Organovo Reports Fiscal Fourth-Quarter and Full-Year 2018 Results; Company Announces Key Goals for Fiscal-Year 2019

May 31, 2018

- Lead Investigational New Drug ("IND") program for Alpha-1-antitrypsin deficiency ("A1AT") received FDA's orphan drug designation and is on track for commencing IND-enabling studies in fiscal 2019

- Second IND-track program in orphan liver disease expected to be nominated in fiscal 2019

SAN DIEGO, May 31, 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 fourth-quarter and full-year 2018 financial results and announced its key goals for fiscal-year 2019.

"Fiscal 2018 was an important transition year for us as we demonstrated preclinical safety and efficacy proof-of-concept data for our NovoTissues® liver implant in animal models of A1AT," said Taylor J. Crouch, CEO, Organovo. "We concluded the year by achieving orphan drug designation from the FDA for this first IND-track program and we look forward to nominating a second IND program within fiscal 2019. Our healthy liver therapeutic tissue has the opportunity to address a number of rare, serious unmet medical needs which often lead to liver transplant, and as such, we're planning to explore additional NovoTissues indications within the spectrum of inborn errors of metabolism, acute on chronic liver failure, and other debilitating liver diseases. We estimate that the unique benefits of bridging patients to transplant or even providing a therapeutic alternative to transplant has the potential to create an addressable peak worldwide sales opportunity in excess of $4 billion. Our first target indication of A1AT alone has the potential to approach $1 billion in peak sales."

Crouch continued, "We'll also continue to demonstrate the robust functionality of our tissues within our *in vitro* testing operations, where we're creating a series of disease conditions that can subsequently be 'treated' with promising new drug candidates. In fiscal 2019, we aim to expand the scope of non-alcoholic steatohepatitis ("NASH") conditions exhibiting the key components of the disease to support high value drug discovery and development. We believe our platform represents the only comprehensive, non-clinical way to investigate key aspects of drug efficacy and safety utilizing histology, which is the gold standard of diagnosing and measuring response in NASH."

Crouch concluded, "As we continue to demonstrate the remarkable utility of our 3D bioprinted tissues, we are focused on critical advances to medicine that our platform may provide, spanning our current support of NASH R&D through to a range of potentially breakthrough clinical applications enabled by our NovoTissues platform. We believe our technology has the potential to transform the care of patients with debilitating and often fatal liver diseases."

Fiscal-Year 2019 Goals & Outlook

- Organovo intends to continue preclinical development and commence IND-enabling studies for its A1AT liver therapeutic tissue program in fiscal 2019.
- The Company plans to pursue orphan drug designation for a second rare disease indication with the FDA, with the objective of ending fiscal 2019 with two liver therapeutic tissue programs on track for an IND targeted for calendar 2020.
- In support of its *in vitro* testing operations, Organovo expects to significantly expand its comprehensive NASH profiling platform, creating a range of drug profiling conditions to facilitate partnering in drug discovery and development.
- The Company plans to continue expanding its global IP portfolio, which currently includes over 100 patents and pending applications.
- As of March 31, 2018, the Company had a cash and cash equivalents balance of $43.7 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 Fourth-Quarter 2018 Financial Highlights

- Total revenue was $1.1 million, a 36 percent gain from the year-ago period, primarily driven by higher cell-based product and grant revenue.
- Research and development costs decreased 28 percent year-over-year to $4.0 million, primarily due to lower employee and lab supply costs related to the Company's organizational restructuring and prioritization of R&D projects.
- Negative Adjusted EBITDA(2) was $5.7 million, as compared to $8.3 million for the year-ago period.
- During the fiscal fourth quarter, the Company generated net proceeds of approximately $2.1 million from the issuance of 1.5 million shares of common stock in at-the-market offerings at a weighted average price of $1.40 per share.

Fiscal-Year 2018 Financial Highlights

- For the full year, the Company reported total revenue of $4.6 million, which was up 9 percent from the year-ago period. Total revenue increased primarily due to higher grant payments related to the Company's National Institutes of Health

project and increased sales from cell-based products. Organovo reported fiscal 2018 net loss of $34.8 million, or $0.32 per share, as compared to net loss of $38.4 million, or $0.39 per share, for fiscal 2017.

Organovo Holdings, Inc.
Supplemental Reconciliation of GAAP Net Loss to Adjusted EBITDA
(in thousands)

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017	Twelve Months Ended March 31, 2018	Twelve Months Ended March 31, 2017
GAAP net loss	$ (7,449)	$ (10,657)	$ (34,803)	$ (38,447)
Interest expense	-	-	-	-
Interest income	(144)	(74)	(478)	(198)
Income taxes	2	-	2	23
Depreciation and amortization	305	325	1,267	1,149
Stock-based compensation	1,303	1,852	6,903	7,392
Restructuring/CEO transition	276	281	2,313	281
Adjusted EBITDA	$ (5,707)	$ (8,273)	$ (24,796)	$ (29,800)

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.

2. In addition to disclosing financial results that are determined in accordance with U.S. GAAP, the Company provides Adjusted EBITDA which is a non-GAAP financial measure, as a supplemental measure to help investors evaluate the Company's fundamental operational performance. Adjusted EBITDA represents earnings before interest, income taxes, depreciation and amortization, stock-based compensation expenses and restructuring/CEO transition costs. Adjusted EBITDA does not represent, and should not be considered in isolation from, as a substitute for, or as superior to, U.S. GAAP measurements such as net income or loss. By eliminating interest, income taxes, depreciation and amortization, stock-based compensation expenses and restructuring/CEO transition costs, the Company believes the result is a useful measure across time in evaluating its fundamental core operating performance. Management also uses Adjusted EBITDA to manage the business, including in preparing its annual operating budget, financial projections and compensation plans. The Company believes that Adjusted EBITDA 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 Adjusted EBITDA, and Adjusted EBITDA as the Company presents it may not be comparable with similarly titled non-GAAP financial measures used by other companies. Since Adjusted EBITDA does not account for certain expenses, its utility as a measure of the Company's operating performance has material limitations. Due to these limitations, investors should not view Adjusted EBITDA in isolation, but should also consider other measurements, such as net income or loss and revenues, to measure the Company's operating performance. Please refer to the schedule above for a reconciliation of consolidated GAAP net loss to Adjusted EBITDA for the fiscal years and quarters ended March 31, 2018 and 2017.

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, May 31, 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 0713772. 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, May 31, 2018 through Thursday, June 7, 2018 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10119460, 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 transplantable tissues 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 help fund 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 for one or more customer's electing to move toward framework agreements involving annual budgets, revenue commitments, and/or dedicated research plans, statements regarding customer demand for and acceptance of our disease modeling services and statements regarding the potential benefits and therapeutic uses of the Company's therapeutic liver tissue, including the benefits of an orphan designation. 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 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; 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; the Company's ability to control the costs and to achieve the expected operational benefits and long-term cost savings of its restructuring plan; 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.

Consolidated Statements of Operations and Comprehensive Loss (in thousands except per share data)

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017	Twelve Months Ended March 31, 2018	Twelve Months Ended March 31, 2017
Revenues				
Products and services	$ 905	$ 771	$ 3,627	$ 3,167
Collaborations and licenses	55	21	422	1,022
Grants	145	20	554	41
Total Revenues	1,105	812	4,603	4,230
Cost of revenues	283	183	1,030	956
Research and development expenses	3,974	5,533	17,956	19,545
Selling, general, and administrative expense	4,431	5,784	20,888	22,304
Total costs and expenses	8,688	11,500	39,874	42,805
Loss from Operations	(7,583)	(10,688)	(35,271)	(38,575)
Other Income (Expense)				
Change in fair value of warrant liabilities	—	8	—	4
Gain (loss) on fixed asset disposals	4	(51)	4	(51)
Interest income	144	74	478	198
Other income (expense)	(12)	—	(12)	—
Total Other Income (Expense)	136	31	470	151
Income Tax Expense	(2)	—	(2)	(23)
Net Loss	$ (7,449)	$ (10,657)	$ (34,803)	$ (38,447)
Net loss per common share—basic and diluted	$ (0.07)	$ (0.10)	$ (0.32)	$ (0.39)
Weighted average shares used in computing net loss per common share—basic and diluted	110,690,335	104,385,617	107,243,974	97,763,032

Comprehensive Loss:				
Net Loss	$ (7,449)	$ (10,657)	$ (34,803)	$ (38,447)
Currency Translation Adjustment	—	(1)	11	(11)
Comprehensive Loss	$ (7,449)	$ (10,658)	$ (34,792)	$ (38,458)

Organovo Holdings, Inc.
Consolidated Balance Sheets (in thousands except per share data)

	March 31, 2018	March 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$ 43,726	$ 62,751
Accounts receivable	883	647
Grant receivable	145	—
Inventory, net	842	550
Prepaid expenses and other current assets	1,164	1,144
Total current assets	46,760	65,092
Fixed assets, net	2,788	3,840
Restricted cash	127	127
Other assets, net	152	121
Total assets	$ 49,827	$ 69,180
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 464	$ 1,171
Accrued expenses	3,341	4,101
Deferred revenue	668	582
Deferred rent	185	157
Total current liabilities	4,658	6,011
Deferred revenue, net of current portion	19	58
Deferred rent, net of current portion	564	749
Total liabilities	$ 5,241	$ 6,818
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 111,032,957 and 104,551,466 shares issued and outstanding at March 31, 2018 and March 31, 2017, respectively	111	104
Additional paid-in capital	278,595	261,586
Accumulated deficit	(234,120)	(199,317)
Accumulated other comprehensive income (loss)	—	(11)
Total stockholders' equity	44,586	62,362
Total Liabilities and Stockholders' Equity	$ 49,827	$ 69,180

Organovo Holdings, Inc.
Consolidated Statements of Cash Flows (in thousands)

	Year Ended March 31, 2018	Year Ended March 31, 2017
Cash Flows From Operating Activities		
Net loss	$ (34,803)	$ (38,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred financing costs	—	—
(Gain) Loss on disposal of fixed assets	(4)	56
Depreciation and amortization	1,267	1,149
Change in fair value of warrant liabilities	—	(4)
Stock-based compensation	6,903	7,392
Donation of fixed assets	25	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(236)	(388)
Grants receivable	(145)	—

Inventory	(292)	(216)
Prepaid expenses and other assets	5	(154)
Accounts payable	(707)	384
Accrued expenses	(760)	1,651
Deferred rent	(157)	(138)
Deferred revenue	47	(470)
Net cash used in operating activities	(28,857)	(29,185)
Cash Flows From Investing Activities		
Deposits released from restriction (restricted cash deposits)	—	(48)
Purchases of fixed assets	(226)	(1,354)
Proceeds from disposals of fixed assets	4	11
Purchases of intangible assets	(70)	—
Net cash used in investing activities	(292)	(1,391)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	9,287	30,665
Proceeds from exercise of stock options	826	582
Principal payments on capital lease obligations	—	—
Net cash provided by financing activities	10,113	31,247
Effect of currency exchange rate changes on cash and cash equivalents	11	(11)
Net Increase in Cash and Cash Equivalents	(19,025)	660
Cash and Cash Equivalents at Beginning of Period	62,751	62,091
Cash and Cash Equivalents at End of Period	$ 43,726	$ 62,751
Supplemental Disclosure of Cash Flow Information:		
Interest	$ —	$ —
Income Taxes	$ 2	$ 23

Investor & Press Contact:

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

Source: Organovo, Inc.