
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED September 30, 2012,

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO

Commission file number 0-22025

AASTROM BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction of incorporation or organization)

94-3096597

(I.R.S. employer identification no.)

24 Frank Lloyd Wright Dr.

P.O. Box 376

Ann Arbor, Michigan

(Address of principal executive offices)

48106

(Zip code)

(800) 556-0311

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 - No -

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

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

Large accelerated filer -

Accelerated filer -

Non-accelerated filer -

Smaller reporting company -

(Do not check if a smaller reporting company)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date.

COMMON STOCK, NO PAR VALUE

(Class)

43,783,559

Outstanding at October 31, 2012

QUARTERLY REPORT ON FORM 10-Q
TABLE OF CONTENTS

	Page
<u>PART I — FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements (Unaudited):</u>	3
<u>Condensed Consolidated Balance Sheets as of December 31, 2011 and September 30, 2012 .</u>	3
<u>Condensed Consolidated Statements of Operations for the quarters and nine months ended September 30, 2011 and 2012 and for the period from March 24, 1989 (Inception) to September 30, 2012</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2012 and for the period from March 24, 1989 (Inception) to September 30, 2012</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	10
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	17
<u>Item 4. Controls and Procedures</u>	17
<u>PART II — OTHER INFORMATION</u>	18
<u>Item 1. Legal Proceedings</u>	18
<u>Item 1A. Risk Factors</u>	18
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
<u>Item 6. Exhibits</u>	18
<u>Signature</u>	19
<u>Exhibit Index</u>	20
<u>Glossary</u>	21

[Table of Contents](#)

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands)

	December 31, 2011	September 30, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,530	\$ 21,089
Receivables	9	9
Other current assets	636	364
Total current assets	6,175	21,462
Property and equipment, net	1,564	1,246
Total assets	\$ 7,739	\$ 22,708

LIABILITIES, CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS’ DEFICIT

Current liabilities:		
Accounts payable and accrued expenses	\$ 2,963	\$ 3,244
Accrued employee benefits	1,042	742
Current portion of long-term debt	40	40
Warrant liabilities	16,625	2,954

Total current liabilities	20,670	6,980
Long-term debt	40	9
Total liabilities	20,710	6,989
Series B-1 non-voting convertible preferred stock, no par value; shares authorized and reserved — 39, at September 30, 2012, shares issued and outstanding — zero	—	2,668
Series B-2 voting convertible preferred stock, no par value; shares authorized and reserved — 39 at September 30, 2012, shares issued and outstanding —12, at September 30, 2012	—	37,690
Total convertible preferred stock	—	40,358
Shareholders' deficit:		
Common stock, no par value; shares authorized — 150,000; shares issued and outstanding — 38,635 and 43,784, respectively	228,877	242,771
Deficit accumulated during the development stage	(241,848)	(267,410)
Total shareholders' deficit	(12,971)	(24,639)
Total liabilities, convertible preferred stock and shareholders' deficit	\$ 7,739	\$ 22,708

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

3

[Table of Contents](#)

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, amounts in thousands except per share amounts)

	Quarter Ended September 30,		Nine Months Ended September 30,		March 24, 1989 (Inception) to September 30, 2012
	2011	2012	2011	2012	
Revenues:					
Product sales and rentals	\$ 9	\$ —	\$ 18	\$ 2	\$ 1,879
Research and development agreements	—	—	—	—	2,105
Grants	—	—	—	—	9,901
Total revenues	9	—	18	2	13,885
Costs and expenses:					
Cost of product sales and rentals	2	—	4	2	3,043
Research and development	5,750	6,147	15,426	20,012	210,717
Selling, general and administrative	1,696	2,138	5,794	6,131	90,979
Total costs and expenses	7,448	8,285	21,224	26,145	304,739
Loss from operations	(7,439)	(8,285)	(21,206)	(26,143)	(290,854)
Other income (expense):					
Decrease in fair value of warrants	5,496	2,241	4,286	3,289	15,578
Other income	—	—	—	—	1,249
Interest income	12	14	48	40	10,812
Interest expense	(3)	(4)	(7)	(10)	(489)
Total other income	5,505	2,251	4,327	3,319	27,150
Net loss	(1,934)	(6,034)	(16,879)	(22,824)	(263,704)
Accretion of convertible preferred stock	—	1,218	—	2,738	3,706
Net loss attributable to common shareholders	\$ (1,934)	\$ (7,252)	\$ (16,879)	\$ (25,562)	\$ (267,410)
Net loss per share attributable to common shareholders (Basic and Diluted)	\$ (0.05)	\$ (0.17)	\$ (0.44)	\$ (0.63)	
Weighted average number of common shares outstanding (Basic and Diluted)	38,632	43,336	38,624	40,331	

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

4

[Table of Contents](#)

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, amounts in thousands)

	Nine Months Ended September 30,		March 24, 1989 (Inception) to September 30, 2012
	2011	2012	

Operating activities:			
Net loss	\$	(16,879)	\$ (22,824) \$ (263,704)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization		464	487 7,985
Loss on property held for resale		—	— 110
Amortization of discounts and premiums on investments		—	— (1,704)
Stock compensation expense		2,767	3,166 17,051
Decrease in fair value of warrants		(4,286)	(3,289) (15,578)
Inventory write downs and reserves		—	— 2,240
Stock issued pursuant to license agreement		—	— 3,300
Provision for losses on accounts receivable		—	— 204
Changes in operating assets and liabilities:			
Receivables		16	— (258)
Inventories		—	— (2,335)
Other current assets		(196)	272 (344)
Accounts payable and accrued expenses		(452)	281 3,012
Accrued employee benefits		218	(300) 742
Net cash used for operating activities		(18,348)	(22,207) (249,279)
Investing activities:			
Organizational costs		—	— (73)
Purchase of short-term investments		—	— (217,041)
Maturities of short-term investments		—	— 218,745
Property and equipment purchases		(803)	(169) (7,386)
Proceeds from sale of property held for resale		—	— 400
Net cash used for investing activities		(803)	(169) (5,355)
Financing activities:			
Net proceeds from issuance of preferred stock		—	37,620 89,267
Net proceeds from issuance of common stock and warrants		32	346 185,054
Payments received for stock purchase rights and other, net		—	— 3,500
Proceeds from long-term debt		—	— 751
Principal payments under long-term debt obligations		(182)	(31) (2,831)
Other, net		—	— (18)
Net cash provided by (used for) financing activities		(150)	37,935 275,723
Net increase (decrease) in cash and cash equivalents		(19,301)	15,559 21,089
Cash and cash equivalents at beginning of period		31,248	5,530 —
Cash and cash equivalents at end of period	\$	11,947	\$ 21,089 \$ 21,089
Supplemental cash flow information (non-cash):			
Accretion of convertible preferred stock	\$	—	\$ 2,738 \$ 3,706
Warrants exchanged for common stock	\$	—	\$ 10,382 \$ 10,382

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

[Table of Contents](#)

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE QUARTER ENDED SEPTEMBER 30, 2012 (UNAUDITED)**

1. Organization and Summary of Significant Accounting Policies

Astrom Biosciences, Inc. was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. The Company operates its business in one reportable segment — research and product development involving the development of patient-specific cell based products for use in regenerative medicine.

Successful future operations are subject to several technical hurdles and risk factors, including satisfactory product development, timely initiation and completion of clinical trials, regulatory approval and market acceptance of the Company's products and the Company's continued ability to obtain future funding.

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. The Company believes that it will have adequate liquidity to finance its planned operations, including development of its products and product candidates, via cash on hand as of September 30, 2012 of \$21,089,000 until at least December 31, 2012. While the Company's budgeted cash usage and operating plan for 2012 does not currently contemplate taking additional actions to reduce the use of cash over the next three months, the Company could, if necessary, delay or forego certain budgeted discretionary expenditures such as anticipated hiring plans or certain non-critical research and development expenditures, as well as slow down or delay certain clinical trial activity (without jeopardizing our Phase 3 clinical trial for CLI). While the Company could sell shares through an At the Market Sales Agreement (ATM) to raise additional capital, there are certain factors, such as volume of trading in our stock, our stock price and the ability to terminate the agreement with notice, which could limit the amount the Company could raise in a short period of time. On a longer-term basis, the Company will need to

raise additional funds in order to complete product development programs and complete clinical trials needed to market and commercialize these products. The Company cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and its overall success include: the rate and degree of progress for product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the United States and other countries, the liquidity and market volatility of the Company's equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If the Company cannot raise such funds, it may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would likely have a material adverse impact on the Company's business, financial condition and results of operations. As a result of the need to raise additional capital, there is uncertainty regarding our ability to maintain liquidity sufficient to operate the business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Basis of Presentation

The condensed consolidated financial statements included herein have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the nine months ended September 30, 2012, are not necessarily indicative of the results to be expected for the full year or for any other period. The December 31, 2011 condensed consolidated balance sheet data was derived from audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the period ended December 31, 2011, as filed with the SEC.

[Table of Contents](#)

The consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany and Aastrom Biosciences, SL, located in Barcelona, Spain (collectively, the Company). All inter-company transactions and accounts have been eliminated in consolidation. The subsidiaries are not a significant component of the consolidated financial statements as each has ceased operations and had limited operations historically.

3. Stock-Based Compensation

The Company issues nonqualified and incentive stock options as well as other equity awards pursuant to its 2009 Omnibus Incentive Plan, as amended (Option Plan). Such awards pursuant to the Option Plan may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants.

During the nine months ended September 30, 2012, the Company granted 4,507,445 service-based options to purchase common stock. These options were granted with exercise prices equal to or greater than the fair market value of the Company's stock at the grant date, vest over four years and expire after ten years. The weighted average grant-date fair value of service-based options granted under the Company's Option Plan during the nine months ended September 30, 2011 and 2012 was \$1.54 and \$1.25, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors were \$1,127,000 and \$3,166,000 for the quarter and nine months ended September 30, 2012, respectively, compared to \$919,000 and \$2,767,000 for the corresponding periods ended September 30, 2011.

The fair value of each service-based stock option grant for the reported periods is estimated on the date of the grant using the Black-Scholes option-pricing model using the weighted average assumptions noted in the following table.

Service-Based Stock Options	Nine Months Ended September 30,	
	2011	2012
Expected dividend rate	0%	0%
Expected stock price volatility	72.9% - 78.9%	72.9% - 74.9%
Risk-free interest rate	1.7% - 2.7%	0.9% - 1.5%
Expected life (years)	6.0 - 6.3	6.0 - 6.3

The following table summarizes the activity for service-based stock options for the indicated periods:

Service-Based Stock Options	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2011	8,079,667	\$ 2.38	8.4	\$ 674,000
Granted	4,507,445	\$ 2.36		
Exercised	(144,167)	\$ 1.48		\$ 52,000
Cancelled	(1,057,700)	\$ 2.03		
Forfeited or expired	(828,432)	\$ 2.20		
Outstanding at September 30, 2012	10,556,813	\$ 2.43	8.4	\$ 206,000
Exercisable at September 30, 2012	3,727,232	\$ 2.75	7.3	\$ 119,000

As of September 30, 2012 there was \$6,603,000 of total unrecognized compensation cost related to non-vested service-based stock options granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 3.0 years.

The total fair value of options vested during the nine months ended September 30, 2011 and 2012 was \$1,582,000 and \$2,136,000, respectively.

[Table of Contents](#)

4. Stock Purchase Warrants

The Company has historically issued warrants to purchase shares of the Company's common stock in connection with certain of its common stock offerings. The following warrants were outstanding at September 30, 2012, and include provisions that could require cash settlement of the warrants or have anti-dilution price protection provisions requiring each to be recorded as liabilities of the Company at the estimated fair value at the date of issuance, with changes in estimated fair value recorded as non-cash income or expense in the Company's statement of operations in each subsequent period:

- (i) warrants to purchase an aggregate of 740,131 shares of the Company's common stock, issued on October 17, 2007 in connection with the Company's registered direct offering, exercisable from April 18, 2008 through April 17, 2013 at an exercise price of \$12.72 per share, all of which remained outstanding as of September 30, 2012;
- (ii) Class A warrants to purchase an aggregate of 4,882,228 shares of the Company's common stock, issued on January 21, 2010 in connection with the Company's registered public offering, exercisable for a five year period commencing on July 21, 2010 at an exercise price of \$2.48 per share (as adjusted for the anti-dilution provision triggered by the close of the Company's exchange program for the December 2010 warrants, as described below, and usage of the ATM during the third quarter), 4,525,978 of which remained outstanding as of September 30, 2012; and
- (iii) warrants to purchase an aggregate of 10,000,000 shares of the Company's common stock, issued on December 15, 2010 in connection with the Company's registered public offering (December 2010 warrants), exercisable for a five year period commencing on December 15, 2010 at an exercise price of \$1.75 per share (as adjusted from \$3.22 per share for the anti-dilution provision triggered by usage of the Company's ATM during the third quarter). On June 27, 2012, the Company announced the closing of a common stock exchange program for the remaining December 2010 warrants, which was completed on July 27, 2012, resulting in the issuance of 4,845,949 shares of common stock in exchange for 9,691,900 warrants. As of September 30, 2012, 308,100 December 2010 warrants remained outstanding.

The fair value of the Class A warrants and the December 2010 warrants are measured using the Monte Carlo valuation model, while the October 2007 warrants are measured using the Black-Scholes valuation model. Both of the methodologies are based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates, however these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liabilities and the change in estimated fair value of the warrants could be materially different.

Inherent in both the Monte Carlo and Black-Scholes valuation models are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The Monte Carlo model is used for the Class A warrants and the December 2010 warrants to value the potential future exercise price adjustments triggered by the anti-dilution provisions as well as the value of the put feature of the December 2010 warrants. These both require Level 3 inputs which are based on the Company's estimates of the probability and timing of potential future financings and fundamental transactions. The other assumptions used by the Company are summarized in the following tables:

October 2007 Warrants	December 31, 2011	September 30, 2012
Closing stock price	\$ 1.82	\$ 1.63
Expected dividend rate	0%	0%
Expected stock price volatility	93.6%	56.2%
Risk-free interest rate	0.1%	0.2%
Expected life (years)	1.25	0.50

[Table of Contents](#)

January 2010 Class A Warrants	December 31, 2011	September 30, 2012
Closing stock price	\$ 1.82	\$ 1.63
Expected dividend rate	0%	0%
Expected stock price volatility	86.1%	73.6%
Risk-free interest rate	0.5%	0.3%
Expected life (years)	3.50	2.75

December 2010 Warrants	December 31, 2011	September 30, 2012
Closing stock price	\$ 1.82	\$ 1.63
Expected dividend rate	0%	0%
Expected stock price volatility	83.6%	70.7%
Risk-free interest rate	0.6%	0.4%
Expected life (years)	3.96	3.21

The following table summarizes the change in the estimated fair value of the Company's warrant liabilities (*in thousands*):

Warrant Liabilities

Balance at December 31, 2011	\$	16,625
Warrants exchanged for common stock		(10,382)
Decrease in fair value		(3,289)
Balance at September 30, 2012	\$	<u>2,954</u>

5. Series B Convertible Preferred Stock

On March 9, 2012, the Company completed the sale of 12,308 shares of Series B-1 Non-Voting Convertible Preferred Stock (Series B-1 Preferred Stock) at an offering price of \$3,250 per share. The Company received \$37,620,000 in net proceeds from the sale of the shares of Series B-1 Preferred Stock, after offering expenses. In addition to the Series B-1 Preferred Stock, which was issued at the closing, the Company also authorized Series B-2 Voting Convertible Preferred Stock (Series B-2 Preferred Stock). The Series B-1 Preferred Stock and Series B-2 Preferred Stock collectively are referred to as the Series B Preferred Stock. The Series B-1 Preferred Stock is not entitled to vote on matters on which the common shareholders are generally entitled to vote. The Series B-2 Preferred Stock are entitled to vote with the holders of the common stock as a single class, with each share of Series B-2 Preferred Stock having the number of votes equal to the number of shares of common stock issuable upon conversion of such Series B-2 Preferred Stock. On May 3, 2012, shareholder approval was obtained in accordance with Nasdaq Marketplace Rule 5635(b), which allowed the holder of Series B-1 Preferred Stock to exchange all of the then outstanding shares for shares of Series B-2 Preferred Stock on a one-for-one basis. The Series B Preferred Stock will, with respect to dividend rights and rights on liquidation, winding-up and dissolution, rank on parity with any other class or series of the Company capital stock that the Company may issue in the future which is designated as being on parity with the Series B Preferred Stock, and rank senior to our common stock and Series A preferred stock (45,000 shares authorized and zero issued and outstanding). The Series B Preferred Stock is convertible, at the option of the holder thereof at any time after the five year anniversary of the closing of the offering, into shares of common stock at a conversion price of \$3.25 per share of common stock. At any time after the five year anniversary of issuance, the Company may elect to convert any or all outstanding shares of Series B Preferred Stock into shares of our common stock, subject to certain limitations. Dividends on the Series B Preferred Stock will be cumulative and compound daily, at a rate of 11.5% per annum, payable upon conversion, liquidation, redemption or other similar events, and payable in cash or Series B-1 Preferred Stock until the five year anniversary of issuance. Following the five year anniversary of issuance and until the earlier of the tenth anniversary of the issuance and the date no Series B Preferred Stock remain outstanding, dividends will accrue at a rate of 8% per annum and will be payable in cash or Series B-1 Preferred Stock, at our option. Unless prohibited by Michigan law governing distributions to shareholders, the Series B-1 Preferred Stock shall be redeemable at the option of holder of the Series B-1 Preferred Stock commencing at any time after the five year anniversary of issuance, liquidation, winding up, dissolution or other similar events, subject to certain terms and limitations.

[Table of Contents](#)

The Series B Preferred Stock does not, in its entirety, require liability classification and has been evaluated for embedded features to determine if those features require bifurcation and separate classification as derivative liabilities. The Series B Preferred Stock host contract was evaluated for equity or mezzanine classification based upon the nature of the redemption and conversion features. Generally, any feature that could require cash redemption for matters not within the Company's control, irrespective of probability of the event occurring, requires classification outside of stockholders' equity. The Series B Preferred Stock has been recorded as mezzanine of the Condensed Consolidated Balance Sheets and will be accreted to its redemption value through charges to stockholders' deficit using the effective interest method.

The carrying value of the Series B-1 Preferred Stock presented as mezzanine in the consolidated financial statements is \$2,668,000, as of September 30, 2012. As of September 30, 2012, there are no outstanding shares of Series B-1 Preferred Stock; however, as the Series B-1 Preferred Stock dividends can be redeemed for cash, the Company is required to accrete to the carrying value of the Series B-1 Preferred Stock to its redemption value of \$31,102,000 by charges to accumulated deficit using the effective interest method. Such accretion for the nine months ended September 30, 2012 amounted to \$2,668,000. The redemption value is determined by the greater of the conversion price of the Series B-1 Preferred Stock or the common stock price, multiplied by the total accumulated dividends at the five year anniversary of issuance.

6. Net Loss Per Common Share

Basic earnings (loss) per share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (loss) per share for the holders of the Company's common shares and holders of the Series B Preferred Stock. The Series B Preferred Stock shares contain participation rights in undistributed earnings, but do not share in the losses of the Company. Therefore, in the event of a loss from continuing operations, the Series B Preferred Stock is not considered in the calculation of basic loss per share.

Net loss per common share is computed using the weighted-average number of common shares outstanding during the period. Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares (related to options, warrants and preferred stock) that have been excluded from the computations of diluted net loss per common share at September 30, 2011 and 2012 were 23,448,500 and 29,260,000, respectively.

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

Overview

We were incorporated in 1989 and are a regenerative medicine company focused on the development of innovative cell therapies to repair or regenerate damaged or diseased tissues. We are developing patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic ischemic cardiovascular diseases. We believe ixmyelocel-T (the generic name for our multicellular therapy) is a disease modifying therapy with multi-functional properties including: tissue remodeling, immuno-modulation and the promotion of angiogenesis. Our proprietary cell-manufacturing technology enables the manufacture of multicellular therapies, expanded from an adult patient's own bone marrow, and delivered directly to damaged tissues. Preclinical and clinical data suggest that ixmyelocel-T may be effective in treating patients with severe, chronic ischemic cardiovascular diseases such as critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD). Preliminary data utilizing ixmyelocel-T in dilated cardiomyopathy (DCM) have provided indications of both efficacy and safety. Over 200 patients have been treated in recent clinical trials using ixmyelocel-T (over 400 patients safely treated since our inception). In November 2011, we released positive Phase 2b data from our RESTORE-CLI clinical trial and launched our pivotal Phase 3 REVIVE trial in CLI in February 2012. During the fourth quarter, we plan to launch a randomized, placebo-controlled, double-blinded Phase 2b ixCELL-DCM trial.

Our Therapy

Ixmyelocel-T is a patient-specific, expanded multicellular therapy developed using our proprietary, fully-closed, automated processing system. Ixmyelocel-T is a product derived from an adult patient's own bone marrow but it is

[Table of Contents](#)

significantly enhanced compared with the original bone marrow. Our process enhances the patient's bone marrow mononuclear cells by expanding the mesenchymal stromal cells and M2 anti-inflammatory macrophages while retaining many of the hematopoietic cells. These cell types, known to regulate the immune response, are important in the resolution of pathologic inflammation and tissue repair. The manufacture of our patient-specific, expanded multicellular therapies is done under current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP) guidelines required by the U.S. Food and Drug Administration (FDA).

Our therapy has several features that we believe are primarily responsible for success in treating adult patients with severe, chronic cardiovascular diseases:

Patient-specific (autologous) — we start with the patient's own cells, which are accepted by the patient's immune system allowing the cells to integrate into existing functional tissues. This characteristic of our therapy, we believe, eliminates both the risk of rejection and of having to use immunosuppressive therapy pre- or post-therapy. Our data also suggests that ixmyelocel-T provides the potential for long-term engraftment and tissue repair.

Expanded — we begin with a small amount of bone marrow from the patient (up to 60 ml) and significantly expand the number of certain cell types, primarily CD90⁺ (mesenchymal stromal cells or MSCs) and CD14⁺ autofluorescent⁺ (M2 anti-inflammatory macrophages) to far more than are present in the patient's own bone marrow (up to 200 times the number of certain cell types compared with the starting bone marrow).

Multicellular — we believe the multiple cell types in ixmyelocel-T, which are normally found in bone marrow — but in smaller quantities, — possess the key functions required for reducing chronic inflammation, immuno-modulation, and the promotion of angiogenesis.

Minimally invasive — our procedure for taking bone marrow (an "aspirate") can be performed in an out-patient setting and takes approximately 15 minutes. For diseases such as CLI, the administration of ixmyelocel-T is performed in an out-patient setting (e.g. a physician's office) in a one-time, approximately 20 minute procedure.

Safe — bone marrow and bone marrow-derived therapies have been used safely and efficaciously in medicine for over three decades. Our product, ixmyelocel-T, a bone marrow-derived, patient-specific, expanded multicellular therapy leverages this body of scientific study and medical experience and appears well tolerated in patients treated to date.

Our therapy is produced at our cell manufacturing facility in the United States, located at our headquarters in Ann Arbor, Michigan.

Clinical Development Programs

Our clinical development programs are focused on addressing areas of high unmet medical needs in severe, chronic ischemic cardiovascular diseases. We have completed a successful Phase 2b clinical trial in CLI. We have reached agreement with the FDA on Chemistry, Manufacturing and Control (CMC) which allowed us to launch our pivotal Phase 3 REVIVE clinical trial in the first quarter of 2012 with a protocol approved by the FDA through the Special Protocol Assessment (SPA) process. Our CLI development program has also received Fast Track Designation from the FDA. We have completed our Phase 1/2 clinical trials in DCM and plan to launch a randomized, placebo-controlled, double-blinded Phase 2b ixCELL-DCM trial in the fourth quarter of 2012. Our DCM development program has received Orphan Disease Designation from the FDA.

Results to date in our clinical trials may not be indicative of results obtained from subsequent patients enrolled in those trials or from future clinical trials. Further, our future clinical trials may not be successful or we may not be able to obtain the required Biologic License Application (BLA) approval to commercialize our products in the United States in a timely fashion, or at all. See "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

[Table of Contents](#)

Critical Limb Ischemia

Background

CLI is the most serious and advanced stage of peripheral arterial disease (PAD) resulting from chronic inflammation and lipid accumulation. PAD is a chronic atherosclerotic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other serious clinical conditions including hypertension, cardiovascular disease, dyslipidemia, diabetes, obesity and stroke. CLI is used to describe patients with the most severe form of PAD: those with chronic ischemia-induced pain (even at rest) or tissue loss (ulcers or gangrene) in the limbs, often leading to amputation and death. Many CLI patients are considered "unsuitable for revascularization" (formerly "no option") patients as they have exhausted all other treatment options with the exception of amputation. The one-year and four-year mortality rates for CLI patients that are unsuitable for revascularization that progress to amputation are approximately 25% and 70%, respectively. Ixmyelocel-T, our disease modifying therapy with multiple functions, has shown significant promise in the treatment of CLI patients with existing tissue loss and unsuitable for revascularization. Currently, there are an estimated 250,000 CLI patients that are unsuitable for revascularization in the U.S.

Phase 2b Clinical Program — RESTORE CLI

Our U.S. Phase 2b RESTORE-CLI program was a multi-center, randomized, double-blind, placebo-controlled clinical trial. This clinical trial was designed to evaluate the safety and efficacy of ixmyelocel-T in the treatment of patients with CLI that are unsuitable for revascularization. It was the largest multi-center, randomized, double-blind, placebo-controlled cellular therapy study ever conducted in CLI patients. We completed enrollment of this trial in February 2010 with a total of 86 patients at 18 sites across the United States, with the last patient treated in March 2010. These patients were followed for a period of 12 months after treatment. In addition to assessing the safety of our product, efficacy endpoints included time to first occurrence of treatment failure — the trial's primary efficacy end-point — (defined as major amputation, all-cause mortality, doubling in wound surface area and de novo gangrene), amputation-free survival (defined as major amputation and all-cause mortality), major amputation rates, level of amputation, wound healing, patient quality of life and pain scores. The primary purpose of the trial was to assess performance of our therapy and, if positive, prepare for a Phase 3 program.

Final results of the Phase 2b RESTORE-CLI clinical trial were presented at the American Heart Association Scientific Sessions in November 2011 and published in the peer-reviewed journal *Molecular Therapy* in April 2012. Patients in the treatment arm showed a 62% reduction in risk relative to placebo in the primary efficacy endpoint of time to first occurrence of treatment failure ($p=0.0032$). While the study was not powered to show statistical significance in the secondary endpoint of amputation free survival, results from a subgroup of 45 patients with wounds at baseline (the approximate profile of the Phase 3 patient population) showed a 61% reduction in risk (21% ixmyelocel-T treated versus 44% control event rate; $p=0.0802$). The study also met the primary safety endpoint with no meaningful differences between the treated and control groups.

Phase 3 Clinical Program — REVIVE

In February 2012, several principal investigators participating in the pivotal Phase 3 REVIVE clinical trial for patients with CLI that are unsuitable for revascularization began screening patients. The first patient was randomized and aspirated in May 2012. We had previously received Fast Track Designation from the FDA for use of ixmyelocel-T for CLI in October 2010 and reached agreement with the FDA on a Special Protocol Assessment (SPA) in July 2011. The Phase 3 REVIVE Trial that we agreed to with the FDA under the SPA process includes 594 CLI patients with tissue loss (ulcers and gangrene) at baseline that are unsuitable for revascularization. Patients will be randomized 1:1 and followed for 12 months for the primary efficacy endpoint of amputation-free survival. Patients will be followed for an additional 6 months for safety. We anticipate that enrollment will occur at approximately 100 sites across the U.S.

Dilated Cardiomyopathy

Background

DCM is a severe, chronic cardiovascular disease that leads to enlargement of the heart, reducing the pumping function of the heart to the point that blood circulation is impaired. Patients with DCM typically present with symptoms of congestive heart failure, including limitations in physical activity and shortness of breath. DCM is

Table of Contents

now the third leading cause of heart failure in the U.S. There are two types of DCM: ischemic and non-ischemic. Ischemic DCM, the most common form representing an estimated 60% of all DCM patients, is associated with atherosclerotic cardiovascular disease. We estimate that there are approximately 125,000 ischemic DCM patients in the U.S., our target patient population for further clinical development. Patient prognosis depends on the stage and cause of the disease but is typically characterized by a very poor quality of life and a high mortality rate.

Current treatments for DCM patients include both heart transplantation and placement of left ventricular assist devices (LVADs). There are less than 2,500 heart transplantations in the U.S. each year, because many DCM patients are not eligible and transplants are expensive at an estimated cost of over \$1 million. LVADs are also expensive at an estimated cost of over \$175,000 and have a mortality rate of 50% at two years.

In February 2007, the FDA granted Orphan Drug Designation to ixmyelocel-T for the treatment of DCM. Our DCM development program is currently in Phase 2. We recently completed follow up on two U.S. Phase 1/2 trials investigating surgical and catheter-based delivery for our product in the treatment of DCM. The final results from these Phase 1/2 clinical trials were presented at the Society for Cardiovascular Angiography and Interventions (SCAI) meeting on May 10, 2012. We will launch a randomized, placebo-controlled, double-blinded Phase 2b ixCELL-DCM trial using catheter delivery in 108 ischemic DCM patients in the U.S. in the fourth quarter of 2012.

Surgical Trial Program — DCM

We completed enrollment of 40 ischemic and non-ischemic DCM patients in the IMPACT-DCM clinical trial in January 2010 and the final patient was treated in March 2010. Participants in the IMPACT-DCM clinical trial were required to have New York Heart Association (NYHA) functional class III or IV heart failure, a left ventricular ejection fraction (LVEF) of less than or equal to 30% (60-75% is typical for a healthy person), and meet other eligibility criteria, including optimized medical therapy. Patients were randomized in an approximate 3:1 ratio of treatment to control group. Patients in the treatment group received our therapy through direct injection into the heart muscle during minimally invasive-surgery (involving a chest incision of approximately 2 inches). The primary objective of this study was to assess the safety of ixmyelocel-T in patients with DCM. Efficacy measures include cardiac dimensions and tissue mass, cardiac function (e.g. cardiac output, LVEF, cardiopulmonary exercise testing parameters), cardiac perfusion and viability, as well as other efficacy endpoints. NYHA functional class and quality of life are also assessed. Patients were followed for 12 months after treatment with an additional 2 year follow-up phone call recently completed in all patients.

Catheter Trial Program — DCM

The Catheter-DCM clinical trial was designed to explore catheter-based direct injection delivery of ixmyelocel-T to treat DCM patients. This multi-center, randomized, controlled, prospective, open-label, Phase 2 study enrolled patients DCM at clinical sites across the United States.

We reported final 12-month results from the Catheter-DCM Phase 2 trial at the SCAI 2012 Scientific Sessions on May 10, 2012. The trial included 22 ischemic DCM (IDCM) and non-ischemic DCM (NIDCM) patients with a NYHA heart failure class of III or IV, or moderate to severe heart failure, and a left ventricular ejection fraction of 30 percent or less, which is a measure of how much blood leaves the heart with each pump. Patients were randomized to receive an injection of the treatment into their heart muscles or to a control group, and were followed at three, six and 12 months. After 12 months, no procedural complications and no difference in adverse events were reported among patients who received the treatment and the control group. IDCM patients who received the cell treatment had a lower mean number of major adverse cardiac events (MACE) (0.22 compared to 1.67 in the control group). IDCM

patients who received the treatment were more likely to see improvement in NYHA class, six-minute walking distance and ejection fraction, compared to those in the control group. No consistent trends were noted in NIDCM patients. In the fourth quarter, we will launch a randomized, placebo-controlled, double-blind Phase 2b ixCELL-DCM trial in for 108 ischemic DCM patients in the U.S. and using catheter administration.

Results of Operations

Research and development expenses increased to \$6,147,000 for the quarter ended September 30, 2012 from \$5,750,000 for the quarter ended September 30, 2011. For the nine months ended September 30, 2012, research and development expense increased to \$20,012,000 from \$15,426,000 during the same period a year ago. The increases

13

[Table of Contents](#)

are due to initial enrollment for the Phase 3 clinical program for ixmyelocel-T, including increased employee costs, clinical site identification and initiation, as well as certain regulatory expenses.

Our major ongoing research and development programs are focused on the clinical development of ixmyelocel-T for treatment of severe, chronic cardiovascular diseases. The following table summarizes the approximate allocation of cost for our research and development projects (*in thousands*):

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2011	2012	2011	2012
Critical Limb Ischemia	\$ 4,562	\$ 5,057	\$ 11,067	\$ 16,850
Dilated Cardiomyopathy	1,183	1,090	4,328	3,162
Other	5	—	31	—
Total research and development expenses	<u>\$ 5,750</u>	<u>\$ 6,147</u>	<u>\$ 15,426</u>	<u>\$ 20,012</u>

Selling, general and administrative expenses increased to \$2,138,000 for the quarter ended September 30, 2012 compared to \$1,696,000 for the quarter ended September 30, 2011. For the nine months ended September 30, 2012, selling, general and administrative expenses increased to \$6,131,000 from \$5,794,000 during the same period a year ago. The increases are due to non-cash stock-based compensation, and legal and consulting expenses.

The income related to the non-cash change in fair value of warrants was \$2,241,000 for the quarter ended September 30, 2012 compared to \$5,496,000 for the quarter ended September 30, 2011. For the nine months ended September 30, 2012, the non-cash change in the fair value of warrants was \$3,289,000 compared to \$4,286,000 for the same period a year ago. The fluctuations in both periods are mainly due to the changes in the fair value of our stock price as well as the exchange of the December 2010 warrants for common stock which reduced the total warrants outstanding. Fluctuations in the fair value of warrants in future periods could result in significant non-cash adjustments to the condensed consolidated financial statements, however any income or expense recorded will not impact our cash and cash equivalents, operating expenses or cash flows.

The non-cash accretion of convertible preferred stock for the quarter and nine months ended September 30, 2012, was \$1,218,000 and \$2,738,000, respectively, compared to zero for the same periods a year ago. The Series B-1 Preferred Stock was issued in March 2012 and is accreted to its redemption value through charges to stockholders' deficit using the effective interest method.

Our net loss attributable to common shareholders was \$7,252,000, or \$0.17 per share, for the quarter ended September 30, 2012 compared to \$1,934,000, or \$0.05 per share, for the quarter ended September 30, 2011. For the nine months ended September 30, 2012, our net loss was \$25,562,000, or \$0.63 per share, compared to \$16,879,000, or \$0.44 per share, for the same period a year ago. The increases in our net loss are primarily due to the non-cash change in the fair value of warrants, non-cash accretion of our convertible preferred stock, and increases in research and development expenses.

Non-cash stock-based compensation expense included in research and development expenses and general, selling and administrative expenses is summarized in the following table (*in thousands*):

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2011	2012	2011	2012
Research and development	\$ 592	\$ 624	\$ 1,627	\$ 1,823
General, selling and administrative	327	503	1,140	1,343
Total non-cash stock-based compensation expense	<u>\$ 919</u>	<u>\$ 1,127</u>	<u>\$ 2,767</u>	<u>\$ 3,166</u>

The increases in stock-based compensation expense are due primarily to an increase in the number of stock options granted which is partially offset by the decrease in the fair value per stock option for such grants.

Liquidity and Capital Resources

We are currently focused on utilizing our technology to produce patient specific cell-based therapies for use in severe chronic ischemic cardiovascular diseases. At such time as we satisfy, if at all, applicable regulatory approval requirements, we expect the sales of our cell-based therapies to constitute nearly all of our product sales revenues.

14

[Table of Contents](#)

We do not expect to generate positive cash flows from our consolidated operations for at least the next several years and then only if we achieve significant product sales. Until that time, we expect that our revenue sources from our current activities will consist of only minor sales of our cell products

and manufacturing supplies to our academic collaborators, grant revenue, research funding and potential licensing fees or other financial support from potential future corporate collaborators.

We expect that we will need to raise significant additional funds or pursue strategic transactions or other strategic alternatives in order to complete our product development programs, complete clinical trials needed to market and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue to seek to obtain the required capital in a similar manner. As a development stage company, we have never been profitable and do not anticipate having net income unless significant product sales commence. With respect to our current activities, such sales are not likely to occur until we obtain additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through September 30, 2012, we had accumulated a net loss attributable to common shareholders of approximately \$267,410,000. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, commence product sales or complete additional corporate partnering or acquisition transactions.

We have also, but to a lesser degree, financed our operations through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments, stock option and warrant exercises and funding under equipment leasing agreements. These financing sources, in addition to our public and private sales of our equity securities, have generally allowed us to maintain adequate levels of cash and other liquid investments.

Our cash and cash equivalents totaled \$21,089,000 at September 30, 2012, an increase of \$15,559,000 from December 31, 2011. During the nine months ended September 30, 2012, the primary uses of cash and cash equivalents included \$22,207,000 for our operations and working capital requirements in preparation for the Phase 3 clinical program for ixmyelocel-T. As of September 30, 2012 we had \$20,639,000 of cash deposited into an Insured Cash Sweep (ICS) program which is administered by Bank of New York Mellon. This program maximizes our Federal Deposit Insurance Company (FDIC) coverage by dividing our ICS funds into amounts under the standard FDIC maximum and places these amounts with other ICS Network member banks (each an FDIC-insured institute). These funds are placed in savings accounts at the member banks earning interest while still maintaining insurance coverage.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of possible acquisition or development of complementary business activities and the cost of product commercialization. We do not expect to generate positive cash flows from operations for at least the next several years due to the expected spending for research and development programs and the cost of commercializing our product candidates. We intend to seek additional funding through research and development agreements or grants, distribution and marketing agreements and through public or private debt or equity financing transactions. Successful future operations are subject to several technical and risk factors, including our continued ability to obtain future funding, satisfactory product development, obtaining required regulatory approvals and market acceptance for our products.

We believe that we have adequate liquidity to finance our operations, including development of our products and product candidates, via our cash and cash equivalents on hand as of September 30, 2012 until at least December 31, 2012. While our budgeted cash usage and operating plan for 2012 does not currently contemplate taking additional actions to reduce the use of cash over the next three months, we could, if necessary, delay or forego certain budgeted discretionary expenditures such as anticipated hiring plans or certain non-critical research and development expenditures, as well as slow down or delay certain clinical trial activity (without jeopardizing our Phase 3 clinical trial for CLI). While we could sell shares through an At the Market Sales Agreement (ATM) in order to raise additional capital, there are certain factors, such as volume of trading in our stock, our stock price and the ability to terminate the agreement with notice, which could limit the amount we could raise in a short period of time. On a

[Table of Contents](#)

longer-term basis, we will need to raise additional funds in order to complete product development programs and complete clinical trials needed to market and commercialize these products. We cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact our ability to raise additional capital and our overall success include: the rate and degree of progress for our product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the United States and other countries, the liquidity and market volatility of our equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If we cannot raise such funds, we will not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on our business, financial condition and results of operations. As a result of the need to raise additional capital, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Off-Balance Sheet Arrangements

At September 30, 2012, we were not party to any off-balance sheet arrangements.

Forward-Looking Statements

This report, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “trends,” “opportunity,” “comfortable,” “current,” “intention,” “position,” “assume,” “potential,” “outlook,” “remain,” “continue,” “maintain,” “sustain,” “seek,” “achieve,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “could,” “may,” or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. The factors described in Part I, Item 1A, “Risk Factors,” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, among others, could have a material adverse effect upon our business, results of operations and financial conditions.

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks

only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These forward-looking statements include statements regarding:

- potential strategic collaborations with others;
- future capital needs and financing sources;
- adequacy of existing capital to support operations for a specified time;
- product development and marketing plan;
- features and successes of our cellular therapies;
- manufacturing and facility capabilities;
- clinical trial plans and anticipated results;
- anticipation of future losses;
- commercialization plans; and
- revenue expectations and operating results.

16

[Table of Contents](#)

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of September 30, 2012, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio.

Our vendors in countries outside the United States are typically paid in Euro. However, such expenditures have not been significant to date. Accordingly, we are not directly exposed to significant market risks from currency exchange rate fluctuations. We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances. We do not enter into hedging transactions and do not purchase derivative instruments.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012. The term “disclosure controls and procedures” is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on their evaluation, our management, including our Chief Executive Office and Chief Accounting Officer, concluded that our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2012, there were no changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

17

[Table of Contents](#)

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we receive threats or may be subject to litigation matters incidental to our business. However, we are not currently a party to any material pending legal proceedings.

Item 1A. Risk Factors

Information regarding risk factors of the Company is set forth in Part 1, Item 1A, “Risk Factors,” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which was filed with the Securities and Exchange Commission on March 15, 2012. There have been no material changes in our risk factors from those disclosed in Part 1, Item 1A., “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

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

On July 30, 2012, the Company announced the results of its previously announced offer to exchange (the “Exchange Offer”) any warrant to purchase shares of common stock, no par value per share, of the Company issued in connection with the Company’s December 2010 public offering, that was tendered and accepted, for shares of the Company’s common stock. Such Exchange Offer was made upon the terms and subject to the conditions set forth in the Company’s offer to exchange, dated June 28, 2012, and in the related Exchange Offer materials filed as exhibits to the Tender Offer Statement on Schedule TO originally filed with the Securities and Exchange Commission on June 28, 2012, as amended. The Exchange Offer expired at 5:00 p.m., Eastern Standard Time, on Friday, July 27, 2012.

The issuance of shares of Common Stock in the warrant exchanges pursuant to the Offer was made pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 3(a)(9) of the Securities Act. No proceeds were received and no commissions

Item 6. Exhibits

The Exhibits listed in the Exhibit Index immediately following the Signature, are filed as a part of this Quarterly Report on Form 10-Q.

[Table of Contents](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 8, 2012

AASTROM BIOSCIENCES, INC.

/s/ TIM M. MAYLEBEN

 Tim M. Mayleben
President and Chief Executive Officer
(Principal Executive Officer)

/s/ BRIAN D. GIBSON

 Brian D. Gibson
Vice President of Finance, Chief Accounting Officer and Treasurer
(Principal Financial and Accounting Officer)

[Table of Contents](#)

EXHIBIT INDEX

Exhibit No.	Description
31.1	Certification by Chief Executive Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (furnished herewith).
31.2	Certification by Chief Accounting Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (furnished herewith).
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

[Table of Contents](#)

GLOSSARY

TERM	DEFINITION
Adverse Event	Any adverse change in health or “side-effect” that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.
Autologous (Patient Specific)	Originating from the patient receiving treatment. (Aastrom uses only autologous cells).
BLA — Biologics License Application	An application containing product safety, efficacy and manufacturing information required by the FDA to market biologics products in the U.S.
CLI — Critical Limb Ischemia	An atherosclerotic vascular disease characterized by insufficient blood flow in the lower extremities that causes severe pain, tissue loss or both.
CMC — Chemistry, Manufacturing and Control	The composition, manufacture, and control of the drug substance and the drug product. It is information on the identification, quality, purity, and strength of the investigational product.
Controlled Clinical Trial	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.

DCM — Dilated Cardiomyopathy	A chronic cardiac disease where expansion of the patient’s heart reduces the pumping function to a point that the normal circulation of blood cannot be maintained.
Double-Blind Clinical Trial	Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo.
FDA — Food & Drug Administration	The U.S. FDA ensures that medicines, medical devices, and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of \$1 trillion worth of goods annually.
GMP — Good Manufacturing Practice	GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
Hematopoietic Cells	All of the cells in the blood system including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells).
IND — Investigational New Drug	An application submitted to the FDA for a new drug

[Table of Contents](#)

	or biologic that, if allowed, will be used in a clinical trial.
Ischemia	A shortage or inadequate flow of blood to a body part (commonly an organ or tissue) caused by a constriction or obstruction of the blood vessels supplying it.
LVEF — Left Ventricular Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heart beat.
Mesenchymal stromal cells	Connective tissue cells that, in the case of bone marrow derived MSC, function to support blood forming cells and secrete anti-inflammatory factors.
M2 anti-inflammatory macrophages	Specialized blood cells that remove damaged tissue and bacteria and secrete anti-inflammatory factors.
Open-label Clinical Trial	A trial in which both the treating physician and the patient know whether they are receiving the experimental treatment or control/placebo treatment.
Orphan Drug Designation	“Orphan drug” refers to a drug or biologic that is intended for use in the treatment of a rare disease or condition. Orphan drug designation from the U.S. Food and Drug Association (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for developing the drug for a rare disease or condition. The drug must then go through the FDA marketing approval process like any other drug or biologic which evaluates for safety and efficacy. Usually a sponsor receives a quicker review time and lower application fees for an orphan product.
Phase 1 Clinical Trial	A Phase 1 trial represents an initial study in a small group of patients to test for safety and other relevant factors.
Phase 2 Clinical Trial	A Phase 2 trial represents a study in a moderate number of patients to assess the safety and efficacy of a product.
Phase 2b Clinical Trial	A Phase 2b trial is a moderately-sized Phase 2 trial that is more specifically designed assess the efficacy of a product than a Phase 2a trial.
Phase 3 Clinical Trial	Phase 3 studies are initiated to establish safety and efficacy in an expanded patient population at multiple clinical trial sites and are generally larger than trials in earlier phases of development.
Prospective Clinical Trial	A clinical trial in which participants are identified and then followed throughout the study going forward in time.
Randomized Clinical Trial	A clinical trial in which the participants are assigned randomly to different treatment groups.

CERTIFICATION

I, Tim M. Mayleben, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aastrom Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2012

/s/ TIM M. MAYLEBEN

Tim M. Mayleben
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Brian D. Gibson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aastrom Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2012

/s/ BRIAN D. GIBSON

Brian D. Gibson

*Vice President of Finance, Chief Accounting Officer and Treasurer
(Principal Financial and Accounting Officer)*

**18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aastrom Biosciences, Inc. (the "Company") on Form 10-Q for the quarter and nine months ended September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

- (1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2012

/s/ TIM M. MAYLEBEN

Tim M. Mayleben
President and Chief Executive Officer
(Principal Executive Officer)

/s/ BRIAN D. GIBSON

Brian D. Gibson
Vice President of Finance, Chief Accounting Officer and Treasurer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Aastrom Biosciences, Inc. and will be retained by Aastrom Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.