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): November 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 November 8, 2018, Organovo Holdings, Inc. (the "Company") issued a press release announcing financial results for the second quarter of its fiscal year, which period ended September 30, 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 November 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: November 8, 2018

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

EXHIBIT 99.1

Investor & Press Contact:

Steve Kunszabo
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skunszabo@organovo.com

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

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

SAN DIEGO – November 8, 2018 – 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 second-quarter 2019 financial results.

"During the fiscal second quarter, we affirmed our key clinical development and operating goals," said Taylor J. Crouch, CEO, Organovo. "We remain on track for a pre-IND meeting with the FDA for our lead indication in calendar 2019 and expect to begin our IND-enabling toxicity study to support multiple orphan disease indications in the second half of calendar 2019. In addition, we plan to conduct proof-of-concept animal studies in multiple rare diseases. We've also made strong progress in pursuing a second orphan designation, and anticipate we'll now receive a response from the FDA in the first half of calendar 2019."

Crouch continued, "We continue to generate favorable preclinical results in our liver therapeutic tissues program and will present data at next week's Liver Meeting® on the performance of our tissues in an animal model of hereditary tyrosinemia Type 1 ("HT-1"). This rare disease is often characterized by severe liver damage and limited treatment options. In early studies in established animal models for HT-1, our tissues demonstrated engraftment, retention and functionality post-implantation, while also showing an improvement in the median survival rate for treated animals. Much like with Alpha-1 antitrypsin deficiency ("A1AT"), the same healthy

tissue construct allows us to potentially treat a broad range of target indications. Our objective in implanting a healthy tissue patch is to restore function or offset the deficiency of a specific enzyme abnormality. Our ultimate goal, which we hope to evaluate in future studies, is delaying or reducing the need for a transplant."

Crouch concluded, "We also continue to build upon our cell and *in vitro* tissue platform, including the launch of a new RNASeq data library by our Samsara division, and several custom projects for our liver tissue research services including disease modeling and toxicology."

Key Clinical Development Goals & Outlook

- The Company continues to conduct supportive proof-of-concept studies in multiple orphan disease indications aimed at treating inborn errors of metabolism.
- Organovo expects to hold a pre-IND meeting with the FDA in calendar 2019 for its lead rare disease program.
- The Company believes that development of its healthy therapeutic liver tissue patch can treat a broad range of rare disease indications. The Company is pursuing a second orphan designation with the FDA, which it now anticipates receiving in the first half of calendar 2019.
- Organovo plans to begin its IND-enabling toxicity study to support multiple indications including A1AT in the second half of calendar 2019.
- The Company expects to file for its first IND in calendar 2020.
- Organovo will continue to opportunistically generate revenue to support its therapeutic research mission by leveraging its cell and *in vitro* tissue platform.
- Samsara Sciences, the Company's wholly-owned subsidiary, recently launched a new product offering an RNA-Seq data library with matched sets of human liver tissues and cell types isolated from a range of healthy and diseased donors. This cost-effective solution enables customers to mine data for discovery and validation of disease and cell type-specific markers.
- Organovo plans to continue expanding its global IP portfolio, which currently includes over 100 patents and pending applications.

- As of September 30, 2018, the Company had a cash and cash equivalents balance of $37.4 million. Organovo continues to expect 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 through fiscal 2020.

Fiscal Second-Quarter 2019 Financial Highlights

- Net loss was $5.8 million, a $3.6 million improvement over the year-ago period, as total costs and expenses declined 36 percent to $7.0 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 $4.3 million, an improvement from $8.3 million in the prior-year quarter.
- Total revenue was $0.9 million, a 30 percent decrease from the year-ago period, primarily driven by lower revenue from products and services, partially offset by higher grant revenue.
- During the fiscal second quarter, the Company generated net proceeds of approximately $2.1 million from the issuance of 1.7 million shares of common stock in at-the-market offerings at a weighted average price of $1.27 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, November 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 2924727. 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 8, 2018 through Thursday, November 15, 2018 at Organovo's Investor Relations webpage. Callers can also dial (877) 344-7529 (U.S. only) or (412) 317-0088, Access Code 10124086, 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; 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 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 September 30, 2018	Three Months Ended September 30, 2017	Six Months Ended September 30, 2018	Six Months Ended September 30, 2017
Revenues				
Products and services	$ 493	$ 946	$ 1,039	$ 1,890
Collaborations and licenses	42	260	85	306
Grants	408	149	508	149
Total Revenues	943	1,355	1,632	2,345
Cost of revenues	125	254	245	555
Research and development expenses	3,187	4,944	6,566	9,977
Selling, general and administrative expenses	3,640	5,736	8,407	11,592
Total costs and expenses	6,952	10,934	15,218	22,124
Loss from Operations	(6,009)	(9,579)	(13,586)	(19,779)
Other Income (Expense)				
Gain (loss) on fixed asset disposals	—	—	2	—
Interest income	172	118	334	216
Total Other Income	172	118	336	216
Income Tax Expense	—	—	(3)	—
Net Loss	$ (5,837)	$ (9,461)	$ (13,253)	$ (19,563)
Currency Translation Adjustment	$ —	$ —	$ —	$ (11)
Comprehensive Loss	$ (5,837)	$ (9,461)	$ (13,253)	$ (19,574)
Net loss per common share—basic and diluted	$ (0.05)	$ (0.09)	$ (0.12)	$ (0.19)
Weighted average shares used in computing net loss per common share—basic and diluted	113,993,237	106,297,699	112,732,767	105,497,939

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

	September 30, 2018 (Unaudited)	March 31, 2018 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 37,355	$ 43,726
Accounts receivable	475	883
Grant receivable	453	145
Inventory, net	1,036	842
Prepaid expenses and other current assets	798	1,164
Total current assets	40,117	46,760
Fixed assets, net	2,236	2,788
Restricted cash	127	127
Other assets, net	145	152
Total assets	$ 42,625	$ 49,827
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 449	$ 464
Accrued expenses	2,026	3,341
Deferred revenue	619	668
Deferred rent	197	185
Total current liabilities	3,291	4,658
Deferred revenue, net of current portion	—	19
Deferred rent, net of current portion	464	564
Total liabilities	3,755	5,241
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 115,200,421 and 111,032,957 shares issued and outstanding at September 30, 2018 and March 31, 2018, respectively	115	111
Additional paid-in capital	286,128	278,595
Accumulated deficit	(247,373)	(234,120)
Total stockholders' equity	38,870	44,586
Total Liabilities and Stockholders' Equity	$ 42,625	$ 49,827

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

	Six Months Ended September 30, 2018	Six Months Ended September 30, 2017
Cash Flows From Operating Activities		
Net loss	$ (13,253)	$ (19,563)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on disposal of fixed assets	(2)	—
Depreciation and amortization	570	647
Stock-based compensation	2,553	4,350
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	408	(386)
Grants receivable	(308)	(149)
Inventory	(194)	54
Prepaid expenses and other assets	366	210
Accounts payable	(15)	(694)
Accrued expenses	(1,315)	(1,280)
Deferred revenue	(68)	81
Deferred rent	(88)	(72)
Net cash used in operating activities	(11,346)	(16,802)
Cash Flows From Investing Activities		
Purchases of fixed assets	(11)	(56)
Proceeds from disposals of fixed assets	2	—
Purchases of intangible assets	—	(70)
Net cash used in investing activities	(9)	(126)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and exercise of warrants, net	5,129	4,135
Employee taxes paid related to net share settlement of equity awards	(145)	(51)
Proceeds from exercise of stock options	—	825
Net cash provided by financing activities	4,984	4,909
Net decrease in cash, cash equivalents, and restricted cash	(6,371)	(12,019)
Cash, cash equivalents, and restricted cash at beginning of period	43,853	62,878
Cash, cash equivalents, and restricted cash at end of period	$ 37,482	$ 50,859
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	37,355	50,732
Restricted cash	127	127
Total cash, cash equivalent and restricted cash	37,482	50,859
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	$ 3	$ —