

Organovo Announces Fiscal Third-Quarter Results; Company Updates Full-Year Fiscal 2016 Outlook and Affirms Long-Range Guidance

February 8, 2016

SAN DIEGO, Feb. 08, 2016 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NYSE MKT:ONVO) ("Organovo"), a three-dimensional biology company focused on delivering scientific and medical breakthroughs using its 3D bioprinting technology, today reported financial results for the fiscal third quarter of 2016, updated its full-year fiscal 2016 outlook and affirmed its long-range guidance. Net loss was \$10.5 million, or \$0.11 per share, for the fiscal third quarter of 2016, as compared to \$7.0 million, or \$0.09 per share, for the fiscal third quarter of 2015.

Organovo reported fiscal third-quarter total revenue of \$0.3 million, which consisted primarily of product and service revenue. Total revenue increased 112 percent versus the comparable period of fiscal 2015 and 9 percent versus the fiscal second quarter of 2016. Product and service revenue, which primarily represents revenue from the exVive3DTM Human Liver Tissue research service and product, increased by \$0.2 million from the year-ago period. The Company commercially released the exVive3D Human Liver Tissue in November 2014.

"We have solid fundamentals and excellent long-term growth prospects supporting our core business," said Keith Murphy, CEO, Organovo. "Our leadership in the 3D bioprinting space is grounded in serving attractive and growing markets with critical unmet needs, a competitive landscape in which our first mover advantage allows us to offer strongly differentiated cutting-edge services, and a growing, world-class IP portfolio. Our technology platform is flexible and is being leveraged to target multiple revenue streams in the preclinical safety, efficacy and disease modeling and therapeutic tissue markets."

Murphy continued, "During the quarter, we found that recent data from methotrexate exposure in our exVive3D Liver serves as compelling additional differentiation for our target customers. We expect these results to drive more rapid adoption going forward. Overall, our customers are pleased with the scientific results we're providing as evidenced by the solid pace of repeat agreements, and we expect this momentum to build now that we have dedicated sale resources across the U.S. and Europe. We updated our fiscal 2016 outlook to reflect an improved net cash utilization rate as we capitalize on operating efficiencies from the thoughtful deployment of our capital resources. In addition, we see a shift in timing for revenue recognition from previously disclosed contract bookings for our commercial liver tissue product. To be more specific, our adjusted guidance for revenue recognition indicates that certain milestones from a large customer are now anticipated in early fiscal 2017 rather than late fiscal 2016, reflecting the need for this customer to finalize aspects of its work plan. There is no change in the total revenue that we expect to recognize from this agreement, only a change in the timing of revenue recognition."

Murphy concluded, "As fiscal 2016 winds down, we continue to make progress in key strategic areas. The development of our kidney tissue product is on track as we move past functional validation and take the necessary steps for commercialization later this year. We're also advancing with business development initiatives in the drug discovery and therapeutic tissue spaces, and expect to achieve important objectives in the next 12 months. We're executing against the key scientific and operating targets that will drive our future success."

Organovo Business Highlights

Revenue

 Product and service revenue was \$0.3 million, up 111 percent from the prior-year period, largely driven by customer contracts for the Company's exVive3D Human Liver Tissue research services.

Operating Expenses

- Selling, general and administrative expenses increased 60 percent from the prior-year period to \$6.2 million, primarily due to higher non-cash share-based compensation expense and employee costs related to sales and administrative staffing.
- Research and development costs grew 42 percent year-over-year to \$4.6 million, reflecting increased employee related costs and lab supplies.

Liquidity & Capital Resources

- The Company ended the fiscal third quarter with a cash and cash equivalents balance of \$70.0 million. Organovo's net cash utilization⁽¹⁾ during the period was \$6.8 million. The Company's net cash utilization for the nine months ended December 31, 2015 was \$23.3 million.
- Working capital was \$65.2 million to end the fiscal third guarter compared to \$46.8 million in the prior-year guarter.

Fiscal-Year 2016 Outlook

The Company updated its full-year fiscal 2016 outlook for revenue recognized from previously disclosed contract bookings for its commercial liver tissue product and net cash utilization. The Company now expects:

- In fiscal 2016, to recognize between \$0.7 million and \$0.9 million of its previously reported approximately \$2 million in contract bookings for its exVive3D Human Liver Tissue for the period from April 1, 2014 to June 9, 2015. The Company had already recognized approximately \$0.3 million from these contract bookings in fiscal 2015. Organovo anticipates that additional revenue from these contract bookings will be recognized in fiscal 2017. In addition, revenue from new contracts signed after June 9, 2015, as well as revenue from grants and collaborations, will continue to be recognized during the remainder of fiscal 2016.
- Net cash utilization of between \$32 million and \$34 million for fiscal-year 2016. The Company had a cash and cash equivalents balance of \$70.0 million for its fiscal third quarter ended December 31, 2015.

Fiscal-Year 2016 Outlook (November 2015) Fiscal-Year 2016 Outlook (February 2016)

Total Revenue Recognized
From Previously Reported \$1.2 million - \$1.4 million \$0.7 million - \$0.9 million
Contract Bookings
Net Cash Utilization

\$32 million - \$36 million \$32 million - \$34 million

Long-Range Outlook

The Company affirmed its long-range outlook for potential revenue from its liver tissue product and initiation of commercial contracting for its kidney tissue product. The Company continues to expect:

- As it penetrates the toxicology market, Organovo's exVive3D Human Liver Tissue and service will grow into the tens of
 millions in annual revenue, and has \$100 million+ revenue potential in the future (inside of a total addressable market of
 over \$1 billion).
- Initiation of commercial contracting for its kidney tissue product in the calendar third quarter of 2016.

Net Cash Utilization Definition

1. In addition to disclosing financial results that are determined in accordance with U.S. GAAP, the Company provides net cash utilization as a supplemental measure to help investors evaluate the Company's fundamental operational performance. The Company defines net cash utilization as the change in the amount of cash and cash equivalents at the beginning of the reporting period as compared to the end of the reporting period, excluding financing activities (which would include proceeds from the sale of common stock and the exercise of warrants and stock options). Net cash utilization is an operational measure that should be considered in addition to our results prepared in accordance with U.S. GAAP. This operational measure should not be considered as a substitute for, or superior to, U.S. GAAP results. The Company believes net cash utilization is a relevant and useful operational measure because it provides information regarding our cash utilization rate. Management uses net cash utilization to manage the business, including in preparing its annual operating budget, financial projections and compensation plans. The Company believes that net cash utilization is also useful to investors because similar measures are frequently used by securities analysts, investors and other interested parties in their evaluation of companies in similar industries. However, there is no standardized measurement of net cash utilization, and net cash utilization as the Company presents it may not be comparable with similarly titled operational measures used by other companies. Due to these limitations, the Company's management does not view net cash utilization in isolation but also uses other measurements, such as cash used in operating activities and revenues to measure operating performance.

Conference Call Information

As previously announced, the Company will host a conference call to discuss its results at 5:00 p.m. ET on Monday, February 8, 2016. Callers should dial (888) 317-6003 (U.S. only) or (412) 317-6061 (from outside the U.S.) to access the call. The conference call ID is 5006379. The conference call will also be simultaneously webcast on Organovo's Investor Relations webpage at www.organovo.com. A replay of the conference call will be available beginning Monday, February 8, 2016 through Monday, February 15, 2016 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 5006379, for an audio replay of the conference call.

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, the exVive3D Human Liver Tissue for use in toxicology and other preclinical drug testing. Additional products are in development, with the anticipated release of the exVive3D Human Kidney Tissue scheduled

for the third quarter 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.

Forward-Looking Statements

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 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; 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 previously 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 and its Quarterly Report on Form 10-Q filed with the SEC on February 8, 2016. 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.

Organovo Holdings, Inc.

Condensed Consolidated Balance Sheets

(in thousands except share data)

	December 31, 2015			March 31, 2015		
	(Unaudited)			(Audited)		
Assets						
Current Assets						
Cash and cash equivalents	\$	70,026	\$	50,142		
Accounts receivable		165		_		
Inventory		71		66		
Prepaid expenses and other current assets		483		1,054		
Total current assets		70,745		51,262		
Fixed assets, net		3,560		2,042		
Restricted cash		79		79		
Other assets, net		152		106		
Total assets	\$	74,536	\$	53,489		
Liabilities and Stockholders' Equity						
Current Liabilities						
Accounts payable	\$	466	\$	1,387		
Accrued expenses		2,494		2,257		
Deferred rent		1,079		759		
Deferred revenue		1,444		227		
Capital lease obligation		_		5		
Warrant liabilities		14		126		
Total current liabilities		5,497		4,761		
Deferred revenue, net of current portion		_		32		
Total liabilities	\$	5,497	\$	4,793		
Commitments and Contingencies						
Stockholders' Equity						
Common stock, \$0.001 par value; 150,000,000 shares authorized, 92,413,951 and 81,536,724 shares issued and outstanding at December 31, 2015 and March 31, 2015, respectively		92		82		
Additional paid-in capital		221,445		170,909		
Accumulated deficit		(152,498)		(122,295)		
Total stockholders' equity		69,039		48,696		
Total Liabilities and Stockholders' Equity	\$	74,536	\$	53,489		

Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands except share and per share data)

	Three Months Ended December 31, 2015		Three Months Ended December 31, 2014		Nine Months Ended December 31, 2015			Nine Months Ended December 31, 2014				
Revenues												
Product and service	\$	293		\$	139		\$	689		\$	139	
Collaborations		25			7			58			121	
Grants		10			9			188			44	
Total Revenues		328			155			935			304	
Selling, general, and administrative expenses		6,212			3,878			17,680			13,350	
Research and development expenses		4,586			3,238			13,467			9,281	
Loss from Operations		(10,470)		(6,961)		(30,212)		(22,327)
Other Income (Expense)												
Change in fair value of warrant liabilities		2			(40)		(27)		24	
Loss on disposals of fixed assets		_			_			_			(3)
Interest income		13			8			39			22	
Total Other Income (Expense)		15			(32)		12			43	
Income Tax Expense		_			_			(3)		_	
Net Loss	\$	(10,455)	\$	(6,993)	\$	(30,203)	\$	(22,284)
Net loss per common share—basic and diluted	\$	(0.11)	\$	(0.09)	\$	(0.34)	\$	(0.28)
Weighted average shares used in computing net loss per common share—basic and diluted		92,396,358			80,491,120			90,026,158			79,225,692	

Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

(in thousands)

				Nine Months Ended			
				Dec	2014		
Cash Flows From Operating Activities							
Net loss	\$	(30,203)	\$	(22,284)	
Adjustments to reconcile net loss to net cash used in operating activities:							
Loss on disposal of fixed assets		_			3		
Depreciation and amortization		560			334		
Change in fair value of warrant liabilities		27			(24)	
Stock-based compensation		7,049			5,215		
Amortization of warrants issued for services		(99)		556		
Increase (decrease) in cash resulting from changes in:							
Accounts receivable		(165)		_		
Inventory		(5)		(6)	
Prepaid expenses and other assets		553			318		

Accounts payable	(921)	169	
Accrued expenses	237		1,206	
Deferred rent	(54)	254	
Deferred revenue	1,185		268	
Net cash used in operating activities	(21,836)	(13,991)
Cash Flows From Investing Activities				
Purchases of fixed assets	(1,711)	(867)
Proceeds from disposals of fixed assets	14		_	
Purchases of intangible assets	(35)	_	
Net cash used in investing activities	(1,732)	(867)
Cash Flows From Financing Activities				
Proceeds from issuance of common stock and exercise of warrants, net	43,137		16,512	
Proceeds from exercise of stock options	320		213	
Principal payments on capital lease obligations	(5)	(7)
Net cash provided by financing activities	43,452		16,718	
Net Increase in Cash and Cash Equivalents	19,884		1,860	
Cash and Cash Equivalents at Beginning of Period	50,142		48,167	
Cash and Cash Equivalents at End of Period	\$ 70,026		\$ 50,027	
Supplemental Disclosure of Cash Flow Information:				
Interest	\$ _		\$ _	
Income Taxes	\$ 3		\$ _	

Investor Contact:

Steve Kunszabo Organovo Holdings, Inc. +1 (858) 224-1092 skunszabo@organovo.com

Press Contact:

Jessica Yingling
Little Dog Communications
+1 (858) 480-2411
jessica@litldog.com



Organovo Holdings, Inc.