

Organovo Highlights Liver Toxicology Achievement, Reports Q1 Fiscal 2015 Results

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SAN DIEGO, Aug. 12, 2014 /PRNewswire/ -- Organovo Holdings, Inc. (NYSE MKT: ONVO) ("Organovo"), a three-dimensional biology company focused on delivering pioneering 3D bioprinting technology, has reported its first quarter, fiscal 2015, results and provided highlights of its recent activities.

During the quarter, Organovo demonstrated, in collaboration with a major pharmaceutical company, that its 3D Human Liver System could detect the toxicity of a drug that had previously been deemed safe in standard preclinical animal studies and *in vitro* toxicity tests but caused liver damage upon clinical use. The toxic profile of the compound was only discovered after use in a large number of patients and after significant expense.

Keith Murphy, chairman and chief executive officer of Organovo, commented on the results: "Organovo met a key challenge in this recent quarter. While we knew our liver tissue showed metabolic activity and basic toxicology results comparable to native tissue, we had to ask the question: could it be predictive of drug problems where other methods have failed? These results demonstrate clearly for the first time that our tissue has been able to detect drug-induced liver injury that other methods in the past failed to predict. With this data in hand, we are continuing to push progress in the commercialization of our 3D Liver Tissue. We remain on track for commercial release of our 3D Human Liver Tissue later this calendar year."

Recent Corporate Highlights:

- Key opinion leader reported Organovo's 3D Human Liver Tissue was able to establish the toxicity of toxic drug known to induce liver injury in humans that did not show toxicity in animal and other pre-clinical testing, an achievement historically unmet by animal models or other liver cell model systems
- Initiated contracting for toxicity testing using its 3D Human Liver Tissue, for selected clients, in advance of its scheduled commercial release
- Entered into additional agreements to utilize 3D bio-printed tissue in drug discovery settings
- Reported that its 3D bio-printed tissues enabled researchers to make compartment-specific assessments (i.e., epithelium, stroma, vasculature) of drug response — something that is not currently possible outside of *in vivo* models to date
- Announced an agreement with the University of Queensland directed toward development of source cell lines for 3D kidney tissue bioprinting activities
- Appointed Gregory T. Lucier, former Chairman and CEO of Life Technologies, as a corporate advisor
- Announced Annual Stockholder meeting will be held on August 20, 2014

On August 6th, the Company announced the appointment of Greg Lucier as a corporate advisor. In the role, Mr. Lucier will advise management relative to the commercial release of the Company's 3D Human Liver Tissue, scheduled to be launched by the end of November, 2014.

On July 11th, the Company announced its annual meeting of stockholders will be held on August 20th, at 9:00 a.m. at its corporate headquarters in San Diego. The notice of meeting and related materials were mailed to stockholders of record on July 11th.

On June 26th, the Company reported that a key opinion leader reported positive results from a collaborative study conducted with Organovo scientists using Organovo's 3D Human Liver Tissues.

On April 11th, the Company reported a sponsored research agreement with the University of Queensland. The agreement calls for the development of source cell lines for 3D kidney tissue bioprinting activities.

On April 10th, the Company announced results of its initial study of 3D breast tissues generated with its NovoGen MMX Bioprinter™ in breast cancer models, which demonstrated that utilizing 3D tissues may enable researchers to make compartment-specific assessments (i.e., epithelium, stroma, and vasculature) of drug response — something that is not currently possible outside of in vivo models. The results were presented at the annual meeting of the American Association for Cancer Research (AACR) held on April 5-9, 2014 in San Diego, California.

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 August 8, 2014. Please reference that document for additional information. Because Organovo's fiscal year end is March 31, the period from April to June 2014 is considered its first quarter for fiscal year 2015 (Q1 FY2015).

As of June 30, 2014, the Company had cash and cash equivalents of approximately \$44.9 million and an accumulated deficit of \$98.6 million. The Company also had negative cash flow from operations of \$3.4 million during the three months ended June 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 June 30, 2014, the Company had total current assets of approximately \$45.7 million and current liabilities of approximately \$3.1 million, resulting in working capital of \$42.6 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 by operating activities for the three months ended June 30, 2014 was approximately \$3.4 million as compared to \$2.7 million used in operating activities for the three months ended June 30, 2013. This \$0.7 million increase in cash usage can be attributed to a \$2.7 million increase in operating expenses, partially offset by an overall increase of \$0.7 million of non-cash expenses included in operations, including share-based compensation, depreciation and amortization, and a decrease in working capital.

Net cash used in investing activities was approximately \$0.2 million and \$0.1 million for the three months ended June 30, 2014 and 2013, respectively. This increase can be attributed to increased capital spending as the Company expands its research capabilities. Net cash from financing activities increased from less than \$0.1 million used during the three months ended June 30, 2013 to \$0.3 million provided during the three months ended June 30, 2014.

For the three months ended June 30, 2014, total revenues of \$0.1 million were consistent with the \$0.1 million in revenues for the same period in 2013. For both periods, the majority of revenues were derived from collaborative research agreements.

Operating expenses increased approximately \$2.7 million, or 71%, from approximately \$3.8 million for the three months ended June 30, 2013 to \$6.5 million for the three months ended June 30, 2014. Of this increase, \$1.4 million is relates to increased selling, general and administrative expense while the other \$1.3 million relates to increased investment in research and development. These increases are 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.

For the three months ended June 30, 2014, research and development expenses increased by approximately \$1.3 million, or 87%, over the same period in 2013, 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 24 full-time employees as of June 30, 2013 to 38 full-time employees as of June 30, 2014. In addition to increases in payroll and benefits expense of approximately \$0.4 million and an increase in share-based compensation of \$0.2 million resulting from increased staffing levels and increasing

stock prices from June 30, 2013 to June 30, 2014, the Company increased its spending on 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 3D bio-printing technology during the period.

For the three months ended June 30, 2014, general and administrative expenses were approximately \$3.7 million, an increase of \$1.4 million, or 61%, over expenses in the same period of 2013 of approximately \$2.3 million. Share-based compensation increased \$0.6 million due to additional grants and increasing stock prices from June 30, 2013 to June 30, 2014. Staffing expense increased \$0.3 million due to an increase in administrative headcount from 11 full-time employees to 14 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 legal costs in the three months ended June 30, 2014 as compared to the three months ended June 30, 2013.

Other expense was less than \$0.1 million for the three months ended June 30, 2014 and 2013, and consisted primarily of expense related to the revaluation of warrant derivative liabilities.

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 as well as our other filings with the Securities and Exchange Commission. 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.

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

	June 30, 2014	March 31, 2014
	(Unaudited)	(Audited)
Assets		
Current Assets		
Cash and cash equivalents	\$ 44,897	\$ 48,167
Accounts receivable	60	—
Inventory	71	63
Prepaid expenses and other current assets	712	931
Total current assets	45,740	49,161
Fixed assets, net	1,001	857
Restricted cash	79	79
Other assets, net	88	89
Total assets	\$ 46,908	\$ 50,186
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 839	\$ 326
Accrued expenses	1,739	1,167
Deferred revenue	144	13
Capital lease obligation	11	10
Warrant liabilities	352	377
Total current liabilities	3,085	1,893
Deferred revenue, net of current portion	3	4
Capital lease obligation, net of current portion	2	5
Total liabilities	\$ 3,090	\$ 1,902
Commitments and Contingencies (Note 4)		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 78,282,460 and 78,113,639 shares issued and outstanding at June 30, 2014 and March 31, 2014, respectively	78	78
Additional paid-in capital	142,386	140,419
Accumulated deficit	(98,646)	(92,213)
Total stockholders' equity	43,818	48,284
Total Liabilities and Stockholders' Equity	\$ 46,908	\$ 50,186

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

Three Months Ended
June 30, 2014 **Three Months Ended**
June 30, 2013

Revenues		
Collaborations	\$ 69	\$ 94
Grants	30	12
Total Revenues	99	106
Selling, general, and administrative expenses	3,695	2,358
Research and development expenses	2,814	1,482
Loss from Operations	(6,410)	(3,734)
Other Income (Expense)		
Change in fair value of warrant liabilities	(30)	(23)
Loss on disposal of fixed assets	—	(4)
Interest expense	—	(13)
Interest income	7	3
Total Other Income (Expense)	(23)	(37)
Net Loss	\$ (6,433)	\$ (3,771)
Net loss per common share—basic and diluted	\$ (0.08)	\$ (0.06)
Weighted average shares used in computing net loss per common share—basic and diluted	78,241,373	64,794,144

Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows (in thousands)

Three Months Ended
June 30, 2014 **Three Months Ended**
June 30, 2013

Cash Flows From Operating Activities		
Net loss	\$ (6,433)	\$ (3,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	4
Depreciation and amortization	96	93
Change in fair value of warrant liabilities	30	23
Expense associated with warrant modification	—	12
Stock-based compensation	1,537	802
Amortization of warrants issued for services	141	72
Increase (decrease) in cash resulting from changes in:		
Grants receivable	—	101
Accounts receivable	(60)	—
Inventory	(8)	3
Prepaid expenses and other assets	117	(72)
Accounts payable	513	(267)
Accrued expenses	572	363

Deferred revenue	130	(26)		
Net cash used in operating activities	(3,365)	(2,663)		
Cash Flows From Investing Activities				
Deposits released from restriction	—	50		
Purchases of fixed assets	(238)	(163)		
Net cash used in investing activities	(238)	(113)		
Cash Flows From Financing Activities				
Proceeds from issuance of common stock and exercise of warrants, net	224	—		
Proceeds from exercise of stock options	111	—		
Principal payments on capital lease obligation	(2)	(3)		
Net cash provided by (used in) financing activities	333	(3)		
Net Decrease in Cash and Cash Equivalents	(3,270)	(2,779)		
Cash and Cash Equivalents at Beginning of Period	48,167	15,628		
Cash and Cash Equivalents at End of Period	\$	44,897	\$	12,849
Supplemental Disclosure of Cash Flow Information:				
Interest	\$	—	\$	—
Income Taxes	\$	—	\$	—

SOURCE Organovo Holdings, Inc.

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