Harvard Apparatus Regenerative Technology, Inc.
Form 10-Q
November 27, 2013

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, 2013

¨ **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 November 18, 2013, there were 7,740,026 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, 2013

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
A BUSINESS SEGMENT OF HARVARD BIOSCIENCE, INC.
(A Development Stage Company)

BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ -	$ -
Prepaid expenses	33	-
Total current assets	33	-
Plant, property and equipment, net	460	438
Total non-current assets	460	438
Total assets	$ 493	$ 438
LIABILITIES AND INVESTED EQUITY		
Current liabilities:		
Accounts payable	$ 126	$ 179
Accrued and other current liabilities	253	232
Total current liabilities	379	411
Total non-current liabilities	-	-
Total liabilities	379	411
Invested equity:		
Harvard Bioscience investment	18,681	12,425
Accumulated deficit	(18,567)	(12,398)
Total invested equity	114	27
Total liabilities and invested equity	$ 493	$ 438

See accompanying notes to unaudited financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
A BUSINESS SEGMENT OF HARVARD BIOSCIENCE, INC.
(A Development Stage Company)

STATEMENTS OF OPERATIONS
(unaudited, in thousands)

	Three months ended September 30,		Nine months ended September 30,		February 24, 2009 (inception) to September 30,
	2013	2012	2013	2012	2013
Revenues	$ -	$ -	$ -	$ -	$ -
Cost of product revenues	-	-	-	-	-
Gross profit	-	-	-	-	-
Sales and marketing expenses	28	35	82	91	466
General and administrative expenses	974	634	2,604	1,631	7,185
Research and development expenses	1,058	1,059	3,483	3,025	10,916
Operating expenses	2,060	1,728	6,169	4,747	18,567
Operating loss	(2,060)	(1,728)	(6,169)	(4,747)	(18,567)
Loss before income taxes	(2,060)	(1,728)	(6,169)	(4,747)	(18,567)
Income taxes	-	-	-	-	-
Net loss	$ (2,060)	$ (1,728)	$ (6,169)	$ (4,747)	$ (18,567)

See accompanying notes to unaudited financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
A BUSINESS SEGMENT OF HARVARD BIOSCIENCE, INC.
(A Development Stage Company)

STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

	Nine months ended September 30,		Period from February 24, 2009 (inception) to September 30,
	2013	2012	2013
Cash flows used in operating activities:			
Net loss:	$ (6,169)	$ (4,747)	$ (18,567)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	514	349	1,422
Depreciation	123	38	203
Changes in operating assets and liabilities:			
Prepaid expenses	(33)	-	(33)
Accounts payable	(53)	(26)	126
Accrued and other current liabilities	21	16	253
Net cash used in operating activities	(5,597)	(4,370)	(16,596)
Cash flows used in investing activities:			
Additions to property, plant and equipment	(145)	(146)	(663)
Net cash used in investing activities	(145)	(146)	(663)
Cash flows from financing activities:			
Investment by Harvard Bioscience	5,742	4,516	17,259
Net cash provided by financing activities	5,742	4,516	17,259
Net increase (decrease) in cash and cash equivalents	-	-	-
Cash and cash equivalents at beginning of the period	-	-	-
Cash and cash equivalents at end of period	$ -	$ -	$ -

See accompanying notes to unaudited financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
A BUSINESS SEGMENT OF HARVARD BIOSCIENCE, INC.
(A Development Stage Company)

NOTES TO UNAUDITED 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 devices for use by clinicians and researchers in the field of regenerative medicine.

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. Accordingly, HART is considered to be in the development stage.

HART was incorporated on May 3, 2012 by Harvard Bioscience, as a wholly-owned subsidiary, to provide a means for separating Harvard Bioscience's regenerative medicine device 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 device business initiative has been operated as a division of Harvard Bioscience. On October 31, 2013, Harvard Bioscience contributed its regenerative medicine device business assets into HART (the "Separation"), capitalized HART via a cash contribution of $15 million and then on November 1, 2013 spun off its interest in HART to Harvard Bioscience's stockholders. See Note 8 for a discussion of the spin-off.

Basis of Presentation

The Company has historically operated as part of Harvard Bioscience, and not as a stand-alone company. The financial statements presented herein, and 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 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").

The Company's financial statements 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 have been 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.

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Harvard Bioscience has historically used a centralized approach to cash management and financing of its operations. Transactions relating to HART have been accounted for through the Harvard Bioscience investment account for HART. Accordingly, none of the cash, cash equivalents or debt at the Harvard Bioscience corporate level has been assigned to HART in the financial statements through September 30, 2013.

The unaudited financial statements of HART as of September 30, 2013 and for the three and nine months ended September 30, 2013 and 2012 and for the period from February 24, 2009 (inception) to September 30, 2013 have been prepared by the Company pursuant to the rules and regulations of the SEC for interim financial reporting. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations.

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

The accounting policies underlying the accompanying unaudited financial statements are those set forth in Note 2 to the financial statements for the year ended December 31, 2012 included in the Company's Form 10 Registration Statement.

(a) Unaudited Interim Financial Information

The accompanying interim balance sheet as of September 30, 2013 and statements of operations for the three and nine months ended September 30, 2013 and 2012 and for the period from February 24, 2009 (inception) to September 30, 2013 are unaudited. The accompanying interim statements of cash flows for the nine months ended September 30, 2013 and 2012 and for the period from February 24, 2009 (inception) to September 30, 2013 are unaudited. The interim unaudited 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, 2013, its results of operations for the three and nine months ended September 30, 2013 and 2012 and for the period from February 24, 2009 (inception) to September 30, 2013, and the Company's statements of cash flows for the nine months ended September 30, 2013 and 2012 and for the period from February 24, 2009 (inception) to September 30, 2013. The financial data and other information disclosed in these notes related to the three and nine month periods ended September 30, 2013 and 2012 and for the period from February 24, 2009 (inception) to September 30, 2013 are unaudited. The results for the three and nine months ended September 30, 2013 and 2012 and for the period from February 24, 2009 (inception) to September 30, 2013 are not necessarily indicative of results to be expected for the year ending December 31, 2013, any other interim periods or any future year or period.

(b) Recently Issued Accounting Pronouncements

There are no 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 operating losses and negative cash flow since inception, and had an accumulated deficit of $18.6 million as of September 30, 2013. Since inception, the Company has received funding for operating losses from Harvard Bioscience. The Company is currently investing significant resources in development and commercialization of devices for use by clinicians and researchers in the field of regenerative medicine. The Company expects to continue to incur operating losses and negative cash flows.

As part of the Separation of the Company from Harvard Bioscience on October 31, 2013, Harvard Bioscience contributed $15.0 million to the Company as initial capital, and then spun-off its 100% interest in the Company's

common stock to Harvard Bioscience shareholders via a pro-rata dividend on November 1, 2013.

See Note 8 for a discussion of the Separation, initial capitalization and the subsequent spin-off of the Company.

4. Related Party Transactions

Cost Allocations

For each of the periods presented, 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 reflect the application of certain estimates and allocations of operating expenses and the Company believes the methods used to allocate these operating expenses are reasonable. The allocation methods include time devoted to HART activities, headcount, percentage of operating expenses or other relevant measures. Allocations of expenses for these services were $0.7 million and $1.9 million for the three and nine month periods ended September 30, 2013, respectively. This compares with allocations of expenses for these services of $0.6 million and $1.6 million for the three and nine month periods ended September 30, 2012, respectively. These allocated expenses are reflected in the total operating expenses in the statements of operations, in addition to direct expenses. The Company's financial statements may not be indicative of the future performance and do not necessarily reflect what the results of operations, financial position and cash flows would have been had the Company operated as an independent, publicly-traded company during the periods presented.

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 will require us to pay fees to Harvard Bioscience for services provided subsequent to the separation.

See Note 8 for a discussion of the Separation, initial capitalization and the subsequent spin-off of the Company.

5. Stock-Based Compensation

Stock-based compensation expense for HART represents an allocation from Harvard Bioscience's stock-based compensation expense for employees and directors whose time has been allocated to HART.

Harvard Bioscience maintains its Third Amended and Restated 2000 Stock Option and Incentive Plan (as amended, the "Plan") for the benefit of certain of its officers, directors and employees. The following disclosure represents the Company's portion of the Plan maintained by Harvard Bioscience in which the employees and directors participated. All options and awards granted under the Plan consist of Harvard Bioscience common shares. Accordingly, the amounts presented are not necessarily indicative of future performance and do not necessarily reflect the results that the Company would have experienced as an independent, publicly-traded company for the periods presented.

Employee options and awards become fully vested over a period of approximately three years and seven months, with the first quarter vesting after approximately seven months of the grant date and the remaining vesting equally over a period of three years thereafter. Options and awards granted to directors become fully vested over periods between one and three years.

The fair value of options granted was determined using the Black-Scholes option-pricing model. The determination of fair value on the date of the grant is affected by the grant date market price of Harvard Bioscience common shares and a number of other variables. These variables include, but are not limited to, the expected stock price volatility of Harvard Bioscience common shares over the term of the awards and actual and projected stock option exercise behaviors. The fair value of restricted stock units was determined by the number of shares granted and the grant date market price of Harvard Bioscience common shares.

The compensation expense recognized for all equity-based awards is net of estimated forfeitures and is recognized using the straight-line method over the applicable service period.

The following summarizes the Company's portion of stock option transactions under the Plan from January 1, 2013 through September 30, 2013:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2012	622,340	$ 4.07	184,264	$ 3.90
Granted	217,902	5.08	63,929	5.08
Exercised	(49,531)	3.46	-	-
Vested (RSUs)	-	-	(55,247)	-
Cancelled / forfeited	(29,972)	4.34	(10,892)	3.83
Balance at September 30, 2013	760,739	$ 4.43	182,054	$ 4.31

The following assumptions were used to estimate the fair value of stock options granted during the nine months ended September 30, 2013 and 2012:

	Nine months ended September 30,			
	2013		2012	
Volatility	57.20	%	55.09	%
Risk-free interest rate	1.18	%	0.80	%
Expected holding period	5.6 years		6.0 years	
Dividend yield	0	%	0	%

The weighted average fair values of the options granted under the 2000 Plan during the nine months ended September 30, 2013 was $2.64, using the Black Scholes option-pricing model. Stock-based compensation expense for the three and nine months ended September 30, 2013 and 2012 consisted of stock-based compensation expense related to stock options and RSUs.

Stock-based compensation expense for the three and nine months ended September 30, 2013 and 2012, was allocated as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
	(in thousands)			
Sales and marketing	$ -	$ 1	$ -	$ 1
General and administrative	188	131	445	288
Research and development	32	24	69	60
Total stock-based compensation	$ 220	$ 156	$ 514	$ 349

The Company did not capitalize any stock-based compensation.

6. Income Taxes

HART operations were historically included in Harvard Bioscience's consolidated U.S. federal and certain state income tax returns. The provision for income taxes has been determined as if HART had filed separate tax returns for the periods presented. Accordingly, the effective tax rate of HART in the future years could vary from its historical effective tax rates depending on the future legal structure of HART and related tax elections. The historical deferred tax assets, including the net operating loss and credit carryforwards generated by HART will remain with Harvard Bioscience subsequent to the separation.

At September 30, 2013 and December 31, 2012, the Company had deferred tax assets of $7.9 million and $5.0 million, respectively, which principally relate to net operating loss carryforwards. The Company has a full valuation allowance on its deferred tax assets. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets and liabilities. Due to the Company's operating results, and its cumulative loss position and uncertainty surrounding its forecasts, the Company concluded that a full valuation allowance was needed to offset its deferred tax assets.

7. Commitments and Contingent Liabilities

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.

8. Subsequent Events

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 record of all the shares of common stock of HART (the "Distribution"). In the Distribution, Harvard Bioscience distributed to its stockholders one share of HART common stock for every four shares of Harvard Bioscience common stock they owned as of the close of business on October 21, 2013, the record date for the Distribution. Fractional shares of HART common stock were not included in the Distribution. Instead, Registrar & Transfer Company aggregated fractional shares into whole shares, and sold the whole shares in the open market and distributed the aggregate net cash proceeds pro rata to each holder who otherwise would have been entitled to receive a fractional share in the Distribution.

Effective with the spin-off, Harvard Bioscience contributed $15.0 million in cash to HART to fund our operations. Harvard Bioscience will no longer fund the Company's operations following the Distribution. Based on the Company's current operating plan, management believes the $15.0 million cash contribution will be sufficient to fund the Company's operating expenses, working capital needs and capital expenditures for at least the next 18 months following the Distribution. The Company has based the estimates on assumptions that may prove wrong, and the Company may use available capital resources sooner than expected. Further, the Company's strategy or business plan may change in the future, possibly changing the rate of spending or need for additional capital. The Company may need to secure future funding through equity offerings, debt financings, government funding, marketing and distribution arrangements and other collaborations or strategic alliances. The Company cannot assure it will be successful in raising additional capital on favorable terms or at all. In addition, to preserve the tax-free treatment to Harvard Bioscience of the Distribution, for the two-year period following the Distribution the Company will be limited in issuing equity securities beyond certain thresholds which may limit its ability to raise additional capital.

Immediately following the Distribution, the Company had 30.0 million common shares authorized and 7.7 million common shares issued and outstanding. Additionally, the Company's Board of Directors has the authority to issue up

to 2.0 million shares of preferred stock and to determine the price, privileges and other terms of these shares, and may exercise this authority without any further approval of stockholders.

In connection with the spin-off, certain required adjustments were made to the Harvard Bioscience outstanding equity compensation awards under their employee benefit plans. Each outstanding option to purchase Harvard Bioscience common stock was converted on the date of the Distribution into both an adjusted Harvard Bioscience option to purchase Harvard Bioscience common stock and an option to purchase HART common stock. Black-Scholes valuation modeling was used to determine the value that each Harvard Bioscience option had lost at the time of the Distribution. To ensure the holder maintained such lost value, 80% of such lost value was provided back to the holder by making appropriate adjustments to the share amount and exercise price of the existing Harvard Bioscience option and 20% of such lost value was provided back to the holder through the issuance of an option to purchase HART common stock. Similar to the adjustment of the existing Harvard Bioscience options, with respect to each unvested Harvard Bioscience restricted stock unit outstanding at the time of the Distribution, such Harvard Bioscience restricted stock units were converted on the date of the Distribution into both an adjusted Harvard Bioscience restricted stock unit and a HART restricted stock unit. The market prices of Harvard Bioscience and HART common stock were used to determine the value that each Harvard Bioscience restricted stock unit lost at the time of the Distribution and then to ensure the holder maintained such lost value, 80% of such lost value was provided back to the holder by making an appropriate increase of the share amount of the existing Harvard Bioscience restricted stock unit and 20% of such lost value was provided back to the holder through the issuance of a HART restricted stock unit. The share amounts and exercise prices of the adjusted Harvard Bioscience options and HART options, as well as the share amounts of the adjusted Harvard Bioscience restricted stock unit and HART restricted stock unit, were each adjusted and set in a manner to ensure the intrinsic value held by the holder pertaining to the existing Harvard Bioscience award just prior to the Distribution would be maintained immediately following the Distribution and were determined such that tax is not triggered under Section 409A of the Internal Revenue Code. As part of these required adjustments, the Company issued approximately 0.3 million HART options and approximately 0.02 million HART restricted stock units and Harvard Bioscience issued an additional approximately 1.7 million options and approximately 0.1 million restricted stock units to holders of outstanding Harvard Bioscience equity compensation awards.

Prior to the Distribution, the Company adopted its 2013 Equity Incentive Plan. In November 2013, following the Distribution, the Company issued option grants to its employees and directors totaling approximately 2.0 million options.

In connection with the spin-off, on October 31, 2013, the Company entered into various commercial agreements with Harvard Bioscience which contain many of the key provisions related to the Distribution. These agreements include: (i) a Separation and Distribution Agreement; (ii) an Intellectual Property Matters Agreement; (iii) a Product Distribution Agreement; (iv) a Tax Sharing Agreement; (v) a Transition Services Agreement; and (vi) a Sublease.

Harvard Bioscience received a Supplemental Ruling to the Private Letter Ruling dated March 22, 2013 from the IRS to the effect that, among other things, the Separation and related distribution of all of the shares of the Company's common stock by Harvard Bioscience will qualify as a transaction that is tax-free for U.S. federal income tax purposes under Section 355 and 368(a)(1)(D) of the Internal Revenue Code continuing in effect. The private letter and supplemental rulings and the tax opinion that Harvard Bioscience expects to receive from Burns & Levinson LLP, special counsel to Harvard Bioscience, rely and will rely on certain representations, assumptions and undertakings, including those relating to the past and future conduct of the HART business, and neither the private letter and supplemental rulings nor the opinion would be valid if such representations, assumptions and undertakings were incorrect. Moreover, the private letter and supplemental rulings do not address all the issues that are relevant to determining whether the Distribution will qualify for tax-free treatment. Notwithstanding the private letter and supplemental rulings and opinion, the IRS could determine the Distribution should be treated as a taxable transaction for U.S. federal income tax purposes if, among other reasons, it determines any of the representations, assumptions or undertakings that were included in the request for the private letter and supplemental rulings are false or have been violated or if it disagrees with the conclusions in the opinion that are not covered by the IRS ruling.

To preserve the tax-free treatment to Harvard Bioscience of the Separation and Distribution, for the two-year period following the Distribution the Company may be limited, except in specified circumstances, from:

entering into certain transactions pursuant to which all or a portion of the Company's stock would be acquired, whether by merger or otherwise;

issuing equity securities beyond certain thresholds;

repurchasing the Company's common stock;

ceasing to actively conduct The Company's regenerative medicine business; and

taking or failing to take any other action that prevents the Separation and Distribution and related transactions from being tax-free.

If the Distribution fails to qualify for tax-free treatment, in general, Harvard Bioscience would be subject to tax as if it had sold the Company's common stock in a taxable sale for its fair market value, and Harvard Bioscience stockholders who receive shares of HART common stock in the Distribution would be subject to tax as if they had received a taxable Distribution equal to the fair market value of such shares.

Under the tax sharing agreement between Harvard Bioscience and the Company, the Company would generally be required to indemnify Harvard Bioscience against any tax resulting from the Distribution to the extent that such tax resulted from (i) an acquisition of all or a portion of our stock or assets, whether by merger or otherwise, (ii) other actions or failures to act by the Company, or (iii) any of the Company's representations or undertakings being incorrect or violated. The Company's indemnification obligations to Harvard Bioscience and its subsidiaries, officers and directors are not limited by any maximum amount. If the Company is required to indemnify Harvard Bioscience or

such other persons under the circumstances set forth in the tax sharing agreement, the Company may be subject to substantial liabilities.

Prior to the Distribution, the Company's Board of Directors adopted a Shareholder Rights Plan and declared a dividend distribution of one preferred stock purchase right for each outstanding share of the Company's common stock. Initially, these rights will not be exercisable and will trade with the shares of the Company's common stock. Under the Shareholder Rights Plan, the rights generally will become exercisable if a person becomes an "acquiring person" by acquiring 20% or more of the common stock of the Company or if a person commences a tender offer that could result in that person owning 20% or more of the common stock of the Company. If a person becomes an acquiring person, each holder of a right (other than the acquiring person) would be entitled to purchase, at the then-current exercise price, such number of shares of preferred stock which are equivalent to shares of the Company's common stock having a value of twice the exercise price of the right. If the Company is acquired in a merger or other business combination transaction after any such event, each holder of a right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the right.

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 this Quarterly Report on Form 10-Q 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

Relationship with Harvard Bioscience

Prior to November 1, 2013, Harvard Apparatus Regenerative Technology, Inc. was a wholly-owned subsidiary of Harvard Bioscience, Inc. We were 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 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 device business initiative has been 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. Since 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. We will continue to pursue our business of developing and making devices for regenerative medicine researchers and clinicians.

Our Business

We are a clinical-stage regenerative medicine company developing life-saving regenerated organs for transplant. Our first product, the InBreath Airway Transplant System, 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 InBreath Airway Transplant System is comprised of a porous plastic scaffold made in the size and shape of the natural trachea, bronchus or tracheobronchial tree and a rotating bioreactor used to seed the patient's own bone marrow cells onto the scaffold prior to implant. Our bioreactor technology has been used in ten successful human airway transplant surgeries and the most recent four of these surgeries also used our InBreath scaffold. We believe the first of these ten surgeries, conducted in 2008, was the world's first transplant of a regenerated airway. A human donor trachea was used as the organ scaffold in that surgery. In addition, we believe the second surgery, conducted in 2011, was the world's first transplant of a regenerated airway using a synthetic scaffold. We use our depth of knowledge, our existing technologies and products and continued research and development to develop and provide devices to be used by physicians for growing organs outside the body for transplant.

Business Drivers/Factors Affecting Results of Operations

Our business efforts focus on developing and providing new organ bioreactor and synthetic scaffold products to regenerative medicine researchers and practitioners. We have not generated revenues to date. Going forward, we intend to generate revenues from the sale of our synthetic scaffold and organ bioreactor systems, some of which will be given to certain key researcher collaborators to accelerate development of new bioreactor technologies and some of which will generate revenues. Until we are able to commercialize our InBreath System 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 InBreath System for surgeons to use in human transplant procedures, especially for 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 InBreath System. Although we hope to receive regulatory approvals to market our organ bioreactor and synthetic scaffold systems for use by surgeons to perform transplants of additional organs, we expect that approval for our trachea transplant products and successful commercialization thereof will lead to sufficient sales for us to achieve profitability.

Basis of Presentation

Historically, we have operated as part of Harvard Bioscience, and not as a stand-alone company. Financial statements were not previously prepared for us since we did not operate as a separate legal entity prior to the Separation from Harvard Bioscience. The discussion and analysis of our financial condition and results of operations are based on the historical Harvard Bioscience regenerative medicine business financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements required that we make estimates and assumptions that affect the reported amounts of assets and liabilities at the dates of the financial statements and the expenses during the reporting periods presented. Assets and liabilities have been presented at Harvard Bioscience's book values for those items at the dates of the financial statements. Certain of the expenses were allocated based on estimates of costs incurred by Harvard Bioscience on behalf of the regenerative medicine business or services provided by Harvard Bioscience personnel who were not wholly engaged in the regenerative medicine business but who supported that business directly or indirectly during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions.

Related Party Relationship with Harvard Bioscience

Harvard Bioscience distributed all of the shares of our common stock it owns to Harvard Bioscience's stockholders on November 1, 2013, by means of a spin-off, via a pro rata distribution by Harvard Bioscience of the shares of our common stock it owned to holders of Harvard Bioscience's common stock.

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 expect to 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 Separation and 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.

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 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 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. We expense research and development costs as incurred.

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.

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.

Comparison of three months ended September 30, 2013 to three months ended September 30, 2012

Research and Development Expense

Research and development expense was flat, at $1.1 million for the three months ended September 30, 2013 compared with $1.1 million for the three months ended September 30, 2012. We had a substantial year over year increase in our activities in scaffold and organ bioreactor research and development. The increased scaffold and bioreactor development costs in 2013 included additional engineering and technical resources. These increases were made to support a greater number of regenerative medicine collaborators and to accelerate the development of several new bioreactors to help further their research efforts. Scaffold and bioreactor research and development costs increased by $0.2 million or 35% compared to the same period last year. The increase was offset by lower costs for our stem cell injector development project which decreased $0.2 million compared to the same period last year.

General and Administrative Expense

General and administrative expense increased $0.3 million, or 53%, to $1.0 million for the three months ended September 30, 2013 compared with $0.6 million for the three months ended September 30, 2012. Of the $0.3 million increase, $0.2 million was due to greater legal, recruiting and facilities related costs associated with the organization and operation of the business. Approximately $0.1 million of the year-to-year increase related to increased management focus from Harvard Bioscience's senior executives and directors which increased our allocated expense. Payroll-related and stock compensation costs for such individuals were allocated to our business based on the percentage of their time spent managing or supporting our business.

Sales and Marketing Expense

Sales and marketing expense decreased approximately $7,000, or 19%, to $28,000 for the three months ended September 30, 2013 compared with $35,000 for the three months ended September 30, 2012. The decrease was primarily due to lower business development costs.

Comparison of nine months ended September 30, 2013 to nine months ended September 30, 2012

Research and Development Expense

Research and development expense increased $0.5 million, or 15%, to $3.5 million for the nine months ended September 30, 2013 compared with $3.0 million for the nine months ended September 30, 2012. The increase was due to a substantial increase in our activities in scaffold and organ bioreactor research and development. The increased scaffold and bioreactor development costs in 2013 included additional engineering and technical resources. These increases were made to support a greater number of regenerative medicine collaborators and to accelerate the development of several new bioreactors to help further their research efforts, and to develop our synthetic scaffold technology. Scaffold and bioreactor research and development costs increased by $1.0 million or 79% compared to the same period last year. The increase was partially offset by lower costs for our stem cell injector development project which decreased $0.5 million compared to the same period last year.

General and Administrative Expense

General and administrative expense increased $1.0 million, or 60%, to $2.6 million for the nine months ended September 30, 2013 compared with $1.6 million for the nine months ended September 30, 2012. Of the $1.0 million increase, $0.6 million was due to greater legal, recruiting and facilities related costs associated with the organization and operation of the business. Approximately $0.4 million of the year-to-year increase related to increased attention from Harvard Bioscience's senior executives and directors which increased our allocated expense. Payroll-related and

stock compensation costs for such individuals were allocated to our business based on the percentage of their time spent managing or supporting our business.

Sales and Marketing Expense

Sales and marketing expense decreased approximately $9,000, or 9%, to $82,000 for the nine months ended September 30, 2013 compared with $91,000 for the nine months ended September 30, 2012.

Financial Condition, Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses and negative operating cash flow since inception, and we had an accumulated deficit of $18.6 million as of September 30, 2013. Since inception, our operations have been funded by contributions from Harvard Bioscience. We are currently investing significant resources in the development and commercialization of our products for use by clinicians and researchers in the field of regenerative medicine. As a result, we expect to incur operating losses and negative operating cash flow for the foreseeable future.

On May 1, 2013 Harvard Bioscience announced that they would continue to move forward with respect to the HART spin-off through a Registration Statement on Form 10 filed by HART and the listing of HART's common shares on the NASDAQ Capital Market. We filed a Registration Statement on Form 10 with the SEC on July 31, 2013 to become a public reporting company under the Securities Exchange Act of 1934. We also applied to list HART's common stock on the NASDAQ Capital Market under the symbol "HART" in connection with the spin-off and related Form 10 filing. We received approval for effectiveness of the Registration Statement on Form 10 from the SEC on October 16, 2013.

On October 31, 2013, Harvard Bioscience contributed all the assets of its regenerative medicine business to us, and contributed $15 million in cash as initial capital in preparation for the spin-off. On November 1, 2013, Harvard Bioscience spun-off 100% of HART's common stock to Harvard Bioscience's stockholders in a pro-rata, tax-free dividend.

The shares of HART common stock distributed in the spin-off trade publicly on NASDAQ. Since the spin-off by Harvard Bioscience of its interest in HART, we and Harvard Bioscience now operate and our equity securities now trade, as two separate, public companies.

Operating activities. Net cash used in operating activities of $5.6 million for the nine months ended September 30, 2013 was primarily a result of our $6.2 million net loss, offset by a $0.5 million add-back of non-cash expenses of stock-based compensation.

Net cash used in operating activities of $4.4 million for the nine months ended September 30, 2012 was primarily a result of our $4.7 million net loss, offset by a $0.3 million add-back of non-cash expenses of stock-based compensation.

Investing activities. Net cash used in investing activities during the nine months ended September 30, 2013 reflected additions to property, plant and equipment.

Financing activities. Cash generated from financing activities in all periods presented represented Harvard Bioscience's funding of our business activities.

Tax Attributes Relating to Historical Operating Losses

All tax attributes, including net operating losses and tax credits, related to our operating losses through the date of our separation from Harvard Bioscience will remain with Harvard Bioscience following the separation.

Option Vesting, Compensation Expense and Exercise Proceeds

In connection with the November 1, 2013 distribution of our common stock by Harvard Bioscience, we issued options to purchase our common stock and restricted stock units to Harvard Bioscience employees and directors who held options and restricted stock units issued by Harvard Bioscience prior to the distribution.

Such stock options and restricted stock units issued at the distribution will vest in tandem with the stock options and restricted stock units originally issued by Harvard Bioscience for the remaining life of such stock options and restricted stock units. The continued vesting and exercisability of the stock options and restricted stock units we issued will be conditional on the recipient's continued service to or employment with Harvard Bioscience or our company.

Separately, certain of our employees and directors, including our executive officers, are holders of vested and unvested options to buy Harvard Bioscience common stock and unvested restricted stock units pertaining to Harvard Bioscience's common stock. Vesting and exercisability of such options and restricted stock units will continue through their original expiration dates so long as the individual holder is employed or providing service to us or Harvard Bioscience.

With respect to individual owners of both options and/or restricted stock units issued by our company and those issued by Harvard Bioscience, the compensation expense for such options and restricted stock units will be recognized by the company receiving the individual's services. However, cash proceeds from the future option exercises will be realized by the company that issued the respective option.

Liquidity

We have generated operating losses each year to date. We do not expect to generate sufficient revenues to achieve annual earnings or positive cash flows until we obtain regulatory approval and commercialize one of our organ bioreactor and synthetic scaffold systems. Until that time, we expect to maintain or increase our ongoing development activities. Also, we expect to incur additional costs associated with operating as a publicly-traded company.

Harvard Bioscience will no longer fund our operations following the Distribution. Based on our current operating plan, we believe the $15 million cash contribution from Harvard Bioscience will be sufficient to fund our operating expenses, working capital needs and capital expenditures for at least the next 18 months following the Distribution. We have based our estimates on assumptions that may prove wrong, and we may use our available capital resources sooner than we expect. Further, our strategy or business plan may change in the future, possibly changing the rate of our spending or need for additional capital. We may need to secure future funding through equity offerings, debt financings, government funding, marketing and distribution arrangements and other collaborations or strategic alliances. Equity offerings would dilute the ownership interests of existing stockholders. Debt financing, if available, could result in agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or paying dividends. If we raise additional funds through government funding, marketing and distribution arrangements or other collaborations or strategic alliances we may have to relinquish rights to our technologies or future revenue streams, or grant licenses on terms that may not be favorable to us. We cannot assure you that we will be successful in raising additional capital on favorable terms or at all. In addition, to preserve the tax-free treatment to Harvard Bioscience of the Distribution, for the two-year period following the Distribution we will be limited in issuing equity securities beyond certain thresholds which may limit our ability to raise additional capital.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Effect of Inflation and Changes in Prices

We do not expect inflation and changes in price to have a material effect on our operations in the next year.

Recent Authoritative Accounting Guidance

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an ‘‘emerging growth company’’ can delay the adoption of certain accounting standards until

those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the U.S., which require that we make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 2 to the financial statements for the year ended December 31, 2012 included in the Company's Form 10 Registration Statement. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

Stock-Based Compensation

We account for stock-based payment awards in accordance with the provisions of FASB ASC 718, *Compensation Stock Compensation*, which requires us to recognize compensation expense for all stock-based payment awards, including stock options and restricted stock units, made to employees and directors. All amounts shown in the financial statements presented in this report related to stock-based compensation pertain to Harvard Bioscience employees and directors who were participants in the Harvard Bioscience stock option plans and/or the Harvard Bioscience Employee Stock Purchase Plan and were directly involved in the regenerative medicine device business and were allocated based upon each participant’s time spent on our business.

We value stock-based payment awards, except restricted stock awards, at grant date using the Black-Scholes option-pricing model. Our determination of fair value of stock-based payment awards has been affected by the Harvard Bioscience common stock price as well as assumptions regarding a number of complex and subjective variables, such as expected stock price volatility and employee forfeitures over the terms of the awards.

Stock-based compensation expense recognized under FASB ASC 718 for the three and nine month periods ended September 30, 2013 was $0.2 million and $0.5 million, respectively. Stock-based compensation expense recognized under FASB ASC 718 for the three and nine month periods ended September 30, 2012 was $0.2 million and $0.3 million, respectively. Stock-based compensation expense related to stock options, the Harvard Bioscience Employee Stock Purchase Plan and restricted stock units. We record stock compensation expense on a straight-line basis over the requisite service period for all awards granted. Also, in November 2013 we issued to certain of our executives, employees and our directors, grants of options for shares of our common stock in order to, among other things, provide executives, employees and directors with a stock-based incentive and align their interests with those of our stockholders. The value of the stock option grants to executives and employees will be expensed over their service periods. Some of these grants are performance-based options which will be earned upon achievement of certain milestones.

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. We do not carry any debt and we invest our excess cash in money market accounts and U.S. Treasury Securities.

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, 2013. 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 1. Legal Proceedings

On December 17, 2012, we received correspondence from legal counsel to Nanofiber Solutions, Inc., or NFS, claiming that in developing our scaffold product and related intellectual property, we may have committed misappropriation, unauthorized use and disclosure of confidential information, and possible infringement of intellectual property rights of NFS. NFS' legal counsel has also threatened us with legal action, including seeking an injunction, if we are unable to respond in a satisfactory manner to NFS' claims. Additionally, we have received correspondence from legal counsel to UCL Business PLC, or UCLB, challenging the validity of the assignment of certain patent applications that have been assigned to us by Professor Paolo Macchiarini. We believe that these claims are without merit, and we will vigorously seek to protect our rights regarding such claims. Until we are able to resolve these respective matters with NFS and UCLB, we believe it is likely that each of NFS and UCLB will continue to pursue the matters against us. Our legal counsel has corresponded with NFS' and UCLB's respective counsel since our receipt of the initial correspondence. While we are still investigating the matters, we do not believe that the matters will have a material adverse effect on our business, financial position or results of operations. In addition we have also received correspondence from an academic researcher implying that one of our products may violate an issued patent. We do not believe that our current products violate this patent.

While we are not currently a party to any legal proceedings, from time to time we may be a party to a variety of legal proceedings that arise in the normal course of our business.

Item 1A. Risk Factors

Our actual results could differ materially from our forward-looking statements. Our business faces a variety of risks. We describe below what we believe are currently the material risks and uncertainties we face, but they are not the only risks and uncertainties we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. In addition, past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods. If any of the following risks and uncertainties develops into actual events, these events could have a material adverse effect on our business, financial condition or results of operations. In such case, the trading price of our common stock could decline. The risk factors generally have been separated

into three groups: (i) risks relating to our business, (ii) risks relating to the Separation and (iii) risks relating to our common stock. These risk factors should be read in conjunction with the other information in this Quarterly Report on Form 10-Q.

Risks Relating to Our Business

Risks Associated with Regulatory Clearances and Approvals

If we fail to obtain, or experience significant delays in obtaining, regulatory clearances or approvals in the U.S. and the EU for our products, or are unable to maintain such clearances or approvals for our products, our ability to commercially distribute and market these products would suffer.

We currently do not have regulatory approval to market any of our products. Our products are subject to rigorous regulation by the FDA, and numerous other federal and state governmental authorities in the U.S., as well as foreign governmental authorities. In the U.S., the FDA permits commercial distribution of new medical products only after approval of a premarket approval application, or PMA, or biologics license application, or BLA, unless the product is specifically exempt from those requirements. A PMA or BLA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use. There are similar approval processes in the EU and other foreign jurisdictions. Our failure to receive or obtain such clearances or approvals on a timely basis or at all would have an adverse effect on our results of operations.

The FDA has informed us that the InBreath™ Airway Transplant System will be viewed by the FDA as a combination product comprised of a biologic (cells) and medical device component. We cannot be sure how the FDA will regulate our products. The FDA may require us to obtain marketing clearance and approval from multiple FDA centers. The review of combination products is often more complex and more time consuming than the review of products under the jurisdiction of only one center within the FDA.

The FDA has informed us that the InBreath™ Airway Transplant System, or InBreath System, will be regulated by the FDA as a combination product. For a combination product, the Office of Combination Products, or OCP, within FDA can determine which center or centers within the FDA will review the product and under what legal authority the product will be reviewed. Generally, the center within the FDA that has the primary role in regulating a combination product is determined based on the primary mode of action of the product. Generally, if the primary mode of action is as a device, then the Center for Devices and Radiological Health, or CDRH, takes the lead. Generally, if the primary mode of action is cellular, then the Center for Biologics Evaluation and Research takes the lead. On August 29th 2013 we received written confirmation from FDA's Office of Combination Products that FDA intends to regulate the InBreath System as a combination product under the primary jurisdiction of the Center for Biologics Evaluation and Research, or CBER. We further understand that CBER may choose to consult or collaborate with CDRH with respect to the characteristics of the synthetic scaffold component of the InBreath System based on CBER's determination of need for such assistance.

Although we have received this written response from the FDA, the process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that our products will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and can be more time consuming than the review of a product under the jurisdiction of only one center within the FDA.

We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only one FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be more lengthy and costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

In the EU, our products may be viewed as advanced therapy medicinal products, which could delay approvals and clearances and increase costs of obtaining such approvals and clearances.

In the EU, we believe that the InBreath System may be regulated as an advanced therapy medicinal product or combined advanced therapy medicinal products. In such circumstances, it would be necessary to seek a marketing authorization for these products granted by the European Commission before being marketed in the EU.

The regulatory procedures leading to marketing approval of our products vary among jurisdictions and can involve substantial additional testing. Compliance with the FDA requirements does not ensure clearance or approval in other jurisdictions, and the ability to legally market our products in any one foreign country does not ensure clearance, or approval by regulatory authorities in other foreign jurisdictions. The foreign regulatory process leading to the marketing of the products may include all of the risks associated with obtaining FDA approval in addition to other risks. In addition, the time required to comply with foreign regulations and market products may differ from that required to obtain FDA approval, and we may not obtain foreign approval or clearance on a timely basis, if at all.

Risks Associated with Clinical Trials

Clinical trials necessary to support a BLA license, a PMA application, a marketing authorization, or a CE mark for our products will be expensive and will require the enrollment of sufficient patients to adequately demonstrate safety and effectiveness for the product's target populations. Suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any products and will adversely affect our business, operating results and prospects.

In the U.S., initiating and completing clinical trials necessary to support either BLA licenses or PMA applications, will be time consuming, expensive and the outcome uncertain. Moreover, the FDA may not agree that clinical trial results support an application for the indications sought in the application for the product. In other jurisdictions such as the EU, the conduct of extensive and expensive clinical trials may also be required in order to demonstrate the quality, safety and efficacy of our products, depending on each specific product, the claims being studied, and the target condition or disease. The outcome of these clinical trials, which can be expensive and are heavily regulated, will also be uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical trials will require the enrollment of a sufficient number of patients to support each trial's claims, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomfort and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products, or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomfort. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA and foreign regulatory authorities may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA and foreign regulatory authorities may not consider our data adequate to demonstrate safety and efficacy. Although FDA regulations allow submission of data from clinical trials outside the U.S., there can be no assurance that such data will be accepted or that the FDA will not apply closer scrutiny to such data. Increased costs and delays necessary to generate appropriate data, or failures in clinical trials could adversely affect our business, operating results and prospects. In the U.S., clinical studies for the company's products may be reviewed either under the Investigational Device Exemptions, or IDE pathway (for medical devices) or through the Investigational New Drug, or IND, pathway for biologics or combination products. The first regenerated trachea transplant approved in the U.S. using the InBreath System was approved under the IND pathway through CBER. Future FDA review under the IDE, IND, or both pathways, depending on the products, proposed study design, and study populations, is possible. In the EU, if the regulatory classification of our products is rejected by the ethics committee or competent authority reviewing our request for a positive opinion, we may be required to prepare a new study protocol reflecting a different classification. This process would be costly and time consuming.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We do not have the ability to independently conduct our preclinical and clinical trials for our products and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to seek or obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all. Our business, operating results and prospects may also be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that the FDA, foreign competent authorities or notified bodies will agree with our conclusions regarding them. Although we have obtained some positive results from the use of our scaffolds and bioreactors for trachea transplants performed to date, we may not see positive results when the bioreactors, or our scaffolds or other technologies undergo clinical testing in humans in the future. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our products are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Also, patients receiving transplants using our products may experience significant adverse events following the transplants, including serious health complications or death, which may or may not be related to our products, and any such adverse events may cause the delay or termination of our clinical trials. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to

commercialize our products and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product's profile. In addition, our current clinical experience and clinical trial for trachea transplant involves a small patient population. Because of the small sample size, the results may not be indicative of future results.

Risk Associated with Product Marketing

Even if our products are cleared or approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval in the U.S. or the EU, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory authorities or notified bodies. In particular, we and our suppliers are required to comply with the FDA's Quality System Regulations, or QSR, and Good Manufacturing Practices, or GMPs, for our medical products, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the system or combination products that the FDA may find are controlled by the biologics regulations. Equivalent regulatory obligations apply in foreign jurisdictions. Regulatory authorities, such as the FDA, the competent authorities of the EU Member States, the European Medicines Agency and notified bodies, enforce the QSR, GMP and other applicable regulations in the U.S. and in foreign jurisdictions through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory authorities or notified bodies in the U.S. or in foreign jurisdictions, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

· untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

· unanticipated expenditures to address or defend such actions;

· customer notifications for repair, replacement, refunds;

· recall, detention or seizure of our products;

· operating restrictions or partial suspension or total shutdown of production;

· withdrawing BLA approvals or PMAs that have already been granted;

· withdrawal of the marketing authorization granted by the European Commission or delay in obtaining such marketing authorization;

- withdrawal of the CE Certificates of Conformity granted by the notified body or delay in obtaining these certificates;

- refusal to grant export approval for our products; and

- criminal prosecution.

Postmarket enforcement actions can generate adverse commercial consequences.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA or a foreign regulatory authority determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical products reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Extensive governmental regulations that affect our business are subject to change, and we could be subject to penalties and could be precluded from marketing our products and technologies if we fail to comply with new regulations and requirements.

As a manufacturer and marketer of medical products, we are subject to extensive regulation that is subject to change. In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA, which may have far-reaching consequences for most healthcare companies, including medical device companies. The PPACA could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, laboratory tests, drugs and devices. These structural changes, as well as those relating to proposals that may be made in the future to change the health care system, could entail modifications to the existing system of private payers and government programs, as well as implementation of measures to limit or eliminate payments for some medical procedures and treatments or subject the pricing of medical products to government control. Government and other third-party payers increasingly attempt to contain health care costs by limiting both coverage and the level of payments of newly approved health care products. In some cases, they may also refuse to provide any coverage of uses of approved products for disease indications other than those for which the regulatory authorities have granted marketing approval. Governments may adopt future legislative proposals and federal, state, foreign or private payers for healthcare goods and services may take action to limit their payments for goods and services.

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In the EU, on September 26, 2012, the European Commission proposed a revision of the legislation currently governing medical devices. If adopted by the European Parliament and the Council in their present form, these proposals, which may apply from 2015 or 2016, will impose stricter requirements on medical device manufacturers. Moreover, the supervising competences of the competent authorities of the EU Member States and the notified bodies will be strengthened. The regulation of advanced therapy medicinal products is also in continued development in the EU, with the European Medicines Agency publishing new clinical or safety guidelines concerning advanced therapy medicinal products on a regular basis.

Any of these regulatory changes and events could limit our ability to form collaborations and our ability to commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

If we fail to complete the required IRS forms for exemptions, make timely semi-monthly payments of collected excise taxes, or submit quarterly reports as required by the Medical Device Excise Tax, we may be subject to penalties, such as Section 6656 penalties for any failure to make timely deposits.

Section 4191 of the Internal Revenue Code, enacted by Section 1405 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)), in conjunction with the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), imposed as of January 1, 2013, an excise tax on the sale of certain medical devices. The excise tax imposed by Section 4191 is 2.3% of the price for which a taxable medical device is sold within the U.S.

The excise tax will apply to future sales of any company medical device listed with the FDA under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. We will need to assess to what extent this excise tax may impact the sales price and distribution agreements under which any of our products are sold in the U.S. We also expect general and administrative expense to increase due to the medical device excise tax. We will need to submit IRS forms applicable to relevant exemptions, make semi-monthly payments of any collected excise taxes, and make timely (quarterly) reports to the IRS regarding the excise tax. To the extent we do not comply with the requirements of the Medical Device Excise Tax we may be subject to penalties.

Financial and Operating Risks

We have not generated any revenue to date and have a history of losses since inception. We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability.

We have not generated any revenue to date and, from February 2009 through September 30, 2013, have incurred losses of approximately $18.6 million. We expect to continue to experience losses in the foreseeable future due to our limited anticipated revenues and significant anticipated expenses. We do not anticipate that we will achieve meaningful revenues for the foreseeable future. In addition, we expect that we will continue to incur significant operating expenses as we continue to focus on additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals or clearances of our products and technologies. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

Our products are in an early stage of development. If we are unable to develop or market any of our products, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

We are in the early stage of product development. You must evaluate us in light of the uncertainties and complexities affecting an early stage medical company. Our products require additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals or clearances before marketing. In addition, we may not succeed in developing new products as an alternative to our existing portfolio of products. If we fail to successfully develop and commercialize our products, including our InBreath bioreactor and scaffold system, our financial condition may be negatively affected, and we may have to curtail or cease our operations.

We have a limited operating history and it is difficult to predict our future growth and operating results.

We have a limited operating history and limited operations and assets. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties encountered by companies in the early stage of development. As a development stage company, our development timelines have been and may continue to be subject to delay that could negatively affect our cash flow and our ability to develop or bring products to market, if at all. Our estimates of patient population are based on published data but are subject to uncertainty and possible future revision as they often require inference or extrapolations from one country to another or one patient condition to another.

Our prospects must be considered in light of inherent risks, expenses and difficulties encountered by all early stage companies, particularly companies in new and evolving markets, such as regenerative medicine. These risks include, but are not limited to, unforeseen capital requirements, delays in obtaining regulatory approvals, failure to gain market acceptance and competition from foreseen and unforeseen sources.

Our operations could be adversely affected if we are unable to raise or obtain needed funding.

Substantial time, financial and other resources will be required to complete ongoing development and clinical testing of our products. Regulatory efforts and collaborative arrangements will also be necessary for our products that are currently under development and testing in order for them to be marketed. Our revenues from operations and cash may not be sufficient over the next several years for commercialization of all of the technologies and products we are currently developing. Consequently, we may seek strategic partners for various phases of development, marketing and commercialization of products employing our technologies. Further, we cannot assure you as to the sufficiency of our resources or the time required to complete any ongoing development and clinical testing, since the extent to which we conduct such testing is dependent on resource allocation decisions that we make from time to time based on numerous financial as well as operational conditions.

In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities and capital equipment and the growth, if any, of our business in general. We may seek to raise necessary funds through public or private equity offerings, debt financings, other financing mechanisms, strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets. In May 2013, we elected not to proceed with a planned initial public offering of our common stock.

Additional equity financing could result in significant dilution to our stockholders. Debt financing, if available, could result in agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or paying dividends. Other financing mechanisms may involve selling intellectual property rights, payment of royalties or participation in our revenue or cash flow. In addition, in order to raise additional funds through strategic collaborations or licensing arrangements, we may be required to relinquish rights to our technologies or products. If we cannot raise funds or engage strategic partners on acceptable terms when needed, we may not be able to continue our research and development activities, develop or enhance our products, take advantage of future opportunities, grow our business or respond to competitive pressures or unanticipated requirements.

If we fail to retain key personnel, we may not be able to compete effectively, which would have an adverse effect on our operations.

Our success is highly dependent on the continued services of key management, technical and scientific personnel and collaborators. Our management and other employees may voluntarily terminate their employment at any time upon short notice. The loss of the services of any member of our senior management team, including our Chief Executive Officer and President, David Green, our Chief Financial Officer, Thomas McNaughton, and our other key scientific, technical and management personnel, as well as the ability to hire and retain the services of a Chief Medical Officer, may significantly delay or prevent the achievement of product development and other business objectives.

If our collaborators do not devote sufficient time and resources to successfully carry out their duties or meet expected deadlines, we may not be able to advance our products in a timely manner or at all.

We are currently collaborating with multiple academic researchers and clinicians at a variety of research and clinical institutions. Our success depends in part on the performance of our collaborators. Some collaborators may not be successful in their research and clinical trials or may not perform their obligations in a timely fashion or in a manner satisfactory to us. Typically, we cannot control the amount of resources or time our collaborators may devote to our programs or potential products that may be developed in collaboration with us. Our collaborators frequently depend on outside sources of funding to conduct or complete research and development, such as grants or other awards. In addition, our academic collaborators may depend on graduate students, medical students, or research assistants to conduct certain work, and such individuals may not be fully trained or experienced in certain areas, or they may elect to discontinue their participation in a particular research program, creating an inability to complete ongoing research in a timely and efficient manner. As a result of these uncertainties, we are unable to control the precise timing and execution of any experiments that may be conducted.

We do not have formal agreements in place with most of our collaborators, who retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If these collaborators elect to prioritize or pursue other programs in lieu of ours, we may not be able to advance product development programs in an efficient or effective manner, if at all. If a collaborator is pursuing a competitive program and encounters unexpected financial or capability limitations, they may be motivated to reduce the priority placed on our programs or delay certain activities related to our programs. Any of these developments could harm or slow our product and technology development efforts. In particular, we depend upon Dr. Paolo Macchiarini, the surgeon who has led all of the clinical surgeries to date using our technology. Dr. Macchiarini's team developed the initial version of our InBreath airway bioreactor, which we have licensed from the inventors. We continue to collaborate with Dr. Macchiarini on grant proposals and product development. If Dr. Macchiarini were not available to continue to collaborate with us or perform surgeries it would materially slow development of our products. On September 27, 2012, Dr. Macchiarini was arrested in Italy for attempted fraud and extortion for allegedly attempting to persuade severely ill patients to choose private hospitals in other countries over less expensive Italian public hospitals. He was temporarily placed under house arrest and on October 15, 2012 was released from house arrest and is free to travel internationally and to perform surgeries. The case is ongoing. Dr. Macchiarini believes these charges are without merit and has, and intends to continue to, vigorously defend these charges. These allegations do not relate to any surgeries involving our products and have not prevented Dr. Macchiarini from performing further surgeries with our products including the April 2013 surgery in the U.S. and the other 2013 surgeries in Sweden and Russia. If Dr. Macchiarini decides to terminate his collaboration with us, if the case described above consumes a significant amount of his time, or if the case prevents him from performing surgeries, our product development efforts could be adversely affected and it could cause harm to our reputation or business.

Public perception of ethical and social issues surrounding the use of cell technology may limit or discourage the use of our technologies, which may reduce the demand for our products and technologies and reduce our revenues.

Our success will depend in part upon our collaborators' ability to develop therapeutic approaches incorporating, or discovered through, the use of cells. If regenerative medicine technology is perceived negatively by the public for social, ethical, medical or other reasons, governmental authorities in the U.S. and other countries may call for prohibition of, or limits on, cell-based technologies and other approaches to regeneration. Although the surgeons using our products have not to date used the more controversial stem cells derived from human embryos or fetuses in the human transplant surgeries using our products, claims that human-derived stem cell technologies are ineffective or unethical may influence public attitudes. The subject of cell and stem cell technologies in general has received negative publicity and aroused public debate in the U.S. and some other countries. Ethical and other concerns about such cells could materially harm the market acceptance of our products.

Our products will subject us to liability exposure.

We face an inherent risk of product liability claims, especially with respect to our products that will be used within the human body, including the scaffolds we manufacture. Product liability coverage is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. We may be subject to claims for liabilities for unsuccessful outcomes of surgeries involving our products, which may include claims relating to patient death. We may also be subject to claims for liabilities relating to patients that suffer serious complications or death during or following transplants involving our products. Our current product liability coverage is $15 million per occurrence and in the aggregate. We will need to increase our insurance coverage if and when we begin commercializing any of our products. There can be no assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. If claims against us substantially exceed our coverage, then our business could be adversely impacted. Regardless of whether we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among others:

- significant awards against us;
- substantial litigation costs;
- injury to our reputation and the reputation of our products;
- withdrawal of clinical trial participants; and
- adverse regulatory action.

Any of these results would substantially harm our business.

If restrictions on reimbursements or other conditions imposed by payers limit our customers' actual or potential financial returns on our products, our customers may not purchase our products or may reduce their purchases.

Our customers' willingness to use our products will depend in part on the extent to which coverage for these products is available from government payers, private health insurers and other third-party payers. These payers are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved treatments and products in the regenerative medicine field, and coverage and adequate payments may not be available for these treatments and products. In addition, third-party payers may require

additional clinical trial data to establish or continue reimbursement coverage. These clinical trials, if required, could take years to complete and could be expensive. There can be no assurance that the payers will agree to continue reimbursement or provide additional coverage based upon these clinical trials. Failure to obtain adequate reimbursement would result in reduced sales of our products.

We depend upon a single-source supplier for the hardware and software used for our organ bioreactor control and acquisition system. The loss of this supplier, or future single-source suppliers we may rely on, or their failure to provide us with an adequate supply of their products or services on a timely basis, could adversely affect our business.

We currently have a single supplier for the hardware and software that we use for our organ bioreactor control and acquisition systems. We may also rely on other single-source suppliers for critical components of our products in the future. If we were unable to acquire hardware or software or other products or services from applicable single-source suppliers, we could experience a delay in developing and manufacturing our products.

We use and generate hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research, development and manufacturing involves the controlled use of hazardous chemicals, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. For example, certain volatile organic laboratory chemicals we use, such as fluorinated hydrocarbons, must be disposed of as hazardous waste. We are subject to laws and regulations enforced by the FDA, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our products, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Our products are novel and will require market acceptance.

Even if we receive regulatory approvals for the commercial use of our products, their commercial success will depend upon acceptance by physicians, patients, third party payers such as health insurance companies and other members of the medical community. Market acceptance of our products is also dependent upon our ability to provide acceptable evidence and the perception of the positive characteristics of our products relative to existing or future treatment methods, including their safety, efficacy and/or other positive advantages. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. If our products do not become widely accepted, our business, financial condition and results of operations would be materially and adversely affected.

Our long-term growth depends on our ability to develop products for other organs.

Our growth strategy includes expanding the use of our products in treatments pertaining to organs other than the trachea, such as lungs, esophagus, gastrointestinal tract, heart valves and heart. These other organs are more complex than the trachea. There is no assurance that we will be able to successfully apply our technologies to these other more complex organs, which will limit our expected growth.

Our success will depend partly on our ability to operate without infringing on, or misappropriating, the intellectual property or confidentiality rights of others.

We may be sued for infringing on the intellectual property or confidentiality rights of others, including the patent rights, trademarks and trade names and confidential information of third parties. For example, we have sublicensed certain rights pertaining to our use of the mark Harvard Apparatus from Harvard Bioscience, including the use in our corporate name. Harvard Bioscience has licensed the rights to such mark from Harvard University. If the license to Harvard Bioscience or our sublicense were terminated, it could have an adverse effect on us. We have also received correspondence from legal counsel to Nanofiber Solutions, Inc., or NFS, claiming that in developing our scaffold product and related intellectual property, we may have committed misappropriation, unauthorized use and disclosure of confidential information, and possible infringement of intellectual property rights of NFS. We have received correspondence from legal counsel to UCL Business PLC, or UCLB, challenging the validity of the assignment of certain patent applications that have been assigned to us by Dr. Macchiarini. We have also received correspondence from an academic researcher implying that one of our products may violate an issued patent. We do not believe that our current products violate this patent. To the extent that any of such claims are valid, if we had utilized, or were to utilize, such patent applications or patents without an agreement from the owner thereof, it could result in infringement of the intellectual property rights of the respective owner. Intellectual property and related litigation is costly and the outcome is uncertain. If we do not prevail in any such intellectual property or related litigation, in addition to any damages we might have to pay, we could be required to stop the infringing activity, or obtain a license to or design around the intellectual property or confidential information in question. If we are unable to obtain a required license on acceptable terms, or are unable to design around any third party patent, we may be unable to sell some of our products and services, which could result in reduced revenue.

We may be involved in lawsuits to protect or enforce our patents that would be expensive and time consuming.

In order to protect or enforce our patent rights, we may initiate patent litigation against third parties. We may also become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine the priority of inventions. The defense and prosecution, if necessary, of intellectual property suits, interference proceedings and related legal and administrative proceedings would be costly and divert our technical and management personnel from their normal responsibilities. We may not prevail in any of these suits should they occur. An adverse determination of any litigation or defense proceedings could put our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of being rejected and patents not being issued.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline.

If we are unable to effectively protect our intellectual property, third parties may use our technology, which would impair our ability to compete in our markets.

Our continued success will depend significantly on our ability to obtain and maintain meaningful patent protection for certain of our products throughout the world. Patent law relating to the scope of claims in the regenerative medicine and medical device fields in which we operate is still evolving. The degree of future protection for our proprietary rights is uncertain. We may rely on patents to protect a significant part of our intellectual property and to enhance our competitive position. However, our presently pending or future patent applications may not be accepted and patents might not be issued, and any patent previously issued to us may be challenged, invalidated, held unenforceable or circumvented. Furthermore, the claims in patents which have been issued or which may be issued to us in the future

may not be sufficiently broad to prevent third parties from producing competing products similar to our products. We may also operate in countries where we do not have patent rights and in those countries we would not have patent protection. We also rely on trademarks and trade names in our business. The laws of various foreign countries in which we compete may not protect our intellectual property to the same extent as do the laws of the U.S. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive could be materially impaired. It is also possible that our intellectual property may be stolen via cyber attacks or similar methods.

In addition to patent protection, we also rely on protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade-secrets and proprietary information, we generally seek to enter into confidentiality agreements with our employees, consultants and strategic partners upon the commencement of a relationship. However, we may not be able to obtain these agreements in all circumstances in part due to local regulations. In the event of unauthorized use or disclosure of this information, these agreements, even if obtained, may not provide meaningful protection for our trade-secrets or other confidential information. In addition, adequate remedies may not exist in the event of unauthorized use or disclosure of this information. The loss or exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects.

Our competitors and potential competitors may have greater resources than we have and may develop products and technologies that are more effective or commercially attractive than our products and technologies or may develop competing relationships with our key collaborators.

We expect to compete with multiple pharmaceutical, biotechnology, medical device and scientific research product companies. Companies working in competing areas include, among others, Aastrom Biosciences, Aldagen, BioTime, Baxter International, Inc., Bose Corporation, Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, Genzyme (acquired by Sanofi-aventis), Harvest Technologies, Mesoblast, Nanofiber Solutions, Organovo, Osiris Therapeutics, Smiths Medical, Tengion, Tissue Genesis, Inc., Tissue Growth Technologies, Transmedics, United Therapeutics and W.L. Gore and Associates. Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot, with any accuracy, forecast when or if these companies are likely to bring regenerative medicine medical products to market for indications that we are also pursuing. Many of these potential competitors may be further along in the process of product development and also operate large, company-funded research and development programs.

We expect that other products will compete with our current and future products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include obtaining marketing exclusivity under certain regulations, including the Orphan Drug Act, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage. Our competitors may develop or market products that are more effective or commercially attractive than our current or future products and may also develop competing relationships with our key collaborators. In addition, we may face competition from new entrants into the field. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. The effects of any such actions of our competitors may have a material adverse effect on our business, operating results and financial condition.

If we do not successfully manage our growth, our business goals may not be achieved.

To manage growth, we will be required to continue to improve existing, and implement additional, operational and financial systems, procedures and controls, and hire, train and manage additional employees. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth and we may not be able to hire, train, retain, motivate and manage required personnel. Competition for qualified personnel in the biotechnology and regenerative medicine area is intense, and we operate in several geographic locations where labor markets are particularly competitive, including Boston, Massachusetts, where demand for personnel with these skills is extremely high and is likely to remain high. As a result, competition for qualified personnel is intense and the process of hiring suitably qualified personnel is often lengthy and expensive, and may become more expensive in the future. If we are unable to hire and retain a sufficient number of qualified employees or otherwise manage our growth effectively, our ability to conduct and expand our business could be seriously reduced.

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We are exposed to a variety of risks relating to our international sales and operations, including fluctuations in exchange rates, local economic conditions and delays in collection of accounts receivable.

We intend to generate significant revenues outside the U.S. in multiple foreign currencies including Euros, British pounds, and in U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. For those foreign customers who purchase our products in U.S. dollars, currency fluctuations between the U.S. dollar and the currencies in which those customers do business may have a negative impact on the demand for our products in foreign countries where the U.S. dollar has increased in value compared to the local currency.

Since we have operations based outside the U.S. and we generate revenues and incur operating expenses in multiple foreign currencies, we experience currency exchange risk with respect to those foreign currency-denominated revenues and expenses.

We cannot predict the consolidated effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries, the U.S. Foreign Corrupt Practices Act and local anti-bribery and other laws regarding interactions with healthcare professionals. Among other things, these laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices in foreign countries.

Local economic conditions, legal, regulatory or political considerations, disruptions from strikes, the effectiveness of our sales representatives and distributors, local competition and changes in local medical practice could also affect our sales to foreign markets. Relationships with customers and effective terms of sale frequently vary by country, often with longer-term receivables than are typical in the U.S.

Risks Related To Separation

We may be unable to achieve some or all of the benefits that we expect to achieve from our separation from Harvard Bioscience.

As a stand-alone, independent public company, we believe that our business will benefit from, among other things, allowing our management to design and implement corporate policies and strategies that are based primarily on the characteristics of our business, allowing us to focus our financial resources wholly on our own operations and implement and maintain a capital structure designed to meet our own specific needs. By separating from Harvard Bioscience there is a risk that our company may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Harvard Bioscience. We may not be able to achieve some or all of the benefits that we expect to achieve as a stand-alone, independent regenerative medicine company or such benefits may be delayed or may not occur at all. For example, there can be no assurance that analysts and investors will place a greater value on our company as a stand-alone regenerative medicine company than on our business as a part of Harvard Bioscience.

We have no operating history as an independent company, and we may be unable to make the changes necessary to operate as an independent public company.

Prior to our separation from Harvard Bioscience, or the Separation, our business was operated by Harvard Bioscience as part of its broader corporate organization rather than as a stand-alone company. Harvard Bioscience assisted us by providing financing and certain corporate functions. Following the Separation, Harvard Bioscience will have no

obligation to provide assistance to us other than the interim transitional services which will be provided by Harvard Bioscience. These transitional services include, among other things, accounting, benefits administration, payroll and information technology services. Because our business has not been operated as an independent company, we cannot assure you that we will be able to successfully implement the changes necessary to operate independently or that we will not incur additional costs operating independently that would have a negative effect on our business, results of operations or financial condition.

If the Separation and related distribution of all of the shares of our common stock by Harvard Bioscience, together with certain related transactions, does not qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, Harvard Bioscience could be subject to significant tax liability and, in certain circumstances, we could be required to indemnify Harvard Bioscience for material taxes pursuant to indemnification obligations under the tax sharing agreement.

Harvard Bioscience has informed us that on June 28, 2013 it received a Supplemental Ruling to the Private Letter Ruling dated March 22, 2013 from the IRS to the effect that, among other things, the Separation and related distribution of all of the shares of our common stock by Harvard Bioscience, or the Distribution, will qualify as a transaction that is tax-free for U.S. federal income tax purposes under Section 355 and 368(a)(1)(D) of the Internal Revenue Code continuing in effect. The private letter and supplemental rulings and the tax opinion that Harvard Bioscience expects to receive from Burns & Levinson LLP, special counsel to Harvard Bioscience, rely and will rely on certain representations, assumptions and undertakings, including those relating to the past and future conduct of our business, and neither the private letter and supplemental rulings nor the opinion would be valid if such representations, assumptions and undertakings were incorrect. Moreover, the private letter and supplemental rulings do not address all the issues that are relevant to determining whether the Distribution will qualify for tax-free treatment. Notwithstanding the private letter and supplemental rulings and opinion, the IRS could determine the Distribution should be treated as a taxable transaction for U.S. federal income tax purposes if, among other reasons, it determines any of the representations, assumptions or undertakings that were included in the request for the private letter and supplemental rulings are false or have been violated or if it disagrees with the conclusions in the opinion that are not covered by the IRS ruling.

If the Distribution fails to qualify for tax-free treatment, in general, Harvard Bioscience would be subject to tax as if it had sold our common stock in a taxable sale for its fair market value, and Harvard Bioscience stockholders who receive shares of our common stock in the Distribution would be subject to tax as if they had received a taxable Distribution equal to the fair market value of such shares.

Under the tax sharing agreement between Harvard Bioscience and us, we would generally be required to indemnify Harvard Bioscience against any tax resulting from the Distribution to the extent that such tax resulted from (i) an acquisition of all or a portion of our stock or assets, whether by merger or otherwise, (ii) other actions or failures to act by us, or (iii) any of our representations or undertakings being incorrect or violated. Our indemnification obligations to Harvard Bioscience and its subsidiaries, officers and directors are not limited by any maximum amount. If we are required to indemnify Harvard Bioscience or such other persons under the circumstances set forth in the tax sharing agreement, we may be subject to substantial liabilities.

We may not be able to engage in desirable strategic or capital-raising transactions following the Distribution. In addition, under some circumstances, we could be liable for adverse tax consequences resulting from engaging in significant strategic or capital-raising transactions.

To preserve the tax-free treatment to Harvard Bioscience of the Separation and Distribution, for the two-year period following the Distribution we may be limited, except in specified circumstances, from:

· entering into certain transactions pursuant to which all or a portion of our stock would be acquired, whether by merger or otherwise;

· issuing equity securities beyond certain thresholds;

· repurchasing our common stock;

· ceasing to actively conduct our regenerative medicine business; and

· taking or failing to take any other action that prevents the Separation and Distribution and related transactions from being tax-free.

These restrictions may limit our ability to pursue strategic transactions or engage in new business or other transactions that may maximize the value of our business.

We may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent company, and we may experience increased costs after the Separation or as a result of the Separation.

Since the completion of the Distribution, Harvard Bioscience has and will be contractually obligated to provide to us only those services specified in the transition services agreement and the other agreements we entered into with Harvard Bioscience in connection with the Separation and Distribution. The transition services agreement provides for services to be provided for various time frames of limited length, ranging from six months from the date of the Distribution to 12 months thereafter. We may be unable to replace in a timely manner or on comparable terms the services or other benefits that Harvard Bioscience previously provided to us that are not specified in the transition services agreement or the other agreements. Also, upon the expiration of the terms of the required services under the transition services agreement or other agreements, such services will be provided internally or by unaffiliated third parties, and we expect that in some instances, we will incur higher costs to obtain such services than we incurred under the terms of such agreements. We anticipate that we will incur additional incremental expenses associated with being an independent, public company. These additional pretax expenses are estimated to be approximately $1.3 million for the first twelve months following the Separation. In addition, if Harvard Bioscience does not continue to perform effectively the transition services and the other services that are called for under the transition services agreement and other agreements, we may not be able to operate our business effectively and our operating results could be adversely affected. Furthermore, after the expiration of the terms of the required services under transition services agreement and the other agreements, we may be unable to replace in a timely manner or on comparable terms the services specified in such agreements. Prior to our Separation, we utilized the executive management team and administrative resources of Harvard Bioscience. Many daily functions have been performed by Harvard Bioscience, including those related to SEC filings and auditing and review by accountants of required financial statements, which have become our responsibility since the Distribution. In addition, there has been and will continue to be a time period during which new personnel will have to learn these functions. The lack of these relationships and resources may harm our operating results, financial condition and our ability to raise any required debt or equity funding.

Our historical financial information is not necessarily representative of the results we would have achieved as a separate publicly traded company and may not be a reliable indicator of our future results.

The historical financial information we have included in this report may not reflect what our results of operations, financial position and cash flows would have been had we been an independent publicly traded company during the periods presented or what our results of operations, financial position and cash flows will be in the future when we are an independent company. This is primarily because:

· our historical and financial information reflects allocations for services historically provided to us by Harvard Bioscience, which allocations may not reflect the costs we will incur for similar services in the future as an independent company; and

· our historical and financial information does not reflect changes that we expect to incur in the future as a result of the Separation, including changes in the cost structure, personnel needs, financing and operations of the contributed business as a result of the Separation and from reduced economies of scale.

Since the Separation and Distribution, we are also responsible for the additional costs associated with being an independent public company, including costs related to corporate governance and listed and registered securities. Therefore, our financial statements may not be indicative of our future performance as an independent company. For additional information about our past financial performance and the basis of presentation of our financial statements, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes thereto included elsewhere in this report.

We may have received better terms from unaffiliated third parties than the terms we received in our agreements with Harvard Bioscience.

The agreements related to the Separation, including the separation and distribution agreement, tax sharing agreement, transition services agreement and the other agreements, were negotiated in the context of the Separation while we were still part of Harvard Bioscience and, accordingly, may not reflect terms that would have resulted from arm's-length negotiations among unaffiliated third parties. The terms of the agreements we negotiated in the context of the Separation related to, among other things, allocation of assets, liabilities, rights, indemnifications and other obligations among Harvard Bioscience and us. We may have received better terms from third parties because third parties may have competed with each other to win our business. Some of the members of our Board of Directors are also members of the Harvard Bioscience Board of Directors.

The ownership by our executive officers and some of our directors of shares of common stock, options, or other equity awards of Harvard Bioscience, as well as the continued roles of our executive officers and certain directors with Harvard Bioscience may create, or may create the appearance of, conflicts of interest.

The ownership by our executive officers and some of our directors of shares of common stock, options, or other equity awards of Harvard Bioscience may create, or may create the appearance of, conflicts of interest. Because of their current or former positions with Harvard Bioscience, certain of our executive officers, and some of our directors, own shares of Harvard Bioscience common stock, options to purchase shares of Harvard Bioscience common stock or other equity awards. The individual holdings of common stock, options to purchase common stock of Harvard Bioscience or our company or other equity awards, may be significant for some of these persons compared to such persons' total assets. Ownership by our directors and officers, after the Separation, of common stock or options to purchase common stock of Harvard Bioscience, or any other equity awards, creates, or, may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Harvard Bioscience than the decisions have for us. In addition, certain of our directors are expected to remain on the Board of Directors of Harvard Bioscience following the Distribution. The continued service at both companies creates, or, may create the appearance of, conflicts of interest when these directors are faced with decisions that could have different implications for Harvard Bioscience than the decisions have for us.

Third parties may seek to hold us responsible for liabilities of Harvard Bioscience that we did not assume in our agreements.

In connection with the Separation, Harvard Bioscience has generally agreed to retain all liabilities that did not historically arise from our business. Third parties may seek to hold us responsible for Harvard Bioscience's retained liabilities. Under our agreements with Harvard Bioscience, Harvard Bioscience has agreed to indemnify us for claims and losses relating to these retained liabilities. However, if those liabilities are significant and we are ultimately liable for them, we cannot assure you that we will be able to recover the full amount of our losses from Harvard Bioscience.

Any disputes that arise between us and Harvard Bioscience with respect to our past and ongoing relationships could harm our business operations.

Disputes may arise between Harvard Bioscience and us in a number of areas relating to our past and ongoing relationships, including:

· intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with non-compete provisions applicable to Harvard Bioscience and us;

· labor, tax, employee benefit, indemnification and other matters arising from the Separation;

· distribution and supply obligations;

· employee retention and recruiting;

· business combinations involving us;

· sales or distributions by Harvard Bioscience of all or any portion of its ownership interest in us;

· the nature, quality and pricing of transitional services Harvard Bioscience has agreed to provide us; and

· business opportunities that may be attractive to both Harvard Bioscience and us.

We may not be able to resolve any potential conflicts, and even if we do, the resolution may be less favorable than if we were dealing with an unaffiliated party.

Risks Relating To Our Common Stock

A trading market that will provide you with adequate liquidity may not develop for our common stock.

The current public market for our common stock has limited trading and liquidity. We cannot predict the extent to which investor interest in our company will lead to the development of a more active trading market in our common stock, or how liquid that market might be.

Our revenues, operating results and cash flows may fluctuate in future periods and we may fail to meet investor expectations, which may cause the price of our common stock to decline.

Variations in our quarterly and year-end operating results are difficult to predict and may fluctuate significantly from period to period. If our sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. In addition to the other factors discussed under these "Risk Factors," specific factors that may cause fluctuations in our operating results include:

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- demand and pricing for our products;
- government or private healthcare reimbursement policies;
- physician and patient acceptance of any of our current or future products;
- manufacturing stoppages or delays;
- introduction of competing products or technologies;
- our operating expenses which fluctuate due to growth of our business; and
- timing and size of any new product or technology acquisitions we may complete.

The market price of our shares may fluctuate widely.

The market price of our common stock may fluctuate widely, depending upon many factors, some of which may be beyond our control, including:

- the success or failure of surgeries and procedures involving the use our products;
- the success and costs of preclinical and clinical testing and obtaining regulatory approvals or clearances for our products;
- a shift in our investor base;
- our quarterly or annual results of operations, or those of other companies in our industry;
- actual or anticipated fluctuations in our operating results due to factors related to our business;
- changes in accounting standards, policies, guidance, interpretations or principles;
- announcements by us or our competitors of significant acquisitions, dispositions or intellectual property developments or issuances;
- the failure to maintain our NASDAQ listing or failure of securities analysts to cover our common stock after the Distribution;
- changes in earnings estimates by securities analysts or our ability to meet those estimates;
- the operating and stock price performance of other comparable companies; our issuance of equity, debt or other financing instruments after the Distribution.

- overall market fluctuations; and

- general economic conditions.

Stock markets in general have experienced volatility that has often been unrelated to the operating performance of a particular company. These broad market fluctuations may adversely affect the trading price of our common stock.

Substantial sales of common stock may continue to occur following the Distribution by Harvard Bioscience, which could cause our stock price to further decline.

Some Harvard Bioscience stockholders, including possibly some of its large stockholders, have likely sold, and may continue to sell, our common stock received in the Distribution for reasons such as that our business profile or market capitalization as an independent company does not fit their investment objectives. The sales of significant amounts of our common stock, or the perception in the market that this will occur, may result in a decline in the price of our common stock.

Your percentage ownership will be diluted in the future.

Your percentage ownership will be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees and the accelerated vesting of other equity awards. Prior to the Distribution, our Board of Directors and Harvard Bioscience approved our 2013 Equity Incentive Plan, which provides for the grant of equity-based awards, including restricted stock, restricted stock units, stock options, stock appreciation rights and other equity-based awards to our directors, officers and other employees, advisors and consultants. In addition, your percentage ownership will be diluted by our issuance of common stock following the exercise of options, or vesting of restricted stock units, we expect to issue pertaining to the adjustment and conversion of outstanding Harvard Bioscience equity awards upon the effectiveness of the Separation.

Our costs will increase significantly as a result of operating as a public company, and our management will be required to devote substantial time to complying with public company regulations.

We have historically operated our business as a division of a public company. As a public company with separate SEC reporting, regulatory, and stock exchange listing requirements, we will incur additional legal, accounting, compliance, and other expenses that we have not incurred historically. We are obligated to file with the SEC annual and quarterly information and other reports that are specified in Section 13 and other sections of the Securities Exchange Act of 1934, as amended, and therefore need to have the ability to prepare financial statements that are compliant with all SEC reporting requirements on a timely basis. In addition, we are subject to other reporting and corporate governance requirements, including certain requirements of the NASDAQ Stock Market and certain provisions of the Sarbanes-Oxley Act and its associated regulations, which impose significant compliance obligations upon us.

Sarbanes-Oxley and the Dodd-Frank Wall Street Reform and the Consumer Protection Act of 2010, as well as new rules subsequently implemented by the SEC and the NASDAQ Stock Market, have increased regulation of, and imposed enhanced disclosure and corporate governance requirements on, public companies. Our efforts to comply with evolving laws, regulations, and standards in this regard are likely to result in increased marketing, selling, and administrative expenses, as well as a diversion of management’s time and attention from revenue-generating activities to compliance activities. These changes will require a significant commitment of additional resources. We may not be successful in implementing these requirements, and implementing them could materially adversely affect our business, results of operations, and financial condition. We also expect these recent regulations to increase our legal and financial compliance costs, make it more difficult to attract and retain qualified officers and members of our Board of Directors, particularly to serve on our audit committee, and make some activities more difficult, time-consuming, and costly. In addition, if we fail to implement the required controls with respect to our internal

accounting and audit functions, our ability to report our results of operations on a timely and accurate basis could be impaired. If we do not implement such required controls in a timely manner or with adequate compliance, we might be subject to sanctions or investigation by regulatory authorities, such as the SEC or the NASDAQ Stock Market. Any such action could harm our reputation and the confidence of investors and clients in our company and could negatively affect our business and cause the price of our common stock to decline.

Provisions of Delaware law, of our amended and restated charter and amended and restated bylaws and our Shareholder Rights Plan may make a takeover more difficult, which could cause our stock price to decline.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and in the Delaware corporate law may make it difficult and expensive for a third party to pursue a tender offer, change in control or takeover attempt, which is opposed by management and the Board of Directors. Public stockholders who might desire to participate in such a transaction may not have an opportunity to do so. Our Board of Directors has adopted a Shareholder Rights Plan that could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our common stock. A third party that acquires 20% or more of our common stock could suffer substantial dilution of its ownership interest under the terms of the Shareholder Rights Plan through the issuance of common stock to all stockholders other than the acquiring person. We also have a staggered Board of Directors that makes it difficult for stockholders to change the composition of the Board of Directors in any one year. Any removal of directors will require a super-majority vote of the holders of at least 75% of the outstanding shares entitled to be cast on the election of directors which may discourage a third party from making a tender offer or otherwise attempting to obtain control of us. These anti-takeover provisions could substantially impede the ability of public stockholders to change our management and Board of Directors. Such provisions may also limit the price that investors might be willing to pay for shares of our common stock in the future.

Any issuance of preferred stock in the future may dilute the rights of our common stockholders.

Our Board of Directors has the authority to issue up to 2,000,000 shares of preferred stock and to determine the price, privileges and other terms of these shares. Our Board of Directors may exercise this authority without any further approval of stockholders. The rights of the holders of common stock may be adversely affected by the rights of future holders of preferred stock.

We do not intend to pay cash dividends on our common stock.

Currently, we do not anticipate paying any cash dividends to holders of our common stock. As a result, capital appreciation, if any, of our common stock will be a stockholder’s sole source of gain.

The recently enacted JOBS Act will allow us to postpone the date by which we must comply with certain laws and regulations and to reduce the amount of information provided in reports filed with the SEC. We cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are and we will remain an “emerging growth company” until the earliest to occur of (i) the last day of the fiscal year during which our total annual revenues equal or exceed $1 billion (subject to adjustment for inflation), (ii) the last day of the fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement, (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt, or (iv) the date on which we are deemed a “large accelerated filer” under the Securities and Exchange Act of 1934, as amended, or the Exchange Act. For so long as we remain an “emerging growth company” as defined in the JOBS Act, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on some or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. If we avail ourselves of certain exemptions from various

reporting requirements, our reduced disclosure may make it more difficult for investors and securities analysts to evaluate us to a level acceptable by them and may result in less investor confidence.

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.
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

\+ 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: November 27, 2013

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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