UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 8, 2018

ORGANOVO HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Commission File Number: 001-35996

Delaware	**27-1488943**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)

6275 Nancy Ridge Dr.,
San Diego, California 92121
(Address of principal executive offices, including zip code)

(858) 224-1000
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On February 8, 2018, Organovo Holdings, Inc. (the "Company") issued a press release announcing financial results for the third quarter of its fiscal year, which period ended December 31, 2017. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished in this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act of 1934 or otherwise subject to the liabilities of that Section and shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission (the "SEC").

Item 9.01 Financial Statements and Exhibits

(d)

Exhibit No.	Exhibits
99.1	Press Release, dated February 8, 2018.

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated February 8, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

ORGANOVO HOLDINGS, INC.

Date: February 8, 2018

/s/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President

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ORGANOVO ANNOUNCES FISCAL THIRD-QUARTER 2018 RESULTS; COMPANY UPDATES FULL-YEAR FISCAL 2018 OUTLOOK

SAN DIEGO – February 8, 2018 – Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo") today reported financial results for the fiscal third quarter of 2018 and updated its full-year fiscal 2018 outlook. The Company reported fiscal third-quarter total revenue of $1.2 million. Total revenue was unchanged from the prior-year period and decreased 15 percent versus the fiscal second quarter of 2018. Net loss was $7.8 million, or $0.07 per share, for the fiscal third quarter of 2018, as compared to $9.6 million, or $0.09 per share, for the fiscal third quarter of 2017. Negative Adjusted EBITDA(1) for the third quarter was $5.2 million, as compared to $7.3 million for the prior-year period.

"Our liver therapeutic tissue program continues to make excellent progress in achieving critical regulatory and scientific milestones," said Taylor J. Crouch, CEO, Organovo. "With the U.S. Food and Drug Administration ("FDA") recently granting orphan designation for our NovoTissues® treatment of Alpha-1 antitrypsin deficiency ("A1AT"), our path to commercializing this novel therapeutic comes with significant developmental and economic incentives. With few alternative therapies and a high annual cost of care, patient need is great in treating this rare, debilitating liver disease. We've also begun new studies in a second therapeutic indication within the category of inborn errors of metabolism, Fumarylacetoacetate Hydrolase ("FAH") deficiency, and look forward to reporting proof-of-principle data in the coming months."

Crouch continued, "In our commercial segment, we continue to shift our R&D and business development efforts to high-value liver disease modeling services. We're seeing meaningful

early uptake as we transition away from routine toxicology projects, with nearly all of our service revenue in the fiscal third quarter representing disease modeling studies. With approximately 250 global programs pursuing treatments in the areas of non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH"), we believe being a pioneer in this area translates into the best path forward for boosting our revenue growth. Sophisticated clients are already partnering with us in a multi-faceted approach to develop custom tissue models, allowing us to target the entire drug discovery and development spectrum. We continue to expect deeper engagement from our customers over the next several months."

Crouch concluded, "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. We'll continue to direct our resources at all of these opportunities as we focus on long-term value creation."

Third-Quarter Organovo Business Highlights

Revenue

- Total revenue was $1.2 million, unchanged from the year-ago period. Higher grant revenue related to the Company's National Institutes of Health ("NIH") project offset lower revenue from collaborative agreements.
- Product and service revenue was $0.8 million, up 19 percent from the prior-year period, largely driven by an increase in liver disease modeling studies and sales from human cell and tissue products.

Operating Expenses

- Cost of revenues was $0.2 million, a decrease of 9 percent from the prior-year period, reflecting a greater contribution from higher-margin primary human cell and tissue products.

- Research and development costs decreased 20 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.
- Selling, general and administrative expenses decreased 12 percent from the prior-year period to $4.9 million, reflecting lower employee and non-cash stock-based compensation expenses, which offset $0.8 million in severance and other costs related to the Company's organizational restructuring.

Liquidity & Capital Resources

- The Company ended the fiscal third quarter with a cash and cash equivalents balance of $47.3 million.
- During the fiscal third quarter, the Company generated net proceeds of approximately $3.1 million from the issuance of 2.3 million shares of common stock in at-the-market ("ATM") offerings at a weighted average price of $1.42 per share. Through January 31, 2018, the Company generated additional net proceeds of approximately $2.1 million from the issuance of 1.5 million shares of common stock in ATM offerings at a weighted average price of $1.40.
- Working capital was $46.0 million to end the fiscal third quarter compared to $67.5 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 $5.2 million for fiscal-year 2018. Fiscal 2017 total revenue was $4.2 million.
- Negative Adjusted EBITDA of between $25.0 million and $26.0 million for fiscal-year 2018. Fiscal 2017 negative Adjusted EBITDA was $29.8 million. The Company's continued improvement in negative Adjusted EBITDA will be largely driven by reduced

operating costs as the result of its organizational restructuring and a more rigorous focus on its existing commercial opportunities and therapeutics research program.

	Fiscal-Year 2018 Outlook (November 2017)	Fiscal-Year 2018 Outlook (February 2018)
Fiscal-Year 2018 Total Revenue	$4.5 million - $6.5 million	$4.5 million - $5.2 million
Fiscal-Year 2018 Negative Adjusted EBITDA	$26.0 million - $28.0 million	$25.0 million - $26.0 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 stock-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, 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 below for a reconciliation of consolidated GAAP net income to Adjusted EBITDA for the fiscal quarters ended December 31, 2017 and 2016.

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

	Three Months Ended December 31, 2017	Three Months Ended December 31, 2016
GAAP net loss	$ (7,791)	$ (9,581)
Interest expense	-	-
Interest income	(118)	(50)
Income taxes	-	1
Depreciation and amortization	315	322
Stock-based compensation	1,250	2,018
Restructuring/CEO transition	1,130	-
Adjusted EBITDA	$ (5,214)	$ (7,290)

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, February 8, 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 2242366. 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, February 8, 2018 through Thursday, February 15, 2018 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10115734, for an audio replay of the conference call.

About Organovo Holdings, Inc.

Organovo is developing and commercializing a platform technology to produce and study living tissues that emulate key aspects of human biology and disease for use in drug discovery, clinical development, and therapeutic applications. The Company develops tissue systems through internal research programs and in collaboration with pharmaceutical, academic and other partners. Organovo's living 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™ 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 its NovoTissues® liver therapeutic tissues for critical unmet medical needs, including certain life-threatening pediatric diseases. 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 2018 outlook. These and other factors are identified and described in more detail in the Company's filings with the SEC, including its Quarterly Report on Form 10-Q filed with the SEC on February 8, 2018 and 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.

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Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Operations and

	Three Months Ended December 31, 2017	Three Months Ended December 31, 2016	Nine Months Ended December 31, 2017	Nine Months Ended December 31, 2016
Revenues				
Products and services	$ 832	$ 699	$ 2,722	$ 2,396
Collaborations and licenses	61	443	367	1,001
Grants	260	9	409	21
Total Revenues	1,153	1,151	3,498	3,418
Cost of revenues	192	212	747	773
Research and development expenses	4,005	5,024	13,982	14,012
Selling, general, and administrative expenses	4,865	5,546	16,457	16,520
Total costs and expenses	9,062	10,782	31,186	31,305
Loss from Operations	(7,909)	(9,631)	(27,688)	(27,887)
Other Income (Expense)				
Change in fair value of warrant liabilities	—	1	—	(4)
Interest expense	—	—	—	—
Interest income	118	50	334	124
Total Other Income (Expense)	118	51	334	120
Income Tax Expense	—	(1)	—	(23)
Net Loss	$ (7,791)	$ (9,581)	$ (27,354)	$ (27,790)
Currency Translation Adjustment	$ (2)	$ (3)	$ (2)	$ (10)
Comprehensive Loss	$ (7,793)	$ (9,584)	$ (27,356)	$ (27,800)
Net loss per common share—basic and diluted	$ (0.07)	$ (0.09)	$ (0.26)	$ (0.29)
Weighted average shares used in computing net loss per common share—basic and diluted	107,345,623	101,174,734	106,107,721	95,595,640

Organovo Holdings, Inc.
Consolidated Balance Sheets

	December 31, 2017 (Unaudited)	March 31, 2017 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	47,338	62,751
Accounts receivable	1,174	647
Grant receivable	260	-
Inventory, net	605	550
Prepaid expenses and other current assets	891	1,144
Total current assets	50,268	65,092
Fixed assets, net	2,978	3,840
Restricted cash	127	127
Other assets, net	181	121
Total assets	$ 53,554	$ 69,180
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 452	$ 1,171
Accrued expenses	2,808	4,101
Deferred revenue	857	582
Deferred rent	180	157
Total current liabilities	4,297	6,011
Deferred revenue, net of current portion	43	58
Deferred rent, net of current portion	613	749
Total liabilities	4,953	6,818
Commitments and Contingencies (Note 3)		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 109,322,626 and 104,551,466 shares issued and outstanding at December 31, 2017 and March 31, 2017, respectively	109	104
Additional paid-in capital	275,176	261,586
Accumulated deficit	(226,671)	(199,317)
Accumulated other comprehensive income (loss)	(13)	(11)
Total stockholders' equity	48,601	62,362
Total Liabilities and Stockholders' Equity	$ 53,554	$ 69,180

Organovo Holdings, Inc.
Unaudited Consolidated Statements of Cash Flows

	Nine Months Ended 12/31/2017	Nine Months Ended 12/31/2016
Cash Flows From Operating Activities		
Net loss	$ (27,354)	$ (27,790)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	962	824
Change in fair value of warrant liabilities	—	4
Stock-based compensation	5,600	5,540
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(527)	(771)
Grants receivable	(260)	—
Inventory	(55)	6
Prepaid expenses and other assets	253	400
Accounts payable	(719)	(65)
Accrued expenses	(1,293)	486
Deferred rent	(113)	(103)
Deferred revenue	260	(490)
Net cash used in operating activities	(23,246)	(21,959)
Cash Flows From Investing Activities		
Restricted cash deposits	—	(48)
Purchases of fixed assets	(90)	(1,061)
Purchases of intangible assets	(70)	—
Net cash used in investing activities	(160)	(1,109)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	7,169	30,401
Proceeds from exercise of stock options	826	582
Net cash provided by financing activities	7,995	30,983
Effect of currency exchange rate changes on cash and cash equivalents	(2)	(10)
Net Increase (Decrease) in Cash and Cash Equivalents	(15,413)	7,905
Cash and Cash Equivalents at Beginning of Period	62,751	62,091
Cash and Cash Equivalents at End of Period	$ 47,338	$ 69,996
Supplemental Disclosure of Cash Flow Information:		
Interest paid	$ —	$ —
Income taxes paid	$ —	$ 23