

Organovo Holdings, Inc. Reports Third Quarter Results

February 9, 2015 2:38 PM ET

SAN DIEGO, Feb. 9, 2015 /PRNewswire/ -- Organovo Holdings, Inc. (NYSE MKT: ONVO) ("Organovo"), a three-dimensional biology company focused on delivering pioneering 3D bioprinting technology, has reported its third quarter fiscal 2015 results.

Keith Murphy, chairman and chief executive officer of Organovo, commented on the results, "Organovo has had a successful launch of its exVive3D™ Human Liver Tissue, and customer response continues to be strong. Our contracted customers include companies from among the top 25 global pharma companies, smaller public pharma companies, and private venture-backed pharma companies. Conversion of potential customers, those requesting quotes, to signed contracts has been high, with a win rate over 80% to date. We are encouraged that we have a high win rate, that our commercial pricing continues to be supported, and that we have received repeat business."

"Continued scientific studies have extended our knowledge of the functionality of the Company's exVive3D bioprinted liver tissues, including the first demonstration of the ability for them to be used in studying the metabolism of drugs. We remain confident that our tissues provide a scientific advantage that is well perceived by pharma customers that this advantage will continue to grow as we expand our demonstration of the superiority of these tissues, and that these results will translate into commercial wins for Organovo and its shareholders."

Organovo's quarter ending December 31, 2014 featured a number of corporate milestones and successes, including:

- Won the Diagnostics & Research Tools category for the 2014 Most Innovative New Product Awards, sponsored by CONNECT, a regional program that catalyzes the creation of innovative technology and life sciences products.
- Released the exVive3D™ Human Liver Tissue for preclinical drug discovery testing, intended to provide human-specific data to aid in the prediction of liver tissue toxicity or ADME outcomes in later stage preclinical drug discovery programs. The tissues produce important liver proteins including albumin, fibrinogen and transferrin, synthesize cholesterol, and possess inducible cytochrome P450 enzymatic activities, including CYP 1A2 and CYP 3A4. They have successfully differentiated between structurally related compounds with known toxic and non-toxic profiles in human beings, and the model has also been employed successfully in the detection of metabolites at extended time points *in vitro*. Importantly, the configuration of the bioprinted liver tissues enables both biochemical and histologic data to be collected so that a customer can investigate compound responses at multiple levels.
- Formed collaboration with Yale School of Medicine to develop 3-D organ tissues for surgical transplantation research, made possible by a generous gift from the Methuselah Foundation. The collaboration combines their expertise and technology with our own, representing one important step in progressing towards developing implantable, therapeutic tissues.
- Kirk Malloy, Ph.D. joined Board of Directors - Dr. Malloy has held management and executive leadership positions in rapidly growing life science and diagnostics companies for 18 years. He is currently Senior Vice President and General Manager of Life Sciences at Illumina, a leading developer and supplier of genetic analysis instrumentation, assays and software for the life science and diagnostics markets, and is experienced in advancing industry-changing technology platforms and building commercial growth in the life science markets

The Company has previously commented that revenue in the quarter ending December 31, 2014 and the year ending March 31, 2015 is expected to come primarily from research services associated with the pre-release availability of its exVive3D™ Human Liver Tissue. The Company expects commercial revenue from post-launch activity to be recognized no earlier than the quarter ending June 30, 2015.

The Company continues in its development of a 3D bioprinted kidney tissue that has the potential to significantly improve researchers' ability to study kidney function in an *in vitro* model. The kidney tissue remains on track for a mid-2016 (calendar year) release. Additionally, the Company continues to advance simple bioprinted tissues for the

potential direct treatment of patients, which are currently at the preclinical research phase.

Financial Summary

A summary of the Company's financial results for the third 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 February 6, 2015. Please refer to that document for additional information. Because Organovo's fiscal year end is March 31, the period from October to December 2014 is the third quarter of fiscal year 2015 (Q3 FY2015).

As of December 31, 2014, the Company had cash and cash equivalents of approximately \$50.0 million and an accumulated deficit of \$114.5 million. The Company also had negative cash flow from operations of \$14.0 million during the nine months ended December 31, 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 December 31, 2014, the Company had total current assets of approximately \$50.5 million and current liabilities of approximately \$3.7 million, resulting in working capital of \$46.8 million. At March 31, 2014, we 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 nine months ended December 31, 2014 was approximately \$14.0 million as compared to \$10.2 million used in operating activities for the nine months ended December 31, 2013. This \$3.8 million increase in cash usage can be attributed to an \$8.4 million increase in operating expenses, partially offset by an overall increase of \$2.8 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 \$0.9 million and \$0.1 million for the nine months ended December 31, 2014 and 2013, respectively. This increase can be attributed to increased capital spending as the Company increased its facility space to expand its research capabilities.

Net cash provided by financing activities decreased from \$44.5 million provided during the nine months ended December 31, 2013 to \$16.7 million provided during the nine months ended December 31, 2014 due to lower net proceeds from the issuance of common stock during the nine months ended December 31, 2014.

For the three months ended December 31, 2014, total revenue of \$155,000 was \$20,000 or approximately 15% higher than total revenue for the three months ended December 31, 2013. Product and service revenue of \$139,000 for the third quarter of fiscal 2015 versus \$0 in the third quarter of fiscal 2014 represents revenue from the initial shipment of exVive3D™ Human Liver Tissue product and from exVive3D™ Human Liver Tissue research services. The Company announced the commercial launch of its exVive3D™ Human Liver Tissue in November 2014. The majority of revenues for the third quarter of fiscal 2015 were derived from research service agreements and product sales related to the exVive3D™ Human Liver Tissue, whereas revenues for the third quarter of fiscal 2014 were derived mainly from existing collaborations and from research funded by grants.

For the nine months ended December 31, 2014 and 2013, total revenues were approximately \$0.3 million. Despite relatively flat revenue on a period-to-period comparative basis, there was a substantial change in the source of revenues as prior year revenue was primarily sourced from collaborations, whereas nearly half of the current year-to-date revenues reflect pre-launch shipments of exVive3D™ Human Liver Tissue product and from exVive3D™ Human Liver Tissue services. The Company announced the commercial launch of its exVive3D™ Human Liver Tissue in November 2014; post-launch revenues are expected to be primarily derived from service agreements and product sales and the respective revenues therefrom are not expected to be recognized on the Company's statement of income for approximately four to six months after the work on each respective project is started.

Operating expenses increased approximately \$2.3 million, or 48%, from approximately \$4.8 million for the three months ended December 31, 2013 to \$7.1 million for the three months ended December 31, 2014. Of this increase, \$1.5 million relates to increased selling, general and administrative expense while the other \$0.8 million relates to increased investment in research and development. Operating expenses increased approximately \$8.4 million, or 59%, from approximately \$14.2 million for the nine months ended December 31, 2013 to \$22.6 million for the nine months ended December 31, 2014. Of this increase, \$4.7 million is related to increased selling, general and administrative expense while the other \$3.8 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 associated with the commercial launch of our exVive3D™ Human Liver Tissue in November 2014, 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 36% from approximately \$2.4 million for the three months ended December 31, 2013 to \$3.2 million for the three months ended December 31, 2014, as the Company increased its research staff to support its obligations under existing collaborative research agreements and to expand its product development efforts in preparation for commercial research services associated with the commercial launch of the Company's first product in the third quarter of fiscal 2015. Full-time research and development staffing increased from twenty-six full-time employees as of December 31, 2013 to forty-nine full-time employees as of December 31, 2014, resulting in an increase in staffing expense of approximately \$0.5 million, an increase in stock-based compensation of \$0.2 million and an increase in facility costs of approximately \$0.4 million. Partially offsetting these increases was a decrease in bioprinter development costs of approximately \$0.3 million as compared to the same quarter of the previous year. In fiscal 2014, the Company began an initiative to advance its bioprinting technology; however, the most significant of these expenditures had already been incurred prior to the third quarter of fiscal 2015. Research and development expenses increased by approximately \$3.8 million, or 69%, from approximately \$5.5 million for the nine months ended December 31, 2013 to approximately \$9.3 million for the nine months ended December 31, 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-six full-time employees as of December 31, 2013 to forty-nine full-time employees as of December 31, 2014. In addition to increases in staffing expense of approximately \$1.2 million and an increase in stock-based compensation of \$0.6 million resulting from increased headcount and additional grants, the Company increased its spending on recruiting, lab equipment, supplies and contracted services in proportion to its increased research activities.

For the three months ended December 31, 2014, general and administrative expenses were approximately \$3.9 million, an increase of \$1.5 million, or 63%, over expenses in the same period of the previous year of approximately \$2.4 million. This increase was related to an increase in staffing expense of \$0.4 million due to an increase in administrative headcount from thirteen full-time employees to eighteen full-time employees to provide strategic infrastructure in developing collaborative relationships and preparation for commercialization of research-derived product introductions as well as an increase in stock-based compensation of \$0.6 million due to additional grants. In addition, legal and other corporate expenses increased \$0.5 million. For the nine months ended December 31, 2014, general and administrative expenses were approximately \$13.3 million, an increase of \$4.7 million, or 54%, over expenses in the same period of 2013 of approximately \$8.7 million. Stock-based compensation increased \$1.8 million due to additional grants and increasing stock prices from December 31, 2013 to December 31, 2014. Staffing expense increased \$1.0 million due to an increase in administrative headcount from thirteen full-time employees to eighteen 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 nine months ended December 31, 2014 as compared to the nine months ended December 31, 2013.

Other expense was less than \$0.1 million for the three months ended December 31, 2014 and consisted primarily of a loss related to the revaluation of warrant derivative liabilities. This loss was caused by an increasing stock price during the

quarter that increased the value of the derivative liability. For the three months ended December 31, 2013, other expense consisted primarily of a \$0.6 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 nine months ended December 31, 2014 and consisted primarily of interest income and 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 nine months ended December 31, 2013, other expense consisted primarily of a \$5.4 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.

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, a 3D Human Liver Tissue for use in Toxicology and other preclinical drug testing. Additional products are in development, with anticipated release for an exVive3D™ Human Kidney Tissue in the latter half 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.

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 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; and the Company's business, research, product and service 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 Securities and Exchange Commission (SEC), including our quarterly report on Form 10-Q filed with the SEC on February 6, 2015, 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.

Financial Statements

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

	December 31, 2014 (Unaudited)	March 31, 2014 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	\$ 50,027	\$ 48,167
Inventory	69	63
Prepaid expenses and other current assets	372	931
Total current assets	50,468	49,161
Fixed assets, net	1,440	857
Restricted cash	79	79
Other assets, net	83	89
Total assets	\$ 52,070	\$ 50,186
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 495	\$ 326
Accrued expenses	2,028	822
Deferred rent	646	345
Deferred revenue	241	13
Capital lease obligation	8	10
Warrant liabilities	298	377
Total current liabilities	3,716	1,893
Deferred revenue, net of current portion	44	4
Capital lease obligation, net of current portion	-	5
Total liabilities	\$ 3,760	\$ 1,902
Commitments and Contingencies (Note 4)		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 80,458,406 and 78,113,639 shares issued and outstanding at December 31, 2014 and March 31, 2014, respectively	80	78
Additional paid-in capital	162,727	140,419
Accumulated deficit	(114,497)	(92,213)
Total stockholders' equity	48,310	48,284
Total Liabilities and Stockholders' Equity	\$ 52,070	\$ 50,186

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

Three Months Ended December 31, 2014	Three Months Ended December 31, 2013	Nine Months Ended	Nine Months Ended
---	---	------------------------------	------------------------------

			December 31, 2014	December 31, 2013
Revenues				
Product and service	\$ 139	—	\$ 139	—
Collaborations	7	97	121	214
Grants	9	38	44	50
Total Revenues	155	135	304	264
Selling, general, and administrative expenses	3,878	2,379	13,350	8,740
Research and development expenses	3,238	2,382	9,281	5,487
Loss from Operations	(6,961)	(4,626)	(22,327)	(13,963)
Other Income (Expense)				
Change in fair value of warrant liabilities	(40)	(586)	24	(5,397)
Loss on disposals of fixed assets	—	—	(3)	(4)
Interest expense	—	—	—	(13)
Interest income	8	4	22	11
Total Other Income (Expense)	(32)	(582)	43	(5,403)
Net Loss	\$ (6,993)	\$ (5,208)	\$ (22,284)	\$ (19,366)
Net loss per common share—basic and diluted	\$ (0.09)	\$ (0.07)	\$ (0.28)	\$ (0.27)
Weighted average shares used in computing net loss	80,491,120	77,235,976	79,225,692	71,606,724
per common share—basic and diluted				

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

	Nine Months Ended December 31, 2014	Nine Months Ended December 31, 2013
Cash Flows From Operating Activities		
Net loss	\$ (22,284)	\$ (19,366)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	3	4
Depreciation and amortization	334	288

Change in fair value of warrant liabilities	(24)	5,397
Expense associated with warrant modification	—	12
Stock-based compensation	5,215	2,840
Amortization of warrants issued for services	556	182
Increase (decrease) in cash resulting from changes in:		
Grants receivable	—	94
Inventory	(6)	6
Prepaid expenses and other assets	318	(25)
Accounts payable	169	(330)
Accrued expenses	1,206	779
Deferred rent	254	—
Deferred revenue	268	(42)
Net cash used in operating activities	(13,991)	(10,161)
Cash Flows From Investing Activities		
Deposits released from restriction	—	9
Purchases of fixed assets	(867)	(156)
Net cash used in investing activities	(867)	(147)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	16,512	44,310
Proceeds from exercise of stock options	213	195
Principal payments on capital lease obligations	(7)	(7)
Net cash provided by financing activities	16,718	44,498
Net Increase in Cash and Cash Equivalents	1,860	34,190
Cash and Cash Equivalents at Beginning of Period	48,167	15,628
Cash and Cash Equivalents at End of Period	\$ 50,027	\$ 49,818
Supplemental Disclosure of Cash Flow Information:		
Interest	\$ —	\$ —
Income Taxes	\$ —	\$ —

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/organovo-holdings-inc-reports-third-quarter-results-300032663.html>

SOURCE Organovo Holdings, Inc.

Investor Contact, Barry Michaels, Chief Financial Officer, 858-224-1000, ext. 3, IR@organovo.com, or Gerry Amato, Amato and Partners Investor Relations, admin@amatoandpartners.com; Media Contact, Mike Renard, EVP, Commercial Operations, 858-224-1006, mrenard@organovo.com