

**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): December 4, 2018

**ORGANOVO HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Commission File Number: 001-35996**

**Delaware**  
(State or other jurisdiction  
of incorporation)

**27-1488943**  
(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.

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**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

(d) On December 4, 2018, the Board of Directors (the “Board”) of Organovo Holdings, Inc. (the “Company”), authorized and approved: (i) an increase in the size of the Board from seven (7) to eight (8) members, (ii) the appointment of David Shapiro, M.D. to the Board as Class I Director, effective December 4, 2018. The Company issued a press release announcing the appointment of Dr. Shapiro. A copy of that press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 5.02.

David Shapiro, M.D. has served as the Chief Medical Officer for Intercept Pharmaceuticals, Inc. (“Intercept”), a publicly-traded biopharmaceutical company, since November 2017, having previously served as Intercept’s Chief Medical Officer and Executive Vice President, Development since 2008. Dr. Shapiro has over 30 years of clinical development experience in the pharmaceutical industry. Dr. Shapiro founded a consulting company, Integrated Quality Resources, that focused on development stage biopharmaceutical companies and was active in this role from 2005 to 2008. From 2000 to 2005, Dr. Shapiro was Executive Vice President, Medical Affairs and Chief Medical Officer of Idun Pharmaceuticals, Inc., prior to its acquisition by Pfizer Inc. From 1995 to 1998, he was President of the Scripps Medical Research Center at Scripps Clinic. He also served as Vice President, Clinical Research at Gensia and as Director and Group Leader, Hypertension Clinical Research at Merck Research Laboratories from 1985 to 1990. Dr. Shapiro has authored more than 20 peer-reviewed publications and organized and chaired several conferences aimed at improving product development. Dr. Shapiro served for two terms on the Executive Committee of the Board of the American Academy of Pharmaceutical Physicians. Dr. Shapiro was a director of Arcturus Therapeutics Ltd., a publicly-traded drug delivery and RNA medicines company, from November 2017 to May 2018. Dr. Shapiro received his medical degree from Dundee University & Medical School, and undertook his postgraduate medical training in the university affiliated hospitals in Oxford, United Kingdom and the University of Vermont. He is an elected Fellow of both the Royal College of Physicians of London and the Faculty of Pharmaceutical Physicians of the United Kingdom.

In appointing Dr. Shapiro as a director, the Board considered Dr. Shapiro’s medical, regulatory and clinical leadership experience at Intercept and other biotechnology companies. Specifically, Dr. Shapiro’s many years of experience in managing and supervising the clinical development and commercialization of biotechnology products allow him to contribute management insight to the Board, particularly in the area of clinical and regulatory strategy.

The Company’s non-employee director compensation program for fiscal 2019 includes an annual cash retainer of \$50,000, plus additional cash retainers for service on the Board’s standing committees. Under this program, Dr. Shapiro received an initial grant of a stock option award to purchase 46,500 shares of the Company’s common stock with an exercise price of \$1.01 per share, the closing price of the Company’s common stock on the Nasdaq Stock Market on the date of grant (the “Initial Option Award”). The Initial Option Award will vest quarterly over three years measured from a vesting start date of December 4, 2018, subject to accelerated vesting in the event of a change of control. Additionally, Dr. Shapiro will receive a pro-rated annual grant of a stock option award to purchase 30,000 shares of the Company’s common stock with an exercise price of \$1.01 per share (the “Annual Option Award”). The Annual Option Award will vest on the earlier of twelve months from December 4, 2018, or the day prior to the 2019 annual meeting of stockholders, subject to accelerated vesting in the event of a change of control. Each Initial and Annual Award is subject to the terms and conditions of the Company’s 2012 Equity Incentive Plan, and is subject to a Stock Option Award Agreement in the form previously approved by the Board for issuance to the Company’s non-employee directors. The Company’s form of Non-Employee Director Stock Option Award Agreement was filed with the Securities and Exchange Commission on June 9, 2015 as Exhibit 10.35 to the Company’s Annual Report on Form 10-K for the year ended March 31, 2015 and is incorporated herein by reference.

The Company also entered into an Indemnification Agreement with Dr. Shapiro. This Indemnification Agreement provides for indemnification and advancement of litigation and other expenses to Dr. Shapiro to the fullest extent permitted by law for claims relating to his service to the Company or its subsidiaries. The Indemnification Agreement is identical in all material respects to the indemnification agreements entered into with the Company’s other directors and officers. The Company’s form of indemnification agreement was filed with the Securities and Exchange Commission on February 13, 2012 as Exhibit 10.17 to the Company’s Current Report on Form 8-K and is incorporated by reference herein.

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There are no family relationships between Dr. Shapiro and any of the Company's directors or executive officers, and there were no arrangements or understandings by which Dr. Shapiro was named a director. In April 2017, the Company entered into a standard services agreement with Intercept. Under this Agreement, the Company provided ExVive™ Liver Tissue Services for Intercept in the amount of \$185,000, pursuant to standard terms and conditions consistent with the Company's practices. The services agreement concluded in March 2018. Dr. Shapiro has no other direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

**Item 9.01 Financial Statements and Exhibits.**

(d)

<u>Exhibit No.</u>	<u>Exhibits</u>
10.1	<a href="#"><u>Form of Non-Employee Director Stock Option Award Agreement (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2015 filed with the Securities and Exchange Commission on June 9, 2015).</u></a>
10.2	<a href="#"><u>Form of Indemnification Agreement (incorporated by reference to Exhibit 10.17 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 13, 2012).</u></a>
99.1	<a href="#"><u>Press Release, dated December 6, 2018.</u></a>

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**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.

Date: December 6, 2018

**ORGANOVO HOLDINGS, INC.**

/s/ Taylor Crouch

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Taylor Crouch

Chief Executive Officer and President



*Investor & Press Contact:*

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## **ORGANOVO APPOINTS NEW BOARD MEMBER**

SAN DIEGO – December 6, 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 announced that its board of directors has appointed one new member. David Shapiro, M.D., Chief Medical Officer of Intercept Pharmaceuticals, Inc. (“Intercept”), will join Organovo’s board, effective immediately. Dr. Shapiro’s appointment increases the number of Organovo directors to eight.

“David brings significant liver-focused clinical development and medical expertise to our board,” said Taylor J. Crouch, CEO, Organovo. “His senior leadership experience across the life sciences sector adds to the strength of our already outstanding board, and I’m confident he’ll make a significant contribution as we complete the preclinical studies for our liver therapeutic tissue and move toward our first Investigational New Drug (“IND”) application in calendar 2020. David has played a key role in establishing his current company as a leader in treating liver disease, including a commercial product addressing primary biliary cholangitis (“PBC”) and a late-stage development program focused on non-alcoholic steatohepatitis (“NASH”). I’m grateful for his willingness to join the board at such an important time in our organizational development, as well as the ongoing support from all of our directors.”

Dr. David Shapiro has over 30 years of clinical development experience in the pharmaceutical industry. He has served as the Chief Medical Officer of Intercept Pharmaceuticals, Inc. since November 2017, having previously served as its Chief Medical Officer and Executive Vice President, Development since 2008. Dr. Shapiro founded a consulting company, Integrated Quality Resources, that focused on development stage biopharmaceutical companies and was

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active in this role from 2005 to 2008. From 2000 to 2005, Dr. Shapiro was Executive Vice President, Medical Affairs and Chief Medical Officer of Idun Pharmaceuticals, Inc., prior to its acquisition by Pfizer Inc. From 1995 to 1998, he was President of the Scripps Medical Research Center at Scripps Clinic. He served as Vice President, Clinical Research at Gensia and as Director and Group Leader, Hypertension Clinical Research at Merck Research Laboratories from 1985 to 1990.

#### **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](http://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*

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*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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