Organovo Announces Fiscal Second-Quarter 2018 Results; Company Shifts Commercial Focus to Higher-Value Disease Modeling Opportunities and Updates Full-Year Fiscal 2018 Outlook

November 9, 2017

SAN DIEGO, Nov. 09, 2017 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo") today reported financial results for the fiscal second quarter of 2018 and updated its full-year fiscal 2018 outlook. The Company is shifting the focus of its commercial and platform development efforts toward higher-demand and higher-value disease modeling services, and is deprioritizing routine toxicology research services. While Organovo has had meaningful early uptake for its disease modeling studies, these revenues are not anticipated to offset a smaller than expected contribution from toxicology research services in the remaining months of its 2018 fiscal year. As a result, the Company has lowered its fiscal 2018 total revenue outlook. The Company believes its focus on disease modeling platforms coupled with its IND-track therapeutics program will best unlock the value of its 3D tissue printing capabilities. As a result of its change in strategic focus and the recently announced restructuring and organizational realignment, the Company also has favorably revised its negative Adjusted EBITDA[(1)] guidance.

Organovo reported fiscal second-quarter total revenue of $1.4 million. Total revenue decreased 2 percent from the prior-year period, and increased 37 percent versus the fiscal first quarter of 2018. Net loss was $9.5 million, or $0.09 per share, for the fiscal second quarter of 2018, as compared to $9.4 million, or $0.10 per share, for the fiscal second quarter of 2017. Negative Adjusted EBITDA for the second quarter was $6.6 million, as compared to $7.1 million for the prior-year period.

"We have the ability to monetize our platform in many ways, including the provision of primary human cells for research applications, compound screening in disease models, licensing agreements that capitalize on our technology, and the ongoing development of novel therapeutics," said Taylor J. Crouch, CEO, Organovo. "Clients are working with us across this value chain, allowing us to target the entire drug discovery and development ecosystem. Given the increased adoption by a number of sophisticated customers of our disease modeling capabilities, and the important role that non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH") play in pharmaceutical R&D, we believe our move to this space represents the highest value opportunity for our commercial business."

Crouch continued, "As we work with multiple industry leaders, we see deeper engagement from them relating to annual budget allocations and framework agreements for our services. These are all important steps as they move from individual platform validation studies with us to dedicated research plans and meaningful annual revenue commitments tied to their specific drug development needs. For example, a number of our customers have already indicated they're building us into their upcoming budgets in a more meaningful way, with programs related to NASH and liver fibrosis leading the way for broader adoption. We've also recently begun to utilize our platform with clients who already have drugs in clinical development, illustrating that collaboration opportunities exist in all stages of drug discovery and development."

Crouch concluded, "Recent progress in developing our liver therapeutic tissue serves both as a way to de-risk the adoption of our services and as a chief source of validation for our customers. Its greatest promise is as a revolutionary therapeutic application for multiple liver diseases, including alpha-1 antitrypsin deficiency. With robust functionality and retention through 125 days post-implantation, and an approximately 75% reduction in the pathologic hallmarks of this disease in the region of implant, our advanced 3D liver model is at the leading edge of mirroring human liver function in our preclinical studies."

Second-Quarter Organovo Business Highlights

Revenue

- Total revenue was $1.4 million, down 2 percent from the year-ago period. The decrease was primarily driven by less revenue from previously completed collaborative research agreements, partially offset by grant payments related to the Company's recently awarded National Institutes of Health ("NIH") grant.
- Product and service revenue was $0.9 million, down 8 percent from the prior-year period, largely driven by fewer customer validation projects for liver tissue toxicology research services. This decrease was partially offset by strong gains in customer contracts for liver tissue disease modeling research services, primarily in the areas of liver fibrosis, NASH and kidney fibrosis.

Operating Expenses

- Cost of revenues was $0.3 million, a decrease of 35 percent from the prior-year period, reflecting a greater contribution from higher-margin primary human cell and tissue products.
- Research and development costs increased 9 percent year-over-year to $4.9 million, primarily due to increased facilities costs and employee related expenses.
- Selling, general and administrative expenses decreased 3 percent from the prior-year period to $5.7 million, reflecting lower external professional services and facilities costs.

Liquidity & Capital Resources

- The Company ended the fiscal second quarter with a cash and cash equivalents balance of $50.7 million.
- Working capital was $49.2 million to end the fiscal second quarter compared to $49.5 million in the prior-year quarter.

Fiscal-Year 2018 Outlook

The Company updated its full-year fiscal 2018 outlook for total revenue and negative Adjusted EBITDA. The Company now expects:

- Total revenue of between $4.5 million and $6.5 million for fiscal-year 2018. Fiscal 2017 total revenue was $4.2 million.
- Negative Adjusted EBITDA of between $26.0 million and $28.0 million for fiscal-year 2018. Fiscal 2017 negative Adjusted EBITDA was $29.8 million. The improvement in negative Adjusted EBITDA will be largely driven by reduced operating costs the Company will benefit from as the result of its recently announced organizational restructuring and a more rigorous focus on its existing commercial opportunities and therapeutics research program.

	Fiscal-Year 2018 Outlook (August 2017)	**Fiscal-Year 2018 Outlook (November 2017)**
Fiscal-Year 2018 Total Revenue	$6.0 million - $8.5 million	$4.5 million - $6.5 million
Fiscal-Year 2018 Negative Adjusted EBITDA	$29.0 million - $31.0 million	$26.0 million - $28.0 million

A reconciliation of non-GAAP negative Adjusted EBITDA, as forecasted for fiscal 2018, to the closest corresponding GAAP measure, net loss, is not available without unreasonable efforts on a forward-looking basis due to the high variability and low visibility of certain charges that may impact our GAAP results on a forward-looking basis, such as the measures and effects of share-based compensation.

Definitions & Supplemental Financial Measures

1. 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, share-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, share-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 below for a reconciliation of consolidated GAAP net income to Adjusted EBITDA for the fiscal quarters ended September 30, 2017 and 2016.

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

	Three Months Ended September 30, 2017	**Three Months Ended September 30, 2016**
GAAP net loss	$ (9,461)	$ (9,442)
Interest expense	-	-
Interest income	(118)	(37)
Income taxes	-	-
Depreciation and amortization	321	251
Share-based compensation	2,298	2,093
Restructuring/CEO transition	409	-
Adjusted EBITDA	$ (6,551)	$ (7,135)

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, November 9, 2017. 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 4644999. 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, November 9, 2017 through Thursday, November 16, 2017 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10111988, for an audio replay of the conference call.

About Organovo Holdings, Inc.

Organovo designs and creates functional, three-dimensional human tissues for use in drug discovery, clinical development, and therapeutic applications. The Company develops 3D human tissue systems through internal research programs and in collaboration with pharmaceutical, academic and other partners. Organovo's 3D human tissues have the potential to transform the drug discovery process, enabling treatments to be developed more effectively and with greater relevance to performance in human trials and commercialization. The Company's ExVive ^{TM} Human Liver and Kidney Tissues are used in high-value drug profiling, including compound screening in disease models, toxicology, target and marker discovery/validation, and other drug testing. The Company is also advancing a preclinical program to develop liver therapeutic tissues for critical unmet medical needs, including certain life-threatening pediatric diseases. In addition to numerous scientific publications, the Company's technology has been featured in The Wall Street Journal, Time Magazine, The Economist, Forbes, and numerous other media outlets. 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, the expected costs, timing and operational benefits of the Company's restructuring plan, the financial impact of the Company's restructuring plan on its future operating costs and financial results, and statements regarding the potential benefits and therapeutic uses of the Company's therapeutic liver tissue. 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 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 2018 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 June 7, 2017. 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 September 30, 2017	Three Months Ended September 30, 2016	Six Months Ended September 30, 2017	Six Months Ended September 30, 2016
Revenues				
Products and services	$ 946	$ 1,023	$ 1,890	$ 1,697
Collaborations and licenses	260	345	306	557
Grants	149	8	149	12
Total Revenues	1,355	1,376	2,345	2,266
Cost of revenues	254	393	555	561
Research and development expenses	4,944	4,544	9,977	8,987
Selling, general, and administrative expenses	5,736	5,918	11,592	10,974
Total costs and expenses	10,934	10,855	22,124	20,522
Loss from Operations	(9,579)	(9,479)	(19,779)	(18,256)
Other Income (Expense)				
Change in fair value of warrant liabilities	—	—	—	(5)
Interest income	118	37	216	74
Total Other Income (Expense)	118	37	216	69
Income Tax Expense	—	—	—	(22)

Net Loss	$ (9,461)	$ (9,442)	$ (19,563)	$ (18,209)
Currency Translation Adjustment	$ —	$ (7)	$ (11)	$ (7)
Comprehensive Loss	$ (9,461)	$ (9,449)	$ (19,574)	$ (18,216)
Net loss per common share—basic and diluted	$ (0.09)	$ (0.10)	$ (0.19)	$ (0.20)
Weighted average shares used in computing net loss per common share—basic and diluted	106,297,699	93,185,400	105,497,939	92,790,850

Organovo Holdings, Inc.

Consolidated Balance Sheets

	September 30, 2017 (Unaudited)	March 31, 2017 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 50,732	$ 62,751
Accounts receivable	1,033	647
Grant receivable	149	-
Inventory, net	496	550
Prepaid expenses and other current assets	934	1,144
Total current assets	53,344	65,092
Fixed assets, net	3,255	3,840
Restricted cash	127	127
Other assets, net	185	121
Total assets	$ 56,911	$ 69,180
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 477	$ 1,171
Accrued expenses	2,821	4,101
Deferred revenue	654	582
Deferred rent	173	157
Total current liabilities	4,125	6,011
Deferred revenue, net of current portion	67	58
Deferred rent, net of current portion	661	749
Total liabilities	4,853	6,818
Commitments and Contingencies (Note 4)		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 106,904,525 and 104,551,466 shares issued and outstanding at September 30, 2017 and March 31, 2017, respectively	107	104
Additional paid-in capital	270,842	261,586
Accumulated deficit	(218,880)	(199,317)
Accumulated other comprehensive income (loss)	(11)	(11)
Total stockholders' equity	52,058	62,362
Total Liabilities and Stockholders' Equity	$ 56,911	$ 69,180

Organovo Holdings, Inc.

Unaudited Consolidated Statements of Cash Flows

	Six Months Ended September 30, 2017	Six Months Ended September 30, 2016
Cash Flows From Operating Activities		
Net loss	$ (19,563)	$ (18,209)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	647	502
Change in fair value of warrant liabilities	—	5
Stock-based compensation	4,350	3,522
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(386)	(347)
Grants receivable	(149)	—
Inventory	54	(111)
Prepaid expenses and other assets	210	80
Accounts payable	(694)	(33)
Accrued expenses	(1,280)	381
Deferred rent	(72)	(68)
Deferred revenue	81	(631)
Net cash used in operating activities	(16,802)	(14,909)
Cash Flows From Investing Activities		
Purchases of fixed assets	(56)	(452)
Purchases of intangible assets	(70)	—
Net cash used in investing activities	(126)	(452)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	4,084	4,500
Proceeds from exercise of stock options	825	500
Net cash provided by financing activities	4,909	5,000
Effect of currency exchange rate changes on cash and cash equivalents	—	(7)
Net (Decrease) in Cash and Cash Equivalents	(12,019)	(10,368)
Cash and Cash Equivalents at Beginning of Period	62,751	62,091
Cash and Cash Equivalents at End of Period	$ 50,732	$ 51,723
Supplemental Disclosure of Cash Flow Information:		
Interest paid	$ —	$ —
Income taxes paid	$ —	$ 22

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