Harvard Apparatus Regenerative Technology, Inc.
Form 8-K
January 30, 2015

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): January 30, 2015

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35853**	**45-5210462**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

84 October Hill Road, Suite11, Holliston, MA 01746

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(774) 233-7300**

(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:

¨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 8.01. Other Events.

Harvard Apparatus Regenerative Technology, Inc., or the Company, recently determined that it will need additional development and testing within its ongoing preclinical large-animal model testing of the HART-Trachea. The Company believes that the additional testing needed is readily achievable, however, it estimates that this testing will require an additional 2 to 6 months beyond the Company's previous estimates. The Company's updated expectations regarding such anticipated milestones are as follows:

- The submission of the application for Clinical Trial Authorization, or CTA, with the Medicines and Healthcare Products Regulatory Agency, or MHRA, of the U.K. and the Investigational New Drug, application, or IND, with the U.S. Food and Drug Administration, or FDA, is expected to take place in the first half of 2016 rather than by the end of 2015.

- If the Company is granted Fast Track, Accelerated Review, Priority Review and Breakthrough status in the U.S., it anticipates completing its clinical trial by the end of 2017, rather than the middle of 2017. Completion of the clinical trial in the EU potentially could be sooner.

- The Company expects to receive FDA approval to market the HART-Trachea in the U.S. during the first half of 2018, rather than by the end of 2017.

The information in Item 8.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Harvard Apparatus Regenerative Technology, INC.
(Registrant)

January 30, 2015 (Date)

/s/ David Green
David Green
Chief Executive Officer