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 7, 2019

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 7, 2019, 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, 2018. 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 7, 2019.

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 7, 2019

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

Investor & Press Contact:

Steve Kunszabo
Organovo Holdings, Inc.
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skunszabo@organovo.com

ORGANOVO AFFIRMS KEY CLINICAL DEVELOPMENT GOALS; COMPANY REPORTS FISCAL THIRD-QUARTER 2019 RESULTS

- *Pre-Investigational New Drug ("IND") meeting with the FDA expected to be held in calendar 2019*
- *Submit first IND in calendar 2020*

SAN DIEGO – February 7, 2019 – 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 affirmed its key clinical development goals and reported its fiscal third-quarter 2019 financial results.

"We remain on track to submit our first IND in calendar 2020," said Taylor J. Crouch, CEO, Organovo. "While this is our most important clinical development goal over the next two years, we're taking a number of important steps along the way to support that milestone. In calendar 2019, we expect to hold a pre-IND meeting with the FDA on our lead program, and plan to begin our IND-enabling toxicity study. To facilitate these important objectives and to ensure our readiness for first-in-human trials, we're conducting proof-of-concept studies in multiple disease areas, running dose ranging studies and enhancing our tissue design."

Crouch continued, "We also continue to generate favorable preclinical results in our liver therapeutic tissue program as we focus increasingly on end-stage liver disease and a select group of inborn errors of metabolism. At industry meetings over the last several months, we've presented data on the performance of our tissues in animal models for Alpha-1-antitrypsin deficiency ("A1AT") and hereditary tyrosinemia Type 1 ("HTT1"). For both rare diseases, our tissues demonstrated engraftment, retention and functionality post-implantation, while reducing

disease hallmarks in the A1AT animal studies and improving the median survival rate for treated animals in the HTT1 studies. Our objective in implanting a healthy tissue patch is to restore function or offset the deficiencies related to a specific condition. We hope to serve as a 'bridge to transplant' for these patients with limited treatment options, with an ultimate goal of delaying or reducing the overall need for transplant."

Crouch concluded, "We're also building upon our cell and *in vitro* tissue platform, and through our partners at UC San Diego, recently presented data on the ongoing development of our non-alcoholic steatohepatitis ("NASH") liver tissue model at the NASH-TAG 2019 Conference. Dr. David Brenner, vice chancellor for health sciences at the University of California, San Diego, presented important findings from a series of studies that showed disease induction in our 3D bioprinted liver tissue model, treatment with two clinical compounds, and a reduced disease phenotype in the treated tissues. We also continue to work with our clients on several custom projects for our liver tissue research services including the exploration of drug combination studies in our NASH disease model."

Key Clinical Development Goals & Outlook

- The Company believes that development of its healthy therapeutic liver tissue patch can treat a broad range of liver disease indications. Organovo continues to conduct supportive proof-of-concept studies in multiple indications aimed at treating end-stage liver disease and inborn errors of metabolism.
- Organovo expects to hold a pre-IND meeting with the FDA in calendar 2019 for its lead program.
- The Company plans to begin the IND-enabling toxicity study for its lead program in the second half of calendar 2019.
- Organovo expects to file for its first IND in calendar 2020.
- The Company will continue to opportunistically generate revenue to support its therapeutic research mission by leveraging its cell and *in vitro* tissue platform.
- Organovo plans to continue expanding its global IP portfolio, which currently includes over 100 patents and pending applications.

- As of December 31, 2018, the Company had a cash and cash equivalents balance of $35.2 million. Organovo now expects an improved net cash utilization(1) rate of $20.5 million to $21.5 million in fiscal 2019, and believes it has sufficient funds to meet its operating and capital requirements through fiscal 2020.

Fiscal Third-Quarter 2019 Highlights

- Net loss was $6.4 million, a $1.4 million improvement over the year-ago period, as total costs and expenses declined 19 percent to $7.3 million, primarily due to lower employee costs related to the Company's organizational restructuring and prioritization of R&D projects.
- Net cash utilization was $4.0 million, an improvement from $6.5 million in the prior-year quarter.
- Total revenue was $0.8 million, a 32 percent decrease from the year-ago period, primarily driven by lower grant revenue.
- During the fiscal third quarter, the Company generated net proceeds of approximately $1.9 million from the issuance of 1.8 million shares of common stock in at-the-market offerings at a weighted average price of $1.03 per share.
- In November 2018, the Company entered into a cell and tissue clinical sourcing agreement with the International Institute for the Advancement of Medicine ("IIAM"). IIAM is one of the world's leading organizations for the procurement of organs used in medical research and the development of therapeutic applications.

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, February 7, 2019. 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 4962923. 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 7, 2019 through Thursday, February 14, 2019 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10127492, 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 Company's ability to successfully complete additional preclinical studies; the Company's ability to meet market demand; and customer demand for and acceptance of its 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; the Company may not be able to obtain sufficient raw materials to meet market demand for its therapeutic products; 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 ability to raise sufficient funds to support its business plan and ongoing operations; 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.

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Organovo Holdings, Inc.

Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Loss

(in thousands except share and per share data)

	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017	Nine Months Ended December 31, 2018	Nine Months Ended December 31, 2017
Revenues				
Products and services	$ 670	$ 832	$ 1,709	$ 2,722
Collaborations and licenses	43	61	128	367
Grants	66	260	574	409
Total Revenues	779	1,153	2,411	3,498
Cost of revenues	136	192	381	747
Research and development expenses	3,782	4,005	10,348	13,982
Selling, general and administrative expenses	3,387	4,865	11,794	16,457
Total costs and expenses	7,305	9,062	22,523	31,186
Loss from Operations	(6,526)	(7,909)	(20,112)	(27,688)
Other Income (Expense)				
Gain (loss) on fixed asset disposals	(65)	—	(63)	—
Interest income	192	118	526	334
Total Other Income	127	118	463	334
Income Tax Expense	—	—	(3)	—
Net Loss	$ (6,399)	$ (7,791)	$ (19,652)	$ (27,354)
Currency Translation Adjustment	$ —	$ (2)	$ —	$ (2)
Comprehensive Loss	$ (6,399)	$ (7,793)	$ (19,652)	$ (27,356)
Net loss per common share—basic and diluted	$ (0.06)	$ (0.07)	$ (0.17)	$ (0.26)
Weighted average shares used in computing net loss per common share—basic and diluted	116,256,561	107,345,623	113,991,794	106,107,721

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

	December 31, 2018 (Unaudited)	March 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	$ 35,224	$ 43,726
Accounts receivable	547	883
Grant receivable	124	145
Inventory, net	1,049	842
Prepaid expenses and other current assets	527	1,164
Total current assets	37,471	46,760
Fixed assets, net	1,946	2,788
Restricted cash	127	127
Other assets, net	141	152
Total assets	$ 39,685	$ 49,827
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 647	$ 464
Accrued expenses	2,156	3,341
Deferred revenue	580	668
Deferred rent	27	185
Total current liabilities	3,410	4,658
Deferred revenue, net of current portion	-	19
Deferred rent, net of current portion	600	564
Total liabilities	4,010	5,241
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 117,769,919 and 111,032,957 shares issued and outstanding at December 31, 2018 and March 31, 2018, respectively	118	111
Additional paid-in capital	289,329	278,595
Accumulated deficit	(253,772)	(234,120)
Total stockholders' equity	35,675	44,586
Total Liabilities and Stockholders' Equity	$ 39,685	$ 49,827

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

	Nine Months Ended December 31, 2018	Nine Months Ended December 31, 2017
Cash Flows From Operating Activities		
Net loss	$ (19,652)	$ (27,354)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on disposal of fixed assets	63	—
Depreciation and amortization	824	962
Stock-based compensation	3,911	5,600
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	336	(527)
Grants receivable	21	(260)
Inventory	(207)	(55)
Prepaid expenses and other assets	637	253
Accounts payable	183	(719)
Accrued expenses	(1,185)	(1,293)
Deferred revenue	(107)	260
Deferred rent	(122)	(113)
Net cash used in operating activities	(15,298)	(23,246)
Cash Flows From Investing Activities		
Purchases of fixed assets	(37)	(90)
Proceeds from disposals of fixed assets	3	—
Purchases of intangible assets	—	(70)
Net cash used in investing activities	(34)	(160)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	6,916	7,243
Employee taxes paid related to net share settlement of equity awards	(136)	(74)
Proceeds from exercise of stock options	50	826
Net cash provided by financing activities	6,830	7,995
Effect of currency exchange rate changes on cash and cash equivalents	-	(2)
Net decrease in cash, cash equivalents, and restricted cash	(8,502)	(15,413)
Cash, cash equivalents, and restricted cash at beginning of period	43,853	62,878
Cash, cash equivalents, and restricted cash at end of period	$ 35,351	$ 47,465
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 35,224	$ 47,338
Restricted cash	127	127
Total cash, cash equivalent and restricted cash	$ 35,351	$ 47,465
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	$ 3	$ 23