

Organovo Reports Fiscal 2015 Financial Results, Corporate Highlights and Total Contract Bookings for exVive3D™ Human Liver Tissue

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SAN DIEGO, June 9, 2015 /PRNewswire/ -- Organovo Holdings, Inc. (NYSE MKT: ONVO) ("Organovo" or the "Company"), a three-dimensional biology company focused on delivering scientific and medical breakthroughs using 3D bioprinting technology, today reported its financial results for the fiscal year ended March 31, 2015. The Company also reported its total contract bookings for the exVive3D™ Human Liver Tissue.

The exVive3D Human Liver Tissue is a combination product and service offered by the Company to pharmaceutical industry customers for use mainly in preclinical safety testing. From April 1, 2014 through the date of this release, the Company has recorded total contract bookings for its commercial liver tissue product of approximately \$1.94 million, which includes \$0.29 million in revenue recognized as of March 31, 2015. The customers who have contracted to utilize the exVive3D Human Liver Tissue include multiple top 25 global pharma companies, additional public pharmaceutical companies from small to large cap and private venture-backed companies. The Company has had multiple customers sign a second contract, representing repeat business for its liver tissue product. The Company has signed liver service contracts with customers in the United States, Europe and Asia. These reported total contract bookings do not include the Company's contract bookings associated with its research and development activities not involving the exVive3D Human Liver Tissue.

While contracting for high-end research services is a long process, and revenues are recognized over time as services are provided, the Company is pleased to announce these early results based on its pre-launch activities and the roughly six months of sales activity since its commercial launch of the exVive3D Human Liver Tissue in November 2014.

"Response to the exVive3D Human Liver Tissue has been strong, and in line with our expectations," commented Keith Murphy, Organovo's chief executive officer. "We continue to expect this tissue to grow into the tens of millions in annual revenue, and that it has \$100M+ revenue potential. The fact that recent data shows that the exVive3D Human Liver Tissue clearly demonstrated the toxicity of another drug missed during preclinical studies, troglitazone (Rezulin), which exhibited a clear response by causing a statistically significant drop in liver function in our liver tissue at 7 days, provides the potential for our commercial penetration to accelerate even faster." This data was presented at the Experimental Biology meeting in Boston on April 1, 2015.

"Fiscal 2015 represented a successful step forward for Organovo with the launch of our commercial liver product and service," stated Organovo Chief Financial Officer Barry Michaels. "We expect continued adoption from the global pharmaceutical industry in the coming year. We are moving forward with confidence and momentum, both in the expansion of our toxicology tissues and in our efforts to advance other programs."

Total contract bookings represents the total value of contracts the Company has entered into for research services related to its exVive3D Human Liver Tissue during the applicable period. Where contracts involve research relating to additional tissue types, only that portion of the total contract applicable to the exVive Human Liver Tissue is included. The Company's contracts typically require the Company to provide services over a four to six month period, though they may in some cases require services over a longer timeframe. In addition, the Company's customers may opt out of having the Company perform all of the services contemplated by the contract or otherwise terminate the contract early. As a result, the revenues represented by any contract included in the total contract bookings may be recognized by the Company over several quarters as the Company completes the research services required by the contract, or not at all, if the customer elects to opt out or otherwise terminate the contract early. Total contract bookings is an operational measure that should be considered in addition to the Company's results prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). This operational measure should not be considered as a substitute for, or superior to, GAAP results. The Company believes total contract bookings is a relevant and useful operational measure for the Company and its investors because it provides information regarding the Company's commercialization efforts and customer uptake of

the Company's liver tissue product. The Company does not intend to update total contract bookings on a quarterly basis, but may update total contract bookings on an annual basis.

Fiscal Year 2015 Corporate Highlights:

- Partnered with L'Oreal USA in skin engineering to develop 3D printed skin tissues for product evaluation and other areas of advanced research. The partnership marks the first-ever application of Organovo's novel bioprinting technology within the beauty industry.
- Presented data on the Company's *in vitro* 3D kidney tissue demonstrating proof of concept. The Company generated the first fully human kidney proximal tubular tissues that are 3D, and consist of multiple tissue-relevant cell types arranged to recapitulate the renal tubular / interstitial interface.
- 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. The tissues have successfully differentiated between structurally related compounds with known toxic and non-toxic profiles in human beings, when such compounds were not successfully differentiated by other available *in vitro* and *in vivo* methods.
- 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.
- exVive3D Human Liver Tissue named one of the Top 10 Innovations for 2014 by The Scientist magazine.
- Formed a collaboration with the Yale School of Medicine to develop 3D organ tissues for surgical transplantation research, made possible by a generous gift from the Methuselah Foundation. The collaboration combines Yale's expertise and technology with the Company's, representing one important step in progressing towards developing implantable, therapeutic tissues.
- Added Kirk Malloy, Ph.D. to the Company's Board of Directors. Dr. Malloy has held management and executive leadership positions in rapidly growing life science and diagnostics companies for over 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 sciences and diagnostics markets, and is experienced in advancing industry-changing technology platforms and building commercial growth in the life sciences markets.
- Recognized as a [2015 Technology Pioneer](#) by the [World Economic Forum \(WEF\)](#). Organovo was one of 24 companies honored for the ability to harness creativity to design and create transformative solutions.
- Named in Fast Company magazine as one of The World's Top 10 Most Innovative Companies of 2015 in Health Care.

Financial Summary

A summary of the Company's financial results for the fiscal year ended March 31, 2015 follows, but is not intended to replace the full financial disclosure enclosed in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on June 9, 2015. Please refer to that document for additional information.

Financial Condition, Liquidity and Capital Resources

The Company had cash and cash equivalents of \$50.1 million and an accumulated deficit of \$122.3 million, with negative cash flows from operations of \$19.6 million for the fiscal year ended March 31, 2015. Total current assets of \$51.3 million and current liabilities of \$4.8 million, resulted in working capital of \$46.5 million, versus prior year total current assets of \$49.2 million and current liabilities of \$1.9 million, which resulted in working capital of \$47.3 million.

Net cash used in investing activities was approximately \$1.5 million and \$0.3 million for the years ended March 31, 2015 and 2014, respectively. The majority of net cash used in investing activities to date has been for the purchases of laboratory equipment, particularly noting that the Company launched its first commercial product and expanded its

research capabilities in Fiscal 2015.

Net cash provided by financing activities was approximately \$23.1 million and \$48.4 million for the years ended March 31, 2015 and 2014, respectively.

During the year ended March 31, 2015, the Company raised net proceeds of approximately \$22.3 million through the sale of 3.2 million shares of its common stock through at-the-market offerings. In addition, the Company raised approximately \$0.4 million from the exercise of warrants, and \$0.4 million from stock option exercises during the year ended March 31, 2015.

Revenues

The Company previously commented that revenues in the quarter ended December 31, 2014 and the year ended March 31, 2015 were 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 its post-launch activities to be primarily recognized beginning with the quarter ending June 30, 2015. Additional future revenues are expected to come from collaborative partnerships. It should also be noted that 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.

Revenues of \$0.6 million for the year ended March 31, 2015 increased approximately \$0.2 million, or 50%, over revenues of \$0.4 million for the year ended March 31, 2014. This increase reflects the recognition of \$0.3 million in commercial revenue since the Company's product launch in November 2014, partially offset by a \$0.1 million decrease in collaboration revenue due to the completion of one of the Company's larger collaborative research agreements during the year ended March 31, 2014.

Operating and Other Expenses

Operating expenses increased approximately \$9.9 million, or 47%, from \$21.0 million for the year ended March 31, 2014 to \$30.9 million for the year ended March 31, 2015. Of this increase, approximately \$5.0 million was related to increased selling, general and administrative expense, while the other \$4.9 million related to increased investment in research and development expense. Those increases were attributed to the Company's continued implementation of its business plan, including hiring additional staff to support its research and development initiatives, incremental investment associated with commercialization project initiatives, expenses related to operating as a publicly traded corporation, expansion to a larger facility, and increased stock compensation expense relative to employees and certain consulting services.

More specifically, research and development expense increased 61%, from approximately \$8.0 million for the year ended March 31, 2014 to approximately \$12.9 million for the year ended March 31, 2015, as the Company significantly increased its research staff to support its obligations under certain collaborative research agreements and grants, and to expand product development efforts in preparation for commercial revenues. Full-time research and development staffing increased from thirty-two full-time employees as of March 31, 2014 to fifty-four full-time employees as of March 31, 2015. In addition to the incremental payroll, benefits and stock-based compensation resulting from increased staffing levels, the Company increased its facility space to accommodate its growing research staff, and increased its spending on lab equipment and supplies in proportion to its increased research activities.

Selling, general and administrative expenses increased approximately 38%, from \$13.0 million for the year ended March 31, 2014 to approximately \$18.0 million for the year ended March 31, 2015. Increased staffing expenses of approximately \$1.0 million was due to the headcount increase from thirteen full-time employees as of March 31, 2014 to twenty-one full-time employees as of March 31, 2015, to provide strategic infrastructure in developing collaborative relationships and preparing for commercialization of products and services, and to address the additional compliance

requirements of operating as a publicly traded corporation. Stock-based compensation costs also increased approximately \$1.7 million due to additional grants to employees and consultants. In addition, due to the Company's overall growth and transition into the commercial phase during the year ended March 31, 2015, fees for legal services, investor outreach, marketing, insurance and consulting increased over the previous year. Finally, facility costs increased due to the expansion of the Company's facility during the latter part of the year ended March 31, 2014.

Other income was approximately \$0.2 million for the year ended March 31, 2015, 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 year ended March 31, 2014, other expense consisted primarily of a \$5.1 million loss related to the revaluation of warrant derivative liabilities 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 the Company's stock price.

Conference Call

Organovo will host a conference call at 5:00 p.m. Eastern time to discuss the financial results. If you would like to participate in the call, please dial-in approximately 10 minutes prior to the start time, and ask to join the Organovo Holdings, Inc. conference call. The dial-in info is as follows:

US Toll Free: 1-888-243-4451

International Toll: 1-4120542-4135

A replay will be made available one hour following the live call and remain available for 30 days. To access the replay, the dial-in info is as follows:

US Toll Free: 1-877-344-7529

International Toll: 1-412-317-0088

Canada Toll Free: 855-669-9658

Replay Access Code: 10066930

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 exVive3DTM portfolio offering, the exVive3DTM Human Liver Tissue for use in toxicology and other preclinical drug testing. Additional products are in development, with the anticipated release of the exVive3DTM Human Kidney Tissue scheduled for 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 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 the Company's 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; the Company's business, research, product development, regulatory approval, marketing and distribution plans

and strategies; and the Company's ability to successfully complete the contracts and recognize the revenue represented by the contracts included in its reported total contract bookings. These and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on June 9, 2015. 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 the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does 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.

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ORGANOVO HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except per share data)

	March 31, 2015	March 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	\$ 50,142	\$ 48,167
Inventory, net	66	63
Prepaid expenses and other current assets	1,054	931
Total current assets	51,262	49,161
Fixed assets, net	2,042	857
Restricted cash	79	79
Other assets, net	106	89
Total assets	\$ 53,489	\$ 50,186
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 1,387	\$ 326
Accrued expenses	2,257	822
Deferred rent	759	345
Deferred revenue	227	13
Capital lease obligation	5	10
Warrant liabilities	126	377
Total current liabilities	4,761	1,893
Deferred revenue, net of current portion	32	4
Capital lease obligation, net of current portion	—	5
Total liabilities	\$ 4,793	\$ 1,902
Commitments and Contingencies (Note 8)		
Stockholders' Equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 81,536,724 and 78,113,639 shares issued and outstanding at March 31, 2015 and March 31, 2014, respectively	82	78
Additional paid-in capital	170,909	140,419
Accumulated deficit	(122,295)	(92,213)
Total stockholders' equity	48,696	48,284
Total Liabilities and Stockholders' Equity	\$ 53,489	\$ 50,186

ORGANOVO HOLDINGS, INC.**CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands except per share data)

	Year Ended March 31, 2015	Year Ended March 31, 2014	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012 (Unaudited)	Year Ended December 31, 2012
Revenues					
Product and service	\$314	\$—	\$—	\$—	\$—
Collaborations	134	248	98	120	1,035
Grants	123	131	117	—	162
Total Revenues	571	379	215	120	1,197
Selling, general, and administrative expenses	17,947	13,054	2,792	902	7,080
Research and development expenses	12,921	7,974	1,448	547	3,436
Loss from Operations	(30,297)	(20,649)	(4,025)	(1,329)	(9,319)
Other Income (Expense)					
Fair value of warrant liabilities in excess of proceeds received	—	—	—	(19,019)	(19,019)
Change in fair value of warrant liabilities	196	(5,120)	(12,034)	(13,506)	(9,931)
Financing transaction costs in excess of proceeds received	—	—	—	(2,130)	(2,130)
Loss on inducement to exercise warrants	—	—	—	—	(1,904)
Loss on disposal of fixed assets	(12)	(84)	—	—	(158)
Interest expense	(1)	(13)	(65)	(1,088)	(1,088)
Interest income	32	18	4	—	5
Other income (expense)	—	—	—	(9)	(9)
Total Other Income (Expense)	215	(5,199)	(12,095)	(35,752)	(34,234)
Net Loss	\$(30,082)	\$(25,848)	\$(16,120)	\$(37,081)	\$(43,553)
Net loss per common share--basic and diluted	\$(0.38)	\$(0.35)	\$(0.26)	\$(1.17)	\$(1.01)
Weighted average shares used in computing net loss per common share--basic and diluted	79,650,087	73,139,618	61,750,157	31,591,663	43,149,657

ORGANOVO HOLDINGS, INC.**CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)**

	Year Ended March 31, 2015	Year Ended March 31, 2014	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012 (Unaudited)	Year Ended December 31, 2012
Cash Flows From Operating Activities					
Net loss	\$ (30,082)	\$ (25,848)	\$ (16,120)	\$ (37,081)	\$ (43,553)

Adjustments to reconcile net loss to net cash used in operating activities:					
Amortization of deferred financing costs	-	-	-	319	319
Amortization of warrants issued for services	557	323	261	-	556
Depreciation and amortization	472	387	80	17	195
Loss on disposal of fixed assets	12	84	-	-	158
Amortization of debt discount	-	-	-	896	896
Interest accrued on convertible notes payable	-	-	-	12	12
Fair value of warrant liabilities in excess of proceeds	-	-	-	19,019	19,019
Change in fair value of warrant liabilities	(196)	5,120	12,034	13,506	9,931
Loss on inducement to exercise warrants	-	-	-	-	1,904
Expense associated with warrant modification	-	12	65	-	-
Stock-based compensation	7,020	4,600	848	4	1,435
Increase (decrease) in cash resulting from changes in:					
Grants receivable	-	101	61	-	(162)
Inventory	(3)	25	-	(45)	(459)
Prepaid expenses and other assets	(389)	(392)	(61)	(65)	(101)
Accounts payable	1,061	(315)	216	(217)	(233)
Accrued expenses	1,435	312	(283)	(28)	384
Deferred rent	270	75	82	(9)	159
Deferred revenue	242	(45)	62	116	(153)
Net cash used in operating activities	(19,601)	(15,561)	(2,755)	(3,556)	(9,693)
Cash Flows From Investing Activities					
Deposits released from restriction (restricted cash deposits)	-	9	-	(38)	(88)
Purchases of fixed assets	(1,517)	(277)	(137)	(6)	(357)
Purchases of intangible assets	-	-	(19)	-	-
Net cash used in investing activities	(1,517)	(268)	(156)	(44)	(445)
Cash Flows From Financing Activities					
Proceeds from issuance of common stock and exercise of warrants, net	22,752	48,016	3,724	13,723	24,714
Proceeds from exercise of stock options	351	402	-	-	18
Principal payments on capital lease obligations	(10)	(10)	(2)	-	(7)
Repayment of convertible notes and interest payable	-	-	-	(110)	(110)
Deferred financing costs	-	(40)	-	-	-
Net cash provided by financing activities	23,093	48,368	3,722	13,613	24,615
Net Increase in Cash and Cash Equivalents	1,975	32,539	811	10,013	14,477
Cash and Cash Equivalents at Beginning of Period	48,167	15,628	14,817	340	340
Cash and Cash Equivalents at End of Period	\$ 50,142	\$ 48,167	\$ 15,628	\$ 10,353	\$ 14,817
Supplemental Disclosure of Cash Flow Information:					
Interest	\$ —	\$ —	\$ —	\$ 10	\$ 10
Income Taxes	\$ 4	\$ —	\$ —	\$ 1	\$ 1

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/organovo-reports-fiscal-2015-financial-results-corporate-highlights-and-total-contract-bookings-for-exvive3d-human-liver-tissue-300096583.html>

SOURCE Organovo Holdings, Inc.

Barry Michaels, Chief Financial Officer, Organovo Holdings, Inc., 1-858-224-1000 ex. 3, IR@organovo.com, or Gerry Amato, Amato & Partners, LLC, admin@amatoandpartners.com