

ORGANOVO HOLDINGS, INC.

Form 8-K

May 27, 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 11, 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.)**

Edgar Filing: ORGANOVO HOLDINGS, INC. - Form 8-K

**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 11, 2014, Organovo signed a sponsored research agreement with the University of Queensland. The agreement calls for the development of source cell lines for 3D kidney tissue bioprinting activities. Professor Melissa Little is a world renowned kidney biology expert, and her lab has shown continuous progress in understanding aspects of kidney biology and kidney tissue engineering. Most recently, her laboratory demonstrated differentiation of specific kidney progenitor cell populations to form early nephrons. The nephron is the basic structural and functional unit of the kidney, and contains features that are small enough to require cellular self-organization to achieve. Prof. Little's work resulted in a proto-kidney tissue that may, under the right conditions, be able to form all or part of a kidney. Organovo seeks to leverage this advancement in the biological understanding of directed nephron development.

The work to be undertaken in the research project is to demonstrate nephron development from a new, alternative cell source that is more suitable to Organovo's needs. By generating a cell source that can be expected to drive nephron development, and utilizing 3D printing to direct the architecture of the engineered tissue, it is hoped that kidney tissues with superior biologic performance can be derived. The use of 3D printing allows for creation of tissues with complex architecture without dependence on the use of polymer scaffolding, and has the potential to enhance the efficiency and accuracy of differentiation outcomes compared to existing approaches. If successful, the new cell source and the learnings about directing nephron development would be incorporated into Organovo's ongoing development program for 3D bioprinted kidney tissue.

Organovo does not intend to update specifically on the progress of this research program. Organovo intends to communicate about the 3D kidney progress at a high level as it relates to demonstration of research proof of concept, functional validation, and other relevant milestones leading to commercialization of kidney tissues.

### **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: May 27, 2014

/s/ Keith Murphy  
Keith Murphy  
Chief Executive Officer