Harvard Apparatus Regenerative Technology, Inc.
Form 10-Q
November 16, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

x Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2015

¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to

Commission file number 001-35853

HARVARD APPARATUS

REGENERATIVE TECHNOLOGY, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**45-5210462**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**

84 October Hill Road, Suite 11, Holliston, MA 01746

(Address of Principal Executive Offices) (Zip Code)

(774) 233-7300

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x YES ¨ NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x YES ¨ NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ YES x NO

As of November 9, 2015, there were 13,452,395 shares of common stock, par value $0.01 per share, outstanding.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

Form 10-Q

For the Quarter Ended September 30, 2015

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands, except par value and share data)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash	$ 8,198	$ 5,272
Related party receivables	-	27
Accounts receivable	59	5
Inventory	144	207
Prepaid expenses	82	317
Total current assets	8,483	5,828
Property, plant and equipment, net of accumulated depreciation of $959 and $611, respectively	1,202	1,376
Total non-current assets	1,202	1,376
Total assets	$ 9,685	$ 7,204
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 220	$ 370
Related party payables	-	16
Accrued and other current liabilities	111	324
Total current liabilities	331	710
Total non-current liabilities	-	-
Total liabilities	331	710
Commitments and contingencies (note 7)		
Stockholders' equity:		

Convertible preferred stock, par value $0.01 per share, 2,000,000 shares authorized; 695,857 and 0 shares issued and 159,864 and 0 shares outstanding, respectively	1,230	-
Common stock, par value $0.01 per share, 30,000,000 shares authorized; 12,652,075 and 7,856,607 shares issued and outstanding, respectively	127	79
Additional paid-in capital	30,453	19,449
Accumulated deficit	(22,449)	(13,035)
Accumulated other comprehensive (loss) income	(7)	1
Total stockholders' equity	9,354	6,494
Total liabilities and stockholders' equity	$ 9,685	$ 7,204

See accompanying notes to unaudited consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited, in thousands, except per share data)

	Three Months ended September 30,		Nine Months ended September 30,	
	2015	2014	2015	2014
Revenues	$37	$2	$110	$48
Cost of revenues	18	1	55	25
Gross profit	19	1	55	23
Operating expenses:				
Research and development	1,269	1,401	3,504	3,832
Sales and marketing	86	77	276	241
General and administrative	956	1,199	5,686	4,165
Total operating expenses	2,311	2,677	9,466	8,238
Operating loss	(2,292)	(2,676)	(9,411)	(8,215)
Other expense, net	-	(4)	(3)	(4)
Loss before income taxes	(2,292)	(2,680)	(9,414)	(8,219)
Income taxes	-	-	-	-
Net loss	$(2,292)	$(2,680)	$(9,414)	$(8,219)
Basic and diluted net loss per share	$(0.19)	$(0.34)	$(0.91)	$(1.05)
Weighted average common shares, basic and diluted	11,974	7,851	10,395	7,809
Comprehensive loss:				
Net loss	$(2,292)	$(2,680)	$(9,414)	$(8,219)
Foreign currency translation adjustments	-	(3)	(8)	-
Total comprehensive loss	$(2,292)	$(2,683)	$(9,422)	$(8,219)

See accompanying notes to unaudited consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	Nine Months ended September 30, 2015	2014
Cash flows used in operating activities:		
Net loss:	$(9,414)	$(8,219)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,612	1,926
Depreciation	347	256
Changes in operating assets and liabilities:		
Decrease in related party receivables	27	19
Increase in accounts receivable	(54)	(29)
Decrease (increase) in inventories	63	(119)
Decrease in prepaid expenses and other current assets	235	274
(Decrease) increase in accounts payable	(150)	10
Decrease in related party payables	(16)	(58)
(Decrease) increase in accrued and other current liabilities	(212)	269
Net cash used in operating activities	(5,562)	(5,671)
Cash flows used in investing activities:		
Additions to property, plant and equipment	(175)	(1,033)
Net cash used in investing activities	(175)	(1,033)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net	5,357	-
Proceeds from issuance of common stock, net	3,314	418
Net cash provided by financing activities	8,671	418
Effect of exchange rate changes on cash	(8)	-
Net increase (decrease) in cash	2,926	(6,286)
Cash at the beginning of the period	5,272	14,008
Cash at the end of the period	$8,198	$7,722

See accompanying notes to unaudited consolidated financial statements.

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HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

Harvard Apparatus Regenerative Technology, Inc. ("HART" or the "Company") is a biotechnology company developing bioengineered organs for life-threatening conditions. The Company's technology initially is focused on restoring organ function to a patient's esophagus or airways (the bronchus and the trachea). Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and acquiring operating assets.

HART was incorporated in Delaware on May 3, 2012 by Harvard Bioscience, Inc. ("Harvard Bioscience"), as a wholly-owned subsidiary, to provide a means for separating Harvard Bioscience's regenerative medicine business from its other businesses.

On October 31, 2013, Harvard Bioscience contributed its regenerative medicine business assets, plus $15 million of cash, into HART (the "Separation"). On November 1, 2013, the spin-off of the Company from Harvard Bioscience was completed. On that date, the Company became an independent company that operates the regenerative medicine business previously owned by Harvard Bioscience. The spin-off was completed through the distribution to Harvard Bioscience stockholders of all the shares of common stock of HART (the "Distribution").

Basis of Presentation

Basic and diluted shares outstanding are the same for each period presented as all common stock equivalents would be antidilutive due to the net losses incurred. The financial statements reflect the Company's financial position, results of operations and cash flows in conformity with accounting principles generally accepted in the United States ("GAAP").

Unaudited Interim Financial Information

The accompanying interim balance sheet as of September 30, 2015 and consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2015 and 2014 are unaudited. The accompanying interim consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014 are unaudited. The interim unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company's financial position as of September 30, 2015, its results of operations for the three and nine months ended September 30, 2015 and 2014, and the Company's consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014. The financial data and other information disclosed in these notes related to the nine month periods ended September 30, 2015 and 2014 are unaudited. The results for the three and nine months ended September 30, 2015 and 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2015, any other interim periods or any future year or period.

2. Summary of Significant Accounting Policies and Recently Issued Accounting Pronouncements

The accounting policies underlying the accompanying unaudited consolidated financial statements are those set forth in Note 2 to the financial statements for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K.

There are no other recently issued accounting standards that are not yet effective that the Company believes would materially impact the financial statements.

3. Capital Stock, Financing and Liquidity

On February 18, 2015, the Company closed an underwritten public offering of 2,070,000 registered shares of its common stock, at a price to the public of $1.75 per share, and 695,857 registered shares of its $0.01 par Series B Convertible Preferred Stock ("Series B") at a price to the public of $8.75 per share. The Series B is convertible into five shares of common stock at the option of the holder, subject to certain limitations related to the holder's ownership percentage of the Company's outstanding common stock. The Series B will vote with the common stock on all matters on an as-converted basis, and has no preference to the common shares in respect of dividends, voting, liquidation or otherwise. Gross proceeds from the offering were $9.7 million and underwriters' fees and issuance costs totaled $1.1 million. Thus, the Company generated net proceeds of $8.6 million from the underwritten public offering.

During the three and nine months ended September 30, 2015, 330,714 and 535,993 shares of Series B Convertible Preferred Stock were converted into 1,653,570 and 2,679,965 shares of common stock, respectively. From October 1, 2015 through November 13, 2015, the date of this filing, 159,864 additional shares of Series B Convertible Preferred Stock were converted into 799,320 shares of common stock, after which the company had no shares of Series B shares outstanding.

The Company has incurred net losses of $41.7 million since inception through September 30, 2015. The Company is currently investing significant resources in development and commercialization of products, including bioengineered organs, for use in the field of regenerative medicine. The Company expects to continue to incur operating losses and negative cash flows from operations. Management believes that the Company's cash at September 30, 2015 will be sufficient to meet the Company's obligations through at least September 30, 2016.

4. Related Party Transactions

During the three and nine months ended September 30, 2015, the Company recognized $0 and $165,000 respectively in recruiting expense related to professional search fees paid to RobinsonButler, an executive recruiting consultancy firm where Thomas Robinson, a member of the Company's Board of Directors, is a partner. RobinsonButler was retained by the Company's Board of Directors to complete the search for the Company's Chief Executive Officer and President.

Agreements with Harvard Bioscience

From inception through April 17, 2015, Harvard Bioscience was considered to be a related party to the Company because David Green, the Company's former Chairman and CEO, was also a director of Harvard Bioscience. After Mr.

Green's April 17, 2015 resignation as Chairman and CEO of HART, Harvard Bioscience is no longer considered a related party. Mr. Green is still a member of the Boards of Directors of both HART and Harvard Bioscience.

In connection with the Separation of the Company from Harvard Bioscience, on October 31, 2013 the Company entered into a series of agreements with Harvard Bioscience, including a separation and distribution agreement, a transition services agreement, a tax sharing agreement, a sublicense agreement, a product distribution agreement, an intellectual property matters agreement and a sublease agreement. Some of these agreements require the Company to pay fees to Harvard Bioscience for services provided subsequent to the Separation. The transition services agreement expired on November 1, 2014. Expenses recorded under these agreements were $0.1 million and $0.2 million for the three and nine months ended September 30, 2014, respectively. Expenses recorded under these agreements for the period of January 1, 2015 through April 17, 2015, was $51,000.

5. Concentrations

At the time of the Separation, the Company entered into a 10-year product distribution agreement with Harvard Bioscience under which each company will become the exclusive distributor for the other party forproducts such other party develops for sale in the markets served by the other. In addition, Harvard Bioscience has agreed that except for certain existing activities of its German subsidiary, to the extent that any Harvard Bioscience businesses desire to resell or distribute any bioreactor that is then manufactured by HART, HART will be the exclusive manufacturer of such bioreactors and Harvard Bioscience will purchase such bioreactors from the Company. Sales to Harvard Bioscience accounted for 100% of the Company's revenues and trade receivables.

6. Stock-Based Compensation

HART maintains the 2013 Equity Incentive Plan (the "2013 Plan") for the benefit of certain of its officers, directors and employees. The securities underlying all options and awards granted under the 2013 Plan consist of shares of HART common stock. Additionally, equity awards related to shares of the Company's common stock were issued from the 2013 Plan at the time of the Distribution to the holders of Harvard Bioscience equity awards as part of an adjustment (the "Adjustment") to those equity awards to prevent a loss of value to the holders due to the Distribution.

Harvard Bioscience award holders were also issued stock-based compensation awards in HART stock options and restricted stock units. HART recognizes compensation expense on those awards to former Harvard Bioscience employees who now are employed by HART, and does not recognize expense on the Adjustment awards given to individuals not now employed by HART. Additionally, HART records expense on grants made under the 2013 Plan to HART officers, directors and employees granted subsequent to the Adjustment.

Harvard Bioscience maintains the Third Amended and Restated 2000 Stock Option and Incentive Plan, (as amended, the "Harvard Bioscience Plan") for the benefit of certain of its officers, directors and employees. The securities underlying all options and awards granted under the Harvard Bioscience Plan consist of shares of Harvard Bioscience common stock. HART continues to record the expense on stock-based awards of Harvard Bioscience stock options and restricted stock units, issued by Harvard Bioscience, to former Harvard Bioscience employees now employed by HART.

Harvard Apparatus Regenerative Technology, Inc. 2013 Equity Incentive Plan

The 2013 Plan was adopted by the Board of Directors on October 11, 2013. The aggregate number of shares authorized for issuance under the Plan is 3,640,000 shares of common stock. The Company currently has 3,640,000 shares of its common stock reserved for the issuance, exercise or vesting of awards under the 2013 Plan. During the nine months ended September 30, 2015, all options granted under the 2013 Plan were at exercise prices equal to or greater than fair market value of the Company's common stock on the date of grant.

The following is a summary of stock option and restricted stock unit activity for the nine months ended September 30, 2015:

	Stock Options	Restricted Stock Units

	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2014	2,006,980	$ 4.73	7,980	$ 6.00
Granted	1,797,900	2.11	-	-
Exercised	-	-	-	-
Vested (RSUs)	-	-	(6,721)	6.00
Cancelled/forfeited	(488,840)	4.22	(154)	6.00
Balance at September 30, 2015	3,316,040	$ 3.38	1,105	$ 6.00

The following assumptions were used to estimate the fair value of stock options granted during the three and nine months ended September 30, 2015:

	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015
Volatility	76%	77%
Risk-free interest rate	1.77%	1.73%
Expected holding period	6.09 years	6.10 years
Dividend Yield	-%	-%

The weighted average fair values of the options granted under the 2013 Plan during the nine months ended September 30, 2015 was $1.29, using the Black-Scholes option-pricing model.

Stock-based compensation expense for the three and nine months ended September 30, 2015 and 2014, respectively, was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)		(in thousands)	
Research and development	$171	$83	$524	$396
Sales and marketing	29	8	80	73
General and administrative	116	162	2,684	893
Total stock-based compensation	$316	$253	$3,288	$1,362

The Company did not capitalize any stock-based compensation related to the 2013 Plan.

In April 2015, David Green resigned as Chief Executive Officer, President and Chairman of the Board of Directors of HART. Mr. Green remained a member of the Board of Directors. Under the terms of Mr. Green’s employment agreement, certain equity awards immediately vested upon his resignation. This acceleration of vesting resulted in a non-cash stock based compensation expense of approximately $1.0 million being recognized in April, 2015. Mr.

Green’s employment agreement also entitled him to a cash payment equal to two years of his salary, or approximately $1.0 million. The Company and Mr. Green agreed to a modification to accelerate vesting on certain options and extend the exercise period on those and other vested stock options in lieu of the cash payment. These modifications resulted in an additional non-cash stock based compensation expense related to Mr. Green of approximately $1.1 million being recorded in April, 2015. Of the modified options, 387,000 were vested prior to resignation, 290,252 were vested as a result of the resignation and as such required no modification to vesting, and 48,375 options were modified to vest immediately. All 725,627 modified options retained their original exercise price of $4.29 and had the time period during which they could be exercised extended from 30 days from resignation to 7 years. All of Mr. Green’s options to buy shares of Harvard Bioscience stock issued under the Harvard Bioscience plan remain outstanding and the Company will continue to record the associated expense on them as long as Mr. Green provides service to HART in his position on the Board of Directors.

Harvard Bioscience Plan Award Information

The following is a summary of stock option and restricted stock unit activity for the nine months ended September 30, 2015:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2014	2,122,648	$ 2.84	171,557	$ 4.41
Granted	-	-	-	-
Exercised	(918,646)	2.73	-	-
Vested (RSUs)	-	-	(88,648)	4.52
Cancelled/forfeited	(6,585)	3.64	-	-
Balance at September 30, 2015	1,197,417	$ 2.92	82,909	$ 4.30

Stock-based compensation expense from the Harvard Bioscience Plan for the three and nine months ended September 30, 2015 and 2014, respectively, was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)		(in thousands)	
Research and development	$11	$17	$31	$48
Sales and marketing	3	4	9	11
General and administrative	98	181	284	505
Total stock-based compensation	$112	$202	$324	$564

The Company did not capitalize any stock-based compensation related to the Harvard Bioscience Plan.

7. Commitments and Contingencies

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. There are no such matters pending that the Company expects to be material in relation to its business, financial condition, and results of operations or cash flows.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains statements that are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). The forward-looking statements are principally, but not exclusively, contained in "Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include, but are not limited to, statements about management's confidence or expectations, and our plans, objectives, expectations and intentions that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "goals," "sees," "estimates," "projects," "predicts," "intends," "think," "potential," "objectives," "optimistic," "strategy," and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause our actual results to differ materially from those in the forward-looking statements include the success of our collaborations, clinical trials and pre-clinical development efforts and programs, which success may not be achieved on a timely basis or at all; our ability to obtain and maintain regulatory approval for our implant products, bioreactors, scaffolds and other devices we pursue, including for the esophagus or airway, which approvals may not be obtained on a timely basis or at all; our ability to access debt and equity markets and raise additional funds when needed; the number of patients who can be treated with our products; the amount and timing of costs associated with our development of implant products, bioreactors, scaffolds and other devices; our failure to comply with regulations and any changes in regulations; unpredictable difficulties or delays in the development of new technology; our collaborators or other third parties we contract with, including with respect to conducting any clinical trial or pre-clinical development efforts, not devoting sufficient time and resources to successfully carry out their duties or meet expected deadlines; our ability to attract and retain qualified personnel and key employees and retain senior management; potential liability exposure with respect to our products; our inability to operate effectively as a stand-alone, publicly traded company; the actual costs of separation may be higher than expected; the availability and price of acceptable raw materials and components from third-party suppliers; difficulties in obtaining or retaining the management and other human resource competencies that we need to achieve our business objectives; increased competition in the field of regenerative medicine and the financial resources of our competitors; our ability to obtain and maintain intellectual property protection for our device and product candidates; our inability to implement our growth strategy; plus factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (the "SEC") on March 27, 2015 or described in our other public filings. Our results may also be affected by factors of which we are not currently aware. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information.

Overview

Our Business

We are a clinical-stage regenerative medicine company developing life-saving organ implants to address life-threatening diseases or conditions. Our technology initially is focused on restoring organ function to a patient's esophagus or airways (bronchus or trachea). Our central focus continues to be the development of bioengineered organs for life-threatening conditions. We have built a dedicated internal team of materials scientists, engineers and biologists who are working with our collaborators at Mayo Clinic and Connecticut Children's Medical Center to bring our products to the patients who need them.

For the past several months our scientific efforts have resulted in significant advances in the development of our second-generation (Gen2) bioengineered implants. Our Gen2 technology reflects design enhancements aimed at improving the body's response to the implant and better guiding the repair of tissue in the healing process. Our recent animal studies tested all three of our Gen2 implants – esophagus, trachea, and bronchus. We believe the trachea study demonstrated the resolution of the negative inflammatory response observed with the prior generation of the technology. This achievement was significant, and we will now proceed to a confirmatory large-animal study of our trachea and bronchus implants with Mayo Clinic. Our bronchus study achieved similar positive results as those seen in the trachea study. The results of the pre-clinical esophageal implant study suggest clinically significant evidence of tissue and nerve regeneration in the esophageal implant. Complete regeneration of the esophagus was achieved in 2 weeks. This result positions the esophageal implant as our current lead development priority. The esophageal implant is intended to address a very significant need as a potentially life-saving treatment for patients with esophageal cancer. Each year in the U.S. approximately 17,000 new cases of esophageal cancer are diagnosed, and more than 4,000 are addressed by surgery.

We plan to confirm the improvements in our Gen2 platform by conducting large-animal studies at Mayo Clinic along with their team of regenerative medicine experts. The study design has been completed, requisite tests are underway, and we expect the animal surgeries to occur in December 2015. We expect that those studies will provide the key data to determine if our Gen2 scaffolds are ready for use in patients. We believe positive results from these studies would support the use of a Gen2 product in compassionate use surgeries.

Collaborations

We continue to advance our development partnerships with Mayo Clinic and Connecticut Children's Medical Center (CCMC). HART's collaboration with Mayo Clinic focuses on developing solutions for cancer and other life-threatening diseases affecting the esophagus, bronchus and trachea. We have initiated our planned confirmatory large-animal studies of Gen2 implants in collaboration with Mayo Clinic. The study design has been completed, prerequisite tests are underway and we expect the animal surgeries to occur in December 2015. Our collaboration with CCMC is focused on developing a solution for a congenital childhood condition, pediatric esophageal atresia, a condition in which a significant or complete separation of a child's esophagus prevents normal eating function. Initial tests with CCMC commenced during the third quarter of 2015.

During the third quarter of 2015 we also established the Scientific Advisory Board and announced that Joseph P. (Jay) Vacanti, M.D., a surgeon and pioneering scientist in the field of tissue engineering, has agreed to serve as Chairman. The Scientific Advisory Board's role is to provide support and guidance for our research and development programs. We expect to add three to five additional members to the Scientific Advisory Board over the next twelve to eighteen months.

Dr. Vacanti has worked in the field of tissue engineering since its beginnings in the early 1980's - a mission that stems from his long-held interest in solving the problem of organ shortages. He has held academic appointments at Harvard Medical School since 1974; has authored over 320 original reports, 69 book chapters, 54 reviews and over 473 abstracts. Dr. Vacanti has 81 patents or patents pending in the United States, Canada, Europe and Japan. Dr. Vacanti's current medical affiliations including Harvard Medical School and Massachusetts General Hospital. Over the past 15 years, Dr. Vacanti has researched the creation of complete vascular networks as part of implantable tissue engineered devices that allow the fabrication of large, complex living structures such as vital organs or extremities. Dr. Vacanti was a founding co-president of what is now the Tissue Engineering Regenerative Medicine International Society (TERMIS) and he was also founding senior editor of "Tissue Engineering".

Regulatory Update

Assuming we receive positive data from the preclinical studies with Mayo Clinic planned for the fourth quarter of 2015, we expect to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) and a Clinical Trial Application (CTA) with the European Medicines Agency (EMA) for our first indication coming from our bioengineered organ implant product platform during 2016.

Our trachea implant product was granted orphan designation by the FDA in September 2014. Given the significant improvements to our second-generation product platform, we expect to file an amendment to our current orphan drug designation with the FDA. Upon marketing authorization, orphan status would provide a seven year marketing exclusivity in the U.S. for the trachea implant product. We applied for orphan status for the trachea implant product with the EMA during the fourth quarter of 2014 and withdrew that application during the second quarter of 2015 because our Gen2 trachea product, which is currently in development, will be sufficiently different from our first-generation product that we believe that filing for orphan status for the Gen2 product will be the fastest path to achieving orphan status in Europe.

Results of Operations

Components of Operating Loss

Research and development expense. Research and development expense consists of salaries and related expenses, including stock-based compensation, for personnel and contracted consultants and various materials and other costs to develop our new products, primarily: synthetic organ scaffolds, including investigation and development of materials and investigation and optimization of cellularization, and 3D organ bioreactors. Other research and development expenses include the costs of outside service providers and material costs for prototype and test units and outside testing facilities performing cell growth and materials experiments, as well as the costs of all other preclinical research and testing and expenses related to potential patents. We expense research and development costs as incurred.

Sales and marketing expense. Sales and marketing expense consists primarily of salaries and related expenses, including stock-based compensation, for personnel performing sales, marketing, and business development roles, and costs associated with their travel and participation in trade shows and conferences. It also includes the costs of marketing communications and web site development and maintenance.

General and administrative expense. General and administrative expense consists primarily of salaries and other related expenses, including stock-based compensation, for personnel in executive, accounting, information technology and human resources roles. Other costs include professional fees for legal and accounting services, insurance, investor relations and facility costs.

Comparison of the three months ended September 30, 2015 to the three months ended September 30, 2014:

Research and Development Expense

Research and development expense decreased $0.1 million, to $1.3 million or 9% for the three months ended September 30, 2015 compared with $1.4 million for the three months ended September 30, 2014. Decreases in recruiting costs of $0.2 million, payroll related cost of $0.1 million and consultancy cost associated with intellectual property of $0.1 million, were partially offset by increased spending on outsourced preclinical studies of $0.2 million and $0.1 million in non-cash stock based compensation.

Sales and Marketing Expense

Sales and marketing expense increased approximately $9,000 or 12%, to $86,000 for the three months ended September 30, 2015 compared with $77,000 for the three months ended September 30, 2014. The increase was primarily due to $20,000 in additional non-cash stock based compensation costs, partially offset by an $11,000 decrease in payroll related costs.

General and Administrative Expense

General and administrative expense decreased $0.2 million, or 20%, to $1.0 million for the three months ended September 30, 2015 compared with $1.2 million for the three months ended September 30, 2014. The $0.2 million decrease was composed of $0.1 million in non-cash stock-based compensation, and $0.1 million in payroll related costs.

Comparison of the nine months ended September 30, 2015 to the nine months ended September 30, 2014:

Research and Development Expense

Research and development expense decreased $0.3 million or 9%, to $3.5 million for the nine months ended September 30, 2015 compared with $3.8 million for the nine months ended September 30, 2014. The decrease of $0.3 million is composed of reductions of $0.2 million related to intellectual property consulting expenses, $0.2 million of recruiting, $0.1 million in other consulting, and $0.1 million in costs associated with our foreign subsidiaries, offset by increases of $0.3 million in spending on outsourced preclinical studies.

Sales and Marketing Expense

Sales and marketing expense increased approximately $35,000 or 15%, to $276,000 for the nine months ended September 30, 2015 compared with $241,000 for the nine months ended September 30, 2014. The increase was primarily due to $75,000 of additional non-cash stock based compensation offset by a $40,000 decrease in payroll related costs.

General and Administrative Expense

General and administrative expense increased $1.5 million, or 37%, to $5.7 million for the nine months ended September 30, 2015 compared with $4.2 million for the nine months ended September 30, 2014. The $1.5 million increase is composed of $2.1 million in non-cash stock-based compensation related to the acceleration and modification of employee stock options in association with the resignation of David Green as CEO on April 17, 2015, $0.2 million in additional recruiting costs related to the search for a new CEO, and $0.1 million in incremental legal fees associated creation and protection of intellectual property. These costs were partially offset by decreases of $0.5 million in non-cash stock-based compensation expense related to employees other than the former CEO, $0.1 million in payroll related costs, and $0.3 million in other costs.

Financial Condition, Liquidity and Capital Resources

Sources of liquidity. We have incurred net losses since inception. We are currently investing significant resources in development and commercialization of products for use by clinicians and researchers in the field of regenerative medicine and have incurred operating losses to date. We expect to continue to incur operating losses and negative cash flows from operations at least until we receive regulatory approval to market a clinical product, as revenues from research bioreactors sales will not generate sufficient gross profits to offset our operating expenses.

Operating activities. Net cash used in operating activities of $5.6 million for the nine months ended September 30, 2015 reflects our $9.4 million net loss, a $3.6 million add-back of non-cash stock-based compensation expense, a $0.3 million add-back for depreciation, and changes in working capital items.

Net cash used in operating activities of $5.7 million for the nine months ended September 30, 2014 reflects our $8.2 million net loss, a $1.9 million add-back of non-cash stock-based compensation expense, a $0.3 million add-back for depreciation, and changes in working capital items.

Investing activities. Net cash used in investing activities during the nine month periods ended September 30, 2015 and 2014 of $0.2 million and $1.0 million respectively, reflects cash used for additions to property, plant and equipment.

Financing activities. Net cash generated from financing activities during the nine months ended September 30, 2015 of $8.7 million was the net proceeds from the issuance of convertible preferred and common shares.

Cash generated from financing activities during the nine months ended September 30, 2014 of $0.4 million was primarily a result of employees' exercises of stock options.

Recent Authoritative Accounting Guidance

There are no recently issued accounting standards that are not yet effective that the Company believes would materially impact the financial statements.

Critical Accounting Policies and Estimates

The critical accounting policies underlying the accompanying unaudited consolidated financial statements are those set forth in Part II, Item 7 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which was filed with the SEC on March 27, 2015.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We do not have any material foreign currency exchange risks, we do not enter into derivative agreements, we do not have any off balance-sheet arrangements, and we do not have any interest rate risks. Also, we have no debt outstanding.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2015. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer have concluded that they believe that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control over Financial Reporting

During the period covered by this report, we have concluded that there were no changes during the fiscal quarter in our internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

To our knowledge and except to the extent additional factual information disclosed in this Quarterly Report on Form 10-Q relates to such risk factors, there have been no material changes in the risk factors described in “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on March 27, 2015.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On February 18, 2015, we closed our public offering of 2,070,000 shares of common stock, including 270,000 shares of common stock issued (the “Offering”) pursuant to the full exercise of the overallotment option granted to the underwriters, and 695,857 shares of Series B Convertible Preferred Stock (“Series B”). At the option of the holder, the

Series B is convertible into five shares of our common stock subject to certain limitations related to the holder's ownership percentage of the Company's outstanding common stock, and will vote with the common stock on all matters on an as converted basis. The Series B has no preference to our common shares in respect of dividends, voting, liquidation or otherwise. The offer and sale of all of the shares in the Offering were registered under the Securities Act pursuant to a shelf registration statement on Form S-3 (File No. 333-200926), which was declared effective by the SEC on December 29, 2014. National Securities Corporation and Summer Street Research Partners acted as the underwriters. The public offering price of the shares of common stock sold in the Offering was $1.75 per share and the public offering price of the shares of Series B sold in the Offering was $8.75 per share. The total gross proceeds from the Offering to us were approximately $9.7 million. After deducting underwriting discounts and commissions of $776,900 and offering expenses payable by us of $340,000 (which included $35,000 of expenses we reimbursed of certain institutional investors who purchased Series B shares in the Offering), we received approximately $8.6 million.

Following the consummation of the Offering payments were made in the ordinary course of business to officers for salaries. No other payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates. Through September 30, 2015, of the net proceeds of the Offering, we used approximately $1.0 million for research and development, including funding preclinical efforts relating to bioengineered organs, approximately $0.7 million to fund General and Administrative costs of operations and $0.1 million to purchase and install laboratory equipment.

Item 6. Exhibits

Exhibit Index

10.1#(1)	Employment Agreement, executed as of June 23, 2015 and effective as of July 6, 2015, between Harvard Apparatus Regenerative Technology, Inc. and James McGorry.
31.1+	Certification of Chief Financial Officer of Harvard Apparatus Regenerative Technology, Inc., pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Executive Officer of Harvard Apparatus Regenerative Technology, Inc., pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Financial Officer of Harvard Apparatus Regenerative Technology, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Executive Officer of Harvard Apparatus Regenerative Technology, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

\# Management contract or compensatory plan or arrangement

(1) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on July 6, 2015) and incorporated by reference thereto.

\+ Filed herewith

* This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

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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 undersigned thereunto duly authorized.

Date: November 13, 2015

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

By: /s/ James McGorry
James McGorry
President and Chief Executive Officer

By: /s/ Thomas McNaughton
Thomas McNaughton
Chief Financial Officer

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