

ORGANOVO HOLDINGS, INC.

Form 8-K

April 10, 2014

**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): April 10, 2014**

**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.)**

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**6275 Nancy Ridge Dr.,**

**San Diego, California 92121**

**(Address of principal executive offices, including zip code)**

**(858) 550-9994**

**(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))

## Item 7.01 Regulation FD Disclosure

On April 10, 2014, Organovo Holdings, Inc. (the Company) released the following information to update investors on the results of its initial study of 3D breast tissues generated with its NovoGen MMX Bioprinter in breast cancer models. The Company presented these results at the annual meeting of the American Association for Cancer Research (AACR) held on April 5-9, 2014 in San Diego, California.

Results from the Company's initial study showed the following:

The Company's NovoGen MMX Bioprinter technology can successfully fabricate 3D breast tissues consisting of cancer cells, fibrous stroma, adipose tissue, and microvasculature on a reproducible basis.

3D bioprinting enables compartmentalization of the breast tissue, with tumor epithelium controllably surrounded by stromal tissue.

Histologic and metabolic (Alamar Blue and ATP) measurements highlighted a consistency in printing from construct to construct.

The Company's experiments involving the delivery of fluorescently-tagged drugs to its 3D breast tissues indicate:

Some drugs like methotrexate, which is small and hydrophilic, can fully penetrate our 3D bioprinted tissues, allowing us to assess the effects of drugs throughout the full thickness of the tissue.

Other drugs, like paclitaxel, which is large and lipophilic, which are known to have trouble penetrating solid tumors due to dense stroma presence, charge, or other factors, are similarly modeled in the Company's 3D breast tissues.

The Company's head-to-head comparisons of common anti-cancer drugs (cisplatin, methotrexate, paclitaxel) in MCF-7 2D tissue cultures versus the MCF-7-containing 3D tissues developed by the Company showed clear, differential responses:

Total 3D tissue viability was decreased in response to cisplatin, but histologic analyses of the cisplatin-treated tissues showed that the bulk of cell death occurred in the stromal fraction, with the tumor epithelial cells demonstrating resistance to the drug.

In contrast, the 3D tissue system was resistant to methotrexate-mediated toxicity compared to the 2D tissue culture system. Based on studies with labeled compound, this cannot be attributed simply to lack of penetration.

These early results from the Company's initial study confirm that the 2D culture systems were not effective in modeling drug responses in complex, multi-cellular tissue systems, like breast cancer. Furthermore, these early results suggest that utilizing 3D tissues may enable researchers to make compartment-specific assessments (i.e., epithelium, stroma, vasculature) of drug response something that is not currently possible outside of in vivo models to date.

As previously announced, on April 10, 2014, Keith Murphy, the Company's Chairman and Chief Executive Officer, will be participating in a live webcast presentation to investors via RetailInvestorConferences.com. The presentation will take place at 12:00 PM ET, and investors may access the presentation at [www.retailinvestorconferences.com](http://www.retailinvestorconferences.com) > click on red register / watch event now button. A copy of the presentation slides will be available on the Company's website under the Investors tab. In addition, investors may access an on-demand archive of the presentation at [www.retailinvestorconferences.com](http://www.retailinvestorconferences.com) for at least 90 days.

### **Safe Harbor Statement**

Any statements contained in this Current Report that do not describe historical facts may 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 the Company's current expectations, but are subject to a number of risks and uncertainties. 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 results of the Company's future

studies, including that the results from future studies may not support further development and/or commercialization of its product candidates; the Company may not successfully develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; and the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in the Company's filings with the SEC, including its prospectus supplement filed with the SEC on November 27, 2013 and its transition report on Form 10-KT filed with the SEC on May 24, 2013 as well as its other filings with the Securities and Exchange Commission. 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 we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do 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.

The information furnished on this Form 8-K shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

**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: April 10, 2014

/s/ Keith Murphy  
Keith Murphy  
Chief Executive Officer