Harvard Apparatus Regenerative Technology, Inc.
Form 10-Q
August 13, 2014

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 June 30, 2014

¨ 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, 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 August 8, 2014, there were 7,846,959 shares of common stock, par value $0.01 per share, outstanding.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

Form 10-Q

For the Quarter Ended June 30, 2014

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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 per share data)

	June 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash	$10,065	$ 14,008
Related party receivables	82	22
Inventories, net	146	38
Prepaid expenses	356	421
Total current assets	10,649	14,489
Property, plant and equipment, net of accumulated depreciation of $400 and $248 at June 30, 2014 and December 31, 2013, respectively	1,038	575
Total non-current assets	1,038	575
Total assets	$11,687	$ 15,064
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$434	$ 244
Related party payable	41	90
Accrued and other current liabilities	350	161
Total current liabilities	825	495
Total non-current liabilities	-	-
Total liabilities	825	495
Commitments and contingencies (note 8)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2014 and December 31, 2013	-	-
Common stock, par value $0.01 per share, 30,000,000 shares authorized; 7,843,362 and 7,742,080 shares issued and outstanding at June 30, 2014 and December 31 2013, respectively	78	77
Additional paid-in capital	18,294	16,466

Accumulated deficit	(7,513)	(1,974)
Accumulated other comprehensive income	3	-
Total stockholders' equity	10,862	14,569
Total liabilities and stockholders' equity	$11,687	$ 15,064

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 June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Revenues	$ 23	$ -	$ 46	$ -
Cost of revenues	12	-	24	-
Gross profit	11	-	22	-
Operating expenses:				
Research and development	1,214	1,265	2,431	2,425
Sales and marketing	88	34	164	54
General and administrative	1,242	790	2,966	1,630
Total operating expenses	2,544	2,089	5,561	4,109
Operating loss	(2,533)	(2,089)	(5,539)	(4,109)
Loss before income taxes	(2,533)	(2,089)	(5,539)	(4,109)
Income taxes	-	-	-	-
Net loss	$ (2,533)	$ (2,089)	$ (5,539)	$ (4,109)
Basic and diluted net loss per share	$ (0.32)	$ (0.27)	$ (0.71)	$ (0.53)
Weighted average common shares, basic and diluted	7,816	7,740	7,788	7,740
Comprehensive loss:				
Net loss	$ (2,533)	$ (2,089)	$ (5,539)	$ (4,109)
Foreign currency translation adjustments	6	-	3	-
Total comprehensive loss	$ (2,527)	$ (2,089)	$ (5,536)	$ (4,109)

See accompanying notes to unaudited consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	Six Months ended June 30,	
	2014	2013
Cash flows used in operating activities:		
Net loss:	$(5,539)	$(4,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,471	294
Depreciation	151	83
Changes in operating assets and liabilities:		
(Increase) in related party receivables	(60)	-
(Increase) in inventories	(108)	-
Decrease in prepaid expenses	65	-
Increase (decrease) in accounts payable	71	(35)
(Decrease) in related party payable	(49)	-
Increase (decrease) in accrued and other current liabilities	189	(66)
Net cash used in operating activities	(3,809)	(3,833)
Cash flows used in investing activities:		
Additions to property, plant and equipment	(495)	(51)
Net cash used in investing activities	(495)	(51)
Cash flows from financing activities:		
Proceeds from funding provided by Harvard Bioscience, Inc.	-	3,884
Proceeds from issuance of common stock	358	-
Net cash provided by financing activities	358	3,884
Effect of exchange rate changes on cash	3	-
Net decrease in cash	(3,943)	-
Cash at the beginning of the period	14,008	-
Cash at the end of the period	$10,065	$-

See accompanying notes to unaudited consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

A BUSINESS SEGMENT OF HARVARD BIOSCIENCE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

Prior to November 1, 2013, Harvard Apparatus Regenerative Technology, Inc. ("HART" or the "Company") was a business segment of Harvard Bioscience, Inc. ("Harvard Bioscience"). The Company is engaged in the development and commercialization of regenerated organs for human transplant.

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, as a wholly-owned subsidiary, to provide a means for separating Harvard Bioscience's regenerative medicine business from its other businesses. Harvard Bioscience has been designing and manufacturing devices for life science researchers for over 100 years. Harvard Bioscience first focused on providing devices to scientists involved in regenerative medicine research in 2008. Since early 2009, Harvard Bioscience's regenerative medicine business initiative was operated as a segment of Harvard Bioscience.

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 previously announced 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

The Company historically operated as part of Harvard Bioscience, and not as a stand-alone company. For periods prior to the Separation on October 31, 2013, the consolidated financial statements presented herein, which include periods prior to the Separation, and are discussed below, have been prepared on a stand-alone basis and are derived from the financial statements and accounting records of Harvard Bioscience using the historical basis of assets and liabilities of HART. The Company's financial statements from that period include expenses of Harvard Bioscience allocated to HART for certain functions provided by Harvard Bioscience, including, but not limited to, general corporate expenses related to executive services, finance, treasury, corporate income tax, human resources, legal services and investor relations. These expenses were allocated to HART on the basis of headcount, time devoted to HART activities, percentage of operating expenses or other relevant measures. The Company believes the assumptions and allocations underlying the financial statements are reasonable and appropriate under the circumstances. Both HART and Harvard Bioscience consider the basis on which the expenses have been allocated to be a reasonable reflection of the utilization of services provided to or the benefits received by the Company during the periods presented. However, the amounts recorded for these transactions and allocations are not necessarily representative of the amounts that would have been reflected in the financial statements had HART operated independently of Harvard Bioscience. Accordingly, the financial statements for these periods are not necessarily indicative of HART's future results of operations, financial position and cash flows.

Prior to the Separation on October 31, 2013, Harvard Bioscience used a centralized approach to manage substantially all of its liquid resources and to finance its operations and, as a result, no separate cash accounts for HART were historically maintained, and debt and liquid resources maintained at the Harvard Bioscience group level are not included in the accompanying consolidated financial statements prior to the Separation. Harvard Bioscience funded all of HART's operating and capital resource requirements prior to the Distribution. After October 31, 2013, the accompanying consolidated financial statements reflect the consolidated financial position and results of operations of the Company as an independent publicly traded company.

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 June 30, 2014 and consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2014 and 2013 are unaudited. The accompanying interim consolidated statements of cash flows for the six months ended June 30, 2014 and 2013 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 June 30, 2014, its results of operations for the three and six months ended June 30, 2014 and 2013, and the Company's consolidated statements of cash flows for the six months ended June 30, 2014 and 2013. The financial data and other information disclosed in these notes related to the three and six month periods ended June 30, 2014 and 2013 are unaudited. The results for the three and six months ended June 30, 2014 and 2013 are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods or any future year or period.

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

In June 2014, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) 2014-10, Development Stage Entities (Topic 915): "Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation", which removes the definition of a development stage entity from the Accounting Standards Codification, eliminated the requirement that development stage entities present inception-to-date information in the company's financial statements, label those financial statements as those of a development stage entity, disclose a description of the development stage activities in which they engage and disclose in the first year the entity is no longer a development stage entity that in prior years it had been. The ASU is effective retrospectively for fiscal years, and interim periods within those years, beginning after December 14, 2014. The Company has elected the permissible early application of the changes in the accompanying interim unaudited consolidated financial statements, and for all future periods.

The accounting policies, other than the change noted above, underlying the accompanying unaudited consolidated financial statements are those set forth in Note 2 to the financial statements for the year ended December 31, 2013 included in the Company's Annual Report on Form 10-K.

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

3. Liquidity

The Company has incurred net losses since inception through June 30, 2014. Since inception, through the Separation, the Company received funding for operating losses from Harvard Bioscience and a $15.0 million cash contribution at the Separation. During the six month period ended June 30, 2014 the Company received an additional $0.36 million from the exercise of stock options. The Company is currently investing significant resources in development and commercialization of products for use in the field of regenerative medicine. The Company expects to continue to incur operating losses and negative cash flows from operations.

4. Inventories

Inventories consisted of the following:

	June 30, 2014	December 31, 2013
	(in thousands)	
Finished goods	$16	$ 7
Raw materials	130	31
Total	$146	$ 38

5. Related Party Transactions

Harvard Bioscience is considered to be a related party to the Company because David Green, the Company's Chairman and CEO, is also a director of Harvard Bioscience.

Cost Allocations

For periods presented prior to the Separation, HART's operations were fully integrated with Harvard Bioscience, including executive services, finance, treasury, corporate income tax, human resources, legal services and investor relations. The accompanying financial statements for periods prior to the Separation reflect the application of certain estimates and allocations of operating expenses and the Company believes the methods used to allocate these operating expenses were reasonable. The allocation methods included time devoted to HART activities, headcount, percentage of operating expenses or other relevant measures. Allocations of expenses for these services were $0.7 million for the three month period ended June 30, 2013 and $1.2 million for the six month period ended June 30, 2013. These allocated expenses are reflected in the total operating expenses in the consolidated statements of operations, in addition to direct expenses.

Agreements with 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 us to pay fees to Harvard Bioscience for services provided subsequent to the Separation, and will remain in place through at least October 31, 2014. Expenses recorded under these agreements were $0.1 million and $0.2 million for the three and six months ended June 30, 2014, respectively.

6. 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 for products 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 revenues and receivables as of and for the six months end June 30,

2014.

7. Stock-Based Compensation

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 disclosure of stock based compensation for the periods prior to the Separation represent the Company's portion of such plan maintained by Harvard Bioscience in which the Company's employees and directors participated. The securities underlying all options and awards granted under the Harvard Bioscience Plan consist of shares of Harvard Bioscience common stock.

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.

Prior to the Separation, HART stock-based compensation expense represented an allocation from Harvard Bioscience's stock-based compensation expense for employees whose time had been allocated to HART. After the Separation, 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.

As noted above relating to the Adjustment, 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 Plan Award Information

During the six months ended June 30, 2013, all awards were granted to employees and directors at exercise prices equal to or greater than fair market value of the Harvard Bioscience's common stock on the date of grant.

The following is a summary of stock option and restricted stock unit activity for the six months ended June 30, 2014:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2013	2,500,339	$ 3.20	326,185	$ 5.46
Granted	-	-	-	-
Exercised	(23,057)	3.36	-	-
Vested (RSUs)	-	-	(154,628)	4.70
Cancelled/forfeited	(311,635)	5.58	-	-
Balance at June 30, 2014	2,165,647	$ 2.85	171,557	$ 6.14

Stock-based compensation expense for the three and six months ended June 30, 2014 and 2013, respectively, was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands)		(in thousands)	
Research and development	$ 11	$ 21	$ 31	$ 37
Sales and marketing	4	-	7	-
General and administrative	165	137	324	257
Total stock-based compensation	$ 180	$ 158	$ 362	$ 294

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

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 3,000,000 shares of common stock.

The Company currently has 3,000,000 shares of its common stock reserved for the issuance, exercise or vesting of awards under the 2013 Plan. During the six months ended June 30, 2014, 150,000 options were granted under the 2013 Plan to HART employees 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 six months ended June 30, 2014:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2013	2,075,707	$ 4.34	19,492	$ 6.00
Granted	150,000	8.40	-	-
Exercised	(102,705)	4.94	-	-
Vested (RSUs)	-	-	(9,796)	6.00
Cancelled/forfeited	(147,301)	4.46	(1,716)	6.00
Balance at June 30, 2014	1,975,701	$ 4.61	7,980	$ 6.00

The following assumptions were used to estimate the fair value of stock options granted during the three and six months ended June 30, 2014:

	Three Months Ended June 30, 2014		Six Months Ended June 30, 2014	
Volatility	74	%	74	%
Risk-free interest rate	1.68	%	1.66	%
Expected holding period	6.22 years		6.22 years	
Dividend Yield	-	%	-	%

The weighted average fair values of the options granted under the 2013 Plan during the six months ended June 30, 2014 was $5.55, using the Black-Scholes option-pricing model.

Stock-based compensation expense for the three and six months ended June 30, 2014 and 2013, respectively, was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands)		(in thousands)	
Research and development	$ 26	$ -	$ 313	$ -
Sales and marketing	-	-	65	-
General and administrative	89	-	731	-
Total stock-based compensation	$ 115	$ -	$ 1,109	$ -

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

8. Commitments and Contingencies

From time to time, we may be involved in various claims and legal proceedings arising in the ordinary course of business. There are no such matters pending that we expect to be material in relation to our business, financial condition, 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 our ability to obtain and maintain regulatory approval for the bioreactors, scaffolds and other devices and product candidates we pursue; the success of our clinical trials and device and product development programs and the number of patients who can be treated with our products; the amount and timing of costs associated with our development of bioreactors, scaffolds and other devices and products; our failure to comply with regulations and any changes in regulations; our ability to access debt and equity markets; unpredictable difficulties or delays in the development of new technology; our collaborators 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; 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, 2013 filed with the SEC on March 31, 2014 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 regenerated organs for transplant. Our first product, the HART-Trachea, is intended to be used by surgeons to restore the structure and/or function of a severely damaged airway in patients who need an airway transplant. The HART-Trachea is comprised of the patient's own bone marrow cells seeded on our proprietary porous plastic scaffolding in our proprietary InBreath™ organ bioreactor. Our HART-Trachea has been used in six successful human airway transplant surgeries to date, each approved under compassionate use exemptions, but none of our products are yet approved by a government regulatory authority for marketing. In addition to pursuing our HART-Trachea product, we are also working with a number of leading researchers in their efforts to regenerate other organs. We use our depth of knowledge, our existing technologies and products and continued research and development to develop and provide devices to be used for growing organs outside the body for transplant.

Business Drivers/Factors Affecting Results of Operations

Our business efforts focus on developing and providing new synthetic scaffolds and organ bioreactor products to regenerative medicine researchers and practitioners. Going forward, we intend to generate revenues from the sale of regenerated organs and related bioreactors and scaffolds. Until we are able to commercialize our HART-Trachea product upon receipt of regulatory agency approvals to market that product for clinical use we expect our costs to exceed our revenues.

Once we receive regulatory agency approvals to market the HART-Trachea product for surgeons to use in human trachea transplants, we expect to generate meaningful revenues. At that time, we anticipate that we will be paid on a per-procedure basis for the use of the HART-Trachea. Although we hope to eventually receive regulatory approvals to market additional regenerated organs, we expect that approval for the HART-Trachea and successful commercialization thereof could lead to sufficient sales for us to achieve profitability.

We began the first quarter 2014 with our pre-IND meeting with the FDA. Based on the feedback from that meeting, we expect to submit our IND request to the FDA in 2015. Between now and then we will be completing the required preclinical large animal model testing, the ex-vivo accelerated lifetime testing and protocol standardization required by the FDA. We expect similar requirements to apply for us to get approval to begin a clinical trial in Europe too. In the pre-IND meeting we did not discuss the design of our proposed clinical trial in any detail but we do expect to have several conversations with the FDA throughout this year as we develop both the pre-clinical testing protocols and proposed clinical trial design. At this point we expect the trial to be open-label and the trial design to be a single-arm trial. With single arm trials, it is important for the trial to be well enough controlled to show that the treatment caused the effect. We intend to propose the patient's lung function before the surgery as the control and the patient's lung function after the surgery as the endpoint. We intend to measure lung function using the FEV1, or forced expiratory volume in one second. This is a common endpoint used for approval in clinical trials for other therapies such as for cystic fibrosis. It was also the endpoint studied in the published 5-year follow up on the very first patient ever treated with a regenerated trachea. In that case the patient's FEV1 improved by approximately 85% from before the surgery to 3 months after the surgery. According to the American Thoracic Society, the change in FEV1 should be greater than 20% to be clinically significant in evaluations in this time frame.

We also applied to the FDA for an orphan drug designation for the HART-Trachea. During the first quarter, the FDA informed us that they accepted our statistics on the number of patients that might require a trachea transplant, but they requested some follow up data on the patients treated so far with the HART-Trachea in order to complete their review of our application. We sent the requested follow up data to the FDA during the second quarter. We expect this submission to be sufficient for the FDA to determine whether or not it will grant orphan drug designation to the HART-Trachea, and we expect that the FDA will notify us of their decision in the next several weeks.

During the second quarter, the European Medicines Agency (EMA), through its Committee for Advanced Therapies (CAT), informed us of CAT's conclusion that our HART-Trachea product is classified as a tissue-engineered, advanced therapy medicinal product, or Combined ATMP. This classification grants our HART-Trachea product a pathway to approval on a European Union-wide basis, although clinical trials are managed through individual countries' regulatory agencies there.

We met with the Medicines and Healthcare Products Regulatory Agency of the U.K. (MHRA) in June to discuss the HART-Trachea product and the MHRA's views on certain preclinical studies, as well as our planned approach to clinical studies. We chose the U.K. to approach first in Europe due to the MHRA's familiarity with cell therapies, and the availability of surgeons and hospitals there that are already familiar with early progress in tissue-engineered products. Based on that meeting we continue to see a path to clinical trials and approval in Europe prior to the United States.

Clinical Update

During the second quarter, a sixth human tracheal transplant was performed using our HART-Trachea product, at Krasnodar Regional Hospital in Russia. The patient was a 24-year-old male suffering from extensive tracheal damage following an automobile accident. The surgery was a success and the patient was recovering well in the days following the procedure.

Basis of Presentation

Historically, we operated as part of Harvard Bioscience, and not as a stand-alone company. On October 31, 2013, Harvard Bioscience contributed the assets of its regenerative medicine business and $15 million of cash to HART, and on November 1, 2013 distributed all of the outstanding common shares of HART to Harvard Bioscience's shareholders on a pro-rata basis. The contribution and related separation is referred to herein as the "Separation" and the distribution is referred to herein as the "Distribution" and the "spin-off". The consolidated HART financial statements for periods prior to the Separation, were prepared on a stand-alone basis and were derived from the financial statements and accounting records of Harvard Bioscience using the historical basis of assets and liabilities of HART. Our financial statements from the periods prior to the Separation include expenses of Harvard Bioscience allocated to HART for certain functions provided by Harvard Bioscience, including, but not limited to, general corporate expenses related to executive services, finance, treasury, corporate income tax, human resources, legal services and investor relations. These expenses were allocated to HART on the basis of headcount, time devoted to HART activities, percentage of operating expenses or other relevant measures. Prior to the Separation, Harvard Bioscience used a centralized approach to manage substantially all of its liquid resources and to finance its operations and, as a result, no separate cash accounts for HART were historically maintained, and debt and liquid resources maintained at the Harvard Bioscience group level are not included in the accompanying consolidated financial statements prior to the Separation. Harvard Bioscience funded all of HART's operating and capital resource requirements prior to the Distribution. After October 31, 2013, the financial statements reflect the consolidated financial position and results of operations of the Company as an independent publicly traded company.

Relationship with Harvard Bioscience

Prior to November 1, 2013, HART was a wholly-owned subsidiary of Harvard Bioscience, Inc. HART was incorporated on May 3, 2012 by Harvard Bioscience to provide a means for separating its regenerative medicine device business from its other businesses. Harvard Bioscience first focused on providing devices to scientists involved in regenerative medicine research in 2008. From early 2009 to the Separation, Harvard Bioscience's regenerative medicine device business initiative operated as a division of Harvard Bioscience. Harvard Bioscience decided to separate its regenerative medicine business into our company, a separate corporate entity, and then to spin off its interest in our business to its stockholders. On October 31, 2013, Harvard Bioscience contributed the assets of its regenerative medicine business and approximately $15 million in cash to us. On November 1, 2013, Harvard Bioscience spun off its interest in HART via a pro-rata distribution of its HART common shares to Harvard Bioscience's stockholders. As a result of that distribution, Harvard Bioscience is no longer a stockholder of our common stock and no longer controls our operations. We had no material assets or activities as a separate corporate entity until the contribution to us by Harvard Bioscience of those assets and that business.

On October 31, 2013, we entered into agreements with Harvard Bioscience that will govern the Separation and various interim and ongoing relationships. They provide for, among other things, the transfer from Harvard Bioscience to us of assets and the assumption by us of liabilities comprising our businesses. In accordance with such agreements, we will pay Harvard Bioscience to provide continued services in the areas of accounting, payroll, facilities usage, benefits administration, human resources, information services and various other corporate services, operations, and engineering for periods ranging from six months to one year following the Distribution. All of the agreements relating to the Separation were made in the context of a parent-subsidiary relationship and were entered into in the overall context of the Separation. The terms of these agreements may be more or less favorable to us than if they had been negotiated with unaffiliated third parties.

Harvard Bioscience is considered to be a related party to HART because David Green, our Chairman and CEO, is also a director of Harvard Bioscience.

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; 3D organ bioreactors; and for periods prior to 2014,

development costs of a stem cell injector, a product that we are not currently pursuing. 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 writing, issuing and defending our 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 catalogs, 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 general legal and accounting services, insurance, investor relations and facility costs.

Comparison of the three months ended June 30, 2014 to the three months ended June 30, 2013:

Research and Development Expense

Research and development expense was flat, at $1.2 million for the three months ended June 30, 2014 compared with $1.2 million for the three months ended June 30, 2013. An increase in fees related to patents and depreciation for lab and test equipment was offset by a year to year reduction of costs related to our stem cell injector development project which we terminated during 2013.

Sales and Marketing Expense

Sales and marketing expense increased approximately $54,000, or 155%, to $88,000 for the three months ended June 30, 2014 compared with $34,000 for the three months ended June 30, 2013. The increase was primarily due to additional salary-related costs of $60,000.

General and Administrative Expense

General and administrative expense increased $0.5 million, or 57%, to $1.2 million for the three months ended June 30, 2014 compared with $0.8 million for the three months ended June 30, 2013. Of the $0.5 million increase, direct salary costs increased by $0.1 million over those allocated to HART by Harvard Bioscience for the three months ended June 30, 2013. General and administrative costs also increased by $0.3 million due to costs associated with being a stand-alone public company, such as external and internal accountants, information technology, legal fees, investor relations, director fees and insurance.

Comparison of the six months ended June 30, 2014 to the six months ended June 30, 2013:

Research and Development Expense

Research and development expense was flat, at $2.4 million for the six months ended June 30, 2014 compared with $2.4 million for the six months ended June 30, 2013. A $0.4 million year to year increase in non-cash stock-based compensation expense related to the initial stock option grants made to employees at the time of the spin-off was offset by a year to year reduction of costs related to our stem cell injector development project which we terminated during 2013.

Sales and Marketing Expense

Sales and marketing expense increased approximately $110,000, or 201%, to $164,000 for the six months ended June 30, 2014 compared with $54,000 for the six months ended June 30, 2013. The increase was primarily due to additional salary-related costs of $127,000.

General and Administrative Expense

General and administrative expense increased $1.4 million, or 82%, to $3.0 million for the six months ended June 30, 2014 compared with $1.6 million for the six months ended June 30, 2013. Of the $1.4 million increase, $0.8 million was related to an increase in non-cash stock-based compensation expense related to the initial stock option grants made to employees at the time of the spin-off. Additionally, direct salary costs increased by $0.2 million over those allocated to HART by Harvard Bioscience for the six months ended June 30, 2013. General and administrative

expense also increased by $0.5 million due to costs associated with being a stand-alone public company, such as external and internal accountants, information technology, legal fees, investor relations, director fees and insurance.

Financial Condition, Liquidity and Capital Resources

Sources of liquidity.

We have incurred net losses since inception. Since inception, through the Separation, we received funding for operating losses from Harvard Bioscience and a $15.0 million cash contribution at the Separation.

During the six month period ended June 30, 2014 we received $0.4 million of cash proceeds from exercise of stock options.

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 $3.8 million for the six months ended June 30, 2014 reflected our $5.5 million net loss, offset by a $1.5 million add-back of non-cash stock-based compensation expense, a $0.1 million add-back for depreciation and $0.1 million of changes in working capital items.

Net cash used in operating activities of $3.8 million for the six months ended June 30, 2013 reflected our $4.1 million net loss, offset by a $0.3 million add-back of non-cash stock-based compensation expense.

Investing activities. Net cash used in investing activities during the six month periods ended June 30, 2014 and 2013 reflected additions to property, plant and equipment.

Financing activities. Cash generated from financing activities during the six months ended June 30, 2014 was primarily a result of employees' exercises of stock options.

Cash generated from financing activities during the six months ended June 30, 2013 represented Harvard Bioscience's funding of our business activities.

Recent Authoritative Accounting Guidance

In June 2014, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) 2014-10, Development Stage Entities (Topic 915): "Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation", which removes the definition of a development stage entity from the Accounting Standards Codification, eliminated the requirement that development stage entities present inception-to-date information in the company's financial statements, label those financial statements as those of a development stage entity, disclose a description of the development stage activities in which they engage and disclose in the first year the entity is no longer a development stage entity that in prior years it had been. The ASU is effective retrospectively for fiscal years, and interim periods within those years, beginning after December 14, 2014. We have elected the permissible early application of the changes in the accompanying interim unaudited consolidated financial statements, and for all future periods.

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, 2013, which was filed with the SEC on March 31, 2014.

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 June 30, 2014. 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-10Q 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, 2013, which was filed with the SEC on March 31, 2014.

Item 6. Exhibits

Exhibit Index

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.
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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

+	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.
**	XBRL (Extensive Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

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: August 13, 2014

HARVARD APPARATUS
REGENERATIVE TECHNOLOGY, INC.

By: /S/ David Green
David Green
President and Chief Executive Officer

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

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