

Harvard Apparatus Regenerative Technology, Inc.
Form 424B3
January 07, 2016

Filed pursuant to Rule 424(b)(3)

Registration No. 333-208559

PROSPECTUS SUPPLEMENT NO. 1

(TO PROSPECTUS DATED DECEMBER 29, 2015)

2,688,933 Shares

Common Stock

This Prospectus Supplement No. 1 supplements and amends the prospectus dated December 29, 2015 relating to the sale of up to 2,688,933 shares of our common stock by Aspire Capital Fund, LLC, or Aspire Capital.

This prospectus supplement should be read in conjunction with the prospectus dated December 29, 2015, which is to be delivered with this prospectus supplement. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any amendments or supplements to it. We will not receive any proceeds from the sale of the shares of common stock by Aspire Capital.

Our common stock is listed on the NASDAQ Capital Market under the ticker symbol "HART." On January 6, 2016, the last reported sale price per share of our common stock was \$2.01 per share.

On January 7, 2016, we filed a Current Report on Form 8-K. That Form 8-K is attached hereto.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 5 of the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the prospectus to which it relates. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is January 7, 2016.

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 7, 2016

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware

001-35853

45-5210462

(State or other jurisdiction

(Commission File Number) (IRS Employer Identification No.)

of incorporation)

84 October Hill Road, Suite 11, 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.

On January 7, 2016, Harvard Apparatus Regenerative Technology, Inc. (the “Company”) issued a press release providing an update on large-animal studies being conducted with its co-development collaborator, Mayo Clinic. The press release is filed as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Number Title

99.1 Press Release of Harvard Apparatus Regenerative Technology, Inc., issued on January 7, 2016.

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 7, 2016 /s/ **Thomas McNaughton**
Thomas McNaughton

(Date)

Chief Financial Officer

INDEX TO EXHIBITS

Exhibit

Description of Exhibit

Number

99.1 Press Release of Harvard Apparatus Regenerative Technology, Inc., issued on January 7, 2016.

EXHIBIT 99.1

HART and Mayo Clinic Confirm Dates for Collaborative

Large-Animal Bioengineered Organ Implant Surgeries

Holliston, MA, January 7, 2016 – Harvard Apparatus Regenerative Technology, Inc. (Nasdaq: HART), a biotechnology company developing bioengineered organ implants for life-threatening conditions of the esophagus, trachea and bronchus, today provided an update on large-animal studies being conducted with its co-development collaborator, Mayo Clinic.

Since the November announcement of positive results from large-animal studies of its esophageal, tracheal and bronchial implants, HART has conducted additional studies to advance its platform for those product candidates and to help shape the design of studies with Mayo Clinic. Initial surgeries in the Mayo Clinic collaboration have been scheduled for January 22 and February 2, 2016, with additional procedures to occur through mid-February.

Dennis Wigle, M.D., Ph.D., Associate Professor of Surgery and Chair of Thoracic Surgery at Mayo Clinic as well as HART Chief Medical Officer, Saverio La Francesca, M.D., will perform the implantation surgeries. Although originally anticipated to begin in December, the surgery schedule was adjusted due to scheduling conflicts amongst the study collaborators.

HART's CEO, Jim McGorry, stated, "We are excited to team with Dr. Wigle and Mayo Clinic and to advance the development of our esophagus, trachea and bronchus organ implants. We also continue to perform additional research internally to further deepen our understanding of our implants and their use in varying applications. We remain committed to advancing our platform development toward our 2016 goals of filing with the FDA to initiate human clinical trials as well as pursuing compassionate use surgeries in humans."

Edgar Filing: Harvard Apparatus Regenerative Technology, Inc. - Form 424B3

Saverio La Francesca, M.D., added, “We are conducting these studies to answer key scientific questions regarding regeneration and mechanism of action. The goal of these studies is to inform our IND filing with the FDA and appropriately translate these findings into human use.”

HART’s management team will be in San Francisco to meet with investors next week, Monday, January 1st through Wednesday, January 13th. Jim McGorry will present at the Biotech Showcase Monday, January 11th at 2:00 p.m. Pacific Time. His presentation will be webcast live and for replay.

About HART (<http://www.harvardapparatusregen.com>)

Harvard Apparatus Regenerative Technology (HART) makes bioengineered implants for life-threatening conditions. Our technology platform is to be used to restore function in the esophagus and the trachea and bronchus airways. Our first generation tracheal implant has been used successfully in five adult human implant procedures approved under compassionate use exemptions, but none of our products are yet approved for marketing by a government regulatory authority. HART is completing further large-animal studies to refine our technology platform with the goals of pursuing one or more compassionate use implantation surgeries and filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration in 2016, seeking to initiate clinical trials for one of our three product candidates.

Forward-Looking Statements

Some of the statements in this press release are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These "forward-looking" statements in this press release include, but are not limited to, statements relating to the development expectations and regulatory approval of any HART products by the FDA, EMA, MHRA or otherwise, which expectations or approvals may not be achieved or obtained on a timely basis or at all; or success with respect to any collaborations, clinical trials and other development and commercialization efforts of HART products, including those pertaining to the airway or esophagus, which such success may not be achieved or obtained on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, our ability to obtain and maintain regulatory approval for the our implant products, bioreactors, scaffolds and other devices and product candidates we pursue; plus other factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 or described in our other public filings. Our results may also be affected by factors of which we are not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. Harvard Apparatus Regenerative Technology expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

Twitter: Investor Relations @HART_IR_Team

StockTwits: @HART_Investor_Relations

Investor Relations:

Harvard Apparatus Regenerative Technology, Inc.

Tom McNaughton

Chief Financial Officer

774-233-7321

Catalyst Global LLC

David Collins, Tanya Kamatu

212-924-9800

hart@catalyst-ir.com