

ORGANOVO HOLDINGS, INC.
Form 8-K
November 18, 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): November 16, 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 November 16, 2014, Dr. Deb Nguyen, the Director of R&D at Organovo Holdings, Inc. (the Company) presented during the Functional Analysis & Screening Technologies (FAST) Congress, held November 16-19th in Boston, MA. Dr. Nguyen shared several new pieces of data highlighting the functionality of the Company's ExVive3D bioprinted liver tissues, including the first demonstration of the ability of Organovo exVive3D Human Liver Tissues to be used in studying metabolism of drugs, excellent donor to donor reproducibility of liver tissue performance, and the demonstration of additional methods allowing the study of two specific mechanisms of drug injury.

Details of the presentation included:

Demonstration of metabolic competence over time. Metabolism of midazolam, including detection and quantitation of metabolite formation (hydroxymidazolam), over the course of 4 weeks was demonstrated. Importantly, induction with rifampicin throughout the full 4-week time course led to robust induction of CYP3A4 and formation of metabolite, demonstrating the ability to show the liver breaking down midazolam appropriately.

Donor-to-Donor Reproducibility. Response to drug-induced liver injury was assessed in exVive3D Human Liver Tissues fabricated with (3) independent liver cell (hepatocyte) donors. Three out of three donor-derived livers responded with an appropriate and predictable injury response to a known toxicant, with a high degree of concordance among donors.

Expansion of detectable end points. A key value driver for the Company's exVive3D Human Liver Tissues is the ability to study liver sections under the microscope in order to collect histopathologic data in addition to biochemical data. To that end, the Company demonstrated that both cell death (necrotic) and fat deposition (steatotic) mechanisms of liver injury can be detected in the exVive3D Human Liver Tissues.

Additionally, on November 18, 2014, the Company issued a press release announcing the full commercial release of the exVive3D Human Liver Tissue for preclinical drug discovery testing. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

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 future functionality of the Company's ExVive3D bioprinted liver tissues, 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 and its report on Form 10-Q filed with the SEC on November 7, 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, including the press release attached as Exhibit 99.1, 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release, dated November 18, 2014.

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 18, 2014

/s/ Keith Murphy
Keith Murphy
Chief Executive Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated November 18, 2014.