Organovo Reports Fiscal First-Quarter 2019 Results; Company Outlines and Expands Key Clinical Development Goals

August 9, 2018

- *Pre-Investigational New Drug ("IND") meeting with the FDA expected to be held in calendar 2019*
- *Lead IND program for Alpha-1-antitrypsin deficiency ("A1AT") expected to commence IND-enabling studies in second half of calendar 2019 and to submit an IND in calendar 2020*
- *CMO Dr. Steven G. Hughes appointed to lead therapeutic tissue development program*

SAN DIEGO, Aug. 09, 2018 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo"), a biotechnology company pioneering the development of 3D bioprinted tissues aimed at treating a range of serious adult and pediatric liver diseases, today reported its fiscal first-quarter 2019 financial results.

"During the fiscal first quarter, we refined our operating and scientific goals," said Taylor J. Crouch, CEO, Organovo. "We have concentrated our financial resources around supporting our healthy liver therapeutic tissue development, which has the potential to address a number of serious unmet medical needs, encompassing an addressable peak worldwide sales opportunity greater than $4 billion."

Crouch continued, "On July 31st, we held a pre-pre-IND meeting with the FDA to review our IND planning for our lead program in A1AT. In light of this meeting's outcome, we intend to submit our pre-IND meeting package to the FDA in calendar 2019. Based on anticipated study designs for our IND-enabling work, we continue to target calendar 2020 for filing our IND, with the possibility of commencing human trials that same year."

Crouch concluded, "We'll also continue to opportunistically generate revenue to support our therapeutics program by leveraging our cell and *in vitro* tissue platform including providing funded access to our developmental non-alcoholic steatohepatitis ("NASH") platform to clients for their own R&D programs."

Key Clinical Development Goals & Outlook

- Organovo expects to hold a pre-IND meeting with the FDA in calendar 2019 for its lead program in A1AT, commence IND-enabling studies in the second half of calendar 2019 and file for an IND in calendar 2020.
- The Company plans to nominate a second indication in the rare disease space in calendar 2019, which has the potential to closely follow its lead program into human clinical trials. The Company will also likely pursue orphan drug designation with the FDA for this second indication in calendar 2019.
- Organovo will continue to opportunistically generate revenue to support its therapeutic research mission by leveraging its cell and *in vitro* tissue platform.
- The Company plans to continue expanding its global IP portfolio, which currently includes over 100 patents and pending applications.
- As of June 30, 2018, the Company had a cash and cash equivalents balance of $39.6 million. Organovo expects to have a net cash utilization(1) rate of $22 million to $24 million in fiscal 2019, and believes it has sufficient funds to meet its operating and capital requirements into fiscal 2020.

Fiscal First-Quarter 2019 Financial Highlights

- Net loss was $7.4 million, a $2.7 million improvement over the year-ago period, as total costs and expenses declined 26 percent to $8.3 million, primarily due to lower employee and lab supply costs related to the Company's organizational restructuring and prioritization of R&D projects.
- Net cash utilization was $7.1 million, an improvement from $10.7 million in the prior-year quarter.
- Total revenue was $0.7 million, a 30 percent decrease from the year-ago period, primarily driven by lower revenue from liver tissue disease modeling research services.
- During the fiscal first quarter, the Company generated net proceeds of approximately $3.0 million from the issuance of 2.1 million shares of common stock in at-the-market offerings at a weighted average price of $1.44 per share.

Definitions & Supplemental Financial Measures

(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 net decrease in cash and cash equivalents during the reporting period less proceeds from the sale of common stock and the exercise of warrants and stock options during the reporting period. Net cash utilization is an operational measure that should be considered as additional financial information regarding our operations. This operational measure should not be considered without also considering our results prepared in accordance with U.S. GAAP, and should not be considered as a substitute for, or superior to, our 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 Thursday, August 9, 2018. 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 3834076. 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 Thursday, August 9, 2018 through Thursday, August 16, 2018 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10122205, for an audio replay of the conference call.

About Organovo Holdings, Inc.

Organovo is a biotech platform company that has developed a leadership position with its revolutionary ability to 3D bioprint tissues with human functionality. The Company is pursuing multiple IND-track programs to develop its NovoTissues® to address a number of serious unmet medical needs in adult and pediatric populations, initially focusing on liver disease. Organovo's first IND-track program for Alpha-1-antitrypsin deficiency recently received orphan drug designation from the FDA, and the Company expects to file its first IND in 2020. In order to support its plan to initiate multiple IND-track programs, the Company is providing access to its ExVive™ *in vitro* tissue disease modeling platform to facilitate high value drug discovery and development collaborations. Organovo's wholly-owned subsidiary, Samsara Sciences, provides the Company and its clients with high quality human liver and kidney cells for research applications. Organovo is changing the shape of life science research and transforming medical care. 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. Forward-looking statements include, but are not limited to, statements regarding the potential benefits and therapeutic uses of the Company's therapeutic liver tissue, including the benefits of an orphan designation; the Company's expectations regarding the FDA regulatory pathway and anticipated timelines for its regulatory filings; the potential market opportunity for the Company's therapeutic tissue candidates; and customer demand for and acceptance of our disease modeling and other in vitro tissue platforms. 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 possibility that the final results of the Company's preclinical studies may be different from the Company's studies or interim preclinical data results and may not support further clinical development of its therapeutic tissues; the Company may not successfully complete the required preclinical and clinical trials required to obtain regulatory approval for its therapeutic tissues on a timely basis or at all; risks that competitive products may adversely impact the market opportunity for the Company's therapeutic tissue candidates; 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 Company's ability to execute framework agreements involving multi-year commitments and routine use on a timely basis, or at all; the Company's ability to successfully complete studies and provide the technical information required to support market acceptance of its products, services and technology, on a timely basis or at all; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies, including its use of third party distributors; the Company's ability to recognize deferred revenue; and the Company's ability to meet its fiscal-year 2019 goals and outlook. 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 May 31, 2018. 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.
Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Income (Loss)

	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017
Revenues		
Products and services	$ 546	$ 944
Collaborations and licenses	43	46
Grants	100	—
Total Revenues	689	990
Cost of revenues	120	301
Research and development expenses	3,379	5,033
Selling, general and administrative expenses	4,767	5,856
Total costs and expenses	8,266	11,190
Loss from Operations	(7,577)	(10,200)
Other Income (Expense)		

Gain (loss) on fixed asset disposals		2			—	
Interest income		162			98	
Total Other Income (Expense)		164			98	
Income Tax Expense		(3	)		—	
Net Loss	$	(7,416	)	$	(10,102	)
Currency Translation Adjustment	$	—		$	(11	)
Comprehensive Loss	$	(7,416	)	$	(10,113	)
Net loss per common share—basic and diluted	$	(0.07	)	$	(0.10	)
Weighted average shares used in computing net loss per common share—basic and diluted		111,458,445			104,689,391	

Organovo Holdings, Inc.
Consolidated Balance Sheets

		June 30, 2018 (Unaudited)		**March 31, 2018 (Audited)**	
Assets					
Current Assets					
Cash and cash equivalents	$	39,613		$ 43,726	
Accounts receivable		628		883	
Grant receivable		100		145	
Inventory, net		1,044		842	
Prepaid expenses and other current assets		927		1,164	
Total current assets		42,312		46,760	
Fixed assets, net		2,504		2,788	
Restricted cash		127		127	
Other assets, net		149		152	
Total assets	$	45,092		$ 49,827	
Liabilities and Stockholders' Equity					
Current Liabilities					
Accounts payable	$	396		$ 464	
Accrued expenses		1,995		3,341	
Deferred revenue		628		668	
Deferred rent		191		185	
Total current liabilities		3,210		4,658	
Deferred revenue, net of current portion		10		19	
Deferred rent, net of current portion		516		564	
Total liabilities		3,736		5,241	
Commitments and Contingencies					
Stockholders' Equity					
Common stock, $0.001 par value; 150,000,000 shares authorized, 113,318,380 and 111,032,957 shares issued and outstanding at June 30, 2018 and March 31, 2018, respectively		113		111	
Additional paid-in capital		282,779		278,595	
Accumulated deficit		(241,536	)	(234,120	)
Total stockholders' equity		41,356		44,586	
Total Liabilities and Stockholders' Equity	$	45,092		$ 49,827	

Organovo Holdings, Inc.
Unaudited Consolidated Statements of Cash Flows

	Three Months Ended	**Three Months Ended**

	June 30, 2018	June 30, 2017
Cash Flows From Operating Activities		
Net loss	$ (7,416)	$ (10,102)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on disposal of fixed assets	(2)	—
Depreciation and amortization	288	326
Stock-based compensation	1,279	2,052
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	255	(125)
Grants receivable	45	—
Inventory	(202)	89
Prepaid expenses and other assets	236	(518)
Accounts payable	(68)	(613)
Accrued expenses	(1,346)	(1,990)
Deferred rent	(42)	(34)
Deferred revenue	(49)	262
Net cash used in operating activities	(7,022)	(10,653)
Cash Flows From Investing Activities		
Purchases of fixed assets	—	(11)
Proceeds from disposals of fixed assets	2	—
Purchases of intangible assets	—	(70)
Net cash provided by investing activities	2	(81)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	3,010	2,964
Employee taxes paid related to net share settlement of equity awards	(103)	(7)
Net cash provided by financing activities	2,907	2,957
Net increase (decrease) in cash, cash equivalents, and restricted cash	(4,113)	(7,777)
Cash, cash equivalents, and restricted cash at beginning of period	43,853	62,878
Cash, cash equivalents, and restricted cash at end of period	$ 39,740	$ 55,101
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	39,613	54,974
Restricted cash	127	127
Total cash, cash equivalent and restricted cash	39,740	55,101
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	$ 3	$ —

Investor & Press Contact:

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

Organovo, Inc.