FINANCIAL INSTITUTIONS INC
Form 10-Q
November 04, 2009

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2009
or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission File Number: 000-26481

(Exact name of registrant as specified in its charter)

NEW YORK	**16-0816610**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
220 LIBERTY STREET, WARSAW, NEW YORK	**14569**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(585) 786-1100**

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. Yes þ No o

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). Yes o No o

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 o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

The registrant had 10,820,268 shares of Common Stock, $0.01 par value, outstanding as of October 30, 2009.

FINANCIAL INSTITUTIONS, INC.
Form 10-Q
For the Quarterly Period Ended September 30, 2009
TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Consolidated Statements of Financial Condition (Unaudited)

(Dollars in thousands, except share and per share data)	September 30, 2009	December 31, 2008
ASSETS		
Cash and cash equivalents:		
Cash and due from banks	$ 48,721	$ 34,528
Federal funds sold and interest-bearing deposits in other banks	11,385	20,659
Total cash and cash equivalents	60,106	55,187
Securities available for sale, at fair value	625,744	547,506
Securities held to maturity, at amortized cost (fair value of $46,122 and $59,147, respectively)	45,056	58,532
Loans held for sale	1,032	1,013
Loans	1,259,362	1,121,079
Less: Allowance for loan losses	20,782	18,749
Loans, net	1,238,580	1,102,330
Company owned life insurance	24,532	23,692
Premises and equipment, net	35,210	36,712
Goodwill	37,369	37,369
Other assets	70,576	54,578
Total assets	$ 2,138,205	$ 1,916,919
LIABILITIES AND SHAREHOLDERS EQUITY		
Deposits:		
Noninterest-bearing demand	$ 298,972	$ 292,586
Interest-bearing demand	383,982	344,616
Savings and money market	402,042	348,594
Certificates of deposit	712,182	647,467
Total deposits	1,797,178	1,633,263
Short-term borrowings	73,265	23,465
Long-term borrowings	46,848	47,355
Other liabilities	24,979	22,536
Total liabilities	1,942,270	1,726,619
Shareholders equity:		
Series A 3% Preferred Stock, $100 par value, 1,533 shares authorized and issued	153	153

Series A Preferred Stock, $100 par value, 7,503 shares authorized and issued, aggregate liquidation preference of $37,515; net of $1,760 and $2,016 discount, respectively	35,755	35,499
Series B-1 8.48% Preferred Stock, $100 par value, 200,000 shares authorized, 174,223 shares issued	17,422	17,422
Total preferred equity	53,330	53,074
Common stock, $0.01 par value, 50,000,000 shares authorized, 11,348,122 shares issued	113	113
Additional paid-in capital	26,815	26,397
Retained earnings	127,941	124,952
Accumulated other comprehensive loss	(2,381)	(4,013)
Treasury stock, at cost 529,826 and 550,103 shares, respectively	(9,883)	(10,223)
Total shareholders equity	195,935	190,300
Total liabilities and shareholders equity	$ 2,138,205	$ 1,916,919

See accompanying notes to the consolidated financial statements.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations (Unaudited)

(Dollars in thousands, except per share amounts)	Three months ended September 30, 2009	2008	Nine months ended September 30, 2009	2008
Interest income:				
Interest and fees on loans	$ 18,712	$ 17,018	$ 53,618	$ 50,146
Interest and dividends on investment securities	4,965	7,472	16,401	23,648
Other interest income	20	68	73	572
Total interest income	23,697	24,558	70,092	74,366
Interest expense:				
Deposits	4,826	6,538	14,729	23,193
Short-term borrowings	77	287	171	571
Long-term borrowings	716	987	2,142	2,584
Total interest expense	5,619	7,812	17,042	26,348
Net interest income	18,078	16,746	53,050	48,018
Provision for loan losses	2,620	1,891	6,614	3,965
Net interest income after provision for loan losses	15,458	14,855	46,436	44,053
Noninterest income:				
Service charges on deposits	2,643	2,794	7,480	7,812
ATM and debit card	920	852	2,639	2,460
Loan servicing	304	112	1,031	530
Company owned life insurance	271	223	806	269
Broker-dealer fees and commissions	238	363	741	1,223
Net gain on sale of loans held for sale	129	48	545	304
Net gain on investment securities	1,721	12	2,928	232
Impairment charges on investment securities	(2,318)	(34,554)	(4,101)	(38,345)
Net gain on sale and disposal of other assets	19	102	177	254
Other	479	700	1,366	1,589
Total noninterest income (loss)	4,406	(29,348)	13,612	(23,672)
Noninterest expense:				
Salaries and employee benefits	8,253	7,021	25,421	23,626
Occupancy and equipment	2,730	2,642	8,289	7,789
FDIC assessments	753	236	3,026	369
Professional services	532	467	1,972	1,504
Computer and data processing	578	603	1,757	1,764
Supplies and postage	473	475	1,414	1,353

Advertising and promotions	227	472	650	905
Other	1,596	1,493	5,131	4,757
Total noninterest expense	15,142	13,409	47,660	42,067
Income (loss) before income taxes	4,722	(27,902)	12,388	(21,686)
Income tax expense	1,313	524	3,384	1,330
Net income (loss)	$ 3,409	$ (28,426)	$ 9,004	$ (23,016)
Preferred stock dividends, net of amortization	927	371	2,770	1,112
Net income (loss) applicable to common shareholders	$ 2,482	$ (28,797)	$ 6,234	$ (24,128)
Earnings (loss) per common share (Note 2):				
Basic	$ 0.23	$ (2.66)	$ 0.58	$ (2.21)
Diluted	$ 0.23	$ (2.66)	$ 0.57	$ (2.21)

See accompanying notes to the consolidated financial statements.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Consolidated Statement of Changes in Shareholders Equity (Unaudited)

(Dollars in thousands, except per share data)	Preferred Equity	Common Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Total Shareholders Equity
Balance at January 1, 2009	**$ 53,074**	**$ 113**	**$ 26,397**	**$ 124,952**	**$ (4,013)**	**$ (10,223)**	**$ 190,300**
Comprehensive income:							
Net income				9,004			9,004
Other comprehensive income, net of tax					1,632		1,632
Total comprehensive income							10,636
Issuance costs of Series A Preferred Stock			(68)				(68)
Share-based compensation plans:							
Share-based compensation			690				690
Stock options exercised			(4)			19	15
Restricted stock awards issued, net			(170)			170	
Directors retainer			(30)			151	121
Accrued undeclared cumulative dividend on Series A Preferred Stock, net of amortization	256			(450)			(194)
Cash dividends declared:							
Series A 3% Preferred-$2.25 per share				(3)			(3)
Series A Preferred-$161.11 per share				(1,209)			(1,209)
Series B-1 8.48% Preferred-$6.36 per share				(1,108)			(1,108)
Common-$0.30 per share				(3,245)			(3,245)
Balance at September 30, 2009	**$ 53,330**	**$ 113**	**$ 26,815**	**$ 127,941**	**$ (2,381)**	**$ (9,883)**	**$ 195,935**

See accompanying notes to the consolidated financial statements.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows (Unaudited)

(Dollars in thousands)	Nine months ended September 30, 2009	2008
Cash flows from operating activities:		
Net income (loss)	$ 9,004	$ (23,016)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	3,067	2,922
Net amortization of premiums and discounts on investment securities	1,792	374
Provision for loan losses	6,614	3,965
Amortization of unvested stock-based compensation	690	529
Deferred income tax expense (benefit)	5,562	(1,865)
Proceeds from sale of loans held for sale	76,704	25,401
Originations of loans held for sale	(76,178)	(25,199)
Increase in company owned life insurance	(806)	(269)
Net gain on investment securities	(2,928)	(232)
Impairment charge on investment securities	4,101	38,345
Net gain on sale of loans held for sale	(545)	(304)
Net gain on sale and disposal of other assets	(177)	(254)
(Increase) decrease in other assets	(5,095)	129
Increase (decrease) in other liabilities	1,562	(2,727)
Net cash provided by operating activities	23,367	17,799
Cash flows from investing activities:		
Purchase of investment securities:		
Available for sale	(451,137)	(287,678)
Held to maturity	(22,350)	(44,065)
Proceeds from principal payments, maturities and calls on investment securities:		
Available for sale	243,439	270,367
Held to maturity	36,512	40,924
Proceeds from sale of securities available for sale	127,142	51,545
Net loan originations	(159,750)	(116,772)
Purchase of company owned life insurance	(34)	(20,066)
Proceeds from sales of other assets	1,577	1,395
Purchase of premises and equipment	(1,439)	(4,058)
Net cash used by investing activities	(226,040)	(108,408)
Cash flows from financing activities:		
Net increase in deposits	163,915	84,443
Net increase in short-term borrowings	49,800	21,566
Proceeds from long-term borrowings		30,000
Repayment of long-term borrowings	(507)	(5,092)

Purchase of common stock		(4,698)
Issuance of preferred and common shares	(68)	112
Stock options exercised	15	32
Cash dividends paid to preferred shareholders	(2,320)	(1,112)
Cash dividends paid to common shareholders	(3,243)	(4,611)
Net cash provided by financing activities	207,592	120,640
Net increase in cash and cash equivalents	4,919	30,031
Cash and cash equivalents, beginning of period	55,187	46,673
Cash and cash equivalents, end of period	$ 60,106	$ 76,704

See accompanying notes to the consolidated financial statements.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(1.) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

Financial Institutions, Inc., a financial holding company organized under the laws of New York State, and its subsidiaries provide deposit, lending and other financial services to individuals and businesses in Central and Western New York. The Company owns 100% of Five Star Bank, a New York State-chartered bank, and Five Star Investment Services, Inc., a broker-dealer subsidiary offering noninsured investment products. The Company also owns 100% of FISI Statutory Trust I (the Trust), which was formed in February 2001 for the purpose of issuing trust preferred securities. References to the Company mean the consolidated reporting entities and references to the Bank mean Five Star Bank.

Basis of Presentation

The consolidated financial statements in this Quarterly Report on Form 10-Q include the accounts of the Company and its subsidiaries. The Trust is not included in the consolidated financial statements of the Company under the requirements of the Variable Interest Entities Subsections of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC). All significant intercompany accounts and transactions have been eliminated in consolidation. The accounting and reporting policies conform to general practices within the banking industry and to U.S. generally accepted accounting principles. Prior years consolidated financial statements are re-classified whenever necessary to conform to the current year s presentation.

These financial statements have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in conformity with U.S. generally accepted accounting principles (GAAP) have been condensed or omitted pursuant to such rules and regulations. However, in the opinion of management, the accompanying consolidated financial statements reflect all adjustments of a normal and recurring nature necessary to present fairly the consolidated balance sheet, statements of operations, shareholders equity and cash flows for the periods indicated, and contain adequate disclosure to make the information presented not misleading. These consolidated financial statements should be read in conjunction with the Company s 2008 Annual Report on Form 10-K. The results of operations for any interim periods are not necessarily indicative of the results which may be expected for the entire year.

Use of Estimates

The preparation of these financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Material estimates relate to the determination of the allowance for loan losses, assumptions used in the defined benefit pension plan accounting, the valuation of goodwill and deferred tax assets, and the valuation and other than temporary impairment considerations related to the securities portfolio.

Cash Flow Information

Supplemental cash flow information addressing certain cash payments (receipts) and noncash investing and financing activities was as follows (in thousands):

	Nine months ended September 30,	
	2009	**2008**
Cash payments (receipts):		
Interest	$ 15,338	$ 28,306
Income taxes	(1,312)	2,349
Noncash investing and financing activities:		
Real estate and other assets acquired in settlement of loans	$ 903	$ 756
Accrued and declared unpaid dividends	1,692	1,992
Increase in net unsettled security transactions	16,795	1,814

Loans securitized	15,983

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(1.) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Recently Adopted Accounting Pronouncements

Accounting Standards Codification. The ASC became effective on July 1, 2009. At that date, the ASC became FASB s officially recognized source of authoritative GAAP applicable to all public and non-public non-governmental entities, superseding existing FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force and related literature. Rules and interpretive releases of the SEC under the authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. All other accounting literature is considered non-authoritative. The switch to the ASC affects the way companies refer to GAAP in financial statements and accounting policies. The ASC was not intended to change or alter existing GAAP, and therefore did not have an impact on the Company s financial statements.

Earnings Per Share. On January 1, 2009, the Company adopted the requirements of the ASC subsections regarding Participating Securities and the Two-Class Method as those requirements relate to the calculation of earnings per common share. The ASC provides that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per common share pursuant to the two-class method. The Company has shares of restricted stock outstanding that are participating securities under the provisions of the ASC. Accordingly, the Company has computed earnings per common share using the two-class method described in the ASC beginning January 1, 2009, and has retrospectively adjusted previously reported earnings per common share data to conform to the two-class method.

Disclosures about Derivative Instruments and Hedging Activities. In March 2008, the FASB issued new guidance regarding disclosures in the Derivatives and Hedging Topic of the ASC (Derivative Disclosure Guidance). The Derivative Disclosure Guidance requires expanded disclosure to provide greater transparency about (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedge items are accounted for under the Derivatives and Hedging Topic, and (iii) how derivative instruments and related hedged items affect an entity s financial condition, results of operations and cash flows. To meet those objectives, the Derivative Disclosure Guidance requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit risk-related contingent features in derivative agreements. The Derivative Disclosure Guidance became effective for the Company on January 1, 2009 and its adoption did not have an impact on the Company s financial statements.

Fair Value Determination. In April 2009, the FASB issued guidance (Fair Value Determination Guidance) in the Fair Value Measurements and Disclosures Topic of the ASC regarding the determination of fair value in instances where market conditions result in either inactive markets for assets and liabilities or disorderly transactions within markets. The Fair Value Determination Guidance affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell the asset in an orderly transaction, and clarifies and includes additional factors for determining whether there has been a significant decrease in market activity for an asset when the market for that asset is not active. The Fair Value Determination Guidance requires an entity to base its conclusion about whether a transaction was not orderly on the weight of the evidence and expands certain disclosure requirements. The Fair Value Determination Guidance became effective for the Company in the quarter ended June 30, 2009, and its adoption did not have a significant impact on the Company s financial statements.

Other-Than-Temporary Impairments. In April 2009, the FASB issued guidance in the Investments-Debt and Equity Securities Topic of the ASC regarding the recognition and presentation of Other-Than-Temporary Impairments (OTTI Guidance). The OTTI Guidance (i) changes existing guidance for determining whether an impairment is other than temporary to debt securities and (ii) replaces the existing requirement that the entity s management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert: (a) it does not have the intent to sell the security; and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. Under the OTTI Guidance, declines in the fair value of held-to-maturity and available-for-sale securities below their cost that are deemed to be other than temporary are reflected in earnings as

realized losses to the extent the impairment is related to credit losses. The amount of the impairment related to other factors is recognized in other comprehensive income. The OTTI Guidance became effective for the Company in the quarter ended June 30, 2009, and its adoption did not have a significant impact on the Company s financial statements.

Interim Disclosure about Fair Value of Financial Instruments. In April 2009, the FASB amended the Fair Value of Financial Instruments Subsection of the ASC to require an entity to provide disclosures about fair value of financial instruments in interim financial information (Fair Value Disclosure Amendment). The Fair Value Disclosure Amendment requires a publicly traded company to include disclosures about the fair value of its financial instruments whenever it issues summarized financial information for interim reporting periods. In addition, entities must disclose, in the body or in the accompanying notes of its summarized financial information for interim reporting periods and in its financial statements for annual reporting periods, the fair value of all financial instruments for which it is practicable to estimate that value, whether recognized or not recognized in the statement of financial condition. The Fair Value Disclosure Amendment became effective for the Company in the quarter ended June 30, 2009, and its adoption did not have a significant effect on Company s financial statements. The Company has included the disclosures required by the Fair Value Disclosure Amendment in Note 9, Fair Value Measurements.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(1.) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Subsequent Events. The Company has applied the provisions of the Subsequent Events Topic of the ASC to its consolidated interim financial statements for periods ended after June 15, 2009. The Subsequent Event Topic establishes general standards of accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or available to be issued. In particular, the Subsequent Events Topic sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements. Accordingly, the Company has evaluated events and transactions occurring through November 4, 2009, the date the consolidated interim financial statements were issued, for potential recognition or disclosure in the financial statements.

Recently Issued Accounting Pronouncements not Yet Adopted

In June 2009, the FASB issued two related accounting pronouncements changing the accounting principles and disclosures requirements related to securitizations and special-purpose entities. Specifically, these pronouncements eliminate the concept of a qualifying special-purpose entity , change the requirements for derecognizing financial assets and change how a company determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. These pronouncements also expand existing disclosure requirements to include more information about transfers of financial assets, including securitization transactions, and where companies have continuing exposure to the risks related to transferred financial assets. These pronouncements will be effective as of the beginning of each reporting entity s first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period and for interim and annual reporting periods thereafter. Earlier application is prohibited. The recognition and measurement provisions regarding transfers of financial assets shall be applied to transfers that occur on or after the effective date. These new pronouncements will be effective January 1, 2010 and are not expected to have a significant impact on the Company s financial statements.

Disclosures about Retirement Benefits. Effective for fiscal years ending after December 15, 2009, the *Compensation Retirement Benefits Topic*, requires additional disclosures about employers plan assets of a defined benefit pension or other postretirement plan. The requirements include disclosing investing strategies, major categories of plan assets, concentrations of risk within plan assets, information about fair value measurements of plan assets, and valuation techniques used to measure the fair value of plan assets. Adoption of these additional requirements will not have a significant impact on the Company s financial statements.

(2.) EARNINGS PER COMMON SHARE

The following table presents the computation of basic and diluted earnings per common share for the three and nine months ended September 30, 2009 and 2008 (in thousands, except per share amounts). The Company uses the two-class method prescribed by the Earnings Per Share Topic of the ASC to compute earnings per common share. Participating securities include non-vested restricted stock.

	Three months ended September 30,		Nine months ended September 30,	
	2009	**2008**	**2009**	**2008**
Net income (loss) applicable to common shareholders	$ 2,482	(28,797)	6,234	(24,128)
Less: Earnings (loss) allocated to participating securities	18	(224)	52	(175)
Earnings allocated to common shares outstanding	$ 2,464	$ (28,573)	$ 6,182	$ (23,953)
	10,738	10,738	10,726	10,852

Weighted average common shares used to calculate basic EPS				
Add: Effect of common stock equivalents	41		38	
Weighted average common shares used to calculate diluted EPS	10,779	10,738	10,764	10,852
Earnings (loss) per common share:				
Basic	$ 0.23	$ (2.66)	$ 0.58	$ (2.21)
Diluted	$ 0.23	$ (2.66)	$ 0.57	$ (2.21)

Shares subject to the following securities were considered antidilutive and, therefore, excluded from the computation of diluted EPS:

Stock options	553	452	528	423
Restricted stock awards		31	14	24
Warrant	378		378	
	931	483	920	447

All shares of restricted stock are deducted from weighted average shares outstanding for the computation of basic EPS. Shares of restricted stock, stock options, and warrant are included in the calculation of diluted EPS using the treasury stock method.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(3.) INVESTMENT SECURITIES

The amortized cost and fair value of investment securities are summarized below (in thousands):

	September 30, 2009			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities available for sale:				
U.S. Government agencies and government sponsored enterprises	$ 177,237	$ 270	$ 242	$ 177,265
State and political subdivisions	86,417	3,258	3	89,672
Mortgage-backed securities:				
Federal National Mortgage Association	80,254	1,616	78	81,792
Federal Home Loan Mortgage Corporation	51,722	1,078	17	52,783
Government National Mortgage Association	118,154	917	35	119,036
Collateralized mortgage obligations:				
Federal National Mortgage Association	18,121	244	122	18,243
Federal Home Loan Mortgage Corporation	23,481	486	20	23,947
Government National Mortgage Association	52,325	40	68	52,297
Privately issued	8,825	464	361	8,928
Total collateralized mortgage obligations	102,752	1,234	571	103,415
Total mortgage-backed securities	352,882	4,845	701	357,026
Asset-backed securities	1,415	366		1,781
Total available for sale securities	$ 617,951	$ 8,739	$ 946	$ 625,744
Securities held to maturity:				
State and political subdivisions	$ 45,056	$ 1,066	$	$ 46,122

	December 31, 2008			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities available for sale:				
U.S. Government agencies and government sponsored enterprises	$ 67,871	$ 609	$ 307	$ 68,173
State and political subdivisions	129,572	2,181	42	131,711
Mortgage-backed securities:				
Federal National Mortgage Association	136,348	3,725	86	139,987
Federal Home Loan Mortgage Corporation	94,960	2,649	14	97,595
Government National Mortgage Association	1,926	17	25	1,918
Collateralized mortgage obligations:				
Federal National Mortgage Association	17,856	74	642	17,288
Federal Home Loan Mortgage Corporation	44,838	334	214	44,958
Government National Mortgage Association	1,350	9		1,359

Privately issued	42,296	5	2,854	39,447
Total collateralized mortgage obligations	106,340	422	3,710	103,052
Total mortgage-backed securities	339,574	6,813	3,835	342,552
Asset-backed securities	3,918			3,918
Equity securities	923	281	52	1,152
Total available for sale securities	$ 541,858	$ 9,884	$ 4,236	$ 547,506
Securities held to maturity:				
State and political subdivisions	$ 58,532	$ 619	$ 4	$ 59,147

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(3.) INVESTMENT SECURITIES (Continued)

Sales of securities available for sale were as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Proceeds from sales	$ 45,878	$ 4,000	$ 144,623	$ 51,545
Gross realized gains	1,887	12	4,860	235
Gross realized losses	166		1,932	3

The scheduled maturities of securities available for sale and securities held to maturity at September 30, 2009 are shown below. Actual expected maturities may differ from contractual maturities because issuers may have the right to call or prepay obligations.

	Amortized Cost	Fair Value
Debt securities available for sale:		
Due in one year or less	$ 47,364	$ 47,864
Due from one to five years	196,173	200,082
Due after five years through ten years	72,306	73,301
Due after ten years	302,108	304,497
	$ 617,951	$ 625,744
Debt securities held to maturity:		
Due in one year or less	$ 35,689	$ 35,940
Due from one to five years	7,087	7,572
Due after five years through ten years	1,791	2,022
Due after ten years	489	588
	$ 45,056	$ 46,122

The following tables show the investments gross unrealized losses and fair value, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at September 30, 2009 and December 31, 2008 (in thousands).

	September 30, 2009					
	Less than 12 months		12 months or longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Securities available for sale:						
U.S. Government agencies and government sponsored enterprises	$ 70,112	$ 37	$ 10,303	$ 205	$ 80,415	$ 242
State and political subdivisions	20	1	195	2	215	3
Mortgage-backed securities:						

Federal National Mortgage Association	16,716	77	3	1	16,719	78
Federal Home Loan Mortgage Corporation	5,346	17			5,346	17
Government National Mortgage Association	13,984	34	61	1	14,045	35
Collateralized mortgage obligations:						
Federal National Mortgage Association	374	1	5,581	121	5,955	122
Federal Home Loan Mortgage Corporation	569	2	888	18	1,457	20
Government National Mortgage Association	15,961	68			15,961	68
Privately issued			3,427	361	3,427	361
Total collateralized mortgage obligations	16,904	71	9,896	500	26,800	571
Total mortgage-backed securities	52,950	199	9,960	502	62,910	701
Total available for sale securities	123,082	237	20,458	709	143,540	946
Securities held to maturity:						
State and political subdivisions						
Total temporarily impaired securities	$ 123,082	$ 237	$ 20,458	$ 709	$ 143,540	$ 946

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)
(3.) INVESTMENT SECURITIES (Continued)

	December 31, 2008					
	Less than 12 months		12 months or longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Securities available for sale:						
U.S. Government agencies and government sponsored enterprises	$ 50	$ 1	$ 11,704	$ 306	$ 11,754	$ 307
State and political subdivisions	6,191	41	84	1	6,275	42
Mortgage-backed securities:						
Federal National Mortgage Association	10,432	65	484	21	10,916	86
Federal Home Loan Mortgage Corporation	5,533	14			5,533	14
Government National Mortgage Association	227	3	1,059	22	1,286	25
Collateralized mortgage obligations:						
Federal National Mortgage Association	828	1	7,181	641	8,009	642
Federal Home Loan Mortgage Corporation			7,224	214	7,224	214
Privately issued	24,425	2,045	10,975	809	35,400	2,854
Total collateralized mortgage obligations	25,253	2,046	25,380	1,664	50,633	3,710
Total mortgage-backed securities	41,445	2,128	26,923	1,707	68,368	3,835
Equity securities	310	52			310	52
Total available for sale securities	47,996	2,222	38,711	2,014	86,707	4,236
Securities held to maturity:						
State and political subdivisions	554	4			554	4
Total temporarily impaired securities	$ 48,550	$ 2,226	$ 38,711	$ 2,014	$ 87,261	$ 4,240

The Company reviews investment securities on an ongoing basis for the presence of other-than-temporary-impairment (OTTI) with formal reviews performed quarterly. Declines in the fair value of held-to-maturity and available-for-sale

securities below their cost that are deemed to be other than temporary are reflected in earnings as realized losses to the extent the impairment is related to credit losses or the security is intended to be sold. The amount of the impairment related to other factors is recognized in other comprehensive income. Evaluating whether the impairment of a debt security is other than temporary involves assessing i.) the intent to sell the debt security or ii.) the likelihood of being required to sell the security before the recovery of its amortized cost basis. In determining whether the other-than temporary impairment includes a credit loss, the Company uses its best estimate of the present value of cash flows expected to be collected from the debt security considering factors such as: a.) the length of time and the extent to which the fair value has been less than the amortized cost basis, b.) adverse conditions specifically related to the security, an industry, or a geographic area, c.) the historical and implied volatility of the fair value of the security, d.) the payment structure of the debt security and the likelihood of the issuer being able to make payments that increase in the future, e.) failure of the issuer of the security to make scheduled interest or principal payments, f.) any changes to the rating of the security by a rating agency, and g.) recoveries or additional declines in fair value subsequent to the balance sheet date.

During the third quarter of 2009, the Company recorded OTTI charges totaling $2.3 million on 12 pooled trust preferred securities, all of which were designated as impaired due to reasons of credit quality, and one privately issued whole loan collateralized mortgage obligation (CMO) which the Company has determined it intends to sell.

The following summarizes the amounts of OTTI recognized during the periods presented by investment category (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	**2008**	**2009**	**2008**
Mortgage-backed securities Privately issued whole loan CMOs	$ 126	$	$ 1,859	$ 1,728
Other asset-backed securities Trust preferred securities	2,192	3,529	2,242	5,592
Equity securities Auction rate securities		31,025		31,025
	$ 2,318	$ 34,554	$ 4,101	$ 38,345

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(3.) INVESTMENT SECURITIES (Continued)

As of September 30, 2009, management does not have the intent to sell any of the securities in a loss position and believes that it is likely that it will not be required to sell any such securities before the anticipated recovery of amortized cost. The unrealized losses are largely due to increases in market interest rates over the yields available at the time the underlying securities were purchased. The fair value is expected to recover as the bonds approach their maturity date or repricing date or if market yields for such investments decline.

Management does not believe any of the securities in a loss position are impaired due to reasons of credit quality. Accordingly, as of September 30, 2009, management has concluded that unrealized losses on its investment securities are temporary and no further impairment loss has been realized in the Company s consolidated statements of operations.

(4.) LOANS

Loans outstanding, including net unearned income and net deferred fees and costs of $16.3 million and $12.3 million as of September 30, 2009 and December 31, 2008, respectively, are summarized as follows (in thousands):

	September 30, 2009	December 31, 2008
Commercial	$ 197,404	$ 158,543
Commercial real estate	296,648	262,234
Agricultural	42,545	44,706
Residential real estate	147,447	177,683
Consumer indirect	345,448	255,054
Consumer direct and home equity	229,870	222,859
Total loans	1,259,362	1,121,079
Less: Allowance for loan losses	20,782	18,749
Total loans, net	$ 1,238,580	$ 1,102,330

(5.) GOODWILL AND OTHER INTANGIBLE ASSETS

The carrying amount of goodwill totaled $37.4 million as of September 30, 2009 and December 31, 2008. The Company performs a goodwill impairment test on an annual basis or more frequently if events and circumstances warrant. As of September 30, 2009, the Company performed the annual goodwill impairment test and determined that no impairment existed.

Declines in the market value of the Company s publicly traded stock price or declines in the Company s ability to generate future cash flows may increase the potential that goodwill recorded on the Company s consolidated statement of financial condition be designated as impaired and that the Company may incur a goodwill write-down in the future.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(6.) COMPREHENSIVE INCOME (LOSS)

Presented below is a reconciliation of net income (loss) to comprehensive income (loss) including the components of other comprehensive income (loss) for the periods indicated (in thousands):

	Nine months ended September 30,					
	2009			2008		
	Pre-tax Amount	Tax Expense (Benefit)	Net-of-tax Amount	Pre-tax Amount	Tax Expense (Benefit)	Net-of-tax Amount
Securities available for sale:						
Net unrealized gains (losses) arising during the period	$ 972	$ 376	$ 596	$ (53,276)	$ (20,610)	$ (32,666)
Reclassification adjustments:						
Realized net gains included in income	(2,928)	(1,133)	(1,795)	(232)	(90)	(142)
Impairment charges included in income	4,101	1,587	2,514	38,345	14,834	23,511
	2,145	830	1,315	(15,163)	(5,866)	(9,297)
Pension and post-retirement benefit liabilities	517	200	317	(34)	(14)	(20)
Other comprehensive income (loss)	$ 2,662	$ 1,030	1,632	$ (15,197)	$ (5,880)	(9,317)
Net income (loss)			9,004			(23,016)
Comprehensive income (loss)			$ 10,636			$ (32,333)

The components of accumulated other comprehensive loss, net of tax, for the periods indicated were as follows (in thousands):

	September 30, 2009	December 31, 2008
Net unrealized gain on securities available for sale	$ 4,778	$ 3,463
Unfunded pension and post-retirement benefit liabilities	(7,159)	(7,476)
	$ (2,381)	$ (4,013)

(7.) SHARE-BASED COMPENSATION PLANS

The Company maintains certain stock-based compensation plans, approved by the Company s shareholders that are administered by the Board, or the Management Development and Compensation Committee of the Board. On May 6, 2009 the shareholders of the Company approved two share-based compensation plans, the 2009 Management Stock Incentive Plan (Management Plan) and the 2009 Directors Stock Incentive Plan (Director s Plan). An aggregate o 690,000 shares has been reserved for issuance by the Company under the terms of the Management Plan pursuant to

the grant of incentive stock options (not to exceed 500,000 shares), non-qualified stock options and restricted stock grants all which are defined in the Plan. An aggregate of 250,000 shares has been reserved for issuance by the Company under the terms of the Director s Plan pursuant to the grant of non-qualified stock options and restricted stock grants, all which are defined in the Plan.

The share-based compensation plans were established to allow for the granting of compensation awards to attract, motivate and retain employees, executive officers and non-employee directors who contribute to the success and profitability of the Company and to give such persons a proprietary interest in the Company, thereby enhancing their personal interest in the Company s success.

The Company awarded grants of 48,500 restricted shares to certain key officers during the nine months ended September 30, 2009. The market price of the restricted shares on the date of grant was $13.21. Both a performance requirement and a service requirement must be satisfied before the participant becomes vested in the shares. The performance period for the awards is the Company s fiscal year ending on December 31, 2009. As a result of not satisfying certain performance requirements for the fiscal year ending December 31, 2008, 41,200 restricted shares granted in the first nine months of 2008 were forfeited during the first nine months of 2009. There was no reversal of restricted stock award expense required during the nine months ended September 30, 2009, as the Company reduced share-based compensation expense related to the forfeited shares during 2008. During the nine months ended September 30, 2009 the Company granted 8,000 restricted shares to directors, of which 4,000 shares vested immediately and 4,000 shares will vest after completion of a one-year service requirement. The market price of the restricted shares on the date of grant was $14.86.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(7.) SHARE-BASED COMPENSATION PLANS (Continued)

The share-based compensation expense associated included in the consolidated statements of operations (unaudited) is as follows for the periods indicated (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Stock options:				
Management Stock Incentive Plan	$ 57	$ 125	$ 179	$ 304
Director Stock Incentive Plan	11	12	34	28
	68	137	213	332
Restricted stock awards:				
Management Stock Incentive Plan	92	(160)	394	197
Director Stock Incentive Plan	15		83	
	107	(160)	477	197
Total share-based compensation	$ 175	$ (23)	$ 690	$ 529

(8.) EMPLOYEE BENEFIT PLANS

Defined Benefit Pension Plan

The Company participates in The New York State Bankers Retirement System (the System), a defined benefit pension plan covering substantially all employees, subject to the limitations related to the plan closure effective December 31, 2006. The benefits are based on years of service and the employee s highest average compensation during five consecutive years of employment. The defined benefit plan was closed to new participants effective December 31, 2006. Only employees hired on or before December 31, 2006 and who met participation requirements on or before January 1, 2008 are eligible to receive benefits.

The components of the Company s net periodic benefit expense for its pension plan were as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Service cost	$ 423	$ 364	$ 1,267	$ 1,092
Interest cost on projected benefit obligation	456	391	1,369	1,171
Expected return on plan assets	(462)	(524)	(1,386)	(1,570)
Amortization of unrecognized prior service cost	3	3	9	9
Amortization of unrecognized loss	182		546	
Net periodic pension cost	$ 602	$ 234	$ 1,805	$ 702

The Company s funding policy is to contribute, at a minimum, an actuarially determined amount that will satisfy the minimum funding requirements determined under the appropriate sections of Internal Revenue Code. In April 2009, the Company made the minimum required contribution for fiscal year 2009 of $1.6 million to the pension plan. The Company may make additional contributions to its pension plan in fiscal year 2009.

Defined Contribution Plan

Employees that meet certain age and service requirements are eligible to participate in the Company sponsored 401(k) plan. Under the plan, participants may make contributions, in the form of salary deferrals, up to the maximum Internal Revenue Code limit. The Company matches a participant s contributions up to 4.5% of compensation, calculated as 100% of the first 3% of compensation and 50% of the next 3% of compensation deferred by the participant. The Company may also make additional discretionary matching contributions, although no such additional discretionary contributions were made in 2008 or during the first nine months of 2009. The expense included in salaries and employee benefits in the consolidated statements of operations for this plan amounted to $234 thousand and $244 thousand for the three months ended September 30, 2009 and September 30, 2008, respectively. For the nine months ended September 30, 2009 and September 30, 2008 the expense for the plan amounted to $686 thousand and $760 thousand, respectively.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(8.) EMPLOYEE BENEFIT PLANS (Continued)

Supplemental Executive Retirement Plans

During the third quarter of 2008 the Company established non-qualified supplemental executive retirement plans (SERPs) for two active executives. The Company has accrued a liability, all of which is unfunded, of $876 thousand as of September 30, 2009, and recorded expense of $78 thousand and $567 thousand for the three and nine month periods, respectively, ended September 30, 2009. The Company expensed $76 thousand during the three month and nine months periods ended September 30, 2008.

(9.) FAIR VALUE MEASUREMENTS

Valuation Hierarchy

On January 1, 2008, the Company adopted the Fair Value Measurements and Disclosures Topic of the ASC (Fair Value Topic). The Fair Value Topic defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Fair Value Topic establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels.

Level 1 Unadjusted quoted prices in active markets for assets or liabilities identical to those to be reported at fair value. An active market is a market in which transactions occur for the item to be fair valued with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Inputs other than quoted prices included within Level 1 inputs that are observable for the asset or liability, either directly or indirectly. These inputs include: (a) quoted prices for similar assets or liabilities in active markets; (b) quoted prices for identical or similar assets or liabilities in markets that are not active, such as when there are few transactions for the asset or liability, the prices are not current, price quotations vary substantially over time or in which little information is released publicly; (c) inputs other than quoted prices that are observable for the asset or liability; and (d) inputs that are derived principally from or corroborated by observable market data by correlation or other means. The Company s Level 2 assets primarily include debt securities classified as available for sale and not included in Level 3.

Level 3 Significant unobservable inputs for the asset or liability. These inputs should be used to determine fair value only when observable inputs are not available. Unobservable inputs should be developed based on the best information available in the circumstances, which might include internally generated data and assumptions being used to price the asset or liability. The Company s Level 3 assets primarily include pooled trust preferred securities.

Investment Securities. Fair values of equity securities are determined using public quotations, when available. Where quoted market prices are not available, fair values may be estimated based on dealer quotes, pricing models, discounted cash flow methodologies, or similar techniques for which the determination of fair value may require significant judgment or estimation. Fair values of public bonds and those private securities that are actively traded in the secondary market have been determined through the use of third-party pricing services using market observable inputs. Private placement securities and other securities where the Company does not receive a public quotation are valued by discounting the expected cash flows. Market rates used are applicable to the yield, credit quality and average maturity of each security. Private equity securities may also utilize internal valuation methodologies appropriate for the specific asset. Fair values might also be determined using broker quotes or through the use of internal models or analysis.

Financial Assets Measured at Fair Value on a Recurring Basis

The following table summarizes financial assets measured and recorded at fair value on a recurring basis as of September 30, 2009, segregated by the level of the valuation inputs within the fair value hierarchy utilized to measure fair value (in thousands):

	Level 1	Level 2	Level 3	Total
Securities available for sale:				

U.S. Government agencies and government sponsored enterprises	$	$ 177,265	$	$ 177,265
State and political subdivisions		89,672		89,672
Mortgage-backed securities		357,026		357,026
Asset-backed securities:				
Trust preferred securities			1,335	1,335
Other		350	96	446
Total available for sale securities	$	$ 624,313	$ 1,431	$ 625,744

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(9.) FAIR VALUE MEASUREMENTS (Continued)

The following table presents changes in Level 3 available for sale securities measured at fair value on a recurring basis during the nine months ended September 30, 2009 (in thousands):

Balance at December 31, 2008	$	3,772
Capitalized interest		184
Principal paydowns and amortization of premiums		(9)
Coupon payments applied to principal		(224)
Total losses (realized/unrealized):		
Included in earnings		(2,192)
Included in other comprehensive income		(100)
Balance at September 30, 2009	$	1,431

Financial Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

Certain financial assets and financial liabilities are measured at fair value on a nonrecurring basis; that is, the instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (for example, when there is evidence of impairment). Examples of these nonrecurring uses of fair value include: loans held for sale, mortgage servicing assets and collateral dependent impaired loans. As of September 30, 2009, the Company had no liabilities measured at fair value on a nonrecurring basis.

Loans held for sale are carried at the lower of cost or fair value. As of September 30, 2009, a valuation allowance against loans held for sale was not necessary as their fair value was in excess of their cost. Fair value is based on observable market rates for comparable loan products which is considered a level 2 fair value measurement.

Mortgage servicing rights (MSR) are carried at the lower of cost or fair value. Due primarily to a decline in the estimated prepayment speed of the Company s sold loan portfolio with servicing retained, the fair value of the Company s MSR increased during 2009. As a result of this increase, the Company reduced its corresponding valuation allowance by $165 thousand during the first nine months of 2009. A valuation allowance of $197 thousand existed as of September 30, 2009. The mortgage servicing rights are a Level 3 fair value measurement, as fair value is determined by calculating the present value of the future servicing cash flows from the underlying mortgage loans.

During the third quarter of 2009, certain impaired loans were remeasured and reported at fair value through a specific valuation allowance allocation of the allowance for loan losses based upon the fair value of the underlying collateral. Impaired loans with a carrying value of $1.1 million were reduced by specific valuation allowance allocations totaling $247 thousand to a total reported fair value of $872 thousand. The collateral dependent impaired loans are a Level 2 fair measurement, as fair value is determined based upon estimates of the fair value of the collateral underlying the impaired loans typically using appraisals of comparable property or valuation guides.

Nonfinancial Assets and Nonfinancial Liabilities

Certain nonfinancial assets measured at fair value on a non-recurring basis include nonfinancial assets and nonfinancial liabilities measured at fair value in the second step of a goodwill impairment test, and intangible assets and other nonfinancial long-lived assets measured at fair value for impairment assessment. There were no nonfinancial assets or nonfinancial liabilities measured at fair value during the three or nine month periods ended September 30, 2009.

Fair Value of Financial Instruments

The Fair Value of Financial Instruments Subsection of the ASC requires disclosure of the fair value of financial assets and financial liabilities, including those financial assets and financial liabilities that are not measured and reported at fair value on a recurring basis or non-recurring basis.

The following discussion describes the valuation methodologies used for assets and liabilities measured or disclosed at fair value. The techniques utilized in estimating the fair values of financial instruments are reliant on the assumptions

used, including discount rates and estimates of the amount and timing of future cash flows. Care should be exercised in deriving conclusions about our business, its value or financial position based on the fair value information of financial instruments presented below.

Table of Contents

FINANCIAL INSTITUTIONS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements (Unaudited)

(9.) FAIR VALUE MEASUREMENTS (Continued)

Fair value estimates are made at a specific point in time, based on available market information and judgments about the financial instrument, including estimates of timing, amount of expected future cash flows and the credit standing of the issuer. Such estimates do not consider the tax impact of the realization of unrealized gains or losses. In some cases, the fair value estimates cannot be substantiated by comparison to independent markets. In addition, the disclosed fair value may not be realized in the immediate settlement of the financial instrument.

The estimated fair value approximates carrying value for cash and cash equivalents, Federal Home Loan Bank (FHLB) and Federal Reserve Bank (FRB) stock, company owned life insurance, accrued interest receivable, short-term borrowings and accrued interest payable. Fair value estimates for other financial instruments are discussed below.

Loans held for sale. The fair value is based on estimates, quoted market prices and investor commitments.

Loans. For variable rate loans that re-price frequently, fair value approximates carrying amount. The fair value for fixed rate loans is estimated through discounted cash flow analysis using interest rates currently being offered on loans with similar terms and credit quality. For criticized and classified loans, fair value is estimated by discounting expected cash flows at a rate commensurate with the risk associated with the estimated cash flows, or estimates of fair value discounts based on observable market information.

Deposits. The fair values for demand accounts, money market and savings deposits are equal to their carrying amounts. The fair values of certificates of deposit are estimated using a discounted cash flow approach that applies prevailing market interest rates for similar maturity instruments.

Long-term borrowings (excluding junior subordinated debentures). The fair value for long-term borrowings is estimated using a discounted cash flow approach that applies prevailing market interest rates for similar maturity instruments.

Junior subordinated debentures. The fair value for the junior subordinated debentures is estimated using a discounted cash flow approach that applies prevailing market interest rates for similar maturity instruments.

The fair value of a financial instrument is the current amount that would be exchanged between willing parties, other than in a forced liquidation. Fair value is best determined based upon quoted market prices. However, in many instances, there are no quoted market prices for the Company s various financial instruments. In cases where quoted market prices are not available, fair values are based on estimates using present value or other valuation techniques. Those techniques are significantly affected by the assumptions used, including the discount rate and estimates of future cash flows. Accordingly, the fair value estimates may not be realized in an immediate settlement of the instrument. The accounting guidelines exclude certain financial instruments and all non-financial instruments from its disclosure requirements. Accordingly, the aggregate fair value amounts presented at September 30, 2009 and December 31, 2008 may not necessarily represent the underlying fair value of the Company.

The estimated fair values of financial instruments were as follows:

	September 30, 2009		December 31, 2008	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Financial assets:				
Cash and cash equivalents	$ 60,106	$ 60,106	$ 55,187	$ 55,187
Securities available for sale	625,744	625,744	547,506	547,506
Securities held to maturity	45,056	46,122	58,532	59,147
Loans held for sale	1,032	1,055	1,013	1,032
Loans	1,238,580	1,305,274	1,102,330	1,169,660
Company owned life insurance	24,532	24,532	23,692	23,692
Accrued interest receivable	8,777	8,777	7,556	7,556

FHLB and FRB stock	7,185	7,185	6,035	6,035
Financial liabilities:				
Demand, savings and money market deposits	1,084,996	1,084,996	985,796	985,796
Time deposits	712,182	719,037	647,467	654,334
Short-term borrowings	73,265	73,265	23,465	23,465
Long-term borrowings (excluding junior subordinated debentures)	30,146	31,097	30,653	32,005
Junior subordinated debentures	16,702	12,249	16,702	12,232
Accrued interest payable	8,745	8,745	7,041	7,041

Table of Contents

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

FORWARD LOOKING INFORMATION

Statements in this Quarterly Report on Form 10-Q that are based on other than historical data are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements provide current expectations or forecasts of future events and include, among others:

- statements with respect to the beliefs, plans, objectives, goals, guidelines, expectations, anticipations, and future financial condition, results of operations and performance of Financial Institutions, Inc. (the parent or FII) and its subsidiaries (collectively the Company, we, our, us);
- statements preceded by, followed by or that include the words may, could, should, would, believe, an estimate, expect, intend, plan, projects, or similar expressions.

These forward-looking statements are not guarantees of future performance, nor should they be relied upon as representing management s views as of any subsequent date. Forward-looking statements involve significant risks and uncertainties and actual results may differ materially from those presented, either expressed or implied, in this Quarterly Report on Form 10-Q, including, but not limited to, those presented in the Management s Discussion and Analysis. Factors that might cause such differences include, but are not limited to:

- changes in financial market conditions, either internationally, nationally or locally in areas in which the Company conducts its operations, including without limitation, reduced rates of business formation and growth, commercial and residential real estate development and real estate prices;
- fluctuations in markets for equity, fixed-income, commercial paper and other securities, including availability, market liquidity levels, and pricing;
- changes in interest rates, the quality and composition of the loan and securities portfolios, demand for loan products, deposit flows and competition;
- changes in fiscal, monetary, regulatory, trade and tax policies and laws, including policies of the U.S. Department of Treasury and the Federal Reserve Board;
- the Company s participation or lack of participation in governmental programs implemented under the Emergency Economic Stabilization Act (EESA) and the American Recovery and Reinvestment Act (ARRA), including without limitation the Troubled Asset Relief Program (TARP), the Capital Purchase Program (CPP), and the Temporary Liquidity Guarantee Program (TLGP) and the impact of such programs and related regulations on the Company and on international, national, and local economic and financial markets and conditions;
- changes in consumer spending and savings habits;
- increased competitive challenges and expanding product and pricing pressures among financial institutions;
- demand for financial services in the Company s market areas;
- legislation or regulatory changes which adversely affect the Company s operations or business, including the Obama Administration s regulatory reform proposals concerning the financial services sector released on June 17, 2009;
- the Company s ability to comply with applicable laws and regulations, including restrictions on dividend payments;
- changes in accounting policies or procedures as may be required by the Financial Accounting Standards Board or regulatory agencies;
- increased costs of deposit insurance and changes with respect to Federal Deposit Insurance Corporation (FDIC) insurance coverage levels; and
- declines in the market value of the Company s publicly traded stock price or declines in the Company s ability to generate future cash flows may increase the potential that goodwill recorded on the Company s consolidated statement of financial condition be designated as impaired and that the Company may incur a goodwill write-down in the future.

The Company cautions readers not to place undue reliance on any forward-looking statements, which speak only as of the date made, and advises readers that various factors, including those described above, could affect the Company s financial performance and could cause the Company s actual results or circumstances for future periods to differ

materially from those anticipated or projected.

Except as required by law, the Company does not undertake, and specifically disclaims any obligation to publicly release any revisions to any forward-looking statements to reflect the occurrence of anticipated or unanticipated events or circumstances after the date of such statements.

Table of Contents

APPLICATION OF CRITICAL ACCOUNTING POLICIES AND ACCOUNTING ESTIMATES

The Company s consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles and are consistent with predominant practices in the banking industry. Application of critical accounting policies, which are those policies that management believes are the most important to the Company s financial condition and results, requires management to make estimates, assumptions, and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes and are based on information available as of the date of the financial statements. Future changes in information may affect these estimates, assumptions and judgments, which, in turn, may affect amounts reported in the financial statements.

The Company has numerous accounting policies, of which the most significant are presented in Note 1, Summary of Significant Accounting Policies, of the notes to consolidated financial statements included in the Company s 2008 Annual Report on Form 10-K. These policies, along with the disclosures presented in the other financial statement notes and in this discussion, provide information on how significant assets, liabilities, revenues and expenses are reported in the consolidated financial statements and how those reported amounts are determined. Based on the sensitivity of financial statement amounts to the methods, assumptions, and estimates underlying those amounts, management has determined that the accounting policies with respect to the allowance for loan losses, valuation of goodwill and deferred tax assets, the valuation of securities and determination of other-than-temporary impairment (OTTI), and accounting for defined benefit plans require particularly subjective or complex judgments important to the Company s financial condition and results of operations, and, as such, are considered to be critical accounting policies. These estimates and assumptions are based on management s best estimates and judgment and are evaluated on an ongoing basis using historical experience and other factors, including the current economic environment. The Company adjusts these estimates and assumptions when facts and circumstances dictate. Illiquid credit markets and volatile equity have combined with declines in consumer spending to increase the uncertainty inherent in these estimates and assumptions. As future events cannot be determined with precision, actual results could differ significantly from the Company s estimates.

For additional information regarding critical accounting policies, refer to Note 1, Summary of Significant Accounting Policies, of the notes to consolidated financial statements and the section captioned Critical Accounting Estimates in Management s Discussion and Analysis of Financial Condition and Results of Operations included in the 2008 Annual Report on Form 10-K. There have been no material changes in the Company s application of critical accounting policies related to the allowance for loan losses, valuation of goodwill and deferred tax assets, the valuation of securities and determination of OTTI, and accounting for defined benefit plans since December 31, 2008.

OVERVIEW

The principal objective of this discussion is to provide an overview of the financial condition and results of operations of the Company for the periods covered in this quarterly report. Certain reclassifications have been made to make prior periods comparable. This discussion and tabular presentations should be read in conjunction with the accompanying consolidated financial statements and accompanying notes.

During third quarter of 2009, we announced the appointment of Karl F. Krebs to the position of Executive Vice President and Chief Financial Officer (CFO). Mr. Krebs succeeded Mr. Ronald Miller, who retired as CFO effective October 1, 2009 as part of the Company s management succession plan. As previously announced, Mr. Miller will continue to serve as Executive Vice President and Secretary and will be assisting with the transition and special projects until his formal retirement in early 2010.

RESULTS OF OPERATIONS

Summary of Performance

Net income was $3.4 million for the third quarter of 2009 compared to a net loss of $28.4 million for the third quarter of 2008. Net income applicable to common shareholders for the third quarter of 2009 was $2.5 million, or $0.23 per diluted share, compared with a net loss of $28.8 million, or $2.66 per diluted share, for the third quarter of last year. Net income for the nine months ended September 30, 2009 totaled $9.0 million compared to a net loss of $23.0 million for the same period in 2008. For the first nine months of 2009 net income applicable to common shareholders was $6.2 million, or $0.57 per diluted share, compared with a net loss of $24.1 million, or $2.21 per diluted share, for the first nine months of 2008.

Included in the results for the three and nine month periods ended September 30, 2008, is a pre-tax OTTI charge of $31.0 million related to auction rate preferred equity securities collateralized by preferred stock of Federal National Mortgage Association (FNMA) and Federal Home Loan Mortgage Corporation (FHLMC). The tax benefit recognized on this OTTI charge was based on its treatment being classified as a capital loss for tax purposes, which significantly limited the tax benefit. A provision of EESA, enacted during the fourth quarter of 2008, permitting banks to recognize losses relating to FNMA and FHLMC preferred stock as an ordinary loss, increased the tax benefit to the Company in the fourth quarter. Had the tax benefit been recognized during the third quarter of 2008, it would have reduced the net losses for the three and nine month periods ended September 30, 2008 by $12.0 million.

Details of the changes in the various components of net income are further discussed in the sections that follow.

Table of Contents

Net Interest Income

The principal source of the Company s revenue is net interest income. Net interest income is the difference between interest income on interest-earning assets, such as loans and investment securities and the interest expense on liabilities used to fund those assets, such as interest-bearing deposits and borrowings. Net interest income is impacted by both changes in the amount and composition of interest-earning assets and interest-bearing liabilities, as well as market interest rates.

Net interest income was $18.1 million and $16.7 million for the three months ended September 30, 2009 and 2008, respectively. For the nine months ended September 30, 2009 and 2008, net interest income was $53.1 million and $48.0 million, respectively. The increases for both periods resulted primarily from favorable changes in the mix of our interest-earning assets and repricing of interest-bearing liabilities at lower interest rates.

Net interest income was $18.1 million for the third quarter, up $1.3 million or 8%, from the third quarter of 2008. For the third quarter of 2009, average loans and securities represented 66% and 31%, respectively, of average earning assets compared to 59% and 41% in the third quarter of 2008. The tax equivalent net interest margin was relatively unchanged at 3.99% and 3.98% for the third quarters of 2009 and 2008, respectively. A decrease of $861 thousand, or 4%, in total interest income was surpassed by a decrease of $2.2 million, or 28%, in total interest expense.

Interest on investment securities and interest-earning deposits was $5.0 million for the third quarter of 2009, compared to $7.5 million for the third quarter of 2008. The average balance of investment securities was $585.8 million with an average tax equivalent yield of 3.79% for the third quarter of 2009, compared to an average balance of $721.4 million with an average yield of 4.66% for the third quarter of 2008. The decrease in yield is primarily due to lower market interest rates, coupled with less risk and shorter average maturities in the investment securities. In addition, selected higher yielding securities were sold for gains during the three months ended September 30, 2009. The sale of these securities, coupled with principal payments, maturities and calls on investment securities has contributed to lower interest income as the proceeds from these transactions were reinvested at lower yields.

Interest on loans was $18.7 million for third quarter of 2009, compared to $17.0 million for the third quarter of 2008. The average balance of loans was $1.236 billion with an average yield of 6.01% for the third quarter of 2009 compared to an average balance of $1.039 billion with an average yield of 6.52% for the third quarter of 2008. Average commercial loans in the third quarter of 2009 increased $83.6 million, as compared to the third quarter of 2008 primarily due to continued strong growth in our commercial loan portfolio. The average balance of consumer indirect loans, comprised almost entirely of automobile loans, increased $133.5 million for the third quarter of 2009 over the corresponding quarter last year. This 67% increase in volume was primarily responsible for the $2.3 million increase in interest income on consumer indirect loans when comparing the third quarter of 2009 to that of 2008.

Interest on deposits was $4.8 million for the third quarter of 2009, compared to $6.5 million for the third quarter of 2008. The average balance of interest-bearing deposits was $1.430 billion with an average cost of 1.34% for the third quarter of 2009 compared to an average balance of $1.300 billion with an average cost of 2.00% for the third quarter of 2008. The average balance of noninterest-bearing deposits increased by 2% to $298.7 million during the third quarter of this year compared to the same quarter last year. The increase in the balance of total average deposits is due to a 7% increase in public and 9% increase in nonpublic deposits, while the decrease in average cost is due primarily to the beneficial repricing of certificates of deposits, and to a lesser extent savings and money market accounts, at lower interest rates. The declines in interest and average cost on total borrowed funds from last year s third quarter to this year s third quarter are due to a combination of lower market interest rates and average borrowings outstanding.

For the nine months ended September 30, 2009, net interest income was $53.1 million, an increase of $5.0 million or 10% over the same period in 2008. For the nine months ended September 30, 2009, average loans and securities represented 65% and 32%, respectively, of average earning assets compared to 56% and 42% for the same period in 2008. The nine month period ended September 30, 2009 reflected an increase of 15 basis points in net interest margin to 4.03% compared to the same period last year. The improved net interest margin resulted principally from lower funding costs and the benefits associated with a higher percentage of earning assets being deployed in higher yielding loan assets. A decrease of $4.3 million, or 6%, in total interest income was surpassed by a decrease of $9.3 million, or 35%, in total interest expense.

Interest on investment securities and interest-earning deposits was $16.5 million for the nine months ended September 30, 2009, compared to $24.2 million for the same period in 2008. The average balance of investment securities was $593.5 million with an average tax equivalent yield of 4.17% for the nine months ended September 30, 2009 compared to an average balance of was $739.9 million with an average yield of 4.87% for the same period in 2008. The decrease in yield is primarily due to lower market interest rates as proceeds from securities transactions, including the sale of selected higher yielding securities during the nine months ended September 30, 2009, were reinvested at lower rates. A change in the mix of the investment portfolio that included a decline in the level of tax-exempt securities and resulting interest income also contributed to the decrease in yield.

Table of Contents

Interest on loans was $53.5 million for first nine months of 2009, compared to $50.1 million for the first nine months of 2008. The average balance of loans was $1.190 billion with an average yield of 6.01% for the nine month period ended September 30, 2009 compared to an average balance of $998.0 million with an average yield of 6.70% for the same period in 2008. Average commercial loans increased by $64.0 million during the first nine months of 2009, as compared to same period in 2008 primarily due to strong growth in our commercial loan portfolio. The average balance of consumer indirect loans, comprised almost entirely of automobile loans, increased $136.0 million for the first nine months of 2009 over the corresponding period last year. This 82% increase in volume was primarily responsible for the $6.9 million increase in interest income on consumer indirect loans when comparing the nine months ended September 30, 2009 to the same period in 2008.

Interest on deposits was $14.7 million for the nine month period ended September 30, 2009, compared to $23.2 million for the same period in 2008. The average balance of interest-bearing deposits was $1.422 billion with an average cost of 1.38% for the nine month period ended September 30, 2009 compared to an average balance of $1.326 billion with an average cost of 2.34% for the same period in 2008. The average balance of noninterest-bearing deposits increased by 4% to $288.9 million during the first nine months of this year compared to the same period last year. The increase in the balance of total average deposits is due to a 4% increase in public and a 10% increase in nonpublic deposits, while the decrease in average cost is due primarily to the beneficial repricing of certificates of deposits, and to a lesser extent savings and money market accounts, at lower interest rates.

The following table provides a reconciliation between tax equivalent net interest income as presented in the average balance sheets above and net interest income in the consolidated financial statements filed herewith in Part I, Item 1, Financial Statements (in thousands).

	Three months ended September 30,		Nine months ended September 30,	
	2009	**2008**	**2009**	**2008**
Net interest income (tax equivalent)	$ 18,669	$ 17,686	$ 55,202	$ 51,448
Less: tax-exempt tax equivalent adjustment	591	940	2,152	3,430
Net interest income	$ 18,078	$ 16,746	$ 53,050	$ 48,018

Table of Contents

The following tables sets forth certain information relating to the consolidated balance sheets and reflects the average yields earned on interest-earning assets, as well as the average rates paid on interest-bearing liabilities for the periods indicated (in thousands).

	Three months ended September 30,					
	2009			2008		
	Average Balance	Interest	Average Rate	Average Balance	Interest	Average Rate
Interest-earning assets:						
Federal funds sold and interest-earning deposits	$ 39,945	$ 20	0.20%	$ 12,897	$ 68	2.10%
Investment securities [1]:						
Taxable	450,266	3,819	3.39	493,438	5,577	4.52
Tax-exempt [2]	135,564	1,737	5.13	227,981	2,835	4.96
Total investment securities	585,830	5,556	3.79	721,419	8,412	4.66
Loans held for sale	1,490	21	5.76	799	14	6.81
Loans:						
Commercial	194,803	2,299	4.68	147,350	2,244	6.06
Commercial real estate	288,658	4,515	6.20	249,769	4,234	6.74
Agricultural	43,250	597	5.48	45,965	732	6.34
Residential real estate	148,325	2,266	6.11	173,175	2,669	6.17
Consumer indirect	334,123	5,938	7.05	200,586	3,626	7.19
Consumer direct and home equity	226,355	3,076	5.39	222,241	3,499	6.26
Total loans	1,235,514	18,691	6.01	1,039,086		

Patent applications relating to engineered hybrid organs	U.S.	2034
Patent applications relating to infrared-based methods for evaluating tissue health including methods for evaluating burns	U.S.	2033
Patent applications relating to methods and compositions for esophageal repair	U.S.	2036

We also rely on unpatented proprietary technologies in the development and commercialization of our products. We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as those of our advisors, consultants and other contractors. To help protect our proprietary know-how that may not be patentable, and our inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require employees, consultants and advisors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions that arise from their activities for us. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us,

or use without proper authorization, any third party’s proprietary technology.

Exclusive License Agreement and Sponsored Research Agreement - InBreath Bioreactor

We had an exclusive license agreement with Sara Mantero and Maria Adelaide Asnaghi to intellectual property rights relating to our InBreath Bioreactor. Under this agreement, we had worldwide rights to intellectual property (including patents, data, and know-how) relating to the hollow organ bioreactor, related techniques, and improvements thereof. We had exclusive worldwide rights to make, use and sell the hollow organ bioreactor, and the right to grant sublicenses and distribution rights. Under this agreement, we were obligated to pay the licensor royalties at various percentage rates in the low to mid-single digits pertaining to any applicable bioreactors we sell. This agreement terminated on August 6, 2016.

We have entered into a sponsored research agreement with Sara Mantero, Maria Adelaide Asnaghi, and the Department of Bioengineering of the Politecnico Di Milano, or PDM. Under the terms of this agreement, PDM is required to use its facilities and best efforts to conduct a research program relating to the development of bioreactors, clinical applications, and automated seeding processes. We are required to provide engineering support to PDM with respect to bioreactor designs. Intellectual property developed by PDM or its employees, including Dr. Mantero or Ms. Asnaghi, under this sponsored research agreement will be owned by Dr. Mantero or Ms. Asnaghi and covered by our exclusive license agreement described above. In addition, we have an option to an exclusive license for intellectual property relating to new technology that may not be covered by the exclusive license agreement. We will own any inventions and discoveries that we solely develop in connection with the research program and any inventions and discoveries that are jointly developed in connection with the research program will be owned jointly by the parties. The sponsored research agreement will continue until terminated by a party thereto upon 90 days prior written notice.

Sublicense Agreement with Harvard Bioscience

We entered into a sublicense agreement with Harvard Bioscience pursuant to which Harvard Bioscience granted us a perpetual, worldwide, royalty-free, exclusive, except as to Harvard Bioscience and its subsidiaries, license to use the mark “Harvard Apparatus” in the name Harvard Apparatus Regenerative Technology. The mark “Harvard Apparatus” is used under a license agreement between Harvard Bioscience and Harvard University, and we have agreed to be bound by such license agreement in accordance with our sublicense agreement. On March 31, 2016, we changed our name from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc. We currently have no affiliation with Harvard University.

Separation Agreements with Harvard Bioscience

On November 1, 2013, to effect the Separation, Harvard Bioscience distributed all of the shares of our common stock to the Harvard Bioscience stockholders (the "Distribution"). Prior to the Distribution Harvard Bioscience contributed the assets of its regenerative medicine business, and approximately $15 million in cash, to our company to fund our operations following the Distribution.

In connection with the Separation and immediately prior to the Distribution, we entered into a Separation and Distribution Agreement, Intellectual Property Matters Agreement, Product Distribution Agreement, Tax Sharing Agreement, Transition Services Agreement, and Sublicense Agreement with Harvard Bioscience to effect the Separation and Distribution and provide a framework for our relationship with Harvard Bioscience after the Separation. These agreements govern the current relationships among us and Harvard Bioscience and provided for the allocation among us and Harvard Bioscience of Harvard Bioscience's assets, liabilities and obligations (including employee benefits and tax-related assets and liabilities) attributable to periods prior to the Separation.

Government Regulation

Any product that we may develop based on our Cellframe technology, and any other clinical products that we may develop, will be subject to considerable regulation by governments. We were in the past informed by the FDA that our previous-generation tracheal product candidate would be regulated under the Biologics License Application, or BLA, pathway in the U.S. and we were informed by the European Medicines Agency (EMA) that the previous generation tracheal product would be regulated under the Advanced Therapy Medicinal Products, or ATMP, pathway in the EU. On October 18, 2016, we also received written confirmation from FDA's Center for Biologics Evaluation and Research, or CBER, that FDA intends to regulate our Cellspan esophageal implant as a combination product under the primary jurisdiction of 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 our product based on CBER's determination of need for such assistance. Although our Cellframe technology differs in design and performance from the first generation product candidate, we expect that Cellframe-based products will be regulated by the FDA and EMA under the same pathways as the first generation tracheal product candidate. This expectation is based on the fact that the Cellframe technology is centered on the delivery of the patient's own cells seeded on an implanted synthetic scaffold in order to restore organ function and our belief that the cells provide the primary mode of action. Of course, it is possible that some of our current and future products may use alternative regulatory pathways.

Combination Product/Biologic

Government Regulation Combination Products/Biologics

We believe that products derived from our Cellframe technology may be defined as combination products consisting of two or more regulated components, a biologic and a medical device. In the U.S., a combination product usually is assigned by the FDA to one of the agency's centers, such as the Center for Biologics Evaluation and Research, or CBER, or the Center for Devices and Radiological Health, or CDRH, with the chosen center to take the lead in pre-marketing review and approval of the combination product. Other FDA centers also may review the product in regard to matters that are within their expertise. The FDA selects the lead center based on an assessment of the combination product's "primary mode of action." Some products also may require approval or clearance from more than one FDA center.

To determine which FDA center or centers will review a combination product submission, companies may submit a Request for Designation to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation. We believe that

regenerative medicine products containing cells will be reviewed by CBER, possibly with CBER's consultation with CDRH.

Domestic Regulation of Our Products and Business

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, import and marketing of our products are subject to extensive regulation by governmental authorities in the U.S. and in other countries. In the U.S., the FDA, under the Public Health Service Act, the Federal Food, Drug and Cosmetic Act, and its implementing regulations, regulates biologics and medical device products.

The labeling, advertising, promotion, marketing and distribution of biopharmaceuticals, or biologics and medical devices also must be in compliance with the FDA and U.S. Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecution. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. Further, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice.

The FDA has broad post-market and regulatory enforcement powers. Manufacturers of biologics and medical devices are subject to unannounced inspections by the FDA to determine compliance with applicable regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by manufacturers or their suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities. Potential FDA enforcement actions include:

- 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;
- operating restrictions;
- refusal to grant export approval for our products; or
- criminal prosecution.

In addition, other government authorities influence the success of our business, including the availability of adequate reimbursement from third party payers, including government programs such as Medicare and Medicaid. Medicare and Medicaid reimbursement policies can also influence corresponding policies of private insurers and managed care providers, which can further affect our business.

Biologics Regulation

Biological products must satisfy the requirements of the Public Health Services Act and the Food, Drug and Cosmetics Act and their implementing regulations. In order for a biologic product to be legally marketed in the U.S., the product must have a BLA approved by the FDA.

The BLA Approval Process

The steps for obtaining FDA approval of a BLA to market a biopharmaceutical, or biologic product in the U.S. include:

- completion of pre-clinical laboratory tests, animal studies and formulation studies under the FDA's GLP regulations;

- submission to the FDA of an IND application, for human clinical testing, which must become effective before human clinical trials may begin and which must include Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;

- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices, or GCP, to establish the safety and efficacy of the product for each indication;

- submission to the FDA of a BLA, which contains detailed information about the chemistry, manufacturing and controls for the product, extensive pre-clinical information, reports of the outcomes of the clinical trials, and proposed labeling and packaging for the product;

- the FDA's acceptance of the BLA for filing;

- satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review or by the advisory committee, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality and purity; and

- FDA approval of the BLA.

Pre-clinical studies include laboratory evaluations of product toxicity, as well as animal studies.

An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to GCP. Adverse events must be reported and investigated in a timely manner. To conduct a clinical trial, a company is also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. The sponsor, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to trial subjects outweigh the anticipated benefits. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each site at which the trial is conducted must approve the protocol and any amendments. If foreign clinical trials are intended to be considered by the FDA for approval of a product in the U.S. then those foreign clinical trials performed under an IND must meet the same requirements that apply to U.S. studies. The FDA will accept a foreign clinical trial not conducted under an IND only if the trial is well-designed, well-conducted, performed by qualified investigators in accordance with international principles for GCP, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. The FDA, however, has substantial discretion in deciding whether to accept data from foreign non-IND clinical trials.

Clinical trials involving biopharmaceutical products are typically conducted in three sequential phases. The phases may overlap or be combined. A fourth, or post-approval, phase may include additional clinical trials. These phases are described generally below. We note, however, that the exact number of study subjects required for each specific intended use, and our intent to combine or "telescope" various study phases together, are both areas where we will actively seek FDA feedback to streamline the clinical evaluation process. Briefly, the phases of clinical development generally include the following:

- Phase I. Phase I clinical trials involve the initial introduction of the product into human subjects to determine the adverse effects associated with increasing doses. Such Phase I studies frequently are highly abbreviated or combined with Phase II studies (as outlined below), when the product involves the patient's own cells.

- Phase II. Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the product for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Products that contain the patient's own cells frequently are studied for initial safety and effectiveness determinations in combined or "telescoped" Phase I/II clinical studies.

- Phase III. If the product is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) trials, the clinical trial program will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites. As noted, the exact number of subjects needed, the duration of clinical follow-up, and the endpoints by which safety and efficacy are demonstrated are based on the condition being treated.

- Post-Approval (Phase IV). Post-approval clinical trials are may be required of or agreed to by a sponsor as a condition of, or subsequent to marketing approval. Further, if the FDA becomes aware of new safety information about an approved product, it is authorized to require post approval trials of the biological product. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase III/IV post approval clinical trials. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

Clinical testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA or the sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional pre-clinical studies or clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, IRBs have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

Certain information about clinical trials, including a description of the trial, participation criteria, location of trial sites, and contact information, is required to be sent to the National Institute of Health, or NIH for inclusion in a publicly-assessable database. Sponsors also are subject to certain state laws imposing requirements to make publicly available certain information on clinical trial results. In addition, the FDA Amendments Act of 2007 directs the FDA to issue regulations that will require sponsors to submit to the NIH the results of certain controlled clinical trials, other than Phase I studies.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical trials, together with other detailed information, including information on the chemistry, manufacture and composition of the product, are submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. In most cases, the BLA must be accompanied by a substantial user fee. The FDA will initially review the BLA for completeness before it accepts the BLA for filing. There can be no assurance that the submission will be accepted for filing or that the FDA may not issue a refusal-to-file, or RTF. If a RTF is issued, there is opportunity for dialogue between the sponsor and the FDA in an effort to resolve all concerns. If the BLA submission is accepted for filing, the FDA will begin an in-depth review of the BLA to determine, among other

things, whether a product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity.

Companies also may seek Fast Track or Breakthrough Therapy designation for their products. Fast Track or Breakthrough Therapy products are those that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs for such a condition. If awarded, the Fast Track or Breakthrough Therapy designation applies to the product only for the indication for which the designation was received.

If the FDA determines after review of preliminary clinical data submitted by the sponsor that a Fast Track or Breakthrough Therapy product may be effective, it may begin review of portions of a BLA before the sponsor submits the complete BLA (rolling review), thereby accelerating the date on which review of a portion of the BLA can begin. There can be no assurance that any of our products will be granted Fast Track or Breakthrough Therapy designation. And even if they are designated as Fast Track or Breakthrough Therapy products, we cannot assure you that our products will be reviewed or approved more expeditiously for their Fast Track or Breakthrough Therapy indications than would otherwise have been the case or will be approved promptly, or at all. Furthermore, the FDA can revoke Fast Track or Breakthrough Therapy designation at any time.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive Accelerated Approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a product receiving Accelerated Approval perform adequate and well-controlled post-approval clinical trials to verify and further define the product's clinical benefit and safety profile. There can be no assurance that any of our products will receive Accelerated Approval. Even if Accelerated Approval is granted, the FDA may withdraw such approval if the sponsor fails to conduct the required post-approval clinical trials, or if the post-approval clinical trials fail to confirm the early benefits seen during the accelerated approval process.

Fast Track or Breakthrough Therapy designation and Accelerated Approval should be distinguished from Priority Review designation although products awarded Fast Track or Breakthrough Therapy designation may also be eligible for Priority Review designation. Products regulated by the CBER may receive Priority Review designation if they provide significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. The agency has agreed to the performance goal of reviewing products awarded Priority Review designation within six months, whereas products under standard review receive a ten-month target. The review process, however, can be significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. Priority Review designation is requested at the time the BLA is submitted, and the FDA makes a decision as part of the agency's review of the application for filing. We intend to seek Priority Review designation for the Cellspan esophageal implant as a biologic through the BLA process. We cannot guarantee that the FDA will grant the designation and cannot predict if awarded, what impact, if any, it will have on the review time for approval of our product.

If granted, Fast Track or Breakthrough Therapy designation, Accelerated Approval and Priority Review designation may expedite the approval process, but they do not change the standards for approval.

Before approving a BLA, the FDA will generally inspect the facility or the facilities at which the finished product and its components are manufactured to ensure compliance with cGMP.

Separate approval is required for each proposed indication. If we want to expand the use of an approved product, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions, such as post-approval studies, on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, companies are required to comply with a number of post-approval requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. For example, as a condition of approval of a BLA, the FDA may require post-approval testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records, to report certain adverse reactions and production deviations and problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Specifically, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death. In addition, the FDA could suspend the marketing of or withdraw a previously approved product from the market upon receipt of newly discovered information regarding the product's safety or effectiveness.

Orphan Drug Designations

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs and biologics for rare diseases and conditions affecting fewer than 200,000 persons in the U.S. at the time of application for orphan drug designation, or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a new drug application, or NDA, or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. In September 2014 the FDA granted orphan designation to our HART-Trachea product in the U.S. In November 2016, we were granted Orphan Drug Designation for our Cellspan esophageal implant by the FDA to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury or congenital abnormalities. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. The first developer to receive FDA marketing approval for an orphan biologic is entitled to a seven year exclusive marketing period in the U.S. for that product as well as a waiver of the BLA user fee. The exclusivity prevents FDA approval of another application for the same product for the same indication for a period of seven years, except in limited circumstances where there is a change in formulation in the original product and the second product has been proven to be clinically superior to the first.

International

We plan to seek required regulatory approvals and comply with extensive regulations governing product safety, quality, manufacturing and reimbursement processes in order to market our products in other major foreign markets. The regulation of our products in the EU and in other foreign markets varies significantly from one jurisdiction to another. The classification of the particular products and related approval or CE marking procedures can involve additional product testing and additional administrative review periods. The time required to obtain these foreign approvals or to CE mark our products may be longer or shorter than that required in the U.S., and requirements for approval may differ from the FDA requirements. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

The marketing authorization of products containing viable human tissues or cells in the EU is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC lays down specific rules concerning the authorization, supervision and pharmacovigilance of medicinal products, cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the European Medicines Agency which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the European Medicines Agency. Regulation 1394/2007/EC also applies to combination products which consist of medical devices and advanced therapy medicinal products. In light of Regulation 1394/2007/EC, a medical device which forms part of a combined advanced therapy medicinal product must meet the Essential Requirements laid down in Annex I to Directive 93/42/EEC. The manufacturer of the combination product must include evidence of such compliance in its marketing authorization application. The application for a marketing authorization for a combined advanced therapy medicinal product must also, where available, include the results of the assessment of the medical device part by a notified body in accordance with Directive 93/42/EEC.

Legislation similar to the Orphan Drug Act has been enacted in other jurisdictions, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The marketing exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Employees

At December 31, 2016, we had 28 employees working in our business, of whom 27 were full-time and one was part-time. At that date, all of our employees were based in the U.S. None of our employees are unionized. In general, we consider our relations with our employees to be good.

Competition

We are not aware of any companies whose products are directly competitive with our cell-seeded biocompatible synthetic scaffold system. However, in our key markets we may in the future compete with multiple pharmaceutical, biotechnology, and medical device, including, among others, Aldagen, Asterias Biotherapeutics, Athersys, BioTime, Caladrius Biosciences, Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, InVivo Therapeutics, Mesoblast, Miramatrix Medical, Nanofiber Solutions, Neuralstem, Organovo, Osiris Therapeutics, Pluristem, Smiths Medical, Tissue Genesis, Inc., Tissue Growth Technologies, United Therapeutics, Vericel Corporation and W.L. Gore and Associates. In addition, there are many academic and clinical centers that are developing regenerative technologies that may one day become competitors with us.

Many of our potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot forecast if or when these or other companies may develop competitive products.

We expect that other products will compete with products and potential products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include, in certain instances, obtaining marketing exclusivity under the Orphan Drug Act, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage.

Properties

On November 1, 2013 we entered into a sublease of approximately 17,000 square feet of mixed use space of the facility located at 84 October Hill Road, Suite 11, Holliston, Massachusetts from Harvard Bioscience, which is our corporate headquarters. Our principal facilities incorporate manufacturing, laboratory, development, sales and marketing, and administration functions. We believe our current facilities are adequate for our needs for the foreseeable future.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings arising in the ordinary course of business. We are not currently a party to any such significant claims or proceedings.

MANAGEMENT

The following table shows information about our executive officers and directors as of February 1, 2017.

Name	Age	Position(s)
Executive Officers		
James McGorry	60	President and Chief Executive Officer and Director
Thomas McNaughton	56	Chief Financial Officer
Saverio LaFrancesca, M.D.	55	Executive Vice President and Chief Medical Officer
Directors		
John F. Kennedy[(1)(2)]	68	Chairman
John J. Canepa[(1)(3)]	61	Director
Blaine H. McKee, Ph.D.[(1)]	52	Director
Thomas H. Robinson[(2)(3)]	58	Director

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Governance Committee

Executive Officers

James McGorry - President and Chief Executive Officer and Director

Mr. McGorry has served as our President and Chief Executive Officer (CEO) since July 6, 2015. He has served as a Member of our Board of Directors since February 2013. Mr. McGorry has more than 30 years of experience as a life science business leader in biologics, personalized medicine and medical devices, including multiple product launches. Prior to becoming President and CEO at Biostage, Mr. McGorry most recently served as Executive Vice President and General Manager, Translational Oncology Solutions for Champions Oncology and previously was Executive Vice President of Commercial Operations at Accellent. During a 12-year tenure at Genzyme, he held leadership positions across several therapeutic areas, including Bio Surgery, Cardiac Surgery, Oncology and Transplant. Mr. McGorry also was President of Clineffect Systems, an electronic medical records company. He began his life sciences career with Baxter Healthcare Corporation, where he spent 11 years in positions of increasing responsibility. Mr. McGorry also served as an officer in the United States Army for six years, including commanding a special operations Green Beret

SCUBA detachment. Mr. McGorry has an MBA with a concentration in healthcare from Duke University, Fuqua School of Business, and a B.S. in engineering from the United States Military Academy at West Point where he was the president of his class. We believe Mr. McGorry's qualifications to sit on our Board of Directors include his extensive executive leadership positions at several biotechnology and healthcare companies over the past 25 years.

Thomas McNaughton - Chief Financial Officer

Mr. McNaughton has served as our Chief Financial Officer since May 3, 2012. Mr. McNaughton joined Harvard Bioscience as its Chief Financial Officer in November 2008, and served in that role until the spin-off of our company from Harvard Bioscience on November 1, 2013. During 2008 and prior to joining Harvard Bioscience, Mr. McNaughton was a consultant providing services primarily to an angel-investing group and a silicon manufacturing start-up. From 2005 to 2007, he served as Vice President of Finance and Chief Financial Officer for Tivoli Audio, LLC, a venture capital-backed global manufacturer of premium audio systems. From 1990 to 2005, Mr. McNaughton served in various managerial positions in the areas of financial reporting, treasury, investor relations, and acquisitions within Cabot Corporation, a global manufacturer of fine particulate products, and served from 2002 to 2005 as Finance Director, Chief Financial Officer of Cabot Supermetals, a $350 million Cabot division that provided high purity tantalum and niobium products to the electronics and semiconductor industries. Mr. McNaughton practiced from 1982 to 1990 as a Certified Public Accountant in the audit services group of Deloitte & Touche, LLP. He holds a B.S. in accounting and finance with distinction from Babson College.

Saverio LaFrancesca, M.D. - Chief Medical Officer

Dr. LaFrancesca has served as our Chief Medical Officer since April 14, 2014. Dr. LaFrancesca has a unique combination of experience that features more than 25 years of academic clinical surgical practice and innovative research, with a foundation in the cardiovascular, thoracic transplantation, cardiac assist device and regenerative medicine fields. He joined our company from the Department of Cardiovascular Surgery and Transplantation at the DeBakey Heart and Vascular Center at the Houston Methodist Hospital, where he developed the current surgical and perfusion techniques for thoracic organ procurement and preservation and where he was also the Director of the Exvivo lung perfusion laboratory. Previously Dr. LaFrancesca was an attending surgeon at the Department of Cardiopulmonary Transplantation at the Texas Heart Institute in Houston, Texas. He also previously held an appointment as Associate Professor of Surgery at the "Sapienza" University of Rome in Rome, Italy. Dr. LaFrancesca received his M.D. in medicine and surgery in 1985 at the University of Palermo. He did his Residency in Cardiovascular Surgery in the Department of Cardiovascular Surgery at the "Sapienza" University of Rome. He then completed his postdoctoral training with fellowships at the Texas Heart Institute under the supervision of pioneer heart surgeon Denton Cooley. He was also a Clinical/ Research fellow at McGill University in Montréal, Québec, Canada and at the Baylor College of Medicine in Houston. He holds UNOS certifications as heart transplant surgeon and lung transplant surgeon. He is also certified as surgeon for the use of the HeartMate and the Jarvik 2000 left ventricular assist devices.

Directors

Class I Director — Term expires 2017

James J. McGorry — President, Chief Executive Officer and Director

Mr. McGorry's biographical information is provided under the caption "Executive Officers" above.

Class II Directors — Term expires 2018

Thomas H. Robinson — Director

Mr. Robinson has served as a member of our Board of Directors since December 3, 2012. Since September 2011, Mr. Robinson has served as a partner with RobinsonButler, an executive search firm. In 2010, Mr. Robinson served as managing director at Russell Reynolds Associates. From 1998 to 2010, Mr. Robinson served as managing partner of the North American medical technology practice, which includes the medical device, hospital supply/distribution and medical software areas, of Spencer Stuart, Inc., a global executive search firm. From 2002 to 2010, Mr. Robinson was a member of Spencer Stuart's board services practice, which assists corporations to identify and recruit outside directors. From 1998 to 2000, Mr. Robinson headed Spencer Stuart's North American biotechnology specialty practice. From 1993 to 1997, Mr. Robinson served as president of the emerging markets business at Boston Scientific Corporation, a global medical devices manufacturer. From 1991 to 1993, Mr. Robinson also served as president and chief operating officer of Brunswick Biomedical, a cardiology medical device company. Mr. Robinson currently serves on the Board of Directors of Cynosure, Inc. He graduated from Brown University with a B.A. degree in mathematics and economics and holds an M.B.A. degree from Harvard Business School. We believe Mr. Robinson's qualifications to sit on our Board of Directors include his executive leadership experience in, and knowledge of, the medical device and regenerative medicine industries, and his significant expertise in the areas of public company corporate governance and operations.

John J. Canepa — Director

Mr. Canepa has served as a member of our Board of Directors since August 14, 2013. Mr. Canepa is the Chief Operating Officer and Chief Financial Officer of Asterand Bioscience, Inc. (formerly known as Stemgent, Inc.) a leading global provider of high quality, well characterized human tissue and human tissue-based research solutions to drug discovery scientists. From August 2005, Mr. Canepa served as the President and Chief Executive Officer of PathoGenetix, Inc., a venture capital backed life science company focused on commercializing proprietary DNA optical mapping technology for pathogen detection and strain identification. From 2001 to 2003, Mr. Canepa served as the Chief Financial Officer at Winphoria Networks. From 1978 to 2001, Mr. Canepa was a Senior Audit Partner in Arthur Andersen's Boston Office Technology Practice with worldwide responsibility for Life Sciences Practice. Currently, Mr. Canepa is Co-Chairman of the Board of Trustees at Mt. Auburn Hospital and a member of the Board of Trustees and the Audit Committee at CareGroup. He graduated from Denison University with a B.A. degree and holders a Masters Degree in Finance from Michigan State University. We believe Mr. Canepa's qualifications to sit on our Board of Directors include his executive leadership experience, his significant operating, accounting and financial management expertise, including with respect to the life sciences, medical technology and biotechnology industries.

Class III Directors — Term Expiring in 2019

John F. Kennedy — Chairman

Mr. Kennedy has served as a member of our Board of Directors since December 3, 2012. From June 2006 until his retirement in October 2008, Mr. Kennedy served as President and Chief Financial Officer of Nova Ventures Corporation, the management company providing executive management services to the operating companies of Nova Holdings LLC, Nova Analytics Corporation and Nova Technologies Corporation. From 2002 to 2006, Mr. Kennedy served as the President and Chief Financial Officer of Nova Analytics Corporation, a worldwide supplier and integrator of analytical instruments. From 1999 to 2002, Mr. Kennedy served as the Senior Vice President, Finance, Chief Financial Officer and Treasurer of RSA Security Inc., an e-business security company. Prior to joining RSA Security, Mr. Kennedy was Chief Financial Officer of Decalog, NV, a developer of enterprise investment management software, from 1998 to 1999. From 1993 to 1998, Mr. Kennedy served as Vice President of Finance, Chief Financial Officer and Treasurer of Natural MicroSystems Corporation, a telecommunications company. Mr. Kennedy, a former CPA, also practiced as a public accountant at KPMG for six years. Mr. Kennedy currently serves on the Boards of Directors of Harvard Bioscience and Datacom Systems, Inc. Mr. Kennedy holds a B.S. in Mathematics from Lowell Technological Institute, now the University of Massachusetts Lowell, and an M.S.B.A. in Accounting from the University of Massachusetts Amherst. We believe Mr. Kennedy's qualifications to sit on our Board of Directors include his executive leadership experience, his significant operating, accounting and financial management expertise and the knowledge and understanding of our Company and industry that he has acquired over 13 years of service on the Board of Directors of Harvard Bioscience.

Blaine H. McKee, Ph.D. — Director

Dr. McKee has served as a member of our Board of Directors since March 10, 2016. Dr. McKee is the Senior Vice President, Head of Transactions at Shire PLC, a position he has held since July 2014. Prior to joining Shire, Dr. McKee served as Executive Vice President and Chief Business Officer of 480 Biomedical from 2011 to 2014, following 15 years at Genzyme Corporation from 1996 to 2011, where he most recently served as Senior Vice President of Strategic Development, leading global business development for the Organ Transplant, Oncology and Multiple Sclerosis business units. Dr. McKee currently serves on the Boards of ArmaGen, Inc., OrbiMed Israel and the New York Pharma Forum. Dr. McKee holds a B.S. in Chemistry with distinction from Colorado State University, a M.B.A. in Finance from MIT Sloan School of Management and a Ph.D. from Massachusetts Institute of Technology. We believe Dr. McKee's qualifications to sit on our Board of Directors include his extensive background in science, finance and strategy functions, including with respect to the life sciences industry.

Information Regarding the Board of Directors and its Committees

Independence

The Board of Directors has determined that all of our Directors are "independent" as such term is currently defined by applicable NASDAQ rules, except for James J. McGorry, who is our President and Chief Executive Officer. Our director John F. Kennedy is currently a director of Harvard Bioscience, Inc. ("Harvard Bioscience"), our former parent company.

Board Structure

The non-employee Directors meet regularly in executive sessions outside the presence of management. Following the resignation of David Green, our former Chairman, President and Chief Executive Officer, the Board of Directors appointed Mr. Kennedy as the Chairman of the Board in April 2015. Among other things, the Chairman provides feedback to the Chief Executive Officer on executive sessions and facilitates discussion among the independent directors outside of meetings of the Board of Directors. The Chief Executive Officer is responsible for the day-to-day management of our Company and the development and implementation of our Company's strategy. Our Board of Directors currently believes that separating the roles of Chief Executive Officer and Chairman contributes to an efficient and effective board. Our Board of Directors does not have a current requirement that the roles of Chief Executive Officer and Chairman of the Board be either combined or separated, because the Board currently believes it is in the best interests of our Company to make this determination based on the position and direction of our Company and the constitution of the Board and management team. From time to time, the Board will evaluate whether the roles of Chief Executive Officer and Chairman of the Board should be combined or separated. The Board has determined that having separate roles of our Company's Chief Executive Officer and Chairman is in the best interest of our stockholders at this time.

The Board of Directors has established an Audit Committee (the "Audit Committee"), a Compensation Committee (the "Compensation Committee") and a Governance Committee (the "Governance Committee").

Audit Committee

The Audit Committee currently consists of Messrs. Kennedy, Canepa and McKee. Mr. Kennedy serves as the Chairman. Dr. McKee was appointed to the Audit Committee in March 2016, as successor to Mr. McGorry who no

longer could serve on the Audit Committee following his July 2015 appointment as our President and Chief Executive Officer. The Audit Committee is comprised entirely of independent Directors and it operates under a Board-approved charter that sets forth its duties and responsibilities.

Under its charter, the Audit Committee is responsible for, among other things:

- reviewing with the independent registered public accounting firm and management the adequacy and effectiveness of internal controls over financial reporting and related matters;
- reviewing and consulting with management and the independent registered public accounting firm on matters related to the annual audit, the annual and quarterly financial statements and related disclosures, earnings releases and related accounting principles, policies, practices and judgments;
- making a recommendation to the Board as to whether our audited financial statements should be included in our Annual Report on Form 10-K;
- appointing, retaining and terminating, and determining compensation of, the Company's independent auditors;
- assurance of the regular rotation of audit partners, including any lead and concurring partners, in accordance with applicable laws and regulations;
- preparation of the Audit Committee report required to be included in our annual proxy statement;
- reporting matters that arise relating to quality or integrity of our financial statements, legal compliance, performance of the independent auditors and other matters, to the Board and reviewing such matters with the Board; and
- the oversight of the Company's independent auditors and the evaluation of the independent auditors' qualifications, performance and independence, including performance of the lead audit partner, and reporting of such evaluation to the Board.

The Audit Committee is responsible for reviewing and discussing with management our policies with respect to risk assessment and risk management. The Board and the Audit Committee discuss matters relating to risks that arise or may arise.

The Audit Committee is also responsible for, and has established policies and procedures with respect to, the pre-approval of all services provided by the independent auditors. When assessing the independence of our auditors, the Audit Committee considers the independent registered public accounting firm's provision of non-audit services to the Company.

The Audit Committee has also established procedures for the receipt, retention and treatment, on a confidential basis, of complaints received by the Company. The Board of Directors and the Audit Committee adopted a Code of Business Conduct and Ethics, a current copy of which is available on the Corporate Governance page in the Investor section of our website at *www.biostage.com.*

With respect to the Company's independent registered public accounting firm, currently KPMG, in accordance with SEC rules and KPMG policies, audit partners are subject to rotation requirements to limit the number of consecutive years an individual partner may provide service to our Company. For lead and concurring audit partners, the maximum number of consecutive years of service in that capacity is five years. Our Audit Committee is involved in the selection of the lead audit partner. The process for selection of our lead audit partner pursuant to this rotation policy involves a meeting between the Chairman of the Audit Committee and the candidate for the role, as well as discussion by the full Audit Committee and with management.

The Board of Directors has determined that all members of the Audit Committee are "independent" as such term is currently defined by NASDAQ rules, meet the criteria for independence set forth under the rules of the Securities and Exchange Commission, and are able to read and understand fundamental financial statements. The Board of Directors has also determined that each of Messrs. Kennedy and Canepa qualifies as an "audit committee financial expert" under the rules of the Securities and Exchange Commission.

The Audit Committee Charter is available on the Corporate Governance page in the Investors section of our website at *www.biostage.com.* Please note that the information contained on the Company website is not incorporated by reference in, or considered to be a part of, this prospectus.

Compensation Committee

The Compensation Committee currently consists of Messrs. Kennedy and Robinson. Mr. Robinson serves as the Chairman. The Compensation Committee is comprised entirely of independent Directors and it operates under a Board-approved charter that sets forth its duties and responsibilities.

The Compensation Committee determines and oversees the execution of our compensation philosophy and oversees the administration of our executive compensation programs. Its responsibilities also include overseeing the Company's compensation and benefit plans and policies, retaining or terminating committee advisors, independence evaluation of compensation advisors, administering its stock plans (including reviewing and approving equity grants) and reviewing and approving annually all compensation decisions for the Company's executive officers, including the President and Chief Executive Officer and the Chief Financial Officer.

The Board of Directors has determined that all members of the Compensation Committee are "independent" as such term is currently defined by NASDAQ rules.

The Compensation Committee Charter is available on the Corporate Governance page in the Investors section of our website at *www.biostage.com*. Please note that the information contained on the website is not incorporated by reference in, or considered to be a part of, this prospectus.

Governance Committee

The current members of the Governance Committee are Messrs. Robinson and Canepa. Mr. Canepa replaced Mr. McGorry as Chairman of the Governance Committee in July 2015, in connection with Mr. McGorry's appointment as our President and Chief Executive Officer. The Governance Committee is comprised entirely of independent directors and it operates under a Board-approved charter that sets forth its duties and responsibilities.

Under the terms of its charter, the Governance Committee is responsible for identifying individuals qualified to become Board members, consistent with criteria recommended by the Governance Committee and approved by the Board of Directors, and recommending that the Board of Directors select the director nominees for election at each annual meeting of stockholders. Its responsibilities also include recommending to the Board of Directors the criteria for membership on Board Committees. The Governance Committee is also responsible for reviewing all stockholder nominations and proposals submitted to the Company, determining whether such nominations or proposals were timely submitted and assisting the Board of Directors with such corporate governance matters as the Board of Directors may request.

In identifying and evaluating nominees for the Board of Directors, the Governance Committee may solicit recommendations from any or all of the following sources: non-management Directors, including our Chairman, the Chief Executive Officer, other executive officers, third-party search firms or any other source it deems appropriate. In addition, the Governance Committee has established a policy that it will review and consider any Director candidates who have been recommended by securityholders in compliance with certain procedures established by the Governance Committee. The Governance Committee will review and evaluate the qualifications of any such proposed Director candidate and conduct inquiries it deems appropriate.

The Governance Committee will evaluate all such proposed Director candidates, including those recommended by securityholders in compliance with the procedures established by the Governance Committee, in the same manner, with no regard to the source of the initial recommendation of such proposed Director candidate. When considering a potential candidate for membership on the Board of Directors, the Governance Committee may consider, in addition to the minimum qualifications and other criteria for Board membership approved by the Board of Directors, all facts and circumstances that the Governance Committee deems appropriate or advisable, including, among other things, the skills of the proposed Director candidate, his or her availability, depth and breadth of business experience or other background characteristics, his or her independence and the needs of the Board of Directors. At a minimum, each nominee must have high personal and professional integrity, have demonstrated ability and judgment, and be effective, in conjunction with the other Directors and nominees, in collectively serving the long-term interests of the stockholders. In addition, the Governance Committee will recommend that the Board select persons for nomination to help ensure that a majority of the Board shall be "independent" in accordance with NASDAQ rules and each of its Audit, Compensation and Governance Committees shall be comprised entirely of independent directors; provided, however, in accordance with NASDAQ rules, under exceptional and limited circumstances, if a committee has at least three members, the Board may appoint one individual to such committee who does not satisfy the independence

standards. Although there is no specific policy regarding the consideration of diversity in identifying director nominees, the Governance Committee may consider whether the nominee, if elected, assists in achieving a mix of Board members that represents a diversity of background and experience. The Governance Committee also may consider whether the nominee has direct experience in the biotechnology, pharmaceutical and/or life sciences industries or in the markets in which the Company operates.

The Board of Directors has determined that all members of the Governance Committee are “independent” as such term is currently defined by NASDAQ rules.

The Governance Committee Charter is available on the Corporate Governance page in the Investor section of our website at *www.biostage.com*. Please note that the information contained on the website is not incorporated by reference in, or considered to be a part of, this prospectus.

The Board's Role in Risk Oversight

Risks to the Company are discussed by the Board of Directors during the year. Management is responsible for the day-to-day management of risks we face, while the Board, as a whole and through its Committees, oversees risk management. The Audit Committee is responsible for reviewing and discussing with management our policies with respect to risk assessment and risk management. The Board of Directors and the Audit Committee review and discuss, including with management, risks that arise or may arise. For example, the Audit Committee discusses financial risk, including with respect to financial reporting and internal controls, with management and our independent registered public accounting firm and the steps management has taken to minimize those risks. Our Board of Directors also administers its risk oversight function through the required approval by the Board (or a Committee of the Board) of significant transactions and other material decisions.

Code of Business Conduct and Ethics

The Board of Directors has adopted a Code of Business Conduct and Ethics, which applies to all Directors, officers and employees of our Company and its subsidiaries including, without limitation, the Chairman of the Board, the President and Chief Executive Officer, and the Chief Financial Officer. The Code of Business Conduct and Ethics is available on the Corporate Governance page in the Investor section of our website at *www.biostage.com*. We intend to post any amendments to or waivers from this Code of Business Conduct and Ethics at this location on its website. Please note, however, that the information contained on the website is not incorporated by reference in, or considered a part of, this prospectus.

EXECUTIVE COMPENSATION

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act of 2012. As a result, we have elected to comply with the reduced disclosure requirements applicable to emerging growth companies in accordance with SEC rules. We have only three executive officers. James McGorry, our President and Chief Executive Officer, Thomas McNaughton, our Chief Financial Officer and Saverio LaFrancesca, M.D., our Chief Medical Officer, are named executive officers.

Summary Compensation Table

The table below summarizes the total compensation paid or earned by each of the named executive officers for services rendered in all capacities during the fiscal years ended December 31, 2015 and December 31, 2016, excluding the compensation Mr. McGorry received in 2015 as an independent director.

Name and Principal Position	Year	Salary	**Option Awards[1]**	All Other Compensation		Total
James McGorry	2016	$375,000	$ 168,720	$ 19,208	(2)	$562,928
President and Chief Executive Officer	2015	$173,077	$ 615,204	$ 4,327	(3)	$792,608
Thomas McNaughton	2016	$309,000	$ 84,360	$ 15,483	(4)	$408,843
Chief Financial Officer	2015	$309,000	$ 201,790	$ 15,450	(5)	$526,240
Saverio LaFrancesca, M.D.	2016	$400,000	$ 84,360	$ —		$484,360
Chief Medical Officer	2015	$400,000	$ 489,292	$ —		$889,292

(1) Based on the aggregate grant date fair value computed in accordance with the provisions of FASB ASC 718, "Compensation — Stock Compensation", excluding the impact of estimated forfeitures. Assumptions used in the calculation of this amount are set forth under 2013 Plan Valuation and Expense Information under Stock-Based-Payment Accounting in Note 13 to our audited financial statements for the fiscal year ended December 31, 2015, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2016.

(2) Amount represents $17,307 for matching contributions made by the Company to Mr. McGorry's tax-qualified 401(k) Savings Plan account and premiums in the amount of $1,901 for a life insurance policy.

(3) Amount represents $4,327 for matching contributions made by the Company to Mr. McGorry's tax-qualified 401(k) Savings Plan account.

(4) Amount represents $15,483 for matching contributions made by the Company to Mr. McNaughton's tax-qualified 401(k) Savings Plan account.

(5) Amount represents $15,450 for matching contributions made by the Company to Mr. McNaughton's tax-qualified 401(k) Savings Plan account.

Discussion of Summary Compensation Table and Related Matters

2016 Executive Compensation

Salary and Bonus

In the first quarter of 2016, the Compensation Committee reviewed the overall executive compensation of the Company's named executive officers. Based on a variety of factors, with respect to the named executive officers, the Compensation Committee elected to not approve any salary increases or cash incentive compensation for 2016.

Long-Term Equity Incentive Compensation

In 2016, the Compensation Committee approved grants of long-term equity incentive awards in the form of stock options to executives as part of our total compensation package. The long-term equity incentive awards were granted in an effort to achieve certain key objectives, including (i) to attract and retain high performing and experienced executives, (ii) motivate and reward executives whose knowledge, skills and performance are critical to our success, and (iii) to align the interests of our executives and our stockholders by providing our executives with strong incentives to increase stockholder value and a significant reward for doing so. Our decisions regarding the amount and type of long-term equity incentive compensation and relative weighting of these awards among total executive compensation have also been based on our understanding of market practices of our peers and take into account additional factors such as level of individual responsibility, experience and performance. The long term incentive grants made to our named executive officers during fiscal 2016 are described in the table below:

	Stock Option Awards (#)	
James McGorry *President and Chief Executive Officer*	150,000	(1)
Thomas McNaughton *Chief Financial Officer*	75,000	(1)
Saverio LaFrancesca, Ph.D. *Chief Medical Officer*	75,000	(1)

(1) These options vest in four equal installments on each of March 22, 2017, 2018, 2019 and 2020 and have a term of ten years from the date of grant, being March 22, 2016.

Employment Agreements and Severance and Change in Control Benefits

Current Named Executive Officers

James McGorry

We entered into an employment agreement with Mr. McGorry dated as of June 23, 2015 and effective as of July 6, 2015, appointing Mr. McGorry as our President and Chief Executive Officer. Mr. McGorry's employment agreement has a term of three years, but will automatically renew for successive one year periods unless either party provides 90 days' notice that it does not wish to extend the agreement. Mr. McGorry's employment agreement provides for an annual base salary in the amount of three hundred seventy-five thousand dollars ($375,000) which will be reevaluated on an annual basis by the Board of Directors or the compensation committee. Mr. McGorry also received an option to purchase 671,400 shares of our common stock upon the commencement of his employment, which vests in four equal installments on January 1 of 2016, 2017, 2018 and 2019. Mr. McGorry is eligible to receive cash incentive compensation as determined by the Board of Directors or the compensation committee, and is also eligible to participate in all of our employee benefit plans, including without limitation, retirement plans, stock option plans, stock purchase plans and medical insurance plans.

Mr. McGorry's employment agreement also provides for payments to be made to Mr. McGorry in the event of his termination under certain circumstances. If Mr. McGorry's employment is terminated by us without "cause" (as such term is defined in Mr. McGorry's employment agreement) or by Mr. McGorry for "good reason" (as such term is defined in Mr. McGorry's employment agreement), we are obligated to pay Mr. McGorry the sum of his average annual base salary for the prior three fiscal years or annual salary for the prior fiscal year, whichever is higher, and his average annual cash incentive compensation for the prior three fiscal years or annual cash incentive compensation for the prior fiscal year, whichever is higher. Such payment is conditioned upon Mr. McGorry's execution of a general release of claims against us. In addition, all of Mr. McGorry's stock options or stock-based awards that would otherwise vest within the 12 month period following such termination shall accelerate and become immediately exercisable. We shall continue to pay health insurance premiums for health insurance coverage for Mr. McGorry and his immediate family for a period of one year following his termination without cause or for good reason.

Mr. McGorry may also be entitled to certain payments in the event of a change in control of our Company. If Mr. McGorry's employment is terminated by us without cause or by Mr. McGorry for good reason within 18 months of a change in control of our Company, Mr. McGorry is entitled to receive a lump sum cash payment in an amount equal to the sum of Mr. McGorry's current or most recent annual salary and his most recent cash incentive compensation. In addition, in the event of a change in control, all of Mr. McGorry's stock options or stock-based awards shall accelerate and become immediately exercisable. We will continue to pay health insurance premiums for health insurance coverage for Mr. McGorry and his immediate family for a period of one year following his termination as a result of a change in control.

Mr. McGorry will not be entitled to severance payments unless mutually agreed upon in writing if Mr. McGorry is terminated for cause, due to death or disability, or he terminates his employment without good reason. In the event Mr. McGorry is terminated due to death or disability, we will continue to pay health insurance premiums for health insurance coverage for Mr. McGorry and his immediate family for a period of one year following his termination.

Pursuant to the terms of his employment agreement, Mr. McGorry is also subject to certain confidentiality, non-solicitation and non-competition obligations. The non-solicitation and non-competition obligations survive during the term of his agreement and for a period of 12 months thereafter.

For purposes of Mr. McGorry's employment agreement, "cause" means: (A) conduct by Mr. McGorry constituting a material act of willful misconduct in connection with the performance of his duties; (B) criminal or civil conviction of Mr. McGorry, a plea of nolo contendere by Mr. McGorry or conduct by Mr. McGorry that would reasonably be expected to result in material injury to our reputation if he were retained in his position with us; (C) continued, willful and deliberate non-performance by Mr. McGorry of his duties; (D) a breach by Mr. McGorry of his confidentiality, non-solicitation and non-competition obligations to us; or (E) a material violation by Mr. McGorry of our employment policies.

For purposes of Mr. McGorry's employment agreement, "good reason" means the occurrence of any of the following events: (A) a substantial diminution or other substantive adverse change, not consented to by Mr. McGorry, in his responsibilities, authorities, powers, functions or duties; (B) any removal of Mr. McGorry's title of President and/or Chief Executive Officer; (C) an involuntary reduction in Mr. McGorry's annual salary except for across-the-board reductions similarly affecting substantially all management employees; (D) a breach by us of any of our other material obligations under Mr. McGorry's employment agreement; (E) the involuntary relocation of our offices at which Mr. McGorry is principally employed to a location more than 30 miles from our current offices; or (F) our failure to obtain the agreement from any successor company to us to assume and agree to perform Mr. McGorry's employment agreement.

Thomas McNaughton

On October 31, 2013, we entered into an Employment Agreement with Mr. McNaughton. The term of this agreement commenced on November 1, 2013. Mr. McNaughton's employment agreement has a term of two years, but will automatically renew for successive two year periods unless either party provides 90 days' notice that it does not wish to extend the agreement. Mr. McNaughton's employment agreement provides for an annual base salary in the amount of three hundred nine thousand dollars ($309,000) which will be reevaluated on an annual basis by the Board of Directors or the compensation committee. Mr. McNaughton is eligible to receive cash incentive compensation as determined by the Board of Directors or the compensation committee, and is also eligible to participate in all of our employee benefit plans, including without limitation, retirement plans, stock option plans, stock purchase plans and medical insurance plans.

Mr. McNaughton's employment agreement also provides for payments to be made to Mr. McNaughton in the event of his termination under certain circumstances. If Mr. McNaughton's employment is terminated by us without "cause" (as such term is defined in Mr. McNaughton's employment agreement) or by Mr. McNaughton for "good reason" (as such term is defined in Mr. McNaughton's employment agreement), we are obligated to pay Mr. McNaughton the sum of his average annual base salary for the prior three fiscal years or annual salary for the prior fiscal year, whichever is higher, and his average annual cash incentive compensation for the prior three fiscal years or annual cash incentive compensation for the prior fiscal year, whichever is higher. Such payment is conditioned upon Mr. McNaughton's execution of a general release of claims against us. In addition, all of Mr. McNaughton's stock options or stock-based awards that would otherwise vest within the 18 month period following such termination shall accelerate and become immediately exercisable. We shall continue to pay health insurance premiums for health insurance coverage for Mr. McNaughton and his immediate family for a period of one year following his termination without cause or for good reason.

Mr. McNaughton may also be entitled to certain payments in the event of a change in control of our Company. If Mr. McNaughton's employment is terminated by us without cause or by Mr. McNaughton for good reason within 18 months of a change in control of our Company, Mr. McNaughton is entitled to receive a lump sum cash payment in an amount equal to the sum of Mr. McNaughton's most recent annual salary and his most recent cash incentive compensation. In addition, in the event of a change in control, all of Mr. McNaughton's stock options or stock-based awards shall accelerate and become immediately exercisable. We will continue to pay health insurance premiums for health insurance coverage for Mr. McNaughton and his immediate family for a period of one year following his termination as a result of a change in control.

Mr. McNaughton will not be entitled to severance payments unless mutually agreed upon in writing if Mr. McNaughton is terminated for cause, due to death or disability, or he terminates his employment without good reason. In the event Mr. McNaughton is terminated due to death or disability, we will continue to pay health insurance premiums for health insurance coverage for Mr. McNaughton and his immediate family for a period of one year following his termination.

Mr. McNaughton is also eligible to receive a gross up payment in the event that any amounts received pursuant to the terms of his employment agreement are subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), or any interest or penalties on such excise tax are incurred by Mr. McNaughton. Such payment will be equal to the amount of (i) the excise tax, (ii) any federal, state or local tax resulting from the gross up payment and (iii) any interest and/or penalties assessed with respect to such excise tax. Pursuant to the terms of his employment agreement, Mr. McNaughton is also subject to certain confidentiality, non-solicitation and non-competition obligations. The non-solicitation and non-competition obligations survive during the term of his agreement and for a period of 12 months thereafter.

For purposes of Mr. McNaughton's employment agreement, "cause" means: (A) conduct by Mr. McNaughton constituting a material act of willful misconduct in connection with the performance of his duties; (B) criminal or civil conviction of Mr. McNaughton, a plea of nolo contendere by Mr. McNaughton or conduct by Mr. McNaughton that would reasonably be expected to result in material injury to our reputation if he were retained in his position with us; (C) continued, willful and deliberate non-performance by Mr. McNaughton of his duties; (D) a breach by Mr. McNaughton of his confidentiality, non-solicitation and non-competition obligations to us; or (E) a violation by Mr. McNaughton of our employment policies.

For purposes of Mr. McNaughton's employment agreement, "good reason" means the occurrence of any of the following events: (A) a substantial diminution or other substantive adverse change, not consented to by Mr. McNaughton, in his responsibilities, powers, or duties; (B) any removal of Mr. McNaughton's title of Chief Financial Officer; (C) an involuntary reduction in Mr. McNaughton's annual salary except for across-the-board reductions similarly affecting substantially all management employees; (D) a breach by us of any of our other material obligations under Mr. McNaughton's employment agreement; (E) the involuntary relocation of our offices at which Mr. McNaughton is principally employed to a location more than 30 miles from our current offices; or (F) our failure to obtain the agreement from any successor company to us to assume and agree to perform Mr. McNaughton's employment agreement.

Saverio LaFrancesca, M.D.

We entered into an employment agreement with Dr. LaFrancesca dated as of April 8, 2014 effective as of April 14, 2014, appointing Dr. LaFrancesca as our Chief Medical Officer. We entered into an amendment to Dr. LaFrancesca's employment agreement on March 24, 2016. Dr. LaFrancesca's employment agreement has a term of one year, but will automatically renew for successive one year periods unless either party provides 90 days' notice that it does not wish to extend the agreement. Dr. LaFrancesca's employment agreement provides for an annual base salary in the amount of four hundred thousand dollars ($400,000) which will be reevaluated on an annual basis by the Board of Directors or the compensation committee. Dr. LaFrancesca also received an option to purchase 100,000 shares of our common stock upon the commencement of his employment, which vests in four equal installments on January 1 of 2015, 2016, 2017 and 2018. Dr. LaFrancesca is eligible to receive cash incentive compensation as determined by the Board of Directors or the compensation committee, and is also eligible to participate in all of our employee benefit plans, including without limitation, retirement plans, stock option plans, stock purchase plans and medical insurance plans.

Dr. LaFrancesca's employment agreement also provides for payments to be made to Dr. LaFrancesca in the event of his termination under certain circumstances. If Dr. LaFrancesca's employment is terminated by us without "cause" (as such term is defined in Dr. LaFrancesca's employment agreement) or by Dr. LaFrancesca for "good reason" (as such term is defined in Dr. LaFrancesca's employment agreement), we are obligated to pay Dr. LaFrancesca the sum of his average annual base salary for the prior three fiscal years or annual salary for the prior fiscal year, whichever is higher, and his average annual cash incentive compensation for the prior three fiscal years or annual cash incentive compensation for the prior fiscal year, whichever is higher. Such payment is conditioned upon Dr. LaFrancesca's

execution of a general release of claims against us. In addition, all of Dr. LaFrancesca's stock options or stock-based awards that would otherwise vest within the 12 month period following such termination shall accelerate and become immediately exercisable. We shall continue to pay health insurance premiums for health insurance coverage for Dr. LaFrancesca and his immediate family for a period of one year following his termination without cause or for good reason.

Dr. LaFrancesca may also be entitled to certain payments in the event of a change in control of our Company. If Dr. LaFrancesca's employment is terminated by us without cause or by Dr. LaFrancesca for good reason within 18 months of a change in control of our Company, Dr. LaFrancesca is entitled to receive a lump sum cash payment in an amount equal to the sum of Mr. Dr. LaFrancesca's current or most recent annual salary and his most recent cash incentive compensation. In addition, in the event of a change in control, all of Dr. LaFrancesca's stock options or stock-based awards shall accelerate and become immediately exercisable. We will continue to pay health insurance premiums for health insurance coverage for Dr. LaFrancesca and his immediate family for a period of one year following his termination as a result of a change in control.

Dr. LaFrancesca will not be entitled to severance payments unless mutually agreed upon in writing if Dr. LaFrancesca is terminated for cause, due to death or disability, or he terminates his employment without good reason. In the event Dr. LaFrancesca is terminated due to death or disability, we will continue to pay health insurance premiums for health insurance coverage for Dr. LaFrancesca and his immediate family for a period of one year following his termination.

Pursuant to the terms of his employment agreement, Dr. LaFrancesca is also subject to certain confidentiality, non-solicitation and non-competition obligations. The non-solicitation and non-competition obligations survive during the term of his agreement and for a period of 12 months thereafter.

For purposes of Dr. LaFrancesca's employment agreement, "cause" means: (A) conduct by Dr. LaFrancesca constituting a material act of willful misconduct in connection with the performance of his duties; (B) criminal or civil conviction of Dr. LaFrancesca, a plea of nolo contendere by Dr. LaFrancesca or conduct by Dr. LaFrancesca that would reasonably be expected to result in material injury to our reputation if he were retained in his position with us; (C) continued, willful and deliberate non-performance by Dr. LaFrancesca of his duties; (D) a breach by Dr. LaFrancesca of his confidentiality, non-solicitation and non-competition obligations to us; or (E) a violation by Dr. LaFrancesca of our employment policies.

For purposes of Dr. LaFrancesca's employment agreement, "good reason" means the occurrence of any of the following events: (A) a substantial diminution or other substantive adverse change, not consented to by Dr. LaFrancesca, in his responsibilities, authorities, powers, functions or duties; (B) any removal of Dr. LaFrancesca's title of Chief Medical Officer; (C) an involuntary reduction in Dr. LaFrancesca's annual salary except for across-the-board reductions similarly affecting substantially all management employees; (D) a breach by us of any of our other material obligations under Dr. LaFrancesca's employment agreement; (E) the involuntary relocation of our offices at which Dr. LaFrancesca is principally employed to a location more than 30 miles from our current offices; or (F) our failure to obtain the agreement from any successor company to us to assume and agree to perform Dr. LaFrancesca's employment agreement.

Retirement and Other Benefits

We have established a 401(k) tax-deferred savings plan, which permits participants, including our named executive officers, to make contributions by salary deduction pursuant to Section 401(k) of the Code. We are responsible for administrative costs of the 401(k) plan. We may, in our discretion, make matching contributions to the 401(k) plan. In addition, all full-time employees, including our named executive officers, may participate in our health and welfare benefit programs, including medical coverage, vision coverage, dental coverage, disability insurance, and life insurance.

71

DIRECTOR COMPENSATION

We use a combination of cash and stock-based incentive compensation to attract and retain qualified candidates to serve on our Board of Directors. In setting director compensation, the Board of Directors and the Compensation Committee consider the significant amount of time that directors expend in fulfilling their duties to the Company as well as the skill-level required by the Company of members of the Board of Directors.

Directors who are also employees of the Company receive no additional compensation for service as a director.

Each non-employee director that is elected to our Board of Directors will receive a non-qualified stock option to purchase 25,000 shares of our Common Stock vesting one year from the date of grant and granted on the fifth business day following his or her initial election to the Board of Directors. Each non-employee director also receives an annual retainer of $30,000 paid in four equal quarterly installments. Each non-employee director is also entitled to receive a non-qualified stock option to purchase 25,000 shares of our Common Stock vesting one year from the date of grant and granted on the third business day following the issuance of our earnings release for year-end results.

Non-employee directors continue to be reimbursed for their expenses incurred in connection with attending Board of directors and committee meetings.

Director Compensation Table

The following table presents the compensation provided by us to the non-employee directors who served during the fiscal year ended December 31, 2016.

Name[1]	Fees earned or paid in cash	**Option awards** [1][2]	Total
John J. Canepa	$ 30,000	$26,513	$56,513
John F. Kennedy	$ 30,000	$26,513	$56,513
Blaine H. McKee	$ 23,736	$55,378	$79,114
Thomas H. Robinson	$ 30,000	$26,513	$56,513
David Green	$ 12,115	$26,513	$38,628

(1) Based on the aggregate grant date fair value computed awards in accordance with the provisions of FASB ASC 718, “Compensation — Stock Compensation” excluding the impact of estimated forfeitures. Assumptions used in the calculation of this amount are included under 2013 Plan Valuation and Expense Information under Share-Based-Payment Accounting in Note 13 to our audited financial statements for the fiscal year ended December 31, 2015, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2016.

(2) The aggregate number of option awards outstanding at our 2016 fiscal year end and held by the non-employee directors were as follows: 75,000 for Mr. Canepa; 80,026 for Mr. Kennedy; 50,000 for Mr. McKee; 75,000 for Mr. Robinson; and 775,627 for Mr. Green. With respect to Mr. Kennedy, these holdings include grants of options to purchase 5,026 shares that were issued by our Company in connection with the required adjustment to the similar outstanding equity awards held by him and issued by Harvard Bioscience resulting from the impact of the spin-off of our Company by Harvard Bioscience.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information concerning the number and value of exercisable and unexercisable options to purchase Common Stock, and the number of restricted stock units held by our named executive officers as of December 31, 2016.

	Option Awards					Restricted Stock Units	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price ($)	Option Expiration Date	Number of Securities Underlying Restricted Stock Units	
James McGorry	25,000	—		$ 4.29	11/18/2023	—	
	25,000	—		$ 1.84	5/29/2025	—	
	167,850	503,550	(1)	$ 1.38	7/6/2025	—	
		150,000	(2)	$ 1.69	3/22/2026	—	
Thomas McNaughton		75,000	(3)	$ 1.69	3/22/2026	—	
	25,000	75,000	(4)	$ 1.40	9/1/2025	—	
	21,250	63,750	(5)	$ 1.84	5/29/2025	—	
	108,844	36,282	(6)	$ 4.29	11/18/2023	—	
	48,375	24,188	(7)	$ 4.29	11/18/2023	—	
	1,546	515	(8)	$ 5.22	5/31/2023	268	(9)
	4,383			$ 3.67	6/1/2022	—	
	2,769	—		$ 5.79	6/2/2021	—	
	11,108	—		$ 3.27	5/21/2019	—	
	5,544	—		$ 2.90	11/14/2018	—	
Saverio LaFrancesca, M.D.	50,000	50,000	(10)	$ 8.66	5/1/2024	—	
	25,000	75,000	(11)	$ 4.08	3/4/2025	—	
	10,000	30,000	(11)	$ 1.84	5/29/2025	—	
	40,000	120,000	(13)	$ 1.40	8/31/2025	—	
	—	75,000	(14)	$ 1.69	3/22/2026	—	

(1) The option was granted on July 6, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on January 1 of each of 2017, 2018 and 2019.

(2) The option was granted on March 22, 2016 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 22 of each of 2017, 2018, 2019 and 2020.

(3) The option was granted on March 22, 2016 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 22 of each of 2017, 2018, 2019 and 2020.

(4) The option was granted on August 31, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on August 31 of each of 2017, 2018 and 2019.

(5) The option was granted on May 29, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on May 29 of each of 2017, 2018 and 2019.

(6) The option was granted on November 1, 2013 and, assuming continued employment with our Company, the unvested shares become exercisable on January 1, 2017.

(7) The option was granted on November 18, 2013 and, assuming continued employment with our Company, the unvested shares become exercisable in two equal increments subject to the achievement of certain milestone targets determined by our Board of Directors.

(8) The option was granted on November 1, 2013 and, assuming continued employment with our Company, the unvested shares become exercisable on January 1, 2017.

(9) The restricted stock units were granted on November 1, 2013 and, assuming continued employment with our Company, these restricted stock units vest on January 1, 2017.

(10) The option was granted on May 1, 2014 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on May 1 of each of 2017 and 2018.

(11) The option was granted on March 4, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 4 of each of 2017, 2018 and 2019.

(12) The option was granted on May 29, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on May 29 of each of 2017, 2018 and 2019.

(13) The option was granted on August 31, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on August 31 of each of, 2017, 2018 and 2019.

(14) The option was granted on March 23, 2016 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 23 of each of 2017, 2018, 2019 and 2020.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

The following table sets forth information regarding the beneficial ownership of our Common Stock as of February 1, 2017 by: (i) all persons known by us to own beneficially more than 5% of our voting securities; (ii) each of our directors; (iii) each of our named executive officers; and (iv) all of our current directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and includes any shares as to which the individual or entity has the right to acquire beneficial ownership within 60 days after February 1, 2017 through the exercise of any warrant, stock option or other right. The inclusion of such shares, however, does not constitute an admission that the named stockholder is a direct or indirect beneficial owner of such shares. Common stock subject to options currently exercisable, or exercisable within 60 days after February 1, 2017, are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options, but are not deemed outstanding for computing the percentage ownership of any other person.

Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of Common Stock, except to the extent spouses share authority under community property laws.

	Common Stock Beneficially Owned				
Name and Address of Beneficial Owner [1]	Shares	**Percent Prior to Offering [2]**		**Percent Following Completion of Offering [2]**	
Greater than 5% Holders					
David Green	1,313,886	7.3	%(3)	3.5	%(3)
First Pecos LLC and affiliates	1,077,018	6.3	%(4)	2.9	%(4)
Named Executive Officers					
James J. McGorry	549,500	3.1	%(5)	1.5	%(5)
Thomas W. McNaughton	466,574	2.7	%(6)	1.2	%(6)
Saverio LaFrancesca, M.D.	212,748	1.2	%(7)		*(7)
Non-Employee Directors					
John J. Canepa	92,241		*(8)		*(8)
John F. Kennedy	138,432		*(9)		*(9)
Thomas H. Robinson	125,000		*(10)		*(10)
Blaine H. McKee	50,000		*(11)		*(11)

All current executive officers and directors, as a group (7 persons)	1,634,495	9.0	%(12)	4.3	%(12)

*Represents less than 1% of all of the outstanding shares of Common Stock.

(1) Unless otherwise indicated, the address for all persons shown is c/o Biostage, Inc., 84 October Hill Road, Suite 11, Holliston, Massachusetts 01746.

(2) Based on 17,116,570 shares of Common Stock outstanding on February 1, 2017, together with the applicable options for each stockholder that become exercisable within 60 days. With respect to percentages following completion of this offering, amounts assume that no shares of Series C Preferred Stock are sold.

(3) Includes options to acquire 775,627 shares that are exercisable within 60 days of February 1, 2017, and 538,259 shares.

(4) This information is based solely upon an amended Schedule 13D filed jointly by First Pecos LLC (“Pecos”), Banco Panamericano, Inc. ("Banco"), Leslie Jabine (“Jabine”) and Chip Greenblatt (“Greenblatt”) on October 27, 2016 reporting beneficial ownership as of October 20, 2016. Consists of:

(a) 547,000 shares held by Pecos;
(b) 490,018 shares held by Banco; and
(c) 40,000 shares held by Jabine.

Greenblatt, as sole manager of Pecos and sole director of Banco, has voting and investment power with respect to the shares held by those entities.

(5) Includes options to acquire 423,200 shares exercisable within 60 days of February 1, 2017, and 126,300 shares.
(6) Includes options to acquire 260,446 shares exercisable within 60 days of February 1, 2017, and 206,128 shares.
(7) Includes options to acquire 168,750 shares exercisable within 60 days of February 1, 2017, and 43,998 shares.
(8) Includes options to acquire 75,000 shares exercisable within 60 days of February 1, 2017and 17,241 shares.
(9) Includes options to acquire 80,026 shares that are exercisable within 60 days of February 1, 2017, and 58,406 shares.
(10) Includes options to acquire 75,000 shares that are exercisable within 60 days of February 1, 2017, and 50,000 shares.
(11) Includes options to acquire 50,000 shares that are exercisable within 60 days of February 1, 2017.
(12) Includes options to acquire 1,132,422 shares that are exercisable within 60 days of February 1, 2017 and 502,073 shares.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2016 concerning the number of shares of Common Stock issuable under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Restricted Stock Units, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights	Number of Securities Remaining Available For Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))

	(a)	(b)	(c)	
Equity compensation plans approved by security holders[1]	3,878,082	$ 2.80	2,036,994	(2)
Equity compensation plans not approved by security holders	—	—	—	
Total	3,878,082	$ 2.80	2,036,994	

(1) Consists of our 2013 Equity Incentive Plan, or 2013 Plan, and our Employee Stock Purchase Plan.

(2) Includes 1,945,632 shares available for future issuance under our 2013 Plan and 91,362 shares available for future issuance under our Employee Stock Purchase Plan.

DESCRIPTION OF OUR CAPITAL STOCK

The following description of our common stock, warrants to purchase our common stock and Series C Convertible Preferred Stock summarizes the material terms and provisions of the securities that we may offer under this prospectus. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our amended and restated certificate of incorporation, or our Charter, and our second amended and restated bylaws, or our Bylaws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. The terms of our common stock and warrants to purchase our common stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 60,000,000 shares of common stock, par value $0.01 per share, and 2,000,000 shares of undesignated preferred stock, par value $0.01 per share. As of February 1, 2017, there were 17,116,570 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders; provided, that, except as otherwise required by law, holders of common stock are not entitled to vote on any amendment to the Charter that changes the powers, preferences, rights or other terms of one or more series of undesignated preferred stock if the holders of the affected series are entitled to vote, separately or together, with the holders of one or more other such series, on such amendment pursuant to our Charter or Delaware General Corporation Law. Our Charter provides that our Board of Directors shall be divided into three classes, each consisting as nearly as reasonably may be possible of one-third of the total number of directors constituting the entire Board of Directors, with each class's term expiring on a staggered basis. Newly-created directorships and vacancies on our Board of Directors may only be filled by a majority of the members of the incumbent board then in office, though less than a quorum, and not by our stockholders. Directors may be removed from office only for cause by the affirmative vote of the holders of at least seventy-five percent (75%) of the outstanding shares entitled to be cast on the election of directors by the then-outstanding shares of all classes and series of capital stock, voting together as a single class. Holders of common stock have no preemptive, redemption or conversion rights and are not subject to future calls or assessments. No sinking fund provisions apply to our common stock. All outstanding shares are fully-paid and non-assessable. In the event of our liquidation, dissolution or winding up, after the satisfaction in full of the liquidation preferences of holders of any preferred stock, holders of common stock are entitled to ratable distribution of the remaining assets available for distribution to stockholders. Holders of common stock are entitled to receive proportionately any such dividends declared by our Board of Directors, out of legally available funds for dividends, subject to any preferences that may be applicable to any shares of preferred stock that may be outstanding at that time.

The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. To the extent our Shareholder Rights Agreement remains in effect at the time we sell any shares of common stock under this prospectus, such shares of common stock would also be accompanied by certain preferred stock purchase rights. See "Description of Capital Stock – Provisions of our Certificate of Incorporation and Bylaws and Delaware Anti-Takeover Law" for additional details regarding our Shareholder Rights Agreement.

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol "BSTG." On February 9, 2017, the closing price for our common stock, as reported on the NASDAQ Capital Market, was $0.507 per share. As of the close of business on February 1, 2017, there were 180 stockholders of record of our common stock. Prior to our name change on March 31, 2016 from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc., our common stock was listed on the NASDAQ Capital Market under the symbol "HART."

On July 16, 2015, we received a notice from NASDAQ of non-compliance with its continuing listing rules, namely that the audit committee of our Board of Directors had two members following James McGorry's appointment as our President and Chief Executive Officer instead of the required minimum of three members. In accordance with NASDAQ continued listing rules, we were given until the earlier of our next annual shareholders' meeting or July 6, 2016 to add a third audit committee member. On March 10, 2016, Blaine McKee, Ph.D. was appointed as a member of the Board of Directors and its audit committee, and we regained compliance with that requirement.

On November 10, 2015, we received a notice from NASDAQ of non-compliance with its listing rules regarding the requirement that the listed securities maintain a minimum bid price of $1 per share. Based upon the closing bid price for the 30 consecutive business days preceding the notice, the Company no longer met this requirement. However, the NASDAQ rules also provide the Company a period of 180 calendar days in which to regain compliance and, in some circumstances, a second 180-day compliance period. On November 25, 2015, we regained compliance with the minimum bid price requirement when the closing price of our common stock was at least $1 per share for ten consecutive business days.

On November 18, 2016, we received a notice from NASDAQ of non-compliance with its listing rules regarding the minimum bid price requirement. As noted above, the NASDAQ rules provide the Company a period of 180 calendar days in which to regain compliance and, in some circumstances, a second 180-day compliance period. We are monitoring the closing bid price of our common stock and will consider available options to resolve the noncompliance with the minimum bid price requirement as may be necessary, including the possibility of seeking stockholder approval of a reverse stock split. There can be no assurance that we would be successful in receiving such stockholder approval.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare.

Series C Convertible Preferred Stock

General

Our Board of Directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without shareholder approval. Our Board of Directors may determine the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualification, limitations and restrictions, of each series of preferred stock. Our Board of Directors has designated 5,000 shares of preferred stock as Series A Junior Participating Cumulative Preferred Stock, 1,000,000 shares of preferred stock as Series B Convertible Preferred Stock and will designate 2,000 shares of preferred stock as Series C Convertible Preferred Stock, which we refer to herein as the Series C Preferred Stock. The Series A Junior Participating Cumulative Preferred Stock and Series B Convertible Preferred Stock is not being registered pursuant to the registration statement of which this prospectus forms a part. As of February 1, 2017, there were no shares of preferred stock outstanding. The placement agent has informed us that it has not received any indications of interest for shares of Series C Preferred Stock, thus we do not expect to confirm any sales of such shares of Series C Preferred Stock. In the event that do not confirm any sales of shares of Series C

Preferred Stock, we will not file a Certificate of Designation with respect to the Series C Preferred Stock.

Rank

The Series C Preferred Stock ranks (1) on parity with our common stock on an "as converted" basis, (2) on parity with our Series A Junior Participating Cumulative Preferred Stock and Series B Convertible Preferred Stock, (3) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series C Preferred Stock, (4) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series C Preferred Stock, and (5) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series C Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

Conversion

Each share of the Series C Preferred Stock is convertible into 2,500 shares of common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of our common stock if, as a result of such conversion, the holder would own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividends

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends are payable on shares of Series C Preferred Stock.

Voting Rights

Except as provided in the Certificate of Designation or as otherwise required by law, the holders of Series C Preferred Stock will have no voting rights. However, we may not, without the consent of holders of a majority of the outstanding shares of Series C Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock, or enter into any agreement with respect to the foregoing.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series C Preferred Stock are entitled to receive, *pari passu* with the holders of common stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, as described below.

Beneficial Ownership Limitation

The Company may not effect any conversion of the Series C Preferred Stock, and a holder does not have the right to convert any portion of the Series C Preferred Stock to the extent that, after giving effect to the conversion set forth in a notice of conversion such holder would beneficially own in excess of the Beneficial Ownership Limitation, or such holder, together with such holder's affiliates, and any persons acting as a group together with such holder or affiliates, would beneficially own in excess of the Beneficial Ownership Limitation. The "Beneficial Ownership Limitation" is 4.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of

shares of common stock issuable upon conversion of Series C Preferred Stock held by the applicable holder. A holder may, with 61 days prior notice to the Company, elect to increase or decrease the Beneficial Ownership Limitation; provided, however, that in no event may either the holder Beneficial Ownership Limitation or the affiliate Beneficial Ownership Limitation be 9.99% or greater.

Exchange Listing

We do not plan on making an application to list the shares of Series C Preferred Stock on the NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system. Our common stock issuable upon conversion of the Series C Preferred Stock is listed on the NASDAQ Capital Market.

Failure to Deliver Conversion Shares

If the Company fails to timely deliver shares of common stock upon conversion of the Series C Preferred Stock (the "Conversion Shares") within the time period specified in the Certificate of Designation (within three trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), and if the holder has not exercised its Buy-In rights as described below with respect to such shares, then the Company is obligated to pay to the holder, as liquidated damages, an amount equal to $50 per business day (increasing to $100 per business day after the third business day and $200 per business day after the tenth business day) for each $5,000 of Conversion Shares for which the Series C Preferred Stock converted which are not timely delivered. If the Company makes such liquidated damages payments, it is not also obligated to make Buy-In payments with respect to the same Conversion Shares.

Compensation for Buy-In on Failure to Timely Deliver Shares

If the Company fails to timely deliver the Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by the holder of the Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Buy-In"), then the Company is obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased, minus any amounts paid to the holder by the Company as liquidated damages for late delivery of such shares, exceeds (y) the amount obtained by multiplying (1) the number of Conversion Shares that the Company was required to deliver times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Series C Preferred Stock and equivalent number of Conversion Shares for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of common stock that would have been issued had the Company timely complied with its conversion and delivery obligations.

Subsequent Rights Offerings; Pro Rata Distributions

If the Company grants, issues or sells any common stock equivalents pro rata to the record holders of any class of shares of common stock (the "Purchase Rights"), then a holder of Series C Preferred Stock will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon conversion of the Series C Preferred Stock (without regard to any limitations on conversion). If the Company declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of common stock, then a holder of Series C Preferred Stock is entitled to participate in such distribution to the same extent as if the holder had held the number of

shares of common stock acquirable upon complete conversion of the Series C Preferred Stock (without regard to any limitations on conversion).

Fundamental Transaction

If, at any time while the Series C Preferred Stock is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding common stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then the Series C Preferred Stock automatically converts and the holder will receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction (without regard to the Beneficial Ownership Limitation), the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of common stock for which the Series C Preferred Stock is convertible immediately prior to such Fundamental Transaction (without regard to the Beneficial Ownership Limitation). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Fundamental Transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder will be given the same choice as to the Alternate Consideration it receives upon automatic conversion of the Series C Preferred Stock following such Fundamental Transaction.

Warrants

The following is a brief summary of the material terms of the warrants offered pursuant to this prospectus and is subject in all respects to the provisions contained in the warrants, the form of which is filed as an exhibit to this prospectus. As of February 1, 2017, there were warrants to purchase 1,560,284 shares of our common stock outstanding. The previously issued warrants all have an exercise price of $1.7625 per warrant and are exercisable commencing November 19, 2016 through their expiration date of May 19, 2021.

Exercisability

Holders may exercise warrants at any time up to 11:59 p.m., New York time, on the date that is five years after the date on which such warrants were issued. The warrants are exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise discussed below). The holder of warrants does not have the right to exercise any portion of the warrant if the holder would beneficially own in excess of 4.99% of the shares of our common stock outstanding immediately after giving effect to such exercise. This percentage may, however, be raised or lowered to an amount not to exceed 9.99% at the option of the holder upon at least 61 days' prior notice from the holder to us.

Cashless Exercise

At any time when a registration statement covering the issuance of the shares of common stock issuable upon exercise of the warrants is not effective, the holder may, at its option, exercise its warrants on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of our common stock purchasable upon such exercise.

Exercise Price

The exercise price of common stock purchasable upon exercise of the warrants is $0.40 per share. The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications or similar events affecting our common stock. Holders of the warrants are entitled to participate in any subsequent rights offering or distribution of our assets on an as-if-exercised basis.

Transferability

The warrants may be transferred at the option of the holder upon surrender of the warrants with the appropriate instruments of transfer.

Exchange Listing

We do not plan on making an application to list the warrants on the NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system. Our common stock underlying the warrants is listed on the NASDAQ Capital Market.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities with cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. In addition, as further described in the form of warrant filed as an exhibit to this registration statement, in the event of any fundamental transaction, the holders of the warrants will have the right at any time concurrently with, or within 30 days after, the consummation of the fundamental transaction to require us or any successor entity to purchase the warrants for an amount in cash equal to the value of the unexercised portion of the warrant using the Black-Scholes Option Pricing Model.

Rights as Stockholder

Except as otherwise provided in the warrants (such as the rights described above of a warrant holder upon our sale or grant of any rights to purchase stock, warrants or securities or other property to our stockholders on a pro rata basis) or by virtue of such holder’s ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the warrants. Rather, the number of shares of common stock to be issued will be rounded down to the nearest whole number.

2013 Equity Incentive Plan

Under our 2013 Equity Incentive Plan, we can grant stock options to employees, directors and consultants. The 2013 Equity Incentive Plan also permits us to make grants of incentive stock options, non-qualified stock options, stock appreciation rights, deferred stock awards, restricted stock awards, unrestricted stock awards, performance shares and dividend equivalent rights. We currently have reserved 5,960,000 shares of common stock for the issuance of awards under the 2013 Equity Incentive Plan.

Employee Stock Purchase Plan

Under our employee stock purchase plan, participating employees can authorize us to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of our common stock. At the conclusion of the period, participating employees can purchase shares of our common stock at eight-five percent (85%) of the lower of the fair market value of our common stock at the beginning or end of the period. Shares are issued under the plan for the six-month periods ending June 30 and December 31. Under this plan, 150,000 shares of common stock are authorized for issuance of which 65,972 were issued as of February 1, 2017.

Provisions of our Certificate of Incorporation and Bylaws and Delaware Anti-Takeover Law

Certain provisions of the Delaware General Corporation Law and of our Charter and Bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our Board of Directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Provisions of our Certificate of Incorporation and Bylaws

Our Charter, our Bylaws and Delaware law contain provisions that could discourage, delay or prevent a third party from acquiring us, even if doing so may be beneficial to our stockholders. In addition, these provisions could limit the price investors would be willing to pay in the future for shares of our common stock. The following are examples of such provisions in our Charter and Bylaws:

- only our Board of Directors, pursuant to a resolution adopted by a majority of our directors, may call special meetings of our stockholders;
- stockholders may not act by written consent and stockholder action must take place at the annual or special meeting of our stockholders;
- stockholder proposals and nominations of candidates for election as directors other than nominations made by or at the direction of our Board of Directors or a committee of our Board of Directors to be brought before any meeting of our stockholders must comply with advance notice procedures;
- our Board of Directors is classified into three classes, each consisting as nearly as reasonably may be possible of one-third of the total number of directors constituting the entire Board of Directors;

- our Board will fix the exact number of directors to comprise our Board of Directors;

subject to any rights that holders of any series of our undesignated preferred stock may have to elect directors and to fill vacancies on our Board of Directors, newly-created directorships and vacancies on our Board of Directors may only be filled by a majority of the members of the incumbent board then in office, even if less than a quorum is present, and not by our stockholders;

- a director may be removed from office only for cause by the affirmative vote of holders of shares representing at least seventy-five percent (75%) of the votes entitled to be cast on such matter by the then-outstanding shares of all classes and series of our capital stock, voting together as a single class;

- our Charter and Bylaws do not provide for cumulative voting in the election of directors;

- our Bylaws may be further amended by either (i) the affirmative vote of at least a majority of our entire Board of Directors or (ii) the affirmative vote of the holders of at least seventy-five percent (75%) of the combined voting power of the outstanding shares of all classes and series of our capital stock entitled to vote on such amendment, voting together as a single class; and

- our Board of Directors is authorized to issue, without further action by our stockholders, up to 2,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board of Directors.

We implemented a Stockholder Rights Plan (the "Rights Plan") on October 31, 2013. Pursuant to the Rights Plan, one preferred stock purchase right will be issued for each outstanding share of our common stock. Each right issued will be subject to the terms of the Rights Plan. The Rights Plan is intended to protect our stockholders in the event of an unfair or coercive offer to acquire us and to provide the Board of Directors with adequate time to evaluate unsolicited offers; however, it may have anti-takeover effects. In general terms, our Rights Plan works by imposing a significant penalty upon any person or group that acquires twenty percent (20%) or more of our outstanding common stock, without the approval of our Board of Directors. The Rights Plan, however, should not affect any prospective offer or willingness to make an offer at a fair price as determined by our Board of Directors, nor should it interfere with any merger or other business combination approved by our Board of Directors. However, because the rights may substantially dilute the stock ownership of a person or group attempting to take us over without the approval of our Board of Directors, our Rights Plan could make it more difficult for a third party to acquire us (or a significant percentage of our outstanding capital stock) without first negotiating with our Board of Directors regarding that acquisition.

Additionally, as required by the Delaware General Corporation Law, any amendment of our Charter must first be approved by a majority of our Board of Directors and, as required by our Charter, thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon, voting together as a single class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability, the amendment of our Bylaws and Charter, forum and transactions with Harvard Bioscience must be approved by not less than seventy-five percent (75%) of the outstanding shares entitled to vote on the amendment, and not less than seventy-five percent (75%) of the outstanding shares of each class entitled to vote thereon as a class. Our Bylaws may be amended by either (i) a vote of at least a majority of our entire Board of Directors or (ii) a vote of the holders of at least seventy-five percent (75%) of the combined voting power of the outstanding shares of all classes and series of our capital stock entitled to vote on such amendment, voting together as a single class.

Delaware Anti-Takeover Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, fifteen percent (15%) or more of the corporation's voting stock. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

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before the stockholder became interested, the Board of Directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least eight-five percent (85%) of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or

- at or after the time the stockholder became interested, the business combination was approved by the Board of Directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Disclosure of SEC Position on Indemnification for Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, officers and persons controlling our company, we have been informed that in the opinion of the SEC such indemnification is against publicly policy as expressed in the Securities Act and is therefore unenforceable.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement, we have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering of our securities pursuant to this prospectus on a reasonable best efforts basis. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The engagement agreement does not give rise to any commitment by the placement agent to purchase any of our securities, and the placement agent will have no authority to bind us by virtue of the engagement agreement. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offering. The placement agent may engage sub-agents or selected dealers to assist with the offering.

Only certain institutional investors purchasing the securities offered hereby will execute a securities purchase agreement with us, providing such investors with certain representations, warranties and covenants from us, which representations, warranties and covenants will not be available to other investors who will not execute a securities purchase agreement in connection with the purchase of the securities offered pursuant to this prospectus. Therefore, those investors shall rely solely on this prospectus in connection with the purchase of securities in the offering.

The placement agent and associated person have agreed to purchase 750,000 shares of our common stock and related warrants upon the same terms as the investors purchasing our securities in this offering for a total purchase price of $300,000.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about February 15, 2017.

We have agreed to pay the placement agent a total cash fee equal to 7% of the gross proceeds of this offering, except with respect to cash consideration paid to us in this offering by certain investors, in which case we will pay the placement agent a cash fee equal to 4% of the gross proceeds received from such investors. We will also pay the placement agent a management fee equal to 1% of the gross proceeds of this offering, a reimbursement for out-of-pocket expenses in the amount of up to $35,000 and a reimbursement for the placement agent’s legal fees and expenses in the amount of $100,000. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent fees and expenses, will be approximately $550,000.

In addition, we have agreed to issue to the placement agent warrants to purchase up to 1,000,000 shares of common stock (which represents 5% of the aggregate number of shares of common stock sold in this offering) at an exercise

price of $0.50 per share (representing 125% of the public offering price for a share of common stock and related warrant to be sold in this offering). The placement agent warrants will have substantially the same terms as the warrants being sold to the investors in this offering. Pursuant to FINRA Rule 5110(g), the placement agent warrants and any shares issued upon exercise of the placement agent warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

We have also agreed to give the placement agent, subject to a successful completion of this offering, a twelve-month right of first refusal to act as our lead underwriter or placement agent for any further capital raising transactions undertaken by us (exclusive for the first six months and with a minimum of 50% of fees for the remaining six months) and, in the event an offering is not completed during the term of the agreement, a twelve-month tail fee equal to the cash and warrant compensation in this offering, if any investor who was contacted by the placement agent provides us with further capital during such twelve-month period following the expiration or termination of our engagement.

We have agreed to indemnify the placement agent and specified other persons against certain liabilities relating to or arising out of the placement agent's activities under the placement agency agreement and to contribute to payments that the placement agent may be required to make in respect of such liabilities.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants by the placement agent acting as principal. Under these rules and regulations, the placement agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Determination of offering price

The public offering price of the securities we are offering was negotiated between us and the investors, in consultation with the placement agent based on the trading of our common stock prior to the offering, among other things. Other factors considered in determining the public offering price of the shares of our common stock we are offering include the history and prospects of the Company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol "BSTG."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare.

Other Relationships

From time to time, the placement agent has provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services.

The placement agent in this offering served as our exclusive placement agent in a securities offering we consummated in May 2016, pursuant to which it received compensation, including warrants to purchase shares of our common stock.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The Audit Committee charter sets forth the standards, policies and procedures that we follow for the review, approval or ratification of any related person transaction that we are required to report pursuant to Item 404(a) of Regulation S-K promulgated by the Securities and Exchange Commission. Under the Audit Committee charter, which is in writing, the Audit Committee must conduct an appropriate review of these related person transactions on an ongoing basis, and the approval of the Audit Committee is required for all such transactions. The Audit Committee relies on management to identify related person transactions and bring them to the attention of the Audit Committee.

During the 2015 and 2016 fiscal years, we were not a participant in any related person transactions that required disclosure under this heading except as it relates to (i) our engagement of, and payment during 2015 of $166,645 to RobinsonButler, an executive recruiting consultancy firm where Thomas Robinson, a member of our Board of Directors, is a partner, to complete the search for our President and Chief Executive Officer, and (ii) our commercial agreements with Harvard Bioscience that were entered into in connection with the spin-off of our Company. Harvard Bioscience remained a related party during a portion of 2015, due in part to Mr. Green, our former Chairman and CEO, also being a director of Harvard Bioscience. Since Mr. Green resigned from the positions of Chairman and CEO of Biostage on April 17, 2015, Harvard Bioscience is no longer considered a related party. These commercial agreements with Harvard Bioscience include: (i) a Separation and Distribution Agreement to effect the separation and spin-off distribution and provide other agreements to govern our relationship with Harvard Bioscience after the spin-off; (ii) an Intellectual Property Matters Agreement, which governs various intellectual property related arrangements between our Company and Harvard Bioscience, including the separation of intellectual property rights between us and Harvard Bioscience, as well as certain related cross-licenses between the two companies; (iii) a Product Distribution Agreement, which provides that each company will become the exclusive distributor for the other party for products such other party develops for sale in the markets served by the other; (iv) a Tax Sharing Agreement, which governs the parties respective rights, responsibilities and obligations with respect to tax liabilities and benefits, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings and other matters regarding taxes for periods before, during and after the spin-off; (v) a Transition Services Agreement, which provided for certain services to be performed on a transitional basis by Harvard Bioscience to facilitate our transition into a separate public reporting company for time frames of limited length, which expired in 2014; and (vi) a Sublease of approximately 17,000 square feet of mixed use space of the facility located at 84 October Hill Road, Suite 11, Holliston, Massachusetts, which is our corporate headquarters.

As part of the Transition Services Agreement, and for up to one year following the spin-off date, Harvard Bioscience provided certain support services to us, including, among others, accounting, payroll, human resources and information technology services, with the charges for the transition services generally intended to allow Harvard Bioscience to fully recover the costs directly associated with providing the services, plus all out-of-pocket costs and expenses. In connection with the spin-off and in accordance with these agreements, Harvard Bioscience contributed capital of approximately $15.0 million to us to fund our operations, and transferred to us approximately $0.8 million in assets, made up primarily of property, plant and equipment. As these agreements evidence ongoing commercial arrangements which may involve varying amounts over time, we are unable to provide an approximate dollar value of the amount involved in the transaction. In fiscal 2015, we paid approximately $0.2 million to Harvard Bioscience with

respect to the Transition Services Agreement, Sublease and related cost, and research and development supplies. With respect to such approximate amount paid during fiscal 2015, approximately $50,000 was paid during the period that Harvard Bioscience continued to be a related party. Neither Mr. Green nor Mr. McNaughton receive any amounts from the transactions with Harvard Bioscience relating to their roles as current or former executive officers, and a director as to Mr. Green, of our Company, and it is our understanding that neither Mr. Green nor Mr. McNaughton receive any direct amounts from such agreements and the transactions in relation to their former roles as executive officers of Harvard Bioscience, and Mr. Green's continued role as a director of such company, and their interest is limited to benefits they may receive solely relating to their ongoing roles as executive officer, as to Mr. McNaughton, and director, as to Mr. Green, and stockholders of our Company. As a non-employee director of Harvard Bioscience, Mr. Green also is entitled to receive director compensation that all non-employee directors are entitled to receive under Harvard Bioscience's director compensation programs.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Sale of Restricted Securities

Shares of our common stock beneficially owned by individuals who are our affiliates will be restricted securities under the Securities Act. Individuals who may be considered our affiliates are those individuals who control, are controlled by or are under common control with us, as those terms generally are interpreted for federal securities law purposes. These individuals may include some or all of our directors and executive officers. Individuals who are our affiliates will be permitted to sell their shares of our common stock only pursuant to an effective registration statement under the Securities Act, or an exemption from the registration requirements of the Securities Act, such as those afforded by Section 4(a)(1) of the Securities Act or Rule 144 thereunder.

Rule 144

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including an affiliate, who beneficially owns “restricted securities” of a “reporting company” may not sell these securities until the person has beneficially owned them for at least six months. Thereafter, affiliates may not sell within any three-month period a number of shares in excess of the greater of: (i) 1% of the then outstanding shares of common stock as shown by the most recent report or statement published by the issuer; and (ii) the average weekly reported trading volume in such securities during the four preceding calendar weeks.

Sales under Rule 144 by our affiliates also will be subject to restrictions relating to manner of sale, notice and the availability of current public information about us and may be affected only through unsolicited brokers’ transactions.

Persons not deemed to be affiliates who have beneficially owned “restricted securities” for at least six months but for less than one year may sell these securities, provided that current public information about us is “available,” which means that, on the date of sale, we are current in our Exchange Act filings. After beneficially owning “restricted securities” for one year, our non-affiliates may engage in unlimited re-sales of such securities.

87

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities offered by this prospectus will be passed upon for us by Burns & Levinson LLP, Boston, MA. Certain legal matters in connection with this offering will be passed upon for the placement agent by Ellenoff Grossman & Schole LLP, New York, NY.

EXPERTS

The consolidated financial statements of Biostage, Inc. as of December 31, 2015 and 2014, and for each of the years in the two-year period ended December 31, 2015, have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The audit report covering the December 31, 2015 consolidated financial statements contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and will require additional financing to fund future operations which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information requirements of the Exchange Act and, in accordance therewith, file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. These documents also may be accessed through the SEC's electronic data gathering, analysis and retrieval system, or EDGAR, via electronic means, including the SEC's home page on the Internet (*www.sec.gov*).

We post on our public website (*http://www.biostage.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

We have the authority to designate and issue more than one class or series of stock having various preferences, conversion and other rights, voting powers, restrictions, limitations as to dividends, qualifications, and terms and conditions of redemption. See "Description of Capital Stock." We will furnish a full statement of the relative rights and preferences of each class or series of our stock which has been so designated and any restrictions on the ownership or transfer of our stock to any shareholder upon request and without charge. Written requests for such copies should be directed to Biostage, Inc., 84 October Hill Road, Suite 11, Holliston, Massachusetts 01746-1371, or by telephone request to (774) 233-7300.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

BIOSTAGE, INC. AND SUBSIDIARIES

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	September 30, 2016	December 31, 2015
Assets		
Current Assets:		
Cash	$ 6,006	$ 7,456
Accounts receivable	66	21
Inventory	41	75
Prepaid expenses	96	330
Total current assets	6,209	7,882
Property, plant and equipment, net	988	1,074
Total assets	$ 7,197	$ 8,956
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 803	$ 357
Accrued and other current liabilities	762	297
Warrant liability	846	-
Total current liabilities	2,411	654
Total liabilities	$ 2,411	$ 654
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value; 1,000,000 shares authorized; none issued and outstanding	-	-
Series B convertible preferred stock, $0.01 par value: 1,000,000 shares authorized; 695,857 shares issued and none outstanding	-	-
Common stock, $0.01 par value; 30,000,000 shares authorized and 17,108,968 and 14,101,395 shares issued and outstanding, respectively	171	141
Additional paid-in capital	37,599	32,908
Accumulated deficit	(32,976)	(24,739)
Accumulated other comprehensive loss	(8)	(8)
Total stockholders' equity	4,786	8,302
Total liabilities and stockholders' equity	$ 7,197	$ 8,956

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Three Months ended September 30,		Nine Months ended September 30,	
	2016	2015	2016	2015
Revenues	$ 26	$ 37	$ 54	$ 110
Cost of revenues	13	18	57	55
Gross profit (deficit)	13	19	(3)	55
Operating expenses:				
Research and development	2,225	1,269	5,279	3,504
Selling, general and administrative	937	1,042	3,261	5,962
Total operating expenses	3,162	2,311	8,540	9,466
Operating loss	(3,149)	(2,292)	(8,543)	(9,411)
Other income (expense):				
Change in fair value of warrant liability, net of issuance costs of $129	96	-	306	-
Other expense	-	-	-	(3)
	96	-	306	(3)
Loss before income taxes	(3,053)	(2,292)	(8,237)	(9,414)
Income taxes	-	-	-	-
Net loss	$ (3,053)	$ (2,292)	$ (8,237)	$ (9,414)
Basic and diluted net loss per share	$ (0.18)	$ (0.19)	$ (0.53)	$ (0.91)
Weighted average common shares, basic and diluted	17,107	11,974	15,585	10,395
Comprehensive loss:				
Net loss	$ (3,053)	$ (2,292)	$ (8,237)	$ (9,414)
Foreign currency translation adjustments	-	-	-	(8)
Total comprehensive loss	$ (3,053)	$ (2,292)	$ (8,237)	$ (9,422)

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (8,237)	$ (9,414)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Share-based compensation expense	1,027	3,612
Depreciation	340	347
Change in fair value of warrant liability, net of issuance costs of $129	(306)	-
Changes in operating assets and liabilities:		
Related party receivables, net	-	11
Accounts receivable	(45)	(54)
Inventories	34	63
Prepaid expenses	234	235
Accounts payable	418	(150)
Accrued and other current liabilities	465	(212)
Net cash used in operating activities	(6,070)	(5,562)
Cash flows from investing activities		
Additions to property and equipment	(225)	(175)
Net cash used in investing activities	(225)	(175)
Cash flows from financing activities		
Proceeds from issuance of common stock and warrants, net of issuance costs	4,496	-
Proceeds from issuance of common stock, net of issuance costs	349	3,314
Proceeds from issuance of convertible preferred stock, net of issuance costs	-	5,357
Net cash provided by financing activities	4,845	8,671
Effect of foreign exchange rates on cash	-	(8)
Net increase (decrease) in cash	(1,450)	2,926
Cash at beginning of period	7,456	5,272
Cash at end of period	$ 6,006	$ 8,198
Supplemental disclosure of cash flow information and non-cash investing and financing activities:		

Equipment purchases included in accounts payable	$ 28	$ -
Grant date fair value of warrants issued to placement agent	$ 116	$ -

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

Biostage, Inc., formerly Harvard Apparatus Regenerative Technology, Inc. ("Biostage" or the "Company") is a biotechnology company developing bioengineered organ implants based on our novel Cellframe ™ technology. Our Cellframe technology is comprised of a biocompatible scaffold that is seeded with the recipient's own stem cells. We believe that this technology may prove to be effective for treating patients across a number of life-threatening medical indications who currently have unmet medical needs. We are currently developing our Cellframe technology to treat life-threatening conditions of the esophagus, bronchus or trachea with the objective of dramatically improving the treatment paradigm for those patients.

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.

The Company changed its name from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc. on March 31, 2016. All references to the Company have been changed to Biostage in the accompanying consolidated financial statements and notes thereto.

Basis of Presentation

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").

Earnings per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants and unvested restricted stock.

The Company applied the two-class method to calculate basic and diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2016, as its warrants to purchase common stock are participating securities.

The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a net loss position for the three and nine months ended September 30, 2016 and warrant holders do not participate in losses.

Basic and diluted shares outstanding are the same for each period presented as all common stock equivalents would be antidilutive due to the net losses incurred.

Reclassification

Sales and marketing expenses of $0.1 million and $0.3 million for the three and nine months ended September 30, 2015, respectively, have been reclassified to selling, general and administrative expenses to conform to the 2016 presentation.

Unaudited Interim Financial Information

The accompanying interim balance sheet as of September 30, 2016 and consolidated interim statements of operations and comprehensive loss and cash flows for the nine months ended September 30, 2016 and 2015 are unaudited. The interim unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company’s financial position as of September 30, 2016 and its results of operations and cash flows for the nine months ended September 30, 2016 and 2015. The financial data and other information disclosed in these notes related to the three month period ended September 30, 2016 and 2015 are unaudited. The results for the nine months ended September 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, any other interim periods or any future year or period.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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

Summary of Significant Accounting Policies

The accounting policies underlying the accompanying unaudited consolidated financial statements are those set forth in Note 2 to the financial statements for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K, and additionally the following accounting policy for warrants issued during the nine months ended September 30, 2016.

Warrant Accounting

The Company classifies a warrant to purchase shares of its common stock as a liability on its consolidated balance sheets as this warrant is a free-standing financial instrument that may require the Company to transfer consideration upon exercise. Each warrant is initially recorded at fair value on date of grant using the Black-Scholes model and net of issuance costs, and it is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, " *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,"* to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. This update is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company has not adopted ASU 2014-15 and does not expect the adoption to have a significant impact on the Company's consolidated financial statements or related disclosures.

In February 2016, the FASB, issued ASU, 2016-02- *Leases (Topic 842)*. The ASU requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will be effective for the Company in the first quarter of 2019, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on the Company's consolidated financial statements or related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Stock Compensation - Improvements to Employee Share-Based Payment Accounting,* ("ASU 2016-09"), which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and policy elections on the impact for forfeitures. ASU 2016-09 is effective for fiscal years beginning after December 15, 2017 and interim periods within annual periods beginning after December 15, 2018. The Company has not adopted ASU 2016-09 and does not expect the adoption to have a significant impact on the Company's consolidated financial statements or related disclosures.

3. Capital Stock, Financing and Liquidity

Capital Stock

On May 19, 2016, the Company closed on a Securities Purchase Agreement (the "Purchase Agreement") for the sale by the Company of 2,836,880 shares of the Company's common stock at a purchase price of $1.7625 per share and the issuance of warrants to purchase 1,418,440 shares of common stock at an exercise price of $1.7625 per warrant for gross proceeds of $5.0 million or $4.6 million, net of issuance costs. Additionally, the Company issued the placement agent warrants to purchase 141,844 shares of common stock to the placement agent for the offering at an exercise price of $1.7625 per warrant. The warrants are initially exercisable commencing November 19, 2016 through their expiration date of May 19, 2021.

On February 18, 2015, the Company closed an underwritten public offering of 2,070,000 registered shares of its common stock, at a price to the public of $1.75 per share, and 695,857 registered shares of its $0.01 par Series B Convertible Preferred Stock ("Series B") at a price to the public of $8.75 per share. Gross proceeds from the offering were $9.7 million and underwriters' fees and issuance costs totaled $1.1 million. Thus, the Company generated net proceeds of $8.6 million from the underwritten public offering.

The Series B was convertible into five shares of common stock at the option of the holder, subject to certain limitations related to the holder's ownership percentage of the Company's outstanding common stock. The Series B voted with the common stock on all matters on an as-converted basis, and had no preference to the common shares in respect of dividends, voting, liquidation or otherwise.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

During 2015, all outstanding shares of Series B were converted to common stock, including 205,279 shares of Series B which were converted into 1,026,395 shares of common stock during the nine months ended September 30, 2015.

3. Capital Stock, Financing and Liquidity (continued)

Aspire Purchase Agreement

On December 15, 2015, the Company entered into a common stock purchase agreement (the "Aspire Purchase Agreement"), with Aspire Capital Fund, LLC, ("Aspire Capital"), under which Aspire Capital is committed to purchase up to an aggregate of $15.0 million of the Company's common stock over the approximately 30-month term of the Purchase Agreement. In consideration for entering into the Aspire Purchase Agreement, concurrently with the execution of the Aspire Purchase Agreement, the Company issued Aspire Capital 150,000 shares of our common stock as a commitment fee (the "Commitment Shares").

Upon execution of the Aspire Purchase Agreement, the Company sold to Aspire Capital 500,000 shares of common stock at $2.00 per share (the "Initial Purchase Shares"), which resulted in net proceeds of approximately $0.9 million. Pursuant to the Aspire Purchase Agreement and Registration Rights Agreement, the Company registered 2,688,933 shares of its common stock. This includes the Commitment Shares and the initial purchase shares issued to Aspire Capital and 2,038,933 shares of common stock which the Company may issue to Aspire Capital in the future.

Under the approximately 30-month term of the Aspire Purchase Agreement, on any trading day on which the closing sale price of the Company's common stock exceeds $0.50, the Company had the right, in its sole discretion, to direct Aspire Capital to purchase up to 150,000 shares of the Company's common stock per trading day, at a per share price calculated by reference to the prevailing market price of the Company's common stock. In addition, the Company had the right, from time to time in its sole discretion, to sell Aspire Capital an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the Nasdaq Capital Market on the next trading day, subject to a maximum number of shares which the Company may determine and a minimum trading price. The purchase price per purchase share pursuant to such purchase notices were calculated by reference to the prevailing market price of the Company's common stock.

There were no trading volume requirements or restrictions under the Aspire Purchase Agreement, and the Company controlled the timing and amount of any sales of our common stock to Aspire Capital. There were no monetary penalties for the Company failing to maintain effectiveness of registration. Aspire Capital had no right to require any sales by the Company, but was obligated to make purchases from us as the Company directs in accordance with the Aspire Purchase Agreement. There were no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Additionally, Aspire Capital could hedge its position in the Company's common stock.

On May 12, 2016, the Company issued 150,000 shares of common stock under this arrangement in exchange for gross proceeds of $371 thousand or $349 thousand, net of issuance costs.

The Company terminated the Aspire Purchase Agreement effective as of May 17, 2016. The agreement was terminated by the Company without any penalty or cost to the Company.

Liquidity

The Company has incurred substantial operating losses since its inception, and as of September 30, 2016 has an accumulated deficit of approximately $33.0 million. The Company expects to continue to incur operating losses and negative cash flows from operations in 2016 and in future years. Management believes that the Company's cash at September 30, 2016 will be sufficient to meet the Company's obligations through December 31, 2016 and into early 2017. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company will need to raise additional funds in future periods to fund its operations. Cash requirements and cash resource needs will vary significantly depending upon the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for the Company's products that are currently under development. The Company will seek to raise necessary funds through a combination of publicly or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on terms favorable to us, if at all.

The Company's operations will be adversely affected if it is unable to raise or obtain needed funding and may materially affect the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and therefore, the financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classifications of liabilities that may result from the outcome of this uncertainty.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

4. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

During the year ended December 31, 2015, the Company had no assets or liabilities requiring fair value measurements. As discussed in Note 3, on May 19, 2016, the Company closed on the Purchase Agreement for the sale by the Company of shares of the Company's common stock and the issuance of warrants to purchase 1,418,440 shares of common stock at an exercise price of $1.7625 per warrant. Additionally, the Company issued the placement agent warrants to purchase 141,844 shares of Common Stock at an exercise price of $1.7625 per warrant. The warrants are initially exercisable commencing November 19, 2016 through their expiration date of May 19, 2021. The liability associated with those warrants was initially recorded at fair value in the Company's consolidated balance sheet upon issuance, and subsequently re-measured each fiscal quarter. The changes in the fair value between issuance and September 30, 2016 recorded as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The Company has concluded that the warrants issued in connection with the Purchase Agreement, meet the definition of a liability under *ASC 480 Distinguishing liabilities From Equity* and has classified the liability as Level 3.

The Company has re-measured the liability to estimated fair value at September 30, 2016, using the Black-Scholes option pricing model with the following assumptions:

	September 30, 2016	
Risk-free interest rate	1.18	%
Expected volatility	73.8	%
Expected term	5.2 years	
Expected dividend yield	0	%

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2016:

	Fair Value Measurement as of September 30, 2016 (In thousands)			
	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 846	$ 846
Total	$ -	$ -	$ 846	$ 846

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2016:

	Warrant Liability (in thousands)
Balance at December 31, 2015	$ -
Issuance of warrants	1,281
Change in fair value upon re-measurement	(435)
Balance at September 30, 2016	$ 846

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

There were no transfers between Level 1 and Level 2 in any of the periods reported.

5. Related Party Transactions

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

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

From inception through April 17, 2015, Harvard Bioscience was considered to be a related party to the Company because David Green, the Company's former Chairman and CEO, was also a director of Harvard Bioscience. After Mr. Green's April 17, 2015 resignation as Chairman and CEO of the Company, Harvard Bioscience is no longer considered a related party. Mr. Green service on the Company's board of directors ended on May 26, 2016 but Mr. Green remains a member of the Board of Directors of Harvard Bioscience. Related party rent expenses with Harvard Bioscience for the period of January 1, 2015 through September 30, 2015, were $51,000.

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

6. Stock-Based Compensation

Biostage 2013 Equity Incentive Plan

The Company maintains the 2013 Equity Incentive Plan (the "Plan") for the benefit of certain of its officers, employees, non-employee directors, and other key persons (including consultants and advisory board members). All options and awards granted under the Plan consist of the Company's shares of common stock.

The Company also issued equity awards under the Plan at the time of the Distribution to all holders of Harvard Bioscience equity awards as part of an adjustment (the "Adjustment") to prevent a loss of value due to the Distribution.

Compensation expense recognized under the Plan relates to service provided by employees, board members and a non-employee of the Company. There was no required compensation associated with the Adjustment awards to employees who remained at Harvard Bioscience.

The Company has granted options to purchase common stock and restricted stock units under the Plan. Stock option activity during the nine months ended September 30, 2016 was as follows:

	Amount	Weighted-average exercise price
Outstanding at December 31, 2015	3,253,118	$ 3.29
Granted	915,000	1.58
Canceled	(288,817)	3.69
Outstanding at September 30, 2016	3,879,301	$ 2.86

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

6. Stock-Based Compensation (continued)

The Company uses the Black- Scholes model to value its stock options. Weighted average estimated value of stock options granted using the Black-Scholes model during the nine months ended September 30, 2016 was $1.04. The weighted average assumptions for valuing those options granted were as follows:

Expected volatility	74.26%
Expected dividends	0.00 %
Expected term in years	6.13
Risk-free rate	1.50 %

There was no material restricted stock unit activity during the nine months ended September 30, 2016.

The Company recorded total stock-based compensation during the three and nine months ended September 30 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Research and development	$ 198	$ 182	$ 535	$ 555
General and administrative	164	246	492	3,057
Total stock-based compensation	$ 362	$ 428	$ 1,027	$ 3,612

Included in the above table is stock-based compensation related to the Harvard Bioscience Plan, which is described below.

Harvard Bioscience Stock Option and Incentive Plan

Harvard Bioscience maintains the Third Amended and Restated 2000 Stock Option and Incentive Plan (as amended, the "Harvard Bioscience Plan") for the benefit of certain of its officers, directors and employees. In connection with the Separation, those employees of Harvard Bioscience who became employees of Biostage were allowed to continue vesting in their stock-based awards of stock options and restricted stock units granted under the Harvard Bioscience Plan. Accordingly, the Company recognizes compensation expense as services are provided by those employees.

7. Commitments and Contingencies

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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Harvard Apparatus Regenerative Technology, Inc.:

We have audited the accompanying consolidated balance sheets of Harvard Apparatus Regenerative Technology, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Harvard Apparatus Regenerative Technology, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2015 in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 4 to the consolidated financial statements, the Company has suffered recurring losses from operations and will require additional financing to fund future operations which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in note 4. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

(Signed) KPMG LLP

Boston, Massachusetts

March 30, 2016

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except par value and share data)

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash	$ 7,456	$ 5,272
Related party receivables	-	27
Accounts receivable	21	5
Inventory	75	207
Prepaid expenses	330	317
Other current assets		
Total current assets	7,882	5,828
Property, plant and equipment, net	1,074	1,376
Total non-current assets	1,074	1,376
Total assets	$ 8,956	$ 7,204
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 357	$ 370
Related party payable	-	16
Accrued and other current liabilities	297	324
Total current liabilities	654	710
Total non-current liabilities	-	-
Total liabilities	654	710
Commitments and contingencies (note 11)		
Stockholders' equity:		
Series B convertible preferred stock, par value $0.01 per share, 2,000,000 shares authorized; 695,857 and 0 shares issued, respectively; and 0 outstanding	-	-
Common stock, par value $0.01 per share, 30,000,000 shares authorized; 14,101,395 and 7,856,607 shares issued and outstanding, respectively	141	79
Additional paid-in capital	32,908	19,449
Accumulated deficit	(24,739)	(13,035)
Accumulated other comprehensive (loss) income	(8)	1
Total stockholders' equity	8,302	6,494
Total liabilities and stockholders' equity	$ 8,956	$ 7,204

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Years ended December 31,	
	2015	2014
Revenues	$ 118	$ 93
Cost of revenues	139	48
Gross (loss) profit	(21)	45
Operating expenses:		
Research and development	4,786	5,119
Sales and marketing	289	329
General and administrative	6,605	5,654
Total operating expenses	11,680	11,102
Operating loss	(11,701)	(11,057)
Other expense, net	(3)	(4)
Loss before income taxes	(11,704)	(11,061)
Income taxes	-	-
Net loss	$ (11,704)	$ (11,061)
Basic and diluted net loss per share	$ (1.05)	$ (1.41)
Weighted average common shares, basic and diluted	11,154	7,821
Comprehensive loss:		
Net loss	$ (11,704)	$ (11,061)
Foreign currency translation adjustments	(9)	1
Total comprehensive loss	$ (11,713)	$ (11,060)

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Number of Common Shares Oustanding	Number of Series B Convertible Preferred Shares Oustanding	Common Stock	Series B Convertible Preferred Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2013	7,743	-	$ 77	$ -	$ 16,466	$ (1,974)	$ -	$ 14,569
Net loss	-	-	-	-	-	(11,061)	-	(11,061)
Share based compensation	-	-	-	-	2,565	-	-	2,565
Stock option exercises	106	-	2	-	418	-	-	420
Vesting of restricted stock units	7	-	-	-	-	-	-	-
Other comprehensive income	-	-	-	-	-	-	1	1
Balance at December 31, 2014	7,856	-	79	-	19,449	(13,035)	1	6,494
Net loss	-	-	-	-	-	(11,704)	-	(11,704)
Share based compensation	-	-	-	-	3,966	-	-	3,966
Issunace of common stock under employee stock purchase plan	39		-	-	76	-	-	76
Vesting of restricted stock units	6	-	-	-	-	-	-	-
Issuance of Series B convertible preferred stock, net of offering cost	-	696	-	5,357	-	-	-	5,357
Conversion of Series B preferred stock to common stock	3,480	(696)	35	(5,357)	5,322	-	-	-
Isuance of common stock, net of offering costs	2,720	-	27	-	4,095	-	-	4,122
Other comprehensive loss	-	-	-	-	-	-	(9)	(9)
Balance at December 31, 2015	14,101	-	$ 141	$ -	$ 32,908	$ (24,739)	$ (8)	$ 8,302

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,	
	2015	2014
Cash flows used in operating activities:		
Net loss:	$ (11,704)	$ (11,061)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,966	2,565
Depreciation	478	363
Changes in operating assets and liabilities:		
Decrease (increase) in related party receivables	27	(5)
Increase in accounts receivable	(16)	(5)
Decrease (increase) in inventories	132	(169)
(Increase) decrease in prepaid expenses	(13)	104
(Decrease) increase in accounts payable	(13)	126
Decrease in related party payable	(16)	(74)
(Decrease) increase in accrued and other current liabilities	(27)	163
Net cash used in operating activities	(7,186)	(7,993)
Cash flows used in investing activities:		
Additions to property, plant and equipment	(176)	(1,164)
Net cash used in investing activities	(176)	(1,164)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	4,198	420
Proceeds from issuance of Series B convertible preferred stock, net	5,357	-
Net cash provided by financing activities	9,555	420
Effect of exchange rate changes on cash	(9)	1
Net (decrease) increase in cash	2,184	(8,736)
Cash at the beginning of the period	5,272	14,008
Cash at the end of the period	$ 7,456	$ 5,272

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Overview

Harvard Apparatus Regenerative Technology, Inc. ("HART" or the "Company") is developing bioengineered organ implants utilizing the recipient's own stem cells to treat life-threatening conditions. HART has developed and initiated the testing of a new technology platform to create organ implants to replace diseased or damaged portions of the esophagus, trachea or bronchus to restore function.

Prior to November 1, 2013, the Company was a business segment of Harvard Bioscience, Inc. ("Harvard Bioscience"). The Company is engaged in the development and commercialization of regenerated organs for human transplant. Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and acquiring operating assets.

HART was incorporated in Delaware on May 3, 2012 by Harvard Bioscience, as a wholly-owned subsidiary, to provide a means for separating Harvard Bioscience's regenerative medicine business from its other businesses. On October 31, 2013, Harvard Bioscience contributed its regenerative medicine business assets, plus $15 million of cash, into HART (the "Separation"). On November 1, 2013, the previously announced spin-off of the Company from Harvard Bioscience was completed. On that date, the Company became an independent company that operates the regenerative medicine business previously owned by Harvard Bioscience. The spin-off was completed through the distribution to Harvard Bioscience stockholders of all the shares of common stock of HART (the "Distribution"). 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.

The Company has one business segment and does not have significant costs or assets outside the United States.

The historical deferred tax assets, including the operating losses and credit carryforwards generated by HART prior to the Separation, remained with Harvard Bioscience subsequent to the Separation.

The financial statements reflect the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles in the United States ("GAAP").

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies

(a) Principles of Consolidation

The consolidated financial statements include the accounts of HART and its three wholly-owned subsidiaries, Harvard Apparatus Regenerative Technology GmbH (Germany), Harvard Apparatus Regenerative Technology AB (Sweden) and Harvard Apparatus Regenerative Technology Limited (UK). All intercompany balances and transactions have been eliminated in consolidation.

(b) Use of Estimates

The process of preparing financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such estimates include, but are not limited to, stock-based compensation, accruals, depreciation and income taxes. Actual results could differ from those estimates and changes in estimates may occur.

(c) Inventories

The Company values its inventories at the lower of the actual cost to purchase (first-in, first-out method) and/or manufacture the inventories or the current estimated market value of the inventories. The Company regularly reviews inventory quantities on hand and records a provision to write down excess and obsolete inventories to its estimated net realizable value if less than cost, based primarily on its estimated forecast of product demand.

(d) Property, Plant and Equipment

Property, plant and equipment are carried at cost and depreciated using the straight-line method over the estimated useful lives of the assets as follows:

Leasehold improvements	Shorter of expected useful life or lease term
Furniture, machinery and equipment, computer equipment and software	3- 7 years

Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized.

(e) Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An asset, or group of assets, are considered to be impaired when the undiscounted estimated net cash flows expected to be generated by the asset, or group of assets, are less than its carrying amount. The impairment recognized is the amount by which the carrying amount exceeds the fair market value of the impaired asset, or group of assets.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies – (continued)

(f) Revenue Recognition

The Company follows the provisions of FASB ASC 605, " *Revenue Recognition* ". The Company recognizes product revenue when persuasive evidence of a sales arrangement exists, the price to the buyer is fixed or determinable, delivery has occurred, and collectability of the sales price is reasonably assured. To date, the Company has recognized revenues only for sales of its research bioreactor systems. Sales of some of its products include additional services such as installation and training. Revenues on these products are recognized when the additional services have been performed. Service agreements on its equipment are typically sold separately from the sale of the equipment.

The Company accounts for shipping and handling fees and costs in accordance with the provisions of FASB ASC 605-45-45, " *Revenue Recognition — Principal Agent Considerations* ", which requires all amounts charged to customers for shipping and handling to be classified as revenues. Costs related to shipping and handling are classified as cost of revenues. Provisions for warranties and product returns are estimated and accrued at the time sales are recorded. The Company has no obligations to customers after the date products are shipped or installed, if applicable, other than pursuant to warranty obligations. The Company provides for the estimated amount of future returns upon shipment of products or installation, if applicable, based on historical experience.

(g) Research and Development

Research and development costs are expensed as incurred.

(h) Stock-based Compensation

The Company accounts for stock-based payment awards in accordance with the provisions of FASB ASC 718, " *Compensation — Stock Compensation* ", which requires it to recognize compensation expense for all stock-based payment awards made to employees, non-employees, and directors including employee stock options, restricted stock units, and employee stock purchases related to the Employee Stock Purchase Plan ("employee stock purchases").

FASB ASC 718 requires companies to estimate the fair value of stock-based payment awards, except restricted stock units, on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in its consolidated statements of income.

We measure share-based awards granted to consultants and non-employees based on the fair value of the award on the date at which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is re-measured using the then-current fair value of our ordinary shares and updated assumption inputs in the Black-Scholes option-pricing model

Under FASB ASC 718, the Company elected the Black-Scholes option-pricing model for valuation of stock-based payment awards. The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes option-pricing model is affected by its stock price as well as assumptions regarding a number of and subjective variables. These variables include, but are not limited to its expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors. The Company records stock compensation expense on a straight-line basis over the requisite service period for all awards granted since the adoption of FASB ASC 718. When performance based grants are issued the Company recognizes no expense until achievement of the performance requirement is deemed probable.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies – (continued)

The fair values of Restricted Stock Units (RSU) are based on the number of shares granted and market price of the stock on the date of grant and are recorded as compensation expense ratably over the applicable service period, which is generally four years. Unvested restricted stock units and vested and unvested stock options are forfeited in the event of termination of employment with HART or Harvard Bioscience.

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, where the minimum amount of expense recorded is at least equal to the percent of an award vested.

(i) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to be applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is recorded when it is more likely than not that some or all of the deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are expected to be realizable.

Tax positions taken or expected to be taken in the course of preparing our tax returns are required to be evaluated to determine whether the tax positions are “more-likely-than-not” of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year.

(j) Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the periods presented. The computation of diluted net loss per share is similar to the computation of basic earnings per share, except that the denominator is increased for the assumed exercise of dilutive options and other potentially dilutive securities using the treasury stock method unless the effect is antidilutive. Basic and diluted net loss per share are the same for all periods presented as the exercise of options and other unvested RSUs would be antidilutive.

(k) Foreign Currency Translation

The functional currency of the Company's foreign subsidiaries is their local currency. All assets and liabilities of its foreign subsidiaries are translated at exchange rates in effect at period-end. Income and expenses are translated at rates which approximate those in effect on the transaction dates. The resulting translation adjustment is recorded as a separate component of stockholders' equity in accumulated other comprehensive loss in the consolidated balance sheets. Gains and losses resulting from foreign currency transactions are included in net loss.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies – (continued)

(l) Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive loss. The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 220, "Comprehensive Income". FASB ASC 220 requires companies to report all changes in equity during a period, resulting from net income (loss) and transactions from non-owner sources, in a financial statement in the period in which they are recognized. We have chosen to disclose comprehensive loss, which encompasses net loss, foreign currency translation adjustments, net of tax, in the consolidated statements of operations and comprehensive loss.

(m) Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, "*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,"* to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. This update is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not expect the adoption of ASU 2014-15 to have a significant impact on our Consolidated Financial Statements or related disclosures.

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update or ASU, 2016-02, *Leases (Topic 842)*. The ASU requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. The ASU will be effective for us in the first quarter of 2019, with early adoption permitted. We are currently evaluating the impact that the adoption of this ASU will have our consolidated financial statements.

3. Concentrations

Effective November 1, 2013 the Company entered into a 10-year product distribution agreement with Harvard Bioscience under which each company will be the exclusive distributor for the other party for products such other party develops for sale in the markets served by the other. In addition, Harvard Bioscience agreed that except for certain then-existing activities of its German subsidiary, to the extent that any Harvard Bioscience businesses desire to resell or distribute any bioreactor that is then manufactured by HART, HART will be the exclusive manufacturer of such bioreactors and Harvard Bioscience will purchase such bioreactors from the Company.

Sales to Harvard Bioscience, the Company's distributor of research bioreactor systems, accounted for 100% of the revenues and receivables for all periods presented.

4. Liquidity

The accompanying consolidated financial statements have been prepared assuming that HART will continue as a going concern. HART has incurred substantial operating losses since its inception, and as of December 31, 2015, has an accumulated deficit of approximately $24.7 million. The Company is currently investing significant resources in development and commercialization of products 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 from operations in 2016 and in future years.

Management of the Company believes that HART will need additional funds in 2016 and in future years to fund its operations. HART's operations will be adversely affected if we are unable to raise or obtain needed funding and may materially affect our ability to continue as a going concern. Cash requirements and cash resource needs will vary significantly depending upon the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for the Company's products that are currently under development. HART will seek to raise necessary funds through a combination of additional sales of common stock to Aspire Capital Fund, LLC. (See Note 12), other public or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Inventories

Inventories consist of the following:

	December 31,	
	2015	2014
	(in thousands)	
Finished goods	$ -	$ -
Raw materials	75	207
Total	$ 75	$ 207

6. Related Party Transactions

During the year ended December 31, 2015, the Company recognized $165,000 in recruiting expense related to professional search fees paid to RobinsonButler, an executive recruiting consultancy firm where Thomas Robinson, a Member of the Company's Board of Directors, is a partner. RobinsonButler was retained by the Company's Board of Directors to complete the search for the Company's President and Chief Executive Officer.

Relationship with Harvard Bioscience

From inception through April 17, 2015, Harvard Bioscience was considered to be a related party to the Company because David Green, the Company's former Chairman and CEO, was also a director of Harvard Bioscience. Since Mr. Green resigned from the positions of Chairman and CEO of HART on April 17, 2015, Harvard Bioscience is no longer considered a related party. Mr. Green is still a Member of the Boards of Directors of both HART and Harvard Bioscience.

In connection with the Separation, the Company entered into a series of agreements with Harvard Bioscience. These agreements include: (i) a Separation and Distribution Agreement to effect the separation and spin-off distribution and

provide other agreements to govern the Company's relationship with Harvard Bioscience after the spin-off; (ii) an Intellectual Property Matters Agreement, which governs various intellectual property related arrangements between the Company and Harvard Bioscience, including the separation of intellectual property rights between the Company and Harvard Bioscience, as well as certain related cross-licenses between the two companies; (iii) a Product Distribution Agreement, which provided that each company be the exclusive distributor for the other party for products such other party develops for sale in the markets served by the other; (iv) a Tax Sharing Agreement, which governs the Company's and Harvard Bioscience's respective rights, responsibilities and obligations with respect to tax liabilities and benefits, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings and other matters regarding taxes for periods before, during and after the spin-off; and (v) a Transition Services Agreement, which provided for certain services to be performed on a transitional basis by Harvard Bioscience to facilitate HART's transition into a separate public reporting company. As part of the Transition Services Agreement, and for one year following the spin-off date, Harvard Bioscience provided certain support services to HART, including, among others, accounting, payroll, human resources and information technology services, with the charges for the transition services generally intended to allow Harvard Bioscience to fully recover the costs directly associated with providing the services, plus all out-of-pocket costs and expenses. The Company's operating expenses for the twelve months subsequent to the Separation included fees paid to Harvard Bioscience for services provided pursuant to the Transition Services Agreement, and operating supplies. Fees for the years ended December 31, 2015 and 2014 under the Transition Services Agreement were zero and $0.2 million, respectively. In addition, the Company's rent and related costs subsequent to the Separation was incurred and paid to Harvard Bioscience pursuant to a sublease between the two companies. Sublease related expenses during the periods which HBIO was a related part were $51 thousand and $183 thousand for the years ended December 31, 2015 and 2014, respectively. Refer to Note 8 for further details on the sublease.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

7. Property, Plant and Equipment, Net

Property, plant and equipment, net consist of the following:

	December 31,	
	2015	2014
	(in thousands)	
Leasehold improvements	$451	$449
Furniture, machinery and equipment	1,292	1,138
Computer equipment and software	406	400
	2,149	1,987
Less: accumulated depreciation	(1,075)	(611)
Property, plant and equipment, net	$1,074	$1,376

8. Leases

In October 2013, the Company entered into a sublease with Harvard Bioscience effective November 1, 2013 for its headquarters, offices, manufacturing, and research and development facilities located in Holliston, Massachusetts. The operating lease was non-cancelable for an initial eighteen month period. The sublease automatically extends for additional successive twelve month periods if neither party provides notice of termination 180 days in advance through May 31, 2017. Total rent expense was $0.1 million and $0.1 million for the years ended December 31, 2015 and 2014, respectively.

Future minimum lease payments for operating leases with initial or remaining terms in excess of one year at December 31, 2015 were:

	Operating Leases
	(in thousands)
2016	$ 101
2017	43

Thereafter		-
Future minimum lease payments	$	144

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Income Taxes

Prior to the Separation, HART's operating results were historically included in Harvard Bioscience's income tax returns. For periods up to the date of the Separation, 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 operating loss and credit carryforwards generated by HART up to the date of Separation, remained with Harvard Bioscience. Net operating loss and tax carryforwards generated by HART after the Separation will remain with HART.

Income taxes for the years ended December 31, 2015 and 2014 differed from the amount computed by applying the U.S. federal income tax rate of 34% to pre-tax loss as a result of the following:

	Years ended December 31,	
	2015	2014
	(in thousands)	
Computed "expected" income tax benefit	$ (3,979)	$ (3,761)
Increase (decrease) in income taxes resulting from:		
Foreign tax rate and regulation differential	17	40
State income tax benefit, net of federal income tax benefit	(703)	(663)
Non-deductible stock-based compensation expense	68	94
Tax credits	(200)	(178)
Change in valuation allowance allocated to income tax expense	4,797	4,468
Total income taxes	$ -	$ -

The Company has incurred pre-tax losses for the years ended December 31, 2015 and 2014:

	Years ended December 31,	
	2015	2014
	(in thousands)	
Domestic	$ (11,601)	$ (10,780)
Foreign	(103)	(281)

Total	$ (11,704)	$ (11,061)

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Income Taxes – (continued)

The components of HART's deferred tax asset are as follows:

	Years ended December 31,	
	2015	2014
	(in thousands)	
Deferred tax assets:		
Operating loss and credit carryforwards	$ 4,459	$ 2,543
Capitalized research and development	2,941	1,612
Stock-based compensation	2,457	1,086
Accrued expenses	17	27
Property, plant and equipment	51	9
Total deferred tax assets	9,925	5,277
Less: valuation allowance	(9,925)	(5,277)
Deferred tax assets, net	$ -	$ -

The amounts recorded as deferred tax assets as of December 31, 2015 and 2014 represent the amount of tax benefits of existing deductible temporary differences or carryforwards that are more likely than not to be realized through the generation of sufficient future taxable income within the carryforward period. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets and liabilities. Due to the operating results, the Company's cumulative loss position and uncertainty surrounding its forecasts, the Company concluded that a full valuation allowance was needed to offset its deferred tax assets at each period end. As previously mentioned, all deferred tax assets prior to the Separation remained with Harvard Bioscience, Inc. The Company has determined that any uncertain tax positions would have no material impact on the consolidated financial statements of the Company.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change.

Subsequent ownership changes may further affect the limitation in future years. During 2015 the Company completed two equity financings transactions which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. The Company has not, as of yet, conducted a study to determine if any such changes have occurred that could limit its ability to use the net operating loss and credit carryforwards.

For all years through December 31, 2015, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position for these two years. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

Tax free distribution

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 received from legal counsel to Harvard Bioscience 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.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Income Taxes – (continued)

To preserve the tax-free treatment to Harvard Bioscience of the Separation and Distribution, for the two-year period following the Distribution, which such period ended November 1, 2015, the Company was 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; and ceasing to actively conduct the Company's regenerative medicine business. In addition, at all times, including during and following such two-year period, the Company may not take or fail 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.

10. Employee Benefit Plans

The Company and Harvard Bioscience sponsor retirement plans for their U.S. employees, which includes employee savings plans established under Section 401(k) of the U.S. Internal Revenue Code (the "401(k) Plans"). The 401(k) Plans cover substantially all full-time employees who meet certain eligibility requirements. Contributions to the retirement plans are at the discretion of management. For the years ended December 31, 2015 and 2014, the Company's matching contributions to the plans were approximately $93 thousand and $90 thousand, respectively.

11. Commitments and Contingent Liabilities

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. The Company is not currently a party to any such significant claims or proceedings.

12. Capital Stock

Preferred Stock

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 the shares. The Board of Directors may exercise this authority without any further approval of stockholders. As of December 31, 2014, the Company had no preferred stock issued or outstanding.

Series B Convertible Preferred Stock

On February 18, 2015 the Company closed an underwritten public offering of 2,070,000 registered shares of its common stock, at a price to the public of $1.75 per share, and 695,857 registered shares of its Series B Convertible Preferred Stock ("Series B") at a price to the public of $8.75 per share. We received proceeds from the sale of Series B of $5.4 million, net of $0.7 million of underwriting and offering costs. At the option of the investor, each share of Series B was convertible into five shares of common stock of HART, and voted with the common stock on all matters on an as-converted basis, each subject to certain beneficial ownership caps. The Series B had no preference to the common shares in respect of dividends, voting, liquidation or otherwise.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. Capital Stock – (continued)

As of December 31, 2015, all 695,857 shares of issued Series B had converted into 3,479,285 shares of common stock. As of December 31, 2015 no shares of preferred stock were outstanding.

Common Stock

Shareholders Rights Plan

The Company has 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.

February 2015 Shares Offering

On February, 18, 2015, in the registered public offering of the Series B Convertible Preferred Stock described above, the Company also issued 2,070,000 shares of its Common Stock, at a price to the public of $1.75 per share. We received proceeds from the sale of common stock of $3.2 million, net of $0.4 million of offering costs.

Aspire Purchase Agreement

On December 15, 2015, the company entered into a common stock purchase agreement (the "Purchase Agreement"), with Aspire Capital Fund, LLC, ("Aspire Capital"), under which Aspire Capital is committed to purchase up to an aggregate of $15.0 million of our common stock over the approximately 30-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, HART issued Aspire Capital 150,000 shares of our common stock as a commitment fee (the "Commitment Shares").

Upon execution of the Purchase Agreement, the Company sold to Aspire Capital 500,000 shares of common stock at $2.00 per share (the "Initial Purchase Shares"). Net proceeds from the sale of shares to Aspire as of December 31, 2015 were approximately $0.9 million.

Pursuant to the Purchase Agreement and Registration Rights Agreement, the Company registered 2,688,933 shares of our common stock. This includes the Commitment Shares and the Initial Purchase Shares issued to Aspire Capital and 2,038,933 shares of common stock which HART may issue to Aspire Capital in the future.

Under the approximately 30-month term of the Purchase Agreement, on any trading day on which the closing sale price of our common stock exceeds $0.50, the Company has the right, in our sole discretion, to direct Aspire Capital to purchase up to 150,000 shares of the Company's common stock per trading day, at a per share price (the "Purchase Price") calculated by reference to the prevailing market price of our common stock. In addition, the Company has the right, from time to time in our sole discretion, to sell Aspire Capital an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the Nasdaq Capital Market on the next trading day, subject to a maximum number of shares which HART may determine and a minimum trading price. The purchase price per purchase share pursuant to such purchase notices are calculated by reference to the prevailing market price of HART's common stock.

There are no trading volume requirements or restrictions under the Purchase Agreement, and HART controls the timing and amount of any sales of our common stock to Aspire Capital. There are no monetary penalties for the Company failing to maintain effectiveness of registration. Aspire Capital has no right to require any sales by HART, but is obligated to make purchases from us as the Company directs in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. Capital Stock – (continued)

Additionally, Aspire Capital cannot hedge its position in HART common stock. The Purchase Agreement may be terminated by the Company at any time, at HART's discretion, without any penalty or cost to the Company.

Employee Stock Purchase Plan

In 2013, the Company approved the 2013 Equity Incentive Plan (the "2013 Plan"). Under this plan, participating employees can authorize the Company to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of the Company's common stock. At the conclusion of the period, participating employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the Company's common stock at the beginning or end of the period. Shares are issued under the plan for the six-month periods ending June 30 and December 31. Under this plan, 150,000 shares of common stock are authorized for issuance of which 38,872 and 17,042 were issued as of December 31, 2015 and 2014 respectively; an additional 8,308 shares related to the second six-month withholding period of 2015 were issued on January 2, 2016.

13. Share-Based Compensation

HART maintains the 2013 Plan for the benefit of certain of its officers, employees, non-employee directors, and other key persons (including consultants and advisory board members). All options and awards granted under the 2013 Plan consist of HART common shares. Additionally, equity awards related to shares of the Company's common stock were issued from the 2013 Plan at the time of the Distribution to the holders of Harvard Bioscience equity awards as part of an adjustment (the "Adjustment") to those equity awards to prevent a loss of value due to the Distribution.

Harvard Bioscience maintains the Third Amended and Restated 2000 Stock Option and Incentive Plan as amended, (the "Harvard Bioscience Plan") for the benefit of certain of its officers, directors and employees. After the Separation, HART continues to record the expense on share-based awards of Harvard Bioscience stock options and restricted stock units, issued by Harvard Bioscience, to former Harvard Bioscience employees now employed by HART.

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

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. As part of these required adjustments, the Company issued approximately 0.3 million HART options and approximately 0.02 million HART restricted stock units, those that have not been exercised, canceled or expired are reflected below. The Company records compensation expense only on those HART awards issued to HART employees. The Company also records compensation expense on those Harvard Bioscience awards issued to HART employees.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

Harvard Apparatus Regenerative Technology, Inc. 2013 Equity Incentive Plan

The 2013 Equity Incentive Plan was adopted by the Board of Directors on October 11, 2013. The aggregate number of shares authorized for issuance under the Plan were 3,640,000 and 3,320,000 shares of common stock as of December 31, 2015 and 2014, respectively. The Company currently has 3,640,000 shares of its common stock reserved for the issuance of awards under the 2013 Plan.

During 2015 and 2014 no options or restricted stock units were granted to Harvard Bioscience employees or directors, and the Company does not anticipate issuing any to Harvard Bioscience employees in the future.

2013 Plan Award Information

The following is a summary of stock option and restricted stock unit activity:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2013	2,075,707	$ 4.34	19,492	$ 6.00
Granted	237,500	7.93	-	-
Exercised	(115,950)	4.90	(9,796)	6.00
Vested (RSUs)	-	-	-	-
Cancelled/forfeited	(190,277)	4.42	(1,716)	6.00
Balance at December 31, 2014	2,006,980	$ 4.73	7,980	$ 6.00
Granted	1,855,916	2.06	-	-
Exercised	-	-	-	-
Vested (RSUs)	-	-	(6,721)	6.00
Cancelled/forfeited	(609,778)	4.26	(154)	6.00

Balance at December 31, 2015	3,253,118	$ 3.29	1,105	$ 6.00

The Company's policy is to issue stock available from its registered but unissued stock pool through its transfer agent to satisfy stock option exercises and vesting of the restricted stock units.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

The following table summarizes information concerning 2013 Plan currently outstanding and exercisable options as of December 31, 2015:

	Options Outstanding				Options Exercisable			
Range of Exercise Price	Number Outstanding at December 31. 2015	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares Exercisable at December 31. 2015	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value
$.64 - 2.00	1,389,416	9.56	$ 1.45	$1,016,407	-	-	$ -	$ -
2.01 - 4.00	62,416	5.63	3.51	-	47,428	4.78	3.45	-
4.01 - 6.00	1,616,286	7.32	4.29	-	1,106,185	6.72	4.33	-
6.01 - 8.00	50,000	8.76	7.32	-	12,500	8.76	7.32	-
8.01 - 9.06	135,000	8.32	8.76	-	33,750	8.32	8.76	-
$2.05- 9.84	3,253,118	8.31	$ 3.29	$1,016,407	1,199,863	6.71	$ 4.45	$ -

The aggregate intrinsic value in the preceding table represents the total pre-tax intrinsic value, based on the Company's closing stock price of $2.18 as of December 31, 2015, which would have been received by the option holders had all option holders exercised their options as of that date. The aggregate intrinsic value of options exercised for the year ended December 31, 2015 and 2014 was approximately $0 and $507,466, respectively. No options were in-the-money and exercisable as of December 31, 2015.

As of December 31, 2015, the total compensation costs related to unvested awards not yet recognized is $2.5 million and the weighted average period over which it is expected to be recognized is 2.59 years.

2013 Plan Valuation and Expense Information under Share-Based-Payment Accounting

Share-based compensation expense related to the 2013 Plan including stock options, restricted stock units, and the employee stock purchase plan for the years ended December 31, 2015 and 2014 was allocated as follows:

	Years Ended December 31,	
	2015	2014
	(in thousands)	
Research and development	$ 682	$ 554
Sales and marketing	40	94
General and administrative	2,819	1,154
Total stock-based compensation	$ 3,541	$ 1,802

The Company did not capitalize any share-based compensation.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

The weighted-average estimated value of stock options granted during 2015 and 2014 was $1.41 and $5.25, respectively, using the Black Scholes model with the following weighted-average assumptions:

	Year Ended December 31,			
	2015		2014	
Volatility	76.84	%	74.00	%
Risk-free interest rate	1.73	%	1.61	%
Expected holding period	6.09 years		6.25 years	
Dividend yield	-	%	-	%

The Company used the volatility of comparable companies, as management did not believe that our trading history was of a sufficient duration to provide an accurate estimate of expected volatility. The risk-free interest rate assumption is based upon observed Treasury bill interest rates (risk-free) appropriate for the term of the Company's employee stock options. The simplified method of estimating expected life was used. The vesting period is approximately four years and the contractual life is ten years.

The Company also estimated the fair value of non-employee share options using the Black-Scholes option pricing model reflecting the same assumptions as applied to employee and director options in each of the reporting periods, other than the expected life, which is assumed to be the remaining contractual life of the options.

Share-based compensation expense recognized in the Company's consolidated statements of operations for the years ended December 31, 2015 and 2014 is based on awards ultimately expected to vest and has been reduced for annualized estimated forfeitures. Share-based-payment accounting requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience and weighting of various employee classes.

In April 2015, David Green resigned as Chief Executive Officer, President and Chairman of the Board of Directors of HART. Mr. Green remained a member of the Board of Directors. Under the terms of Mr. Green's employment

agreement, certain equity awards immediately vested upon his resignation. This acceleration of vesting resulted in a non-cash share based compensation expense of approximately $1.0 million being recognized in the year ended December 31, 2015. Mr. Green's employment agreement also entitled him to a cash payment equal to two years of his salary, or approximately $1.0 million. The Company and Mr. Green agreed to a modification to accelerate vesting on certain options and extend the exercise period on those and other vested stock options in lieu of the cash payment. These modifications resulted in an additional non-cash share-based compensation expense related to Mr. Green of approximately $1.1 million being recorded in the year ended December 31, 2015. Of the modified options, 387,000 were vested prior to resignation, 290,252 were vested as a result of the resignation and as such required no modification to vesting, and 48,375 options were modified to vest immediately. All 725,627 modified options retained their original exercise price of $4.29 and had the time period during which they could be exercised extended from 30 days from resignation to 7 years. All of Mr. Green's options to buy shares of Harvard Bioscience stock issued under the Harvard Bioscience Plan remain outstanding and the Company will continue to record the associated expense on them as long as Mr. Green provides service to HART in his position on the Board of Directors.

Harvard Bioscience Plan

Harvard Bioscience maintains the Harvard Bioscience Plan for the benefit of certain of its officers, directors and employees.

All awards were granted to the Company's employees and directors at exercise prices equal to or greater than fair market value of the Harvard Bioscience's common stock on the date of grant.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

Harvard Bioscience Plan Award Information

The following is a summary of stock option and restricted stock unit activity:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2013	2,500,339	$ 3.20	326,185	$ 5.46
Granted	—	—	—	—
Exercised	(66,056)	3.34	—	—
Vested (RSUs)	—	—	(154,628)	—
Cancelled/forfeited	(311,635)	5.58	—	—
Balance at December 31, 2014	2,122,648	2.84	171,557	5.67
Granted	—	—	—	—
Exercised	(918,646)	2.73	—	—
Vested (RSUs)	—	—	(88,648)	4.52
Cancelled/forfeited	(6,585)	3.64	—	—
Balance at December 31, 2015	1,197,417	$ 2.92	82,909	$ 4.30

The following table summarizes information concerning the Harvard Bioscience Plan currently outstanding and exercisable options as of December 31, 2015:

	Options Outstanding				Options Exercisable			
Range of Exercise Price	Number Outstanding at December 31. 2015	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares Exercisable at December 31. 2014	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value
$2.02 - 3.00	739,636	4.71	$ 2.36	$817,936	651,046	4.47	$ 2.34	$737,319

3.01-4.00	247,357	7.10	3.64	-	125,690	6.79	3.65	-
4.01 - 4.04	210,424	5.42	4.04	-	210,424	5.42	4.04	-
$2.02- 4.04	1,197,417	5.33	$ 2.92	$817,936	987,160	4.97	$ 2.87	$737,319

The aggregate intrinsic value in the preceding table represents the total pre-tax intrinsic value, based on Harvard Bioscience's closing stock price of $3.47 as of December 31, 2015, which would have been received by the option holders had all option holders exercised their options as of that date. The aggregate intrinsic value of options exercised for the years ended December 31, 2015 and 2014 was approximately $2.6 million and $0.1 million, respectively. The total number of in-the-money options that were exercisable as of December 31, 2015 was 651,046.

For the year ended December 31, 2015, the total compensation costs related to unvested awards not yet recognized is $0.1 million and the weighted average period over which it is expected to be recognized is 1.00 year.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

Harvard Bioscience Plan Valuation and Expense Information under Share-Based-Payment Accounting

Share-based compensation expense related to Harvard Bioscience employee stock options and restricted stock units for the years ended December 31, 2015 and 2014 was allocated as follows:

	Years Ended December 31,	
	2015	2014
	(in thousands)	
Research and development	$ 42	$ 66
Sales and marketing	-	14
General and administrative	383	683
Total stock-based compensation	$ 425	$ 763

The Company did not capitalize any share-based compensation.

Share-based compensation expense recognized in the Company's consolidated statements of operations related to Harvard Bioscience options for the years ended December 31, 2015 and 2014 is based on awards ultimately expected to vest and has been reduced for annualized estimated forfeitures. Share-based-payment accounting requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience of Harvard Bioscience.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

15. Quarterly Financial Information (Unaudited)

Statement of Operations Data:

2015	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
	(in thousands, except per share data)				
Revenues	$-	$73	$37	$8	$118
Cost of product revenues	-	37	18	84	139
Gross (loss) profit	-	36	19	(76)	(21)
Total Operating expenses	2,620	4,535	2,311	2,214	11,680
Operating loss	(2,620)	(4,499)	(2,292)	(2,290)	(11,701)
Other expense, net	(3)	-	-	-	(3)
Loss before income taxes	(2,623)	(4,499)	(2,292)	(2,290)	(11,704)
Income taxes	-	-	-	-	-
Net loss	$(2,623)	$(4,499)	$(2,292)	$(2,290)	$(11,704)
Basic and diluted net loss per share	$(0.30)	$(0.44)	$(0.19)	$(0.17)	$(1.05)

Statement of Operations Data:

2014	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
	(in thousands, except per share data)				
Revenues	$23	$23	$2	$45	$93
Cost of product revenues	12	12	1	23	48
Gross profit	11	11	1	22	45
Total Operating expenses	3,017	2,544	2,677	2,864	11,102
Operating loss	(3,006)	(2,533)	(2,676)	(2,842)	(11,057)
Other expense, net	-	-	(4)	-	(4)
Loss before income taxes	(3,006)	(2,533)	(2,680)	(2,842)	(11,061)
Income taxes	-	-	-	-	-

Net loss	$(3,006)	$(2,533)	$(2,680)	$(2,842)	$(11,061)
Basic and diluted net loss per share	$(0.39)	$(0.32)	$(0.34)	$(0.36)	$(1.41)

Up to 20,000,000 Shares of Common Stock,
Warrants to Purchase up to 20,000,000 Shares of Common Stock and
Up to 2,000 Shares of Series C Convertible Preferred Stock

(5,000,000 shares of Common Stock underlying the Series C

Convertible Preferred Stock)

PROSPECTUS

Rodman & Renshaw
a unit of H.C. Wainwright & Co.

February 9, 2017