Organovo Reports Q2 Fiscal 2014 Results, Provides Business Update

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SAN DIEGO, Nov. 12, 2013 /PRNewswire/ -- Organovo Holdings, Inc. (NYSE MKT: ONVO) ("Organovo"), a three-dimensional biology company focused on delivering breakthrough 3D bioprinting technology, has reported its second quarter results and provided highlights of its recent activities.

Keith Murphy, Chairman and Chief Executive Officer of Organovo, commented on the results, "The quarter was marked by excellent progress across financial, operational and business development areas. Our progress in the development of 3D liver tissues has been exceptional, including the demonstration of 40 days of viability and functionality, and we remain on-track for releasing our first commercial liver toxicity assay product in calendar 2014. Our new strategic agreements are expected to assist in growing our commercial opportunities long term. With our recent successful public equity offering, Organovo now has cash reserves in excess of \$50 million to enable us to increase research and development efforts, advance additional projects, and position the Company to take advantage of multiple commercial opportunities using our 3D tissues. We have strengthened our Board of Directors with the addition of Ms. Tamar Howson and Richard Heyman, Ph.D., and we look forward to achieving significant milestones in calendar 2014."

Recent Highlights

- Achieved greater than one month performance and drug responsiveness for 3D bioprinted liver tissues
- Listed common stock on the NYSE MKT, began trading on July 11th
- Successfully completed a \$46.6 million public offering on August 7th
- Elected Ms. Howson and Dr. Heyman to the Company's Board of Directors
- Organovo and Methuselah Foundation announced funding of bioprinting research at research institutions
- Organovo entered into new agreements with strategic partners to expand the use of our 3D tissues
- Appointed Continental Stock Transfer & Trust as our transfer agent and registrar

On July 9th, Organovo announced that its common stock had been approved for listing on the New York Stock Exchange MKT. Trading commenced on the NYSE MKT on July 11th, and the Company rang the opening bell at the NYSE on July 15th.

On July 24th, Organovo announced that Methuselah Foundation had initiated a campaign in which it will fund research at major research institutions using Organovo's proprietary NovoGen Bioprinting technology. The program will feature grants of research funding from the non-profit Methuselah Foundation to major academic research centers engaged in cutting-edge biomedical research. Eligible institutions will include public and private research universities and private non-profit research institutes. Under the program, Methuselah Foundation will divide a donation of at least \$500,000 in direct funding for research projects across several institutions.

On August 7th, Organovo successfully completed a public offering in which it raised gross proceeds of \$46.6 million through the issuance of 10,350,000 shares of its common stock.

On August 21st, Organovo held its Annual Meeting of Stockholders and elected Ms. Howson and Dr. Heyman, as Class II directors to hold office until the 2016 Annual Meeting of Stockholders. In addition, stockholders approved an amendment to the 2012 Equity Incentive Plan to increase the number of shares of common stock issuable under the Plan by 5,000,000 shares.

On October 22nd, Organovo provided a summary of the data presented at the 3rd Annual Cell Therapy Bioprocessing Conference in Bethesda, MD. Building on data first presented at the Experimental Biology conference in April 2013, the Company presented data demonstrating retention of key liver functions in bioprinted tissues for longer than one month.

Financial Summary

A summary of the Company's financial results for the second fiscal quarter follows, but is not intended to replace the financial disclosure enclosed in the Quarterly Report on Form 10-Q the Company filed on November 8, 2013. Please reference that document for additional information. At September 30, 2013, the Company had total current assets of approximately \$53.7 million and current liabilities of approximately \$2.9 million, resulting in working capital of \$50.8 million, as compared to balances of \$16.1 million, \$8.4 million, and \$7.7 million, respectively at March 31, 2013. Net cash used by operating activities fiscal year-to-date was approximately \$6.3 million as compared to \$4.2 million used in the same period, prior year.

Net cash used in investing activities was approximately \$0.1 million and \$0.3 million for the six months ended September 30, 2013 and 2012, respectively. Net cash provided by financing activities increased from approximately \$1.8 million to \$44.1 million from the six months ended September 30, 2012 to 2013. This increase was primarily due to the infusion of \$43.4 million in net proceeds from the issuance of common stock on August 7, 2013.

As of September 30, 2013, the Company had 76,818,625 total issued and outstanding shares of common stock, five year warrants to purchase an additional 1,698,832 shares of common stock at exercise prices between \$0.85 and \$1.00 per share, 306,500 warrants with terms between two and five years and exercise prices between \$2.21 and \$2.28 per share. If all warrants were exercised on a cash basis, the Company would realize approximately \$2.3 million additional gross proceeds.

On August 21, 2013, investors approved the addition of 5 million shares to the Company's 2012 Equity Incentive Plan, and the Company subsequently filed a Form S-8 to register the shares on November 8, 2013. The 2012 Equity Incentive Plan, as amended with the inclusion of the additional shares approved by shareholders, has 6,263,110shares of common stock remaining available for issuance to the Company's executive officers, directors, advisory board members, employees and consultants. On a fully-diluted basis, including the issued and outstanding common stock, shares underlying outstanding warrants and options, and shares reserved for future issuance under the 2012 Equity Incentive Plan, the Company has 89,262,019 shares of common stock as of September 30, 2013.

Organovo is a development stage company, and does not expect product-based revenue until the commercial release of our liver toxicity assay product in 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 revenue for the quarter was down from the same period of the prior year, decreasing approximately from \$469,000 to \$23,000. That decrease reflected a declining schedule of payments under existing collaborative agreements, and a lack of revenue contribution to date from recently signed agreements.

The Company has continued to invest in prudently expanding its scientific capabilities and resources, and has increased its headcount from 26 full-time employees as of September 30, 2012 to 36 full-time employees as of September 30, 2013 to support its obligations under certain collaborative research agreements and to expand its product development efforts in preparation for research-derived revenues. These staff increases contributed to an increase in operating expenses, which increased approximately \$1.5 million in the quarter over the same period in 2012, from approximately \$4.1 million to \$5.6 million. In addition, approximately \$0.7 million of the increase was attributable to employee payroll taxes remitted by the Company related to the vesting of restricted stock units previously issued to certain of its executives. In exchange for payroll taxes paid by the Company, the affected executives surrendered a commensurate number of shares of common stock back to the Company. Payments of this type may intermittently continue for approximately two more years, the timing thereof directly tied to the vesting of certain restricted stock grants previously issued to some of the Company's executives. These sums may be recaptured by the Company if it elects to sell the surrendered shares in the future. Corporate public company expenses for the quarter, compared to same period prior-year, increased approximately \$0.3 million due to increased activity including regulatory filings, activities related to the Company's up-listing to the NYSE MKT, its annual shareholder meeting and related proxy materials, the public offering completed during the quarter, as well as the addition of a fifth Board member.

The approximate \$46.9 million decrease in other income (expense) for the three-month period ending September 30, 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 the Company's 2012 Private Placement. During the first quarter of calendar 2012, the Company issued warrants to purchase 6,099,195 shares of its common stock to the placement agent and warrants to purchase 15,247,987 shares of its 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 decreasing stock prices during the three months ended September 30, 2012, the fair value of the derivative liability decreased significantly, resulting in the recognition of other income of approximately \$42.3 million. The majority of the underlying warrants have been exercised prior to September 30, 2013 or modified and reclassified as equity instruments. The increase in the fair value of the warrant liability during the three months ended September 30, 2013 was \$4.8 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. The derivative liability at September 30, 2013 has been reduced to \$0.8 million. In addition, the Company disposed of property, plant and equipment during the three months ended September 30, 2012, resulting in a loss on disposal of \$0.2 million, while there were no significant disposals during the three months ended September 30, 2013.

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.

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 report on Form 10-Q filed November 8, 2013, the prospectus supplement filed with the SEC on August 2, 2013 and the transition report on Form 10-KT filed with the SEC on May 24, 2013 and 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)

Assets	Septembe (Unaudite		2013March 31, 2013 (Audited)		
Current Assets					
Cash and cash equivalents	\$	53,357\$	15,628		
Grant receivable	ф —	101	10,020		
Inventory	74	88			
Prepaid expenses and other current assets	304	327			
Total current assets	53,735	16,144			
Fixed Assets – Net	1,031	1,045			
Restricted Cash	38	88			
Other Assets - Net	94	98			
Total assets	\$	54,898\$	17,375		
Liabilities and Stockholders' Equity Current Liabilities					
Accounts payable	\$	477\$	641		
Accrued expenses	1,583	780			
Deferred revenue	75	53			
Capital lease obligation, current portion	10	10			
Warrant liabilities	795	6,898			
Total current liabilities	2,940	8,382			
Deferred revenue, net of current portion	6	9			
Capital lease obligation, net of current portion	10	15			
Total liabilities	\$	2,956\$	8,406		

Commitments and Contingencies (Note 5) Stockholders' Equity

Common stock, \$0.001 par value; 150,000,000 shares authorized, 76,818,625					
and 64,686,919 shares issued and outstanding at September 30, 2013 and	77	65			
March 31, 2013, respectively					
Additional paid-in capital	132,387	75,269			
Deficit accumulated during the development stage	(80,522)	(66,365))		
Total stockholders' equity	51,942	8,969			
Total Liabilities and Stockholders' Equity	\$	54,898\$	17,375		

Organovo Holdings, Inc. (A development stage company) Unaudited Condensed Consolidated Statements of Operations (in thousands except per share data)

	Three Months Ended September 30,		Six Months Ended September 30,		April 19, 2007 (Inception)		
	-		-		through		
					September	· 30,	
	2013	2012	2013	2012	2013		
Revenues							
Product	\$	\$	- \$	\$	\$	224	
Collaborations	23	374	117	633	2,013		
Grants	_	95	12	95	955		
Total Revenues	23	469	129	728	3,192		
Cost of product revenue	—		—	—	134		
Selling, general, and administrative expenses	4,026	2,981	6,404	4,037	18,943		
Research and development expenses	1,599	1,106	3,061	1,759	11,143		
Loss from Operations	(5,602)	(3,618)	(9,336)	(5,068)	(27,028)		
Other Income (Expense)							
Fair value of warrant liabilities in excess of proceeds received	ed—	_		_	(19,019)		
Change in fair value of warrant liabilities	(4,787)	42,252	(4,811)	8,315	(26,782)		
Financing transaction costs in excess of proceeds received	—		—	—	(2,130)		
Loss on inducement to exercise warrants	—		—	—	(1,904)		
Loss on disposal of fixed assets	—	(158)	(4)	(158)	(162)		
Interest expense	—		(13)	_	(3,484)		
Interest income	3	1	7	3	17		

Period from

Other income (expense)	_	1		1	(30)	
Total Other Income (Expense)	(4,784)	42,096	(4,821) 8,161	(53,49	4)
Net Income (Loss)	\$	(10,386)\$	38,478\$	(14,157)\$	3,093\$	(80,522)
Net income (loss) per common share - basic	\$	(0.14)\$	0.87\$	(0.21)\$	0.07	
Net income (loss) per common share - diluted	\$	(0.14)\$	0.69\$	(0.21)\$	0.05	
Weighted average shares used in computing net income (los per common share - basic Weighted average shares used in computing net income (los per common share - diluted			, ,	, , ,		

Organovo Holdings, Inc (A development stage company) Unaudited Condensed Consolidated Statements of Cash Flows (in thousands)

				Period from	
	Six Months Ended Six Months Ender Six Months Ender September 30, 2013 September 30, 20		Ended 30, 2012	(Inception)	
				September 30, 2013	
Cash Flows From Operating Activities					
Net income (loss)	\$	(14,157)\$	3,093	(80,522))
Adjustments to reconcile net income (loss) to net cash used in operating activities:					
Amortization of deferred financing costs		_		438	
Amortization of warrants issued for services	72	36		890	
Depreciation and amortization	190	100		621	
Loss on disposal of fixed assets	4	158		162	
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	4,811	(8,315)		26,782	
Loss on inducement to exercise warrants	—	—		1,904	
Expense associated with warrant modification	12	—		77	
Stock-based compensation	2,088	1,281		4,388	
Warrants issued in connection with exchange agreement	_	—		528	
Increase (decrease) in cash resulting from changes in:					
Grants receivable	101	(96)		_	
Inventory	14	(283)		(737)	
Prepaid expenses and other assets	(49)	12		(304)	
Accounts payable	(164)	(380)		477	
Accrued expenses	803	429		1,583	
Deferred revenue	19	(194)		81	

Net cash used in operating activities	(6,256)	(4,159)	(22,034)	
Cash Flows From Investing Activities				
Deposits released from restriction (restricted cash deposits)	50	(50)	(38)	
Purchases of fixed assets	(176)	(250)	(1,097)	
Purchases of intangible assets	—		(114)	
Net cash used in investing activities	(126)	(300)	(1,249)	
Cash Flows From Financing Activities				
Proceeds from issuance of convertible notes payable			4,630	
Proceeds from issuance of common stock and warrants, net	44,096	1,768	72,534	
Proceeds from exercise of stock options	20	18	38	
Proceeds from issuance of related party notes payable	_	_	250	
Repayment of related party notes payable	_	_	(250)	
Principal payments on capital lease obligation	(5)	(4)	(14)	
Repayment of convertible notes and interest payable			(110)	
Deferred financing costs	_	_	(438)	
Net cash provided by financing activities	44,111	1,782	76,640	
Net Increase (Decrease) in Cash and Cash Equivalents	37,729	(2,677)	53,357	
Cash and Cash Equivalents at Beginning of Period	15,628	10,353	_	

SOURCE Organovo Holdings, Inc.

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