
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, 2011,

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)

(734) 418-4400

(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)

38,635,225

Outstanding at October 31, 2011

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AASTROM BIOSCIENCES, INC.
(a clinical development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands)

	December 31, 2010	September 30, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 31,248	\$ 11,947
Receivables	25	9
Other current assets	426	622
Total current assets	31,699	12,578
Property and equipment, net	1,128	1,494
Total assets	\$ 32,827	\$ 14,072
LIABILITIES AND SHAREHOLDERS’ EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,900	\$ 2,448
Accrued employee benefits	796	1,014
Current portion of long-term debt	214	51
Warrant liabilities	25,954	21,668
Total current liabilities	29,864	25,181
Long-term debt	41	49
Shareholders’ equity (deficit):		
Common stock, no par value; shares authorized — 62,500 and 150,000, respectively; shares issued and outstanding — 38,616 and 38,635, respectively	225,102	227,901
Deficit accumulated during the development stage	(222,180)	(239,059)
Total shareholders’ equity (deficit)	2,922	(11,158)
Total liabilities and shareholders’ equity (deficit)	\$ 32,827	\$ 14,072

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

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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
	2010	2011	2010	2011	(Inception) to September 30, 2011
Revenues:					
Product sales and rentals	\$ —	\$ 9	\$ —	\$ 18	\$ 1,877
Research and development agreements	—	—	—	—	2,105
Grants	—	—	—	—	9,901
Total revenues	—	9	—	18	13,883
Costs and expenses:					
Cost of product sales and rentals	—	2	—	4	3,041
Research and development	4,167	5,750	10,631	15,426	184,801
Selling, general and administrative	1,686	1,696	4,625	5,794	82,918
Total costs and expenses	5,853	7,448	15,256	21,224	270,760
Loss from operations	(5,853)	(7,439)	(15,256)	(21,206)	(256,877)
Other income (expense):					
(Increase) decrease in fair value of warrants	(99)	5,496	2,808	4,286	7,246
Other income	—	—	—	—	1,249
Interest income	25	12	91	48	10,767
Interest expense	(5)	(3)	(21)	(7)	(476)
Total other income (expense)	(79)	5,505	2,878	4,327	18,786
Net loss	\$ (5,932)	\$ (1,934)	\$ (12,378)	\$ (16,879)	\$ (238,091)
Net loss per share (Basic and Diluted)	\$ (0.21)	\$ (0.05)	\$ (0.45)	\$ (0.44)	
Weighted average number of common shares outstanding (Basic and Diluted)	28,255	38,632	27,755	38,624	

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

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AASTROM BIOSCIENCES, INC.
(a clinical development stage company)

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

	Nine Months Ended September 30,		March 24, 1989
	2010	2011	(Inception) to September 30, 2011
Operating activities:			
Net loss	\$ (12,378)	\$ (16,879)	\$ (238,091)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	420	464	7,315
Loss on property held for resale	—	—	110
Amortization of discounts and premiums on investments	—	—	(1,704)
Stock compensation expense	845	2,767	12,909
Decrease in fair value of warrants	(2,808)	(4,286)	(7,246)
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	6	16	(258)
Inventories	—	—	(2,335)
Other current assets	(23)	(196)	(602)
Accounts payable and accrued expenses	1,373	(452)	2,216
Accrued employee benefits	156	218	1,014
Net cash used for operating activities	(12,409)	(18,348)	(220,928)
Investing activities:			
Organizational costs	—	—	(73)
Purchase of short-term investments	(5,000)	—	(217,041)
Maturities of short-term investments	5,000	—	218,745
Property and equipment purchases	(132)	(803)	(6,989)
Proceeds from sale of property held for resale	—	—	400
Net cash used for investing activities	(132)	(803)	(4,958)
Financing activities:			

Financing activities:

Net proceeds from issuance of preferred stock	—	—	51,647
Net proceeds from issuance of common stock and warrants	12,426	32	184,708
Payments received for stock purchase rights and other, net	—	—	3,500
Restricted cash used as compensating balance	140	—	—
Proceeds from long-term debt	—	—	751
Principal payments under long-term debt obligations	(298)	(182)	(2,755)
Other, net	—	—	(18)
Net cash provided by (used for) financing activities	<u>12,268</u>	<u>(150)</u>	<u>237,833</u>
Net increase (decrease) in cash and cash equivalents	(273)	(19,301)	11,947
Cash and cash equivalents at beginning of period	<u>14,739</u>	<u>31,248</u>	<u>—</u>
Cash and cash equivalents at end of period	<u>\$ 14,466</u>	<u>\$ 11,947</u>	<u>\$ 11,947</u>

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

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AASTROM BIOSCIENCES, INC.
(a clinical development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Organization and Summary of Significant Accounting Policies

Aastrom 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 therapies for use in severe, chronic cardiovascular diseases.

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 therapies 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 therapies. The Company believes that it has adequate liquidity to finance its operations, including development of its products and product candidates, via its cash and cash equivalents through December 31, 2011. In addition to cash on hand, the Company entered into an At the Market Sales Agreement (ATM) on June 16, 2011, which allows the Company to raise approximately \$20,000,000 through sales of its common stock from time to time. However, there are certain factors, such as volume of trading in the Company's stock and the stock price, which limits the amount that can be raised in a short period of time through the ATM. Regardless of the usage of the ATM, the Company will need to raise additional capital by early to mid-2012 in order to fund the phase 3 clinical trial of ixmyelocel-T for CLI, complete its product development programs, complete clinical trials needed to market its products 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 its 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 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 the Company's business, financial condition and results of operations. As a result of the short-term need to raise additional capital, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively over at least the next twelve months, which raises substantial doubt as to its ability to continue as a going concern. The 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 three and nine months ended September 30, 2011, are not necessarily indicative of the results to be expected for the full year or for any other period. The December 31, 2010 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 Transition Report on Form 10-KT for the six month transition period ended December 31, 2010, as filed with the SEC.

The condensed consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany, Aastrom Biosciences Ltd., located in Dublin, Ireland, and

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AASTROM BIOSCIENCES, INC.
(a clinical development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (Continued)

Aastrom Biosciences, SL, located in Barcelona, Spain. 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. Fair Value Measurements

The Company measures certain assets and liabilities at fair value on a recurring basis. Fair value represents the amount that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices included in Level 1 that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

At September 30, 2011, the Company had \$10,618,000 invested in three money market funds with original maturities of three months or less that are included within the "Cash and cash equivalents" line on the Condensed Consolidated Balance Sheet. Because there is an active market for shares in the money market funds, the Company considers its fair value measures of these investments to be based on Level 1 inputs. The valuation technique used to measure these assets is a market approach, using prices and other relevant information generated by market transactions involving identical assets.

See Note 5 for disclosures related to the fair value of the Company's warrants. The Company does not have any other assets or liabilities on the balance sheet as of September 30, 2011 that are measured at fair value.

4. 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, 2011, the Company granted 3,985,550 service-based options to purchase common stock. These options were granted with exercise prices equal to the fair value of the Company's stock at the grant date, vest over four years (other than 505,975 non-employee director options which vest over three 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, 2010 and 2011 was \$1.02 and \$1.54, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors were \$919,000 and \$2,767,000 for the quarter and nine months ended September 30, 2011, respectively, compared to \$485,000 and \$845,000 for the corresponding periods ended September 30, 2010.

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AASTROM BIOSCIENCES, INC.
(a clinical development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (Continued)

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.

	Nine Months Ended September 30,	
	2010	2011
Service-Based Stock Options		
Expected dividend rate	0%	0%
Expected stock price volatility	70.5% - 72.3%	72.9% - 78.9%
Risk-free interest rate	1.7% - 3.1%	1.7% - 2.7%
Estimated forfeiture rate (per annum)	10%	10%
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, 2010	4,297,209	\$ 2.43	8.9	\$ 3,158,978
Granted	3,985,550	\$ 2.31		
Exercised	(19,688)	\$ 1.64		\$ 21,007
Forfeited or expired	(116,974)	\$ 3.67		
Outstanding at September 30, 2011	8,146,097	\$ 2.36	8.9	\$ 1,854,375

As of September 30, 2011 there was \$4,778,000 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 3.2 years.

The total fair value of options vested during the nine months ended September 30, 2010 and 2011 was \$902,000 and \$1,582,000, respectively.

5. 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, 2011, 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, 2011;
- (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 \$2.52 per share (as adjusted from \$2.97 per share for the anti-dilution provision triggered in the December 2010 financing), 4,525,978 of which remained outstanding as of September 30, 2011; and

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AASTROM BIOSCIENCES, INC. (a clinical development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (Continued)

- (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, exercisable for a five year period commencing on December 15, 2010 at an exercise price of \$3.22 per share, all of which remained outstanding as of September 30, 2011.

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, 2010	September 30, 2011
Closing stock price	\$ 2.56	\$ 2.24
Expected dividend rate	0%	0%
Expected stock price volatility	100.3%	85.2%
Risk-free interest rate	0.6%	0.2%
Expected life (years)	2.25	1.50

January 2010 Class A Warrants	December 31, 2010	September 30, 2011
Closing stock price	\$ 2.56	\$ 2.24
Expected dividend rate	0%	0%
Expected stock price volatility	79.6%	85.2%
Risk-free interest rate	1.8%	0.7%
Expected life (years)	4.56	3.81

December 2010 Warrants	December 31, 2010	September 30, 2011
Closing stock price	\$ 2.56	\$ 2.24
Expected dividend rate	0%	0%
Expected stock price volatility	78.0%	82.5%
Risk-free interest rate	2.0%	0.8%
Expected life (years)	4.96	4.21

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

AASTROM BIOSCIENCES, INC.
(a clinical development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (Continued)

Warrant Liabilities

Balance at December 31, 2010	\$	25,954
Decrease in fair value		(4,286)
Balance at September 30, 2011	\$	<u>21,668</u>

6. Shareholders' Equity

At the Market Sales Agreement

On June 16, 2011, the Company entered into an At the Market Sales Agreement (ATM) with McNicoll, Lewis & Vlak LLC (MLV), pursuant to which the Company may sell shares of its common stock through MLV, as sales agent, in registered transactions from its shelf registration statement filed in November 2010, for aggregate proceeds of up to \$20,300,000. Shares of common stock sold under the ATM are to be sold at market prices. The Company will pay up to 3% of the gross proceeds to MLV as a commission. As of September 30, 2011, the Company had not sold any shares under the ATM.

Shareholder Rights Plan

On August 11, 2011, the Board of Directors of the Company adopted a Shareholder Rights Plan, as set forth in the Shareholder Rights Agreement between the Company and the rights agent, the purpose of which is, among other things, to enhance the Board's ability to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of the Company is made in the future. The Shareholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, the Company or a large block of the Company's common stock. The following summary description of the Shareholder Rights Plan does not purport to be complete and is qualified in its entirety by reference to the Company's Shareholder Rights Plan, which was filed with the Securities and Exchange Commission as an exhibit to a Registration Statement on Form 8-A on August 12, 2011.

In connection with the adoption of the Shareholder Rights Plan, the Board of Directors of the Company declared a dividend distribution of one preferred stock purchase right (a "Right") for each outstanding share of common stock to stockholders of record as of the close of business on August 15, 2011. In addition, one Right will automatically attach to each share of common stock issued between August 15, 2011 and the distribution date. The Rights currently are not exercisable and are attached to and trade with the outstanding shares of common stock. Under the Shareholder Rights Plan, the Rights become exercisable if a person or group becomes an "acquiring person" by acquiring 15% or more of the outstanding shares of common stock or if a person or group commences a tender offer that would result in that person owning 15% or more of the common stock. If a person or group becomes an "acquiring person," each holder of a Right (other than the acquiring person and its affiliates, associates and transferees) would be entitled to purchase, at the then-current exercise price, such number of shares of the Company's preferred stock which are equivalent to shares of 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.

The Rights may be redeemed in whole, but not in part, at a price of \$0.001 per Right (payable in cash, common stock or other consideration deemed appropriate by the Board of Directors) by the Board of Directors only until the earlier of (i) the time at which any person becomes an "acquiring person" or (ii) the expiration date of the Rights Agreement. Immediately upon the action of the Board of Directors ordering redemption of the Rights, the Right will terminate and thereafter the only right of the holders of Rights will be to receive the redemption price. The Rights will expire at the close of business on August 15, 2021, unless previously redeemed or exchanged by the Company as described above.

7. Net Loss Per Common 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

AASTROM BIOSCIENCES, INC.
(a clinical development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (Continued)

would be anti-dilutive. The aggregate number of common equivalent shares (related to options and warrants) that have been excluded from the computations of diluted net loss per common share at September 30, 2010 and 2011 were 12,200,500 and 23,448,500, respectively.

Overview

We are developing patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic ischemic cardiovascular diseases. We believe ixmyelocel-T (the new generic name approved in March 2011 for our cardiovascular cell therapy) is a disease modifying therapy with multi-functional properties including: tissue remodeling, immuno-modulation and the promotion of angiogenesis, which is targeted to address the multiple underlying causes of many severe, chronic cardiovascular diseases such as critical limb ischemia (CLI). Our proprietary cell-manufacturing technology enables the manufacture of cell therapies expanded from a 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 CLI. Preliminary data utilizing ixmyelocel-T in dilated cardiomyopathy (DCM) have provided indications of efficacy and safety. Nearly 200 patients have been treated in recent clinical trials using ixmyelocel-T (over 400 patients safely treated since our inception) with no treatment related serious adverse events.

Our Therapy

Ixmyelocel-T is a patient specific, expanded multicellular therapy developed using our proprietary, automated processing system to produce human cell products for clinical use. The Aastrom process enhances bone marrow mononuclear cells by expanding the mesenchymal stromal cells and alternatively activated macrophages while retaining many of the hematopoietic cells. 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 critical for success in treating 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 the risk 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 (approximately 50 ml) and significantly expand the number of certain cell types, primarily CD90⁺ (mesenchymal stromal cells or MSCs), CD14⁺auto⁺ (alternatively activated 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 aspirate).

Multicellular — we believe the multiple cell types in ixmyelocel-T, which are normally only found in bone marrow but in different quantities, possess the necessary functions required for tissue remodeling, 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 in a one-time, approximately 20 minute procedure.

Safe — bone marrow and bone marrow-like 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.

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

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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 our Phase 2b clinical trial in CLI and expect to advance into a Phase 3 clinical trial in the fourth quarter of 2011 with a protocol approved by FDA through the Special Protocol Assessment (SPA) process. Our CLI development program has received Fast Track Designation from the FDA. Our DCM program is in early Phase 2 clinical development and is focused on achieving proof of concept in this indication. 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 Transition Report on Form 10-KT for the six month period ended December 31, 2010.

Critical Limb Ischemia

Background

CLI is the most serious and advanced stage of peripheral arterial disease (PAD). 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 clinical conditions including hypertension, cardiovascular disease, hyperlipidemia, diabetes, obesity and stroke. CLI is used to describe patients with the most severe forms 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. The one-year and four-year mortality rates for no-option CLI patients 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 tissues loss and no option for revascularization. There are currently an estimated 250,000 of these patients in the U.S.

Clinical Programs

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 and no option for revascularization. It was the largest multi-center, randomized, double-blind, placebo-controlled cellular therapy study ever conducted in these 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 size 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.

Results to date of the RESTORE-CLI trial have included two planned interim analyses and a final top-line report:

- In June 2010, we reported results at the Society of Vascular Surgery Meeting. This interim analysis included the six-month results for the first 46 patients enrolled in the trial. Results of this analysis demonstrated that the study achieved both its primary safety endpoint and primary efficacy endpoint of time to first occurrence of treatment failure. The results related to the primary endpoint were statistically significant ($p=0.0053$). Analysis of the data for amputation free survival, a secondary efficacy endpoint which the study was not powered to demonstrate, showed a statistically significant reduction in event rates in favor of our therapy ($p=0.038$). Other endpoints measured (e.g., major amputation rate, complete wound healing, change in Wagner wound scale) showed encouraging trends, but had not reached statistical significance at the interim analysis.

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- In November 2010, we presented six-month data on all 86 patients enrolled in the trial at the VEITHsymposium™ non-CME satellite session. Results of this analysis showed that the study again achieved both its primary safety endpoint and primary efficacy endpoint of time to first occurrence of treatment failure. The findings related to time to first occurrence of treatment failure were statistically significant ($p=0.0132$). Further analyses showed a clinically meaningful reduction of 56% in treatment failure events. Analysis of the data for amputation-free survival, showed a clinically meaningful reduction in event rates of 24%, but did not show statistical significance ($p=0.5541$).
- In June 2011, we announced 12-month, top-line results from all 86 patients enrolled in the trial. Results of this analysis showed that the trial met its final primary safety and efficacy endpoints, demonstrating a statistically significant improvement in the time to first occurrence of treatment failure at 12 months. The full data from the RESTORE-CLI trial will be presented at the American Heart Association National Meeting in Orlando, Florida on November 14, 2011.

We continue to make progress towards the Phase 3 clinical development program in CLI — called REVIVE. In October 2010, we announced that the FDA had granted Fast Track Designation for the use of ixmyelocel-T for the CLI indication. The Fast Track program is designed to facilitate the development and expedite the review of new drugs and biologics, intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. During discussions with the FDA in June 2010, Aastrom was encouraged to use the Special Protocol Assessment (SPA) process for the Phase 3 program. In October 2010, we submitted two SPA requests to the FDA, one for the “no option” CLI patient population and another for the “poor option” CLI patient population. The primary SPA - the No-Option CLI SPA - focuses on patients that have exhausted all other treatment options with the exception of amputation. We reached agreement with the FDA on the No-Option CLI SPA in July 2011. The secondary SPA - the Poor-Option CLI SPA - focuses on patients that have not yet exhausted all other treatment options; however the options available are associated with poor outcomes. Discussions regarding the Poor-Option protocol will continue with the FDA.

The Phase 3 No Option Trial agreed to under the SPA process includes 594 no option CLI patients with tissue loss (ulcers and gangrene) at baseline. Patients will be randomized in a 1:1 manner and followed for 12 months for the primary efficacy endpoint of amputation-free survival. An additional 6 months of follow-up will address the length of safety follow-up after ixmyelocel-T treatment. Enrollment at approximately 80 sites is expected to start next quarter.

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. There are two types of DCM: ischemic and non-ischemic. Ischemic DCM, the most common form, is associated with atherosclerotic cardiovascular disease. Among other causes, non-ischemic DCM can be triggered by toxin or virus exposure or genetic diseases. Patient prognosis depends on the stage and cause of the disease but is typically characterized by a high mortality rate. Other than heart transplantation or ventricular assist devices, there are currently no effective treatment options for end-stage patients with this disease. According to the book, *Heart Failure: A Combined Medical and Surgical Approach* (2007), DCM affects 200,000-400,000 patients in the United States alone.

In February 2007, the FDA granted Orphan Drug Designation to our investigational therapy for the treatment of DCM. Our DCM development program is currently in Phase 2 and we have two ongoing U.S. Phase 2 trials investigating surgical and catheter-based delivery for our product in the treatment of DCM.

Surgical Trial Program — DCM

In May 2008, the FDA activated our investigational new drug application (IND) for surgical delivery of our therapy. The 40-patient U.S. IMPACT-DCM clinical trial began with the treatment of the first patient in November

2008. This multi-center, randomized, controlled, prospective, open-label, Phase 2 study was designed to include 20 patients with ischemic DCM and 20 patients with non-ischemic DCM. We completed enrollment of the 40 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 is 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 post-treatment.

Six-month data from the IMPACT-DCM interim analysis were presented at The Sixth International Conference on Cell Therapy for Cardiovascular Disease on January 20, 2011. Results indicated that ixmyelocel-T is safe and showed that serious adverse events were associated with the surgical procedure and not the cellular therapy. Adverse events after the initial peri-operative period were roughly equal between the control and treatment groups. Efficacy findings include positive trends in clinical endpoints, quality of life, functional, and structural parameters in the treatment group as compared with the control group.

In September 2011, we presented 12-month data on all 40 patients enrolled in the IMPACT-DCM trial at the 15th Annual Heart Failure Society of America Scientific Meeting. Results were consistent with the six-month interim analysis, indicating that ixmyelocel-T is safe and showed that serious adverse events were associated with the surgical procedure and not the cellular therapy. Efficacy results were also consistent with the 6 month data and demonstrated promising efficacy results in patients with ischemic DCM.

Catheter Trial Program — DCM

In November 2009, the FDA activated our second IND in DCM to allow for the evaluation of our therapy delivered by a percutaneous direct catheter injection as opposed to surgically. The Catheter-DCM clinical trial is 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 approximately 11 patients with ischemic DCM and 10 patients with non-ischemic DCM at clinical sites across the United States. Participants met the same criteria as stated above for the IMPACT-DCM surgical trial. The first patient was enrolled into the trial in April 2010 and enrollment concluded in December 2010 with 21 patients enrolled.

On September 19, 2011, we reported results from a six-month interim analysis of patients treated in the Catheter-DCM Phase 2 trial. In this analysis, efficacy parameters were consistent with those seen in the IMPACT-DCM trial results. In addition, the adverse event profile suggests that catheter administration of ixmyelocel-T is safe and appears to cause fewer adverse events compared to surgical administration of ixmyelocel-T. We expect to report 12-month results from the Catheter-DCM Phase 2 trial in the first half of 2012. Discussions are underway with FDA to plan the next steps in the clinical development of ixmyelocel-T in DCM patients.

Results of Operations

Research and development expenses increased to \$5,750,000 for the quarter ended September 30, 2011 from \$4,167,000 for the quarter ended September 30, 2010. For the nine months ended September 30, 2011, research and development expense increased to \$15,426,000 from \$10,631,000 during the same period a year ago. The increases are due to advanced preparation related to the Phase 3 clinical program for ixmyelocel-T, including increased employee costs, clinical site identification and set-up, as well as regulatory expenses. These amounts include non-cash stock-based compensation expense of \$592,000 for the quarter ended September 30, 2011, compared to expense of \$255,000 for the quarter ended September 30, 2010. For the nine months ended September 30, 2011, non-cash stock-based compensation expense increased to \$1,627,000 from \$379,000 for the same period a year ago. The increases in stock-based compensation expense are due primarily to an increase in the number of stock options granted and an increase in the fair value per stock option for such grants. Additionally, stock-based compensation

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expenses during the quarter and nine months ended September 30, 2010 were partially offset by the reversal of expense for certain non-vested stock options forfeited in excess of our assumed forfeiture rate.

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,	
	2010	2011	2010	2011
Critical Limb Ischemia	\$ 1,924	\$ 4,562	\$ 4,632	\$ 11,067
Dilated Cardiomyopathy	2,235	1,183	5,931	4,328
Other	8	5	68	31
Total research and development expenses	\$ 4,167	\$ 5,750	\$ 10,631	\$ 15,426

Selling, general and administrative expenses remained flat at \$1,696,000 for the quarter ended September 30, 2011 compared to \$1,686,000 for the quarter ended September 30, 2010. For the nine months ended September 30, 2011, selling, general and administrative expenses increased to \$5,794,000 from \$4,625,000 during the same period a year ago due to expenses associated with the previously announced restatement of the Company's historical financial statements, as well as an increase in non-cash stock-based compensation and consulting costs. Non-cash stock-based compensation expense included in selling, general and administrative expenses increased to \$327,000 for the quarter ended September 30, 2011 from \$230,000 for the quarter ended September 30, 2010. For the nine months ended September 30, 2011, non-cash stock-based compensation expense increased to \$1,140,000 from \$466,000 for the same period a year ago. The increases in stock-based compensation expense are due primarily to an increase in the number of stock options granted and an increase in the fair value per stock option for such grants. Additionally, stock-based compensation expenses during the nine months ended September 30, 2010 were offset by the reversal of expense for certain non-vested stock options forfeited in excess of our assumed forfeiture rate.

The income (expense) related to the non-cash change in fair value of warrants was \$5,496,000 for the quarter ended September 30, 2011 compared to (\$99,000) for the quarter ended September 30, 2010. For the nine months ended September 30, 2011, the non-cash change in the fair value of warrants was \$4,286,000 compared to \$2,808,000 for the same period a year ago. The changes are due primarily to decreases in the fair value of our common stock and the issuance of additional warrants in December 2010. 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.

Our net loss was \$1,934,000, or \$0.05 per share, for the quarter ended September 30, 2011 compared to \$5,932,000, or \$0.21 per share, for the quarter ended September 30, 2010. For the nine months ended September 30, 2011, our net loss was \$16,879,000, or \$0.44 per share, compared to \$12,378,000, or \$0.45 per share, for the same period a year ago. The changes in net loss are primarily due to the non-cash change in the fair value of warrants, increases in research and development expenses, and the increase in selling, general and administrative expenses as described above. The per share comparisons were also impacted by the issuance of 10,000,000 shares of common stock in December 2010.

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.

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.

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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 our products, 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 significant additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through September 30, 2011, we had accumulated a net loss of approximately \$238,091,000. 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 \$11,947,000 at September 30, 2011, a decrease of \$19,301,000 from December 31, 2010. During the nine months ended September 30, 2011, the primary uses of cash and cash equivalents included \$18,348,000 for our operations and working capital requirements and \$803,000 in capital expenditures for facility and equipment upgrades in preparation for the Phase 3 clinical program for ixmyelocel-T. Our cash and cash equivalents as of September 30, 2011 included money market securities with original maturities of three months or less.

On June 16, 2011, we entered into an At the Market Sales Agreement (ATM) with McNicoll, Lewis & Vlak LLC (MLV), pursuant to which we may sell shares of our common stock through MLV, as sales agent, in registered transactions from our shelf registration statement filed in November 2010, for aggregate proceeds of up to \$20,300,000. Shares of common stock sold under the ATM are to be sold at market prices. We will pay up to 3% of the gross proceeds to MLV as a commission. As of September 30, 2011, we had not sold any shares under the ATM.

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, 2011 until at least December 31, 2011. While we could sell shares through the ATM in order to raise additional capital, there are certain factors, such as volume of trading in our stock and our stock price, that could limit the amount we could raise in a short period of time. Regardless of the usage of the ATM, we will need to raise additional capital by early to mid-2012 in order to fund the phase 3 clinical trial of ixmyelocel-T for CLI, complete our product development programs, complete clinical trials needed to market our products 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,

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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 short-term need to raise additional capital, there is uncertainty regarding our ability to maintain liquidity sufficient to operate its business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Off-Balance Sheet Arrangements

At September 30, 2011, 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 Transition Report on Form 10-KT for the six months ended December 31, 2010, 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not Applicable.

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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, 2011. 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, 2011, 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, the Company’s internal control over financial reporting.

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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

The following information updates, and should be read in conjunction with, the information disclosed in Part 1, Item 1A, "Risk Factors," of our Transition Report on Form 10-KT for the six month period ended December 31, 2010, which was filed with the Securities and Exchange Commission on April 14, 2011. Except as disclosed below, there have been no material changes in our risk factors from those disclosed in Part 1, Item 1A., "Risk Factors" of our Transition Report on Form 10-KT for the six month period ended December 31, 2010.

Provisions in our corporate documents and Michigan law and our shareholder rights plan may make it more difficult for us to be acquired.

Our Board has the authority, without shareholder approval, to issue additional shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders.

Michigan law contains a provision that makes it more difficult for a 10% shareholder, or its officers, to acquire a company. This authority, together with certain provisions of our charter documents, may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of our company. This effect could occur even if our shareholders consider the change in control to be in their best interest.

We have adopted a shareholder rights plan, the purpose of which is, among other things, to enhance our Board's ability to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of the company is made in the future. The shareholder rights plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our company's common stock.

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.

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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, 2011

AASTROM BIOSCIENCES, INC.

/s/ TIMOTHY M. MAYLEBEN

Timothy 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)

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1	Certificate of Designations, Preferences and Rights of a Series of Preferred Stock of Aastrom Biosciences, Inc. classifying and designating the Series A Junior Participating Cumulative Preferred Stock, filed as Exhibit 3.1 to the Company's Registration Statement on Form 8-A, filed on August 12, 2011, incorporated herein by reference.
4.1	Shareholder Rights Agreement, dated as of August 11, 2011, between Aastrom Biosciences, Inc. and Continental Stock Transfer & Trust Company, as Rights Agent, filed as Exhibit 4.1 to the Company's Registration Statement on Form 8-A, filed on August 12, 2011, incorporated herein by reference.
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

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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.
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.
Catheter-DCM	Aastrom’s U.S. Phase 2 clinical trial investigating catheter-based delivery of our product in the treatment of dilated cardiomyopathy.
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.
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.
IMPACT-DCM	Aastrom’s U.S. Phase 2 clinical trial investigating surgical delivery of our product in the treatment of dilated cardiomyopathy.
IND — Investigational New Drug	An application submitted to the FDA for a new drug 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

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LVEF — Left Ventricular Ejection Fraction	supplying it. The fraction of blood pumped out of the left ventricle with each heart beat.
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.
Patient Specific (Autologous)	Originating from the patient receiving treatment. (Aastrom uses only patient specific cells)
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.

A clinical trial in which the participants are assigned randomly to different treatment groups.

CERTIFICATION

I, Timothy 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, 2011

/s/ TIMOTHY M. MAYLEBEN

Timothy 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, 2011

/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, 2011, 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, 2011

/s/ TIMOTHY M. MAYLEBEN

Timothy 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.
