.0 million - \$8.5 million
Fiscal-Year 2018 Negative Adjusted EBITDA	\$29.0 million - \$31.0 million

A reconciliation of non-GAAP negative Adjusted EBITDA, as forecasted for fiscal 2018, to the closest corresponding GAAP measure, net loss, is not available without unreasonable efforts on a forward-looking basis due to the high variability and low visibility of certain charges that may impact our GAAP results on a forward-looking basis, such as the measures and effects of share-based compensation.

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 a decrease of \$7.2 million during the fourth 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 \$0.3 million during the fourth 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.

(4) In addition to disclosing financial results that are determined in accordance with U.S. GAAP, the Company provides Adjusted EBITDA which is a non-GAAP financial measure, as a supplemental measure to help investors evaluate the Company's fundamental operational performance. Adjusted EBITDA represents earnings before interest, income taxes, depreciation and amortization, share-based compensation expenses and CEO transition costs. Adjusted EBITDA does not represent, and should not be considered, an alternative to U.S. GAAP measurements such as net income or loss. By eliminating interest, income taxes, depreciation and amortization, share-based compensation expenses and CEO transition costs, the Company believes the result is a useful measure across time in evaluating its fundamental core operating performance. Management also uses Adjusted EBITDA to manage the business, including in preparing its annual operating budget, financial projections and compensation plans. The Company believes that Adjusted EBITDA 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 Adjusted EBITDA, and Adjusted EBITDA as the Company presents it may not be comparable with similarly titled non-GAAP financial measures used by other companies. Since Adjusted EBITDA does not account for certain expenses, its utility as a measure of the Company's operating performance has material limitations. Due to these limitations, the Company's management does not view Adjusted EBITDA in isolation, but also uses other measurements, such as net income or loss and revenues to measure operating performance. Please refer to the schedule below for a reconciliation of consolidated GAAP net income to Adjusted EBITDA for the fiscal years ended March 31, 2017 and 2016.

Organovo Holdings, Inc.

Supplemental Reconciliation of GAAP Net Income to Adjusted EBITDA

(in thousands)

	Twelve Months Ended March 31, 2017	Twelve Months Ended March 31, 2016
GAAP net loss	\$ (38,447)	\$ (38,575)
Interest expense	-	-
Interest income	(198)	(88)
Income taxes	23	3

Depreciation and amortization	1,149	815
Share-based compensation	7,392	8,556
CEO transition costs	281	-
Adjusted EBITDA	\$ (29,800) \$ (29,289)

Conference Call Information

As previously announced, the Company will host a conference call to discuss its results at 5:00 p.m. ET on Wednesday, June 7, 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 7936733. 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 Wednesday, June 7, 2017 through Wednesday, June 14, 2017 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10104415, 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 2018 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 7, 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.

Organovo Holdings, Inc.

Consolidated Statements of Operations and Other Comprehensive Loss

(in thousands except per share data)

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016	Twelve Months Ended March 31, 2017	Twelve Months Ended March 31, 2016
Revenues				
Products and services	\$ 771	\$ 117	\$ 3,167	\$ 806
Collaborations	21	\$ 427	1,022	486
Grants	20	\$ 4	41	191
Total Revenues	812	548	4,230	1,483
Cost of revenues	183	-	956	-
Research and development expenses	5,533	4,542	19,545	18,008
Selling, general, and administrative expenses	5,784	4,438	22,304	22,118
Total Costs and Expenses	11,500	8,980	42,805	40,126

Loss from Operations	(10,688)	(8,432)	(38,575)	(38,643)
Other Income (Expense)								
Change in fair value of warrant liabilities	8		10		4		(17)
Loss on disposal of fixed assets	(51)	-		(51)	-	
Interest expense	-		-		-		-	
Interest income	74		50		198		88	
Total Other Income (Expense)	31		60		151		71	
Income Tax Expense	-		-		(23)	(3)
Net Loss	\$ (10,657)	\$ (8,372)	\$ (38,447)	\$ (38,575)
Net loss per common share-basic and diluted	\$ (0.10)	\$ (0.09)	\$ (0.39)	\$ (0.43)
Weighted average shares used in computing net loss per common share-basic and diluted	104,385,617		92,402,668		97,763,032		90,057,356	
Comprehensive Loss:								
Net Loss	\$ (10,657)	\$ (8,372)	\$ (38,447)	\$ (38,575)
Currency Translation Adjustment	(1)	-		(11)	-	
Comprehensive Loss	\$ (10,658)	\$ (8,372)	\$ (38,458)	\$ (38,575)

Organovo Holdings, Inc.

Consolidated Balance Sheets

(in thousands except per share data)

	March 31, 2017	March 31, 2016
Assets		
Current Assets		
Cash and cash equivalents	\$ 62,751	\$ 62,091
Accounts receivable	647	259
Inventory, net	550	334
Prepaid expenses and other current assets	1,144	968
Total current assets	65,092	63,652
Fixed assets, net	3,840	3,711
Restricted cash	127	79
Other assets, net	121	134
Total assets	\$ 69,180	\$ 67,576

Liabilities and Stockholders' Equity

Current Liabilities

Accounts payable	\$ 1,171	\$ 787
Accrued expenses	4,101	2,450
Deferred rent	157	139
Deferred revenue	582	1,110
Warrant liabilities	-	4
Total current liabilities	6,011	4,490
Deferred revenue, net of current portion	58	-
Deferred rent, net of current portion	749	905
Total liabilities	\$ 6,818	\$ 5,395

Commitments and Contingencies (Note 6)

Stockholders' Equity

Common stock, \$0.001 par value; 150,000,000 shares authorized, 104,551,466 and 92,391,989 shares issued and outstanding at March 31, 2017 and March 31, 2016, respectively	104	92
Additional paid-in capital	261,586	222,959
Accumulated deficit	(199,317)	(160,870)
Accumulated other comprehensive income (loss)	(11)	-
Total stockholders' equity	62,362	62,181
Total Liabilities and Stockholders' Equity	\$ 69,180	\$ 67,576

Organovo Holdings, Inc.

Consolidated Statements of Cash Flows (in thousands)

	Year Ended March 31, 2017	Year Ended March 31, 2016
Cash Flows From Operating Activities		
Net loss	\$ (38,447)	\$ (38,575)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of warrants issued for services	-	(92)
Depreciation and amortization	1,149	815
Loss on disposal of fixed assets	56	-
Change in fair value of warrant liabilities	(4)	17
Stock-based compensation	7,392	8,556
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(388)	(259)
Inventory	(216)	(268)
Prepaid expenses and other assets	(154)	83
Accounts payable	384	(600)
Accrued expenses	1,651	193
Deferred rent	(138)	(89)

Deferred revenue	(470)	851
Net cash used in operating activities	(29,185)	(29,368)
Cash Flows From Investing Activities		
Deposits released from restriction (restricted cash deposits)	(48)	-
Purchases of fixed assets	(1,354)	(2,114)
Proceeds from disposals of fixed assets	11	14
Purchases of intangible assets	-	(35)
Net cash used in investing activities	(1,391)	(2,135)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	30,665	43,137
Proceeds from exercise of stock options	582	320
Principal payments on capital lease obligations	-	(5)
Net cash provided by financing activities	31,247	43,452
Effect of currency exchange rate changes on cash and cash equivalents	(11)	-
Net Increase (Decrease) in Cash and Cash Equivalents	660	11,949
Cash and Cash Equivalents at Beginning of Period	62,091	50,142
Cash and Cash Equivalents at End of Period	\$ 62,751	\$ 62,091
Supplemental Disclosure of Cash Flow Information:		
Income Taxes	\$ 23	\$ 3

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