

## Organovo Reports Q3 Fiscal 2014 Results, Provides Business Update

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SAN DIEGO, Feb. 7, 2014 /PRNewswire/ -- Organovo Holdings, Inc. (NYSE MKT: ONVO) ("Organovo"), a three-dimensional biology company focused on delivering breakthrough 3D bioprinting technology, has reported its third quarter results and provided highlights of its recent activities.

Keith Murphy, chairman and chief executive officer of Organovo, commented on the results. "The quarter continues our progress throughout our scientific, operational and business development activities. Our progress in the development of 3D Liver tissues continues to be ahead of plan, highlighted by the demonstration of 40 days of characteristic liver activity and additional evidence of appropriate response to known hepatotoxic insults. We remain on-track for releasing our first commercial liver toxicity assay product later this calendar year," Mr. Murphy stated. "Further, our new agreements are expected to assist in growing our commercial opportunities long term."

### Recent Highlights

- Announced collaboration with the National Center for Advancing Translational Sciences (NCATS) and the National Eye Institute (NEI), two institutes of the National Institutes of Health (NIH)
- Announced first delivery of 3D Liver tissue to Key Opinion Leader
- Released initial data on a 3D bioprinted human breast cancer tissue
- Achieved greater than one month performance for 3D bioprinted liver tissues
- Released additional data on its NovoGen Bioprinted 3D Liver demonstrating responsiveness to known toxins
- Announced a collaborative agreement in 3D skin tissues

On January 29<sup>th</sup>, the Company announced the first delivery of 3D Liver tissue to a Key Opinion Leader ahead of schedule, marking the achievement of a key milestone along the pathway to commercial launch of its 3D Liver tissue product.

On January 14<sup>th</sup>, the Company announced a collaboration with the National Center for Advancing Translational Sciences (NCATS) and the National Eye Institute (NEI) to develop better and more clinically predictive tissue models using Organovo's NovoGen MMX Bioprinter®. The collaboration with these two institutes from the National Institutes of Health (NIH) will include use of the NovoGen Bioprinting platform to create three-dimensional, architecturally correct, functional living tissues to help scientists develop more reliable tools for bringing safer, more effective treatments to patients on a faster timeline.

On December 18<sup>th</sup>, the Company released initial data on a 3D bioprinted human breast cancer tissue for *in vitro* screening of therapeutics targeted against cancer progression, demonstrating that NovoGen bioprinted breast cancer tissues retain compartmentalized structures with interaction between stromal and cancer cells. Formation of endothelial networks and differentiation of adipocytes were observed in these tissues, and the constructs were demonstrated to be less susceptible to tamoxifen-induced toxicity than isolated 2D cancer cells when treated with the same dose of tamoxifen for the same duration, highlighting the potential utility of this model in identifying superior drugs with greater toxicity against complex, multicellular 3D tumor models.

On December 18<sup>th</sup>, the Company also released additional data on its NovoGen Bioprinted 3D Liver, citing evidence of the formation of tight junctions in the liver tissues as evidenced by claudin staining by day 3 of tissue formation. NovoGen Bioprinted 3D Liver tissues also showed additional evidence of appropriate response to hepatotoxic insults from acetaminophen, acetaminophen in combination with ethanol, and diclofenac.

On December 5<sup>th</sup>, the Company announced it had entered into an agreement to expand its current facility from approximately 15,000 to 30,000 sq. ft. to accommodate new collaborative agreement activities and expand manufacturing

capacity for commercial launch of its first product.

On October 22<sup>nd</sup>, the Company announced achieving greater than one month performance and drug responsiveness for 3D bioprinted liver tissues, demonstrating that Organovo's 3D Liver Tissue can potentially have value in assessing toxicology problems in human liver over a long period, including sub-acute and multiple dose efforts.

## **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 on February 6, 2014. Please reference that document for additional information. At December 31, 2013, the Company had total current assets of approximately \$50.5 million and current liabilities of approximately \$2.9 million, resulting in working capital of \$47.6 million. At March 31, 2013, we had total current assets of approximately \$16.1 million and current liabilities of approximately \$8.4 million, resulting in working capital of \$7.7 million.

Net cash used in investing activities was approximately \$0.1 million and \$0.4 million for the nine months ended December 31, 2013 and December 31, 2012, respectively. Net cash provided by financing activities increased from approximately \$11.0 million provided during the nine months ended December 31, 2012 to \$44.5 million provided during the nine months ended December 31, 2013. This increase was primarily due to the inclusion of \$43.4 million in net proceeds from the issuance of common stock in August, 2013.

As of December 31, 2013, the Company had 77,424,956 total issued and outstanding shares of Common Stock, and five year warrants for the opportunity to purchase an additional 1,203,656 shares of Common Stock at exercise prices between \$0.85 and \$1.00 per share and 313,870 warrants with terms between two and five years and exercise prices between \$2.21 and \$7.36 per share. If all warrants were exercised on a cash basis, the Company would realize approximately \$2.4 million additional gross proceeds. In aggregate, issued and outstanding common stock, shares underlying outstanding warrants, and shares reserved for the 2008 and 2012 incentive plans total 89,195,246 shares of common stock as of December 31, 2013.

Organovo is a development stage company, and does not expect product-based revenue until the commercial release of its liver toxicity assay product, currently planned to be before the end of November, 2014. Since inception, the Company has periodically received revenue from grants and collaborative research agreements. Revenue recognition from these sources, however, is intermittent and not necessarily indicative of the significance of the Company's achievements related to those grants and partnerships.

Total revenues for the quarter of \$0.1 million were \$0.2 million or 67% below the approximately \$0.3 million in revenues for the same period in 2012. Collaborative research revenues of less than \$0.1 million decreased \$0.2 million or 67% from the same period of prior year of approximately \$0.3 million in revenues. This decrease reflects declining activity under an existing collaborative agreement and the conclusion of a previous collaborative research agreement during the quarter, partially offset by increasing revenue contributions from three recently signed agreements.

The Company doubled its research and development expenses during the quarter over the same period last year, while general and administrated expenses increased 14%. The Company has continued to prudently expand its scientific capabilities and resources, and increased its headcount from 29 full-time employees as of December 31, 2012 to 39 full-time employees as of December 31, 2013 to support its obligations under certain collaborative research agreements and to expand its product development efforts in preparation for product and research based service revenues. These staff increases resulted in increased staffing expenses of approximately \$0.4 million or 34% over the same period in 2012. In addition, share-based compensation expense increased \$0.6 million for the three months ended December 31, 2013 due to initial grants to new employees during the year and a significant increase in the Company's stock price from December 31, 2012 to December 31, 2013. Total operating expenses increased approximately \$1.5 million or 45% in the three months ended December 31, 2013 over the same period in 2012, from approximately \$3.3 million in 2012 to \$4.8 million in 2013.

The approximate \$6.1 million decrease in other expense for the three month period ending December 31, 2013 compared

to the same period of the prior year, was primarily related to the change in fair value associated with the warrants issued in our 2012 Private Placement financing. During the first quarter of calendar 2012, we issued warrants to purchase 6,099,195 shares of our common stock to the placement agent and warrants to purchase 15,247,987 shares of our common stock to investors in the Private Placement. The warrants issued to the placement agent and Private Placement investors were determined to be derivative liabilities as a result of the anti-dilution provisions in the warrant agreements that may result in an adjustment to the warrant exercise price. As a result of increasing stock prices during the three months ended December 31, 2012, the fair value of the derivative liability increased, resulting in the recognition of other expense of approximately \$4.7 million. The majority of the underlying warrants have been exercised prior to December 31, 2013 or modified and reclassified as equity instruments. The increase in the fair value of the warrant liability during the three months ended December 31, 2013 was \$0.6 million, which was recognized to other expense during the period. The Company will continue to revalue the derivative liability at each balance sheet date until the securities to which the derivative liabilities relate are exercised or expire. In addition, the Company completed a warrant tender offer in December 2012 to amend certain outstanding warrants to include a reduction of the exercise price of the warrants from \$1.00 per share to \$0.80 per share of common stock. In connection with the transaction, the Company recognized an expense for the inducement to exercise the warrants of approximately \$1.9 million.

### **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. 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](http://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; 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 prospectus supplement filed with the SEC on August 2, 2013 and our transition report on Form 10-KT filed with the SEC on May 24, 2013 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**  
**(A development stage company)**  
**Condensed Consolidated Balance Sheets**  
**(in thousands except per share data)**

	December 31, 2013 (Unaudited)	March 31, 2013 (Audited)
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 49,818	\$ 15,628
Grant receivable	7	101
Inventory	82	88
Prepaid expenses and other current assets	622	327
Total current assets	50,529	16,144
Fixed assets—Net	915	1,045
Restricted cash	79	88
Other assets—Net	92	98
Total assets	\$ 51,615	\$ 17,375
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 311	\$ 641
Accrued expenses	1,559	780
Deferred revenue	15	53
Capital lease obligation	10	10
Warrant liabilities	1,006	6,898
Total current liabilities	2,901	8,382
Deferred revenue, net of current portion	5	9
Capital lease obligation, net of current portion	8	15
Total liabilities	\$ 2,914	\$ 8,406
<b>Commitments and Contingencies (Note 5)</b>		
<b>Stockholders' Equity</b>		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 77,424,956 and 64,686,919 shares issued and outstanding at December 31, 2013 and March 31, 2013, respectively	77	65
Additional paid-in capital	134,355	75,269
Deficit accumulated during the development stage	(85,731)	(66,365)
Total stockholders' equity	48,701	8,969
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 51,615</b>	<b>\$ 17,375</b>

**Unaudited Condensed Consolidated Statements of Operations**  
**(in thousands except per share data)**

	<b>Three Months Ended December 31, 2013</b>				<b>Nine Months Ended December 31, 2012</b>				<b>Period from April 19, 2007 (Inception) Through December 31, 2013</b>
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>	<b>2013</b>
<b>Revenues</b>									
Product	\$	—	\$	—	\$	—	\$	—	\$ 224
Collaborations	97		282		214		915		2,110
Grants	38		67		50		162		993
<b>Total Revenues</b>	<b>135</b>		<b>349</b>		<b>264</b>		<b>1,077</b>		<b>3,327</b>
Cost of product revenue	—		—		—		—		134
Selling, general, and administrative expenses	2,402		2,141		8,807		6,178		21,346
Research and development expenses	2,359		1,130		5,420		2,889		13,502
<b>Loss from Operations</b>	<b>(4,626)</b>		<b>(2,922)</b>		<b>(13,963)</b>		<b>(7,990)</b>		<b>(31,655)</b>
<b>Other Income (Expense)</b>									
Fair value of warrant liabilities in excess of proceeds received	—		—		—		—		(19,019)
Change in fair value of warrant liabilities	(586)		(4,740)		(5,397)		3,575		(27,369)
Financing transaction costs in excess of proceeds received	—		—		—		—		(2,130)
Loss on inducement to exercise warrants	—		(1,904)		—		(1,904)		(1,904)
Gain (loss) on disposal of fixed assets	—		—		(4)		(158)		(162)
Interest expense	—		—		(13)		—		(3,484)
Interest income	4		2		11		5		22
Other income (expense)	—		—		—		—		(30)
<b>Total Other Income (Expense)</b>	<b>(582)</b>		<b>(6,642)</b>		<b>(5,403)</b>		<b>1,518</b>		<b>(54,076)</b>
<b>Net loss</b>	<b>\$ (5,208)</b>	<b>\$ (9,564)</b>	<b>\$ (19,366)</b>	<b>\$ (6,472)</b>	<b>\$ (85,731)</b>				
Net loss per common share—basic and diluted	\$ (0.07)	\$ (0.20)	\$ (0.27)	\$ (0.14)					
Weighted average shares used in computing net loss per common	77,235,976	48,428,186	71,606,724	45,224,906					

share—basic and diluted

**Organovo Holdings, Inc**

(A development stage company)

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

	<b>Nine Months Ended December 31, 2013</b>	<b>Nine Months Ended December 31, 2012</b>	<b>Period from April 19, 2007 (Inception) Through December 31, 2013</b>
<b>Cash Flows From Operating Activities</b>			
Net loss	\$ (19,366)	\$ (6,472)	\$ (85,731)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred financing costs	—	—	438
Loss on disposal of fixed assets	4	158	162
Depreciation and amortization	288	178	719
Amortization of debt discount	—	—	2,084
Interest accrued on convertible notes payable	—	—	495
Fair value of warrant liabilities in excess of proceeds	—	—	19,019
Change in fair value of warrant liabilities	5,397	(3,575)	27,369
Loss on inducement to exercise warrants	—	1,904	1,904
Expense associated with warrant modification	12	—	77
Stock-based compensation	2,840	1,431	5,140
Amortization of warrants issued for services	182	556	999
Warrants issued in connection with exchange agreement	—	—	528
Increase (decrease) in cash resulting from changes in:		—	
Grants receivable	94	(162)	(7)
Inventory	6	(414)	(745)
Prepaid expenses and other assets	(25)	(36)	(280)
Accounts payable	(330)	(16)	311
Accrued expenses	779	580	1,559
Deferred revenue	(42)	(269)	20
<b>Net cash used in operating activities</b>	<b>(10,161)</b>	<b>(6,137)</b>	<b>(25,939)</b>
<b>Cash Flows From Investing Activities</b>			
Deposits released from restriction (restricted cash deposits)	9	(50)	(79)
Purchases of fixed assets	(156)	(351)	(1,077)
Purchases of intangible assets	—	—	(114)
<b>Net cash used in investing activities</b>	<b>(147)</b>	<b>(401)</b>	<b>(1,270)</b>

<b>Cash Flows From Financing Activities</b>				
Proceeds from issuance of convertible notes payable	—	—		4,630
Proceeds from issuance of common stock and exercise of warrants, net	44,310	10,991		72,748
Proceeds from exercise of stock options	195	18		213
Proceeds from issuance of related party notes payable	—	—		250
Principal payments on capital lease obligation	(7)	(7)		(16)
Repayment of related party notes payable	—	—		(250)
Repayment of convertible notes and interest payable	—	—		(110)
Deferred financing costs	—	—		(438)
<b>Net cash provided by financing activities</b>	<b>44,498</b>	<b>11,002</b>		<b>77,027</b>
<b>Net Increase in Cash and Cash Equivalents</b>	<b>34,190</b>	<b>4,464</b>		<b>49,818</b>
<b>Cash and Cash Equivalents at Beginning of Period</b>	<b>15,628</b>	<b>10,353</b>		<b>—</b>
<b>Cash and Cash Equivalents at End of Period</b>	<b>\$</b>	<b>49,818 \$</b>	<b>14,817 \$</b>	<b>49,818</b>
<b>Supplemental Disclosure of Cash Flow Information:</b>				
Interest	\$	— \$	— \$	10
Income Taxes	\$	— \$	— \$	3

SOURCE Organovo Holdings, Inc.

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