

Organovo Holdings, Inc. Reports Second Quarter Results

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SAN DIEGO, Nov. 10, 2014 /PRNewswire/ -- Organovo Holdings, Inc. (NYSE MKT: ONVO) ("Organovo"), a three-dimensional biology company focused on delivering pioneering 3D bioprinting technology, has reported its second quarter, fiscal 2015, results.

Keith Murphy, chairman and chief executive officer of Organovo, commented on the results: "Last quarter Organovo demonstrated that our exVive3D™ Human Liver Model is clearly able to detect drug-induced liver injury that other methods in the past failed to predict. With that data in hand we are ready to initiate the commercialization of our 3D Liver Tissue before the end of November, 2014. Our achievements in the development of this technology were honored this past quarter in multiple ways, including through selection of our company as a 2015 Technology Pioneer by the World Economic Forum (WEF)."

Financial Summary

A summary of the Company's financial results for the first fiscal quarter follows, but is not intended to replace the full financial disclosure enclosed in the Quarterly Report on Form 10-Q the Company filed with the Securities and Exchange Commission on November 7, 2014. Please refer to that document for additional information. Because Organovo's fiscal year end is March 31, the period from July to September 2014 is the second quarter of fiscal year 2015 (Q2 FY2015).

As of September 30, 2014, the Company had cash and cash equivalents of approximately \$54.4 million and an accumulated deficit of \$107.5 million. The Company had negative cash flow from operations of \$9.7 million during the six months ended September 30, 2014. At March 31, 2014, the Company had cash and cash equivalents of approximately \$48.2 million and an accumulated deficit of \$92.2 million.

At September 30, 2014, the Company had total current assets of approximately \$55.1 million and current liabilities of approximately \$3.1 million, resulting in working capital of \$52.0 million. At March 31, 2014, the Company had total current assets of approximately \$49.2 million and current liabilities of approximately \$1.9 million, resulting in working capital of \$47.3 million.

Net cash used in operating activities for the six months ended September 30, 2014 was approximately \$9.7 million as compared to \$6.3 million used in operating activities for the six months ended September 30, 2013. This \$3.4 million increase in cash usage can be attributed to a \$6.0 million increase in operating expenses, partially offset by an overall increase of \$2.0 million of non-cash expenses included in operations, including stock-based compensation, depreciation and amortization, as well as changes in working capital.

Net cash used in investing activities was approximately \$0.6 million and \$0.1 million for the six months ended September 30, 2014 and 2013, respectively. This increase can be attributed to increased capital spending as the Company expands its research capabilities.

Net cash resulting from financing activities decreased from \$44.1 million during the six months ended September 30, 2013 to \$16.5 million during the six months ended September 30, 2014. This decrease is primarily due to the inclusion of \$43.4 million in net proceeds from the issuance of common stock during the six months ended September 30, 2013, as compared to \$16.1 million in net proceeds from the issuance of common stock during the six months ended September 30, 2014.

For the three months ended September 30, 2014, total revenues of \$50,000 were \$27,000 or 117% above the \$23,000 in revenues for the same period in 2013. For the six months ended September 30, 2014, total revenues of \$0.1 million were consistent with the \$0.1 million in revenues for the same period in 2013. For all periods, the majority of revenues were derived from collaborative research agreements.

Operating expenses increased approximately \$3.4 million, or 61%, from approximately \$5.6 million for the three months ended September 30, 2013 to \$9.0 million for the three months ended September 30, 2014. Of this increase, \$1.8 million relates to increased selling, general and administrative expense while the other \$1.6 million relates to increased investment in research and development. Operating expenses increased approximately \$6.0 million, or 64%, from approximately \$9.5 million for the six months ended September 30, 2013 to \$15.5 million for the six months ended September 30, 2014. Of this increase, \$3.1 million is related to increased selling, general and administrative expense while the other \$2.9 million relates to increased investment in research and development. These increases can be attributed to the Company's continued implementation of its business plan, including hiring additional staff to support research and development initiatives, incremental investments associated with strategic growth and commercialization project initiatives, expenses related to operating as a publicly traded corporation, expansion of its facility, and increased stock compensation expense relative to employees and certain consulting services.

Research and development expenses increased nearly 100% from approximately \$1.6 million for the three months ended September 30, 2013 to \$3.2 million for the three months ended September 30, 2014, as the Company grew its research staff to support its obligations under certain collaborative research agreements and to expand its product development efforts in preparation for research-derived revenues. Full-time research and development staffing increased from twenty-four full-time employees as of September 30, 2013 to forty-four full-time employees as of September 30, 2014. In addition to an increase in staffing expense of approximately \$0.5 million and an increase in stock-based compensation of \$0.2 million resulting from growth in headcount and increasing stock prices from September 30, 2013 to September 30, 2014, the Company increased its spending on recruiting, lab equipment and supplies in proportion to its increased research activities. In addition, the Company has continued to invest additional resources to advance its bioprinting technology during the period. Research and development expenses increased by approximately \$2.9 million, or 95%, from approximately \$3.1 million for the six months ended September 30, 2013 to approximately \$6.0 million for the six months ended September 30, 2014, as the Company increased its research staff to support its obligations under certain collaborative research agreements and to expand its product development efforts in preparation for research-derived revenues. Full-time research and development staffing increased from twenty-four full-time employees as of September 30, 2013 to forty-four full-time employees as of September 30, 2014. In addition to increases in staffing expense of approximately \$0.9 million and an increase in stock-based compensation of \$0.4 million resulting from increased headcount and increasing stock prices from September 30, 2013 to September 30, 2014, the Company increased its spending on recruiting, lab equipment, supplies and contracted services in proportion to its increased research activities. In addition, the Company has continued to invest additional resources to advance its bioprinting technology during the period.

For the three months ended September 30, 2014, general and administrative expenses were approximately \$5.8 million, an increase of \$1.8 million, or 44%, over expenses in the same period of 2013 of approximately \$4.0 million. Stock-based compensation increased \$0.6 million due to additional grants and increasing stock prices from September 30, 2013 to September 30, 2014. Staffing expense increased \$0.4 million due to an increase in administrative headcount from twelve full-time employees to sixteen full-time employees to provide strategic infrastructure in developing collaborative relationships and preparation for commercialization of research-derived product introductions. In addition, the Company incurred additional expenses for investor outreach initiatives and consulting activities in the three months ended September 30, 2014 as compared to the three months ended September 30, 2013. For the six months ended September 30, 2014, general and administrative expenses were approximately \$9.5 million, an increase of \$3.1 million, or 49%, over expenses in the same period of 2013 of approximately \$6.4 million. Stock-based compensation increased \$1.1 million due to additional grants and increasing stock prices from September 30, 2013 to September 30, 2014. Staffing expense increased \$0.7 million due to an increase in administrative headcount from twelve full-time employees to sixteen full-time employees to provide strategic infrastructure in developing collaborative relationships and preparation for commercialization of research-derived product introductions. In addition, the Company incurred additional expenses for investor outreach initiatives, consulting and legal activities in the six months ended September 30, 2014 as compared to the six months ended September 30, 2013.

Other income was less than \$0.1 million for the three months ended September 30, 2014 and consisted primarily of a gain related to the revaluation of warrant derivative liabilities. This gain was caused by a declining stock price during the quarter that decreased the value of the derivative liability. For the three months ended September 30, 2013, other expense consisted primarily of a \$4.8 million loss related to the revaluation of the warrant derivative liability due to rising stock prices during the period that caused an increase in the value of the derivative liability. In addition, the majority of the underlying warrants to which the derivative relates were exercised or converted to equity instruments during fiscal 2014, significantly lessening the impact of subsequent changes in our stock price. Other income was less than \$0.1 million for the six months ended September 30, 2014 and consisted primarily of a gain related to the revaluation of warrant derivative liabilities. This gain was caused by a declining stock price during the period that decreased the value of the derivative liability. For the six months ended September 30, 2013, other expense consisted primarily of a \$4.8 million loss related to the revaluation of the warrant derivative liability due to rising stock prices during the period that caused an increase in the value of the derivative liability. In addition, the majority of the underlying warrants to which the derivative relates were exercised or converted to equity instruments during fiscal 2014, significantly lessening the impact of subsequent changes in our stock price.

Financial Statements

Organovo Holdings, Inc.

Condensed Consolidated Balance Sheets

(in thousands except for share data)

	September 30, 2014 (Unaudited)	March 31, 2014 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	\$ 54,389	\$ 48,167
Accounts receivable	30	—
Inventory	70	63
Prepaid expenses and other current assets	616	931
Total current assets	55,105	49,161
Fixed assets, net	1,273	857
Restricted cash	79	79
Other assets, net	85	89
Total assets	\$ 56,542	\$ 50,186
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 530	\$ 326
Accrued expenses	1,559	822
Deferred rent	615	345
Deferred revenue	140	13
Capital lease obligation	10	10
Warrant liabilities	258	377
Total current liabilities	3,112	1,893
Deferred revenue, net of current portion	1	4

Capital lease obligation, net of current portion	1	5
Total liabilities	\$ 3,114	\$ 1,902
Commitments and Contingencies (Note 4)		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 80,404,648 and 78,113,639 shares issued and outstanding at September 30, 2014 and March 31, 2014, respectively	80	78
Additional paid-in capital	160,852	140,419
Accumulated deficit	(107,504)	(92,213)
Total stockholders' equity	53,428	48,284
Total Liabilities and Stockholders' Equity	\$ 56,542	\$ 50,186

Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands except share and per share data)

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Six Months Ended September 30, 2014	Six Months Ended September 30, 2013
Revenues				
Collaborations	\$ 45	\$ 23	\$ 114	\$ 117
Grants	5	—	35	12
Total Revenues	50	23	149	129
Selling, general, and administrative expenses	5,777	4,003	9,472	6,361
Research and development expenses	3,229	1,622	6,043	3,104
Loss from Operations	(8,956)	(5,602)	(15,366)	(9,336)
Other Income (Expense)				
Change in fair value of warrant liabilities	94	(4,787)	64	(4,811)
Loss on disposal of fixed assets	(3)	—	(3)	(4)
Interest expense	—	—	—	(13)
Interest income	7	3	14	7
Total Other Income (Expense)	98	(4,784)	75	(4,821)
Net Loss	\$ (8,858)	\$ (10,386)	\$ (15,291)	\$ (14,157)

Net loss per common share—basic and diluted	\$	(0.11)	\$	(0.14)	\$	(0.19)	\$	(0.21)
Weighted average shares used in computing net loss per common share—basic and diluted	78,933,884		72,716,031		78,589,521		68,776,718	

Organovo Holdings, Inc.

**Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)**

	Six Months Ended		Six Months Ended	
	September 30, 2014		September 30, 2013	
Cash Flows From Operating Activities				
Net loss	\$	(15,291)	\$	(14,157)
Adjustments to reconcile net loss to net cash used in operating activities:				
Loss on disposal of fixed assets		3		4
Depreciation and amortization		208		190
Change in fair value of warrant liabilities		(64)		4,811
Expense associated with warrant modification		—		12
Stock-based compensation		3,634		2,088
Amortization of warrants issued for services		469		72
Increase (decrease) in cash resulting from changes in:				
Grants receivable		—		101
Accounts receivable		(30)		—
Inventory		(7)		14
Prepaid expenses and other assets		113		(49)
Accounts payable		204		(164)
Accrued expenses		737		833
Deferred rent		223		(30)
Deferred revenue		124		19
Net cash used in operating activities		(9,677)		(6,256)
Cash Flows From Investing Activities				
Deposits released from restriction		—		50
Purchases of fixed assets		(576)		(176)
Net cash used in investing activities		(576)		(126)
Cash Flows From Financing Activities				
Proceeds from issuance of common stock and exercise of warrants, net		16,291		44,096
Proceeds from exercise of stock options		188		20
Principal payments on capital lease obligation		(4)		(5)

Net cash provided by financing activities	16,475	44,111
Net Increase in Cash and Cash Equivalents	6,222	37,729
Cash and Cash Equivalents at Beginning of Period	48,167	15,628
Cash and Cash Equivalents at End of Period	\$ 54,389	\$ 53,357

Supplemental Disclosure of Cash Flow Information:

Interest	\$ —	\$ —
Income Taxes	\$ —	\$ —

About Organovo Holdings, Inc.

Organovo designs and creates functional, three-dimensional human tissues for medical research and therapeutic applications. The Company is collaborating with pharmaceutical and academic partners to develop human biological disease models in three dimensions. These 3D human tissues have the potential to accelerate the drug discovery process, enabling treatments to be developed faster and at lower cost. The Company plans to market the first product of a planned portfolio offering, 3D Human Liver Tissue for use in Toxicology and other preclinical drug testing prior to the end of 2014, and remains on track to bring this breakthrough technology to customers. In addition to numerous scientific publications, the Company's technology has been featured in The Wall Street Journal, Time Magazine, The Economist, and numerous others. Organovo is changing the shape of medical research and practice. Learn more at www.organovo.com

Safe Harbor Statement

Any statements contained in this press release that do not describe historical facts may 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 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 based on its technology; the expected benefits and efficacy of the Company's products and technology; the market acceptance of the Company's products; and the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in our filings with the SEC, including our annual report on Form 10-K filed with the SEC on June 10, 2014 and its report on Form 10-Q filed with the SEC on November 7, 2014, as well as our other filings with the SEC. 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 we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do 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.

SOURCE Organovo Holdings, Inc.

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