

ORGANOVO HOLDINGS, INC.

Form 8-K

June 26, 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): June 25, 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 June 26, 2014, Organovo Holdings, Inc. (Organovo) announced that a key opinion leader reported positive results from a collaborative study conducted with Organovo scientists using Organovo s 3D Human Liver Tissues. Dr. Adrian Roth, Head of Mechanistic Safety for Roche Pharmaceutical Research and Early Development at the Roche Innovation Center Basel, presented results from a collaborative study executed by Organovo scientists at the Company s San Diego facility. The results of the study showed Organovo s 3D Liver system was able to distinguish a toxic drug known to cause drug induced liver injury (DILI) from a close chemical analogue that is known to be non-toxic. Further, the toxicity of the toxic compound was detected at physiologically relevant doses, an important observation not previously reported with the same compounds in other model liver systems. Dr. Roth presented the material at the 3D Cell Culture 2014 conference in Freiburg, Germany on June 25, 2014.

Organovo continues to be on track to launch its upcoming 3D Human Liver Tissue on its previously announced timelines, before the end of 2014. Organovo announced in April that it had initiated contracting for toxicity testing using its 3D Human Liver Tissue for selected clients prior to full release, making 3D Human Liver Tissue technology available to clients who have specific testing needs in their preclinical drug discovery programs. Organovo began signing research service contracts at that time and is in discussions with additional customers for near-term needs, in a limited initial release of this service. Customers with needs in a research setting that align with the preliminary offering are now able to engage, with fuller testing services including metabolic function to be offered over time. All testing will be performed at Organovo s facility by Organovo s laboratory services tissue experts.

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 annual report on Form 10-K filed with the SEC on June 10, 2014 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: June 26, 2014

/s/ Keith Murphy
Keith Murphy
Chief Executive Officer