



**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q/A**

**Amendment No. 1**

(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, 2010**

**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) 930-5555

(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)

28,251,787  
Outstanding at October 31, 2010

## Explanatory Note

We are filing this Amended Quarterly Report on Form 10-Q/A (the “Amended Filing”) to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, which was filed with the Securities and Exchange Commission (“SEC”) on November 8, 2010 (the “Original Filing”), to amend and restate our unaudited consolidated condensed financial statements and related disclosures for the three months ended September 30, 2009 and September 30, 2010, and the period from inception to September 30, 2010, as discussed below and in Note 3 to the accompanying restated consolidated condensed financial statements, as well as to amend certain other Items within the Original Filing as listed out in “Items Amended in this Filing” below, as a result of the restatement of our consolidated condensed financial statements.

### Background of Restatement

On February 11, 2011, in connection with responding to certain comments raised by the Staff of the SEC in its periodic review of our SEC filings, the Company in consultation with its Audit Committee, concluded that its previously issued consolidated financial statements for all periods included in our annual report on Form 10-K for the fiscal year ended June 30, 2010 and included in our quarterly reports on Form 10-Q for the quarters ended September 30, 2009 through September 30, 2010 (collectively, the “Affected Periods”) should be restated because of a misapplication in the guidance around accounting for Warrants (as defined below) and should no longer be relied upon. However, the non-cash adjustments to the consolidated financial statements, in all of the Affected Periods, do not impact the amounts previously reported for the Company’s cash and cash equivalents, operating expenses or cash flows.

The warrants at issue (collectively, the “Warrants”) include:

- (i) warrants to purchase an aggregate of 300,000 shares of the Company’s common stock, issued in April 2004 at an exercise price of \$13.20 per share;
- (ii) warrants to purchase an aggregate of 320,248 shares of the Company’s common stock, issued in October 2004 at an exercise price of \$13.92 per share;
- (iii) warrants to purchase an aggregate of 740,131 shares of the Company’s common stock, issued in October 2007 at an exercise price of \$12.72 per share;
- (iv) Class A warrants to purchase an aggregate of 4,882,228 shares of the Company’s common stock, issued in January 2010 at an exercise price of \$2.97 per share; and
- (v) Class B warrants to purchase an aggregate of 3,254,818 shares of the Company’s common stock, issued in January 2010 at an exercise price of \$2.08 per share.

Historically, the Warrants were reflected as a component of equity as opposed to liabilities on the balance sheets and the statements of operations did not include the subsequent non-cash changes in estimated fair value of the Warrants in accordance with Accounting Standards Codification 815, *Derivatives and Hedging* (“ASC 815”). The Warrants generally provide that, in the event the related registration statement is not available for the issuance of the Warrant shares, the holder may exercise the Warrant on a cashless basis (i.e., applying a portion of the Warrant shares to the payment of the exercise price). In addition, the Class A warrants and Class B warrants listed above provide the holder with weighted-average anti-dilution price protection in the event we issue securities at a price per share that is less than the exercise price of the warrants.

However, under the guidance of ASC 815, warrant instruments that could potentially require net cash settlement in the absence of express language precluding such settlement, and, additionally, warrants that provide for anti-dilution price protection, should be initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. In periods subsequent to issuance, changes in the estimated fair value of the derivative instruments should be reported in the statement of operations. Our Audit Committee, together with management, determined that the financial statements in the Affected Periods should be restated to reflect the Warrants as liabilities, with subsequent changes in their estimated fair value recorded as non-cash income or expense in each Affected Period.

The cumulative effect of these adjustments on our financial statements is a 4.7% decrease in the deficit accumulated during the development stage in the amount of \$10.4 million as of September 30, 2010. These adjustments do not impact the amounts previously reported for the Company’s cash and cash equivalents, operating cash flows or operating expenses in any of the Affected Periods. An explanation of the impact on our financial statements is contained in Note 3 to the consolidated condensed financial statements contained in Part I — Item 1 of this Amended Filing.

## **Restatement of Other Financial Statements**

Along with the filing of this Amended Filing, we are concurrently filing amendments to our Annual Report on Form 10-K for the fiscal year ended June 30, 2010 and Quarterly Reports on Form 10-Q for the quarters ended September 30, 2009, December 31, 2009 and March 31, 2010. The amendments to our Quarterly Reports on Form 10-Q are being filed to restate our unaudited consolidated condensed financial statements and related financial information for the periods contained in those reports and to amend certain other Items within the previously-issued quarterly filings, including Item 4 — “Controls and Procedures” to reflect a reassessment of our disclosure controls and procedures, and internal control over financial reporting. There is no impact on the amounts previously reported for the Company’s cash and cash equivalents, operating cash flows or operating expenses in any of the Affected Periods as a result of the restatement. The cumulative adjustment to shareholders’ equity as of the beginning of the quarter ended September 30, 2010 was to reduce previously reported shareholders’ equity at that time by \$3.0 million.

## **Internal Control Considerations**

Our management determined that there was a control deficiency in its internal control that constitutes a material weakness, as discussed in Part I — Item 4 of the Amended Filing. A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. For a discussion of management’s consideration of the Company’s disclosure controls and procedures and the material weakness identified, see Part I — Item 4 included in this Amended Filing.

## **Items Amended in This Filing**

For the convenience of the reader, this Amended Filing sets forth the Original Filing, as modified and superseded where necessary to reflect the restatement. The following items have been amended as a result of, and to reflect, the restatement:

- Part I — Item 1. Financial Statements;
- Part I — Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations; and
- Part I — Item 4. Controls and Procedures.

In accordance with applicable SEC rules, this Amended Filing includes new certifications required by Rule 13a-14 under the Securities and Exchange Act of 1934 (“Exchange Act”) from our Chief Executive Officer and Chief Financial Officer dated as of the date of filing of this Amended Filing.

Except for the items noted above, no other information included in the Original Filing is being amended or updated by this Amended Filing. This Amended Filing continues to describe the conditions as of the date of the Original Filing and, except as contained herein, we have not updated or modified the disclosures contained in the Original Filing. Accordingly, this Amended Filing should be read in conjunction with our filings made with the SEC subsequent to the filing of the Original Filing, including any amendment to those filings.

AASTROM BIOSCIENCES, INC.  
QUARTERLY REPORT ON FORM 10-Q/A  
September 30, 2010

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## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements

**AASTROM BIOSCIENCES, INC.**  
**(a clinical development stage company)**  
**CONSOLIDATED CONDENSED BALANCE SHEETS**  
**(Unaudited, amounts in thousands)**

	June 30, 2010 <u>(Restated)</u>	September 30, 2010 <u>(Restated)</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,119	\$ 14,466
Short-term investments	5,000	—
Receivables, net	16	17
Other current assets	383	505
Total current assets	<u>19,518</u>	<u>14,988</u>
Property and equipment, net	1,013	982
Total assets	<u>\$ 20,531</u>	<u>\$ 15,970</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,749	\$ 2,739
Accrued employee benefits	686	508
Current portion of long-term debt	226	240
Warrant liabilities	3,010	3,109
Total current liabilities	<u>5,671</u>	<u>6,596</u>
Long-term debt	79	40
Total liabilities	<u>5,750</u>	<u>6,636</u>
Shareholders' equity:		
Common stock, no par value; shares authorized — 62,500; shares issued and outstanding — 28,256 and 28,252, respectively	217,873	218,358
Deficit accumulated during the development stage	<u>(203,092)</u>	<u>(209,024)</u>
Total shareholders' equity	<u>14,781</u>	<u>9,334</u>
Total liabilities and shareholders' equity	<u>\$ 20,531</u>	<u>\$ 15,970</u>

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

**AASTROM BIOSCIENCES, INC.**  
**(a clinical development stage company)**  
**CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS**  
**(Unaudited, amounts in thousands except per share amounts)**

	2009 (Restated)	Quarter ended September 30, 2010 (Restated)	March 24, 1989 (Inception) to September 30, 2010 (Restated)
Revenues:			
Product sales and rentals	\$ 73	\$ —	\$ 1,850
Research and development agreements	—	—	2,105
Grants	—	—	9,657
Total revenues	<u>73</u>	<u>—</u>	<u>13,612</u>
Costs and expenses:			
Cost of product sales and rentals	32	—	3,035
Research and development	2,911	4,167	164,933
Selling, general and administrative	946	1,686	75,545
Total costs and expenses	<u>3,889</u>	<u>5,853</u>	<u>243,513</u>
Loss from operations	<u>(3,816)</u>	<u>(5,853)</u>	<u>(229,901)</u>
Other income (expense):			
(Increase) decrease in fair value of warrants	9	(99)	10,361
Other income	—	—	1,249
Interest income	28	25	10,704
Interest expense	(13)	(5)	(469)
Total other income (expense)	<u>24</u>	<u>(79)</u>	<u>21,845</u>
Net loss	<u>\$ (3,792)</u>	<u>\$ (5,932)</u>	<u>\$ (208,056)</u>
Net loss per share (Basic and Diluted)	<u>\$ (0.18)</u>	<u>\$ (0.21)</u>	
Weighted average number of common shares outstanding (Basic and Diluted)	<u>20,679</u>	<u>28,255</u>	

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

**AASTROM BIOSCIENCES, INC.**  
**(a clinical development stage company)**  
**CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS**  
**(Unaudited, amounts in thousands )**

	2009 (Restated)	Quarter ended September 30, 2010 (Restated)	March 24, 1989 (Inception) to September 30, 2010 (Restated)
<b>Operating activities:</b>			
Net loss	\$ (3,792)	\$ (5,932)	\$ (208,056)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	151	129	6,722
Loss on property held for resale	—	—	110
Amortization of discounts and premiums on investments	—	—	(1,704)
Stock compensation expense	47	485	9,584
Increase (decrease) in fair value of warrants	(9)	99	(10,361)
Inventory write downs and reserves	—	—	2,239
Stock issued pursuant to license agreement	—	—	3,300
Provision for losses on accounts receivable	—	—	204
Changes in operating assets and liabilities:			
Receivables	(461)	(1)	(266)
Inventories	1	—	(2,335)
Other current assets	(238)	(122)	(485)
Accounts payable and accrued expenses	482	990	2,682
Accrued employee benefits	(21)	(178)	508
Net cash used for operating activities	<u>(3,840)</u>	<u>(4,530)</u>	<u>(197,858)</u>
<b>Investing activities:</b>			
Organizational costs	—	—	(73)
Purchase of short-term investments	—	—	(217,041)
Maturities of short-term investments	—	5,000	218,745
Property and equipment purchases	(54)	(68)	(5,949)
Proceeds from sale of property held for resale	—	—	400
Net cash provided by (used for) investing activities	<u>(54)</u>	<u>4,932</u>	<u>(3,918)</u>
<b>Financing activities:</b>			
Net proceeds from issuance of preferred stock	—	—	51,647
Net proceeds from issuance of common stock and warrants	4,300	—	162,871
Repurchase of common stock	—	—	(49)
Payments received for stock purchase rights	—	—	3,500
Payments received under shareholder notes	—	—	31
Restricted cash used as compensating balance	68	—	—
Proceeds from long-term debt	—	—	751
Principal payments under long-term debt obligations	(117)	(55)	(2,509)
Net cash provided by (used for) financing activities	<u>4,251</u>	<u>(55)</u>	<u>216,242</u>
Net increase in cash and cash equivalents	357	347	14,466
Cash and cash equivalents at beginning of period	17,000	14,119	—
Cash and cash equivalents at end of period	<u>\$ 17,357</u>	<u>\$ 14,466</u>	<u>\$ 14,466</u>

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

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

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

**1. Organization and Summary of Significant Accounting Policies**

Aastrom Biosciences, Inc. (the “Company” or “Aastrom”) 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 autologous cell 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 operations, including development of its products and product candidates, via its cash and cash equivalents on hand as of September 30, 2010 until at least June 30, 2011. While the Company’s budgeted cash usage and operating plan through June 30, 2011 does not currently contemplate taking additional actions to reduce the use of cash over that period, 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 pursuit of a Phase 3 clinical trial for CLI) such that the Company will have sufficient cash on hand through June 30, 2011. The Company will need to raise additional funds in order to complete its product development programs, complete clinical trials needed to market its products (including a Phase 3 clinical trial for CLI), 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 may 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.

**2. Basis of Presentation**

The consolidated condensed 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 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 months ended September 30, 2010, are not necessarily indicative of the results to be expected for the full year or for any other period. The June 30, 2010 consolidated condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

These financial statements should be read in conjunction with the audited restated financial statements and the notes thereto included in our Amendment No. 1 to Annual Report on Form 10-K/A for the year ended June 30, 2010, that is being concurrently filed with the SEC.

The consolidated condensed financial statements include the accounts of Aastrom and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany, Aastrom Biosciences SL, located in Barcelona, Spain, and Aastrom Biosciences Ltd., located in Dublin, Ireland (collectively, the Company). All inter-company transactions and accounts have been eliminated in consolidation. As of September 30, 2010, all subsidiaries had limited operations and were not a significant component of the consolidated financial statements.

On February 18, 2010, the Company’s board of directors, by unanimous written consent, authorized an eight-for-one reverse stock split. Accordingly, all references to numbers of common stock and per share data in the accompanying financial statements have been adjusted to reflect the reverse stock split on a retroactive basis.

### 3. Restatement of Consolidated Financial Statements

#### *Background*

On February 11, 2011, in connection with responding to certain comments raised by the Staff of the SEC in its periodic review of the Company's SEC filings, the Company in consultation with its Audit Committee, concluded that its previously issued financial statements for all periods included in the Company's annual report on Form 10-K for the fiscal year ended June 30, 2010 and included in the Company's quarterly reports on Form 10-Q for the quarters ended September 30, 2009 through September 30, 2010 (collectively, the "Affected Periods") should be restated because of a misapplication in the guidance around accounting for Warrants (as defined below) and should no longer be relied upon. However, the non-cash adjustments to the financial statements, in all of the Affected Periods, do not impact the amounts previously reported for the Company's cash and cash equivalents, operating expenses or cash flows.

The warrants at issue (collectively, the "Warrants") include:

- (i) warrants to purchase an aggregate of 300,000 shares of the Company's common stock, issued in April 2004 at an exercise price of \$13.20 per share;
- (ii) warrants to purchase an aggregate of 320,248 shares of the Company's common stock, issued in October 2004 at an exercise price of \$13.92 per share;
- (iii) warrants to purchase an aggregate of 740,131 shares of the Company's common stock, issued in October 2007 at an exercise price of \$12.72 per share;
- (iv) Class A warrants to purchase an aggregate of 4,882,228 shares of the Company's common stock, issued in January 2010 at an exercise price of \$2.97 per share; and
- (v) Class B warrants to purchase an aggregate of 3,254,818 shares of the Company's common stock, issued in January 2010 at an exercise price of \$2.08 per share.

Historically, the Warrants were reflected as a component of equity as opposed to liabilities on the balance sheets and the statement of operations did not include the subsequent non-cash changes in estimated fair value of the Warrants in accordance with Accounting Standards Codification 815, *Derivatives and Hedging* ("ASC 815"). The Warrants generally provide that, in the event the related registration statement is not available for the issuance of the Warrant shares, the holder may exercise the Warrant on a cashless basis (i.e., applying a portion of the Warrant shares to the payment of the exercise price). In addition, the Class A warrants and Class B warrants listed above provide the holder with weighted-average anti-dilution price protection in the event we issue securities at a price per share that is less than the exercise price of the warrants.

However, under the guidance of ASC 815, warrant instruments that could potentially require net cash settlement in the absence of express language precluding such settlement, and, additionally, warrants that provide for anti-dilution price protection, should be initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. In periods subsequent to issuance, changes in the estimated fair value of the derivative instruments should be reported in the statement of operations. The Audit Committee, together with management, determined that the financial statements in the Affected Periods should be restated to reflect the Warrants as liabilities, with subsequent changes in their estimated fair value recorded as non-cash income or expense in each Affected Period.

#### *Impact of the Restatement*

The cumulative effect of these adjustments on the Company's previously-reported deficit accumulated during the development stage and total shareholders' equity was a decrease of \$7.3 million and \$0.5 million, respectively, as of the beginning of the quarter ended September 30, 2009. These adjustments do not impact the amounts previously reported for the Company's cash and cash equivalents, net cash used for operating activities or operating expenses in any of the Affected Periods.

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The effects of the restatement on the following financial statement line items as of and for the periods indicated are summarized in the following tables (*in thousands except per share amounts*):

	Consolidated Condensed Balance Sheets		
	As Previously Reported	Adjustments	As Restated
<b>As of June 30, 2010</b>			
Warrant liabilities	\$ —	\$ 3,010	\$ 3,010
Total current liabilities	\$ 2,661	\$ 3,010	\$ 5,671
Total liabilities	\$ 2,740	\$ 3,010	\$ 5,750
Common stock	\$ 231,343	\$ (13,470)	\$ 217,873
Deficit accumulated during the development stage	\$ (213,552)	\$ 10,460	\$ (203,092)
Total shareholders' equity	\$ 17,791	\$ (3,010)	\$ 14,781
<b>As of September 30, 2010</b>			
Warrant liabilities	\$ —	\$ 3,109	\$ 3,109
Total current liabilities	\$ 3,487	\$ 3,109	\$ 6,596
Total liabilities	\$ 3,527	\$ 3,109	\$ 6,636
Common stock	\$ 231,828	\$ (13,470)	\$ 218,358
Deficit accumulated during the development stage	\$ (219,385)	\$ 10,361	\$ (209,024)
Total shareholders' equity	\$ 12,443	\$ (3,109)	\$ 9,334
	Consolidated Condensed Statements of Operations		
	As Previously Reported	Adjustments	As Restated
<b>For the quarter ended September 30, 2009:</b>			
(Increase) decrease in fair value of warrants	\$ —	\$ 9	\$ 9
Total other income (expense)	\$ 15	\$ 9	\$ 24
Net loss	\$ (3,801)	\$ 9	\$ (3,792)
Net loss per share (basic and diluted)	\$ (0.18)	\$ —	\$ (0.18)
<b>For the quarter ended September 30, 2010:</b>			
(Increase) decrease in fair value of warrants	\$ —	\$ (99)	\$ (99)
Total other income (expense)	\$ 20	\$ (99)	\$ (79)
Net loss	\$ (5,833)	\$ (99)	\$ (5,932)
Net loss per share (basic and diluted)	\$ (0.21)	\$ —	\$ (0.21)
<b>March 24, 1989 (Inception) to September 30, 2010:</b>			
(Increase) decrease in fair value of warrants	\$ —	\$ 10,361	\$ 10,361
Total other income (expense)	\$ 11,484	\$ 10,361	\$ 21,845
Net loss	\$ (218,417)	\$ 10,361	\$ (208,056)
	Consolidated Condensed Statements of Cash Flows		
	As Previously Reported	Adjustments	As Restated
<b>For the quarter ended September 30, 2009:</b>			
Net loss	\$ (3,801)	\$ 9	\$ (3,792)
Increase (decrease) in fair value of warrants	\$ —	\$ (9)	\$ (9)
<b>For the quarter ended September 30, 2010:</b>			
Net loss	\$ (5,833)	\$ (99)	\$ (5,932)
Increase (decrease) in fair value of warrants	\$ —	\$ 99	\$ 99
<b>March 24, 1989 (Inception) to September 30, 2010:</b>			
Net loss	\$ (218,417)	\$ 10,361	\$ (208,056)
Increase (decrease) in fair value of warrants	\$ —	\$ (10,361)	\$ (10,361)

#### **4. Fair Value Measurements**

Effective July 1, 2008, the Company began measuring assets and liabilities at fair value on a recurring basis. In addition to expanding the disclosures surrounding fair value measurements, U.S. GAAP (Generally Accepted Accounting Principles) clarifies that 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, 2010, the Company had \$14,466,000 invested in three money market funds with maturities of three months or less that are included within the "Cash and cash equivalents" line on the consolidated condensed balance sheet. Because there are quoted prices in an active market for shares of these money market funds, the Company considers its fair value measure of these investments to be based on Level 1 inputs.

See Note 6 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, 2010 that are measured at fair value.

#### **5. Stock-Based Compensation**

The Company has a stock incentive plan (Option Plan) that provides for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants.

##### ***Service-Based Stock Options***

During the quarter ended September 30, 2010, the Company granted 1,453,000 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 104,000 non-employee director options which vest over three years) and have lives of ten years. The weighted average grant-date fair value of service-based options granted under the Company's Option Plan during the quarters ended September 30, 2009 and 2010 was \$2.16 and \$0.95, respectively.

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The net compensation costs recorded for the service-based stock options related to employees and directors (including the impact of the forfeitures) were approximately \$38,000 and \$485,000 for the quarters ended September 30, 2009 and 2010, respectively. Included in net compensation cost for the quarter ended September 30, 2009 was the reversal of previously recognized expense of \$279,000 for options held by our former Chief Executive Officer, President and Chief Financial Officer, George W. Dunbar, that were forfeited in excess of our estimated rate of forfeiture.

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.

<b>Service-Based Stock Options</b>	<b>Quarter ended September 30,</b>	
	<b>2009</b>	<b>2010</b>
Expected dividend rate	0%	0%
Expected stock price volatility	72.3% - 72.8%	70.6% - 71.4%
Risk free interest rate	2.8% - 3.0%	1.7% - 2.1%
Estimated forfeiture rate (per annum)	10%	10%
Expected life (years)	6.3	6.0 - 6.3

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

<b>Service-Based Stock Options</b>	<b>Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at June 30, 2010	3,283,180	\$ 3.40	8.6	\$ 2,750
Granted	1,453,000	\$ 1.49		
Forfeited or expired	(411,849)	\$ 5.44		
Outstanding at September 30, 2010	<u>4,324,331</u>	<u>\$ 2.56</u>	<u>9.0</u>	<u>\$ 114,050</u>
Exercisable at September 30, 2010	<u>768,914</u>	<u>\$ 6.06</u>	<u>6.5</u>	<u>\$ —</u>

As of September 30, 2010 there was approximately \$2,624,000 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 1.9 years.

### **Performance-Based Stock Options**

There were no grants of performance-based stock options during the three months ended September 30, 2010. There have been no changes to the terms of the performance-based stock options from those disclosed in our Annual Report on Form 10-K/A for the year ended June 30, 2010.

For the three months ended September 30, 2010, management reviewed the progress toward the performance conditions necessary for these options to vest and concluded that it was not yet probable that the performance conditions of any of the tranches of options would be met and, accordingly, no compensation expense has been recorded.

The following table summarizes the activity for performance-based stock options for the indicated period:

<b>Performance-Based Stock Options</b>	<b>Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at June 30, 2010	40,164	\$ 12.17	6.4	\$ 0
Forfeited or expired	(2,083)	\$ 12.24		
Outstanding at September 30, 2010	<u>38,081</u>	<u>\$ 12.17</u>	<u>6.1</u>	<u>\$ 0</u>

The aggregate estimated fair value of these awards that are outstanding as of September 30, 2010 was approximately \$309,000.

## 6. Stock Purchase Warrants

The Company had the following warrants to purchase shares of common stock of the Company outstanding during the years ended June 30, 2008, 2009 and 2010:

- (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;
- (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 \$2.97 per share; and
- (iii) Class B warrants to purchase an aggregate of 3,254,818 shares of common stock, issued on January 21, 2010 in connection with the Company's registered public offering, exercisable at any time from January 21, 2010 through July 21, 2010 at an exercise price of \$2.08 per share.

The foregoing warrants are recorded as liabilities at their estimated fair value at the date of issuance, with subsequent changes in estimated fair value recorded in other income (expense) in the Company's statement of operations in each subsequent period. The estimated fair value of these warrants is determined using Level 3 inputs. The liability is measured using the Black Scholes valuation model, which is based, in part, upon unobservable inputs for which there is little or no market data, requiring the Company to develop its own assumptions. The assumptions used by the Company are summarized in the following tables:

<u>October 2007 Warrants</u>	<u>June 30, 2010</u>	<u>September 30, 2010</u>
Closing stock price	\$ 1.49	\$ 1.55
Expected dividend rate	0%	0%
Expected stock price volatility	80.4%	79.7%
Risk free interest rate	1.0%	0.6%
Expected life (years)	2.75	2.50

  

<u>January 2010 Class A Warrants</u>	<u>June 30, 2010</u>	<u>September 30, 2010</u>
Closing stock price	\$ 1.49	\$ 1.55
Expected dividend rate	0%	0%
Expected stock price volatility	66.3%	67.6%
Risk free interest rate	1.8%	1.3%
Expected life (years)	5.00	4.75

The following table summarizes the changes in the estimated fair value of our warrant liabilities (*in thousands*):

<u>Warrant Liabilities</u>	
Balance at June 30, 2010	\$ 3,010
Increase in fair value	99
Balance at September 30, 2010	<u>\$ 3,109</u>

## 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 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 for the periods ended September 30, 2009 and 2010 was approximately 2,599,000 and 9,985,000, respectively.

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

### Restatement

As discussed in the Explanatory Note and Note 3 to this Amended Filing, we are amending and restating our unaudited consolidated condensed financial statements and related disclosures for all periods presented in this Amended Filing.

The following discussion and analysis of our financial condition and results of operations incorporates the restated amounts. For this reason, the data set forth in this section may not be comparable to discussion and data in our previously filed Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.

### 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 currently focused on developing autologous cell therapies for the treatment of severe, chronic cardiovascular diseases. Using our proprietary technology, we are able to expand the number of stem and early progenitor cells from a small amount of bone marrow (approximately 50 ml) collected from the patient. Preclinical and interim clinical data suggest that our cell therapy is effective in treating patients with critical limb ischemia (CLI). We are currently investigating the effectiveness of our therapy in other severe, chronic cardiovascular diseases, such as dilated cardiomyopathy (DCM). Nearly 200 patients have been treated in recent clinical trials using our current cell therapy (over 400 patients safely treated since our inception) with no treatment related adverse events or safety issues.

Our technology is an autologous, expanded cellular therapy developed, using our proprietary, automated cell processing system, which utilizes "single-pass perfusion" to produce human cell products for clinical use. Single-pass perfusion is our patented manufacturing technology for growing large numbers of human cells. The production of our cell therapy products is done under current Good Manufacturing Practices (cGMP) guidelines required by the U.S. Food and Drug Administration (FDA). Our therapies begin with a small amount of the patient's own bone marrow to produce large numbers of stem and early progenitor cells, many times more than what is found in the patient's bone marrow. Our proprietary mixture of cell types may be capable of developing into cardiovascular and other tissues as well as stimulating a patient's own existing repair mechanisms.

Our cellular therapies have several features that we believe are critical for success in treating patients with severe, chronic cardiovascular diseases:

**Safe** — our bone marrow derived, expanded, autologous cellular therapy leverages decades of scientific and medical experience, as bone marrow and bone marrow-like therapies have been used safely and efficaciously in medicine for decades.

**Autologous** — we start with the patient's own cells, which are accepted by the patient's immune system allowing the cells to differentiate and integrate into existing functional tissues, and may provide long-term engraftment and repair.

**Expanded** — we begin with a small amount of bone marrow from a patient (approximately 50 ml) and significantly expand the number of stem and progenitor cells to more than are present in the patient's own bone marrow.

**A mixed population of cells** — we believe our proprietary mixture of cell populations contains the cell types required for tissue regeneration, which are also found in natural bone marrow, though in smaller quantities.

**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 our therapy can be performed in an out-patient setting in a short procedure. We are pursuing a minimally invasive approach to cell delivery in diseases such as DCM.

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

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Our clinical development programs are focused on advancing therapies for unmet medical needs in cardiovascular diseases. Our CLI program is currently in phase 2b clinical development, and we expect it to advance to Phase 3 development in 2011. Our DCM program is in early Phase 2 clinical development and is focused on achieving proof of concept in this indication.

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) registration in the United States for our products in a timely fashion, or at all.

### Critical Limb Ischemia

CLI is the most serious and advanced stage of peripheral arterial disease (PAD). PAD is a chronic 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), ulcers, tissue loss or gangrene in the limbs, often leading to amputation and death. CLI leads to more than 160,000 amputations per year. The one-year and four-year mortality rates for no-option CLI patients that progress to amputation are approximately 25% and 80%, respectively. Our technology has shown promise in the treatment of CLI.

In June 2010, we reported results from the planned interim analysis of our multi-center, randomized, double-blind, placebo controlled U.S. Phase 2b RESTORE-CLI clinical trial. This clinical trial is designed to evaluate the safety and efficacy of our therapy in the treatment of patients with CLI. It is 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. These patients are being followed for a period of 12 months following treatment. In addition to assessing the safety of our product, efficacy endpoints include amputation-free survival, time to first occurrence of treatment failure (defined as major amputation, all-cause mortality, doubling in wound size and de novo gangrene), major amputation rates, level of amputation, complete wound healing, patient quality of life, and pain scores.

Results from the RESTORE-CLI interim analysis were presented at the Society of Vascular Surgery Meeting in June 2010. The results included the finding that amputation free survival — defined as time to major amputation or death — was statistically significant in favor of our therapy ( $p=0.038$ ). Additionally, statistical analysis revealed a significant increase in time to treatment failure (e.g., major amputation, doubling in wound size de novo gangrene, and death) (log-rank test,  $p=0.0053$ ). Other endpoints measured (e.g., major amputation rate, complete wound healing, change in Wagner wound scale) showed encouraging trends, but had not yet reached statistical significance at the interim analysis. The primary purpose of the interim analysis was to assess performance of our therapy and, if positive, to help plan the Phase 3 program. Discussions held with the FDA in June 2010 confirmed the appropriateness of using amputation free survival as the primary endpoint for the Phase 3 program. The last patient enrolled in this trial was treated in March 2010 and we expect to present six-month data on all patients in this study later this year.

We continue to make progress towards the Phase 3 clinical development program in CLI. In October, we announced that the FDA had granted fast track designation for the use of our cellular therapy 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 and that demonstrate the potential to address unmet medical needs. At the June FDA meeting, Aastrom was encouraged to use the Special Protocol Assessment (SPA) process for the Phase 3 program. The SPA's supporting the Phase 3 program were submitted in October of 2010.

### Dilated Cardiomyopathy

In February 2007, the FDA granted Orphan Drug Designation to our investigational therapy involving the use of our therapy in the treatment of DCM. 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 exposure, virus or genetic diseases. Patient prognosis depends on the stage 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.

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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.

In May 2008, the FDA activated our IND application 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. We expect to report interim results of all patients who have completed six months of follow-up during fiscal year 2011.

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 our therapy 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 will be followed for 12 months post-treatment.

In November 2009, the FDA activated our second IND application to allow for the evaluation of our therapy delivered by a percutaneous catheter as opposed to surgically. The Catheter-DCM clinical trial is designed to explore catheter-based delivery of our therapy to treat DCM patients. This multi-center, randomized, controlled, prospective, open-label, Phase 2 study will enroll up to 12 patients with ischemic DCM and 12 patients with non-ischemic DCM at clinical sites across the United States. Participants must meet the same criteria above for the IMPACT-DCM surgical trial. The first patient was enrolled into the trial in April 2010 and enrollment is progressing. As of October 31, 2010, 20 patients had been enrolled in the study and we expect to conclude enrollment by December 2010.

### **Results of Operations**

The Company had no revenue during the quarter ended September 30, 2010 compared to \$73,000 for the quarter ended September 30, 2009. Sales in 2009 related to cell production sales for investigator sponsored clinical trials in Spain and limited cell manufacturing supplies to a research institute in the United States. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our cell-based products will constitute nearly all of our product sales revenues.

Research and development expenses were \$4,167,000 for the quarter ended September 30, 2010, compared to \$2,911,000 for the quarter ended September 30, 2009. This increase was associated with preparations for the Phase 3 CLI development program. Research and development expenses also include non-cash stock-based compensation expense of \$255,000 and \$186,000 for the quarters ended September 30, 2010 and 2009, respectively, which reflects the increased headcount from the prior year.

Selling, general and administrative expenses were \$1,686,000 for the quarter ended September 30, 2010, compared to \$946,000 for the quarter ended September 30, 2009. The increase relates to employee expenses, general consulting costs and an increase in non-cash stock-based compensation expense to \$230,000 for the quarter ended September 30, 2010, from a net expense reversal of \$139,000 for the quarter ended September 30, 2009. Stock-based compensation expense for the quarter ended September 30, 2009 was impacted by the reversal of previously recognized expense of \$279,000 for options held by our former Chief Executive Officer, President and Chief Financial Officer, George W. Dunbar, that were forfeited in excess of our estimated rate of forfeiture. The remaining increase from the prior year is primarily due the hiring of new senior management subsequent to the first quarter of fiscal 2010.

Income (expense) from the change in fair value of warrants was \$(99,000) for the quarter ended September 30, 2010 compared to \$9,000 for the quarter ended September 30, 2009. The fluctuation is due primarily to changes in the fair value of our common stock and the related impact on our warrant liabilities.

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Our net loss was \$5,932,000, or \$0.21 per share for the quarter ended September 30, 2010, compared to \$3,792,000, or \$0.18 per share for the quarter ended September 30, 2009. The changes in net loss are due to the fluctuations in research and development expenses and selling, general and administrative expenses as described above. The loss per share comparisons are impacted by the issuance of 6.5 million shares of common stock on January 21, 2010.

Our major ongoing research and development programs are focused on the clinical development of our technology platform for treatment of severe, chronic cardiovascular diseases. Research and development expenses outside of the development of our technology platform consist primarily of engineering and cell production costs.

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to our products, estimating the completion dates or cost to complete our major research and development programs would be highly speculative and subjective. The risks and uncertainties associated with developing our products, including significant and changing governmental regulation and the uncertainty of future clinical study results, are discussed in greater detail under the caption "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K/A for the year-ended June 30, 2010. The lengthy process of seeking regulatory approvals for our product candidates, and the subsequent compliance with applicable regulations, will require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, could have a material adverse effect on our results of operations. We cannot be certain when any net cash inflow from products validated under our major research and development project, if any, will commence.

### **Liquidity and Capital Resources**

We are currently focused on utilizing our technology to produce autologous cell-based products for use in regenerative medicine applications. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our cell-based products 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.

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 and until significant product sales commence. With respect to our current activities, this is 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, 2010, we had accumulated a net loss of approximately \$208,056,000. 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, or complete additional corporate partnering or acquisition transactions.

We have financed our operations since inception primarily through public and private sales of our equity securities, which, from inception through September 30, 2010, have totaled approximately \$218,358,000 and, to a lesser degree, through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments, and funding under equipment leasing agreements. These financing sources have generally allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash, cash equivalents and short-term investments totaled \$14,466,000 at September 30, 2010, a decrease of \$4,653,000 from June 30, 2010. The primary use of cash, cash equivalents and short-term investments during the quarter ended September 30, 2010 included \$4,530,000 to finance our operations and working capital requirements, and \$68,000 in capital expenditures.

Our cash and cash equivalents included money market securities with maturities of three months or less.

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 regulatory approval and market acceptance for our products.

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We believe that we will 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, 2010 until at least June 30, 2011. While our budgeted cash usage and operating plan through June 30, 2011 does not currently contemplate taking additional actions to reduce the use of cash over that period, we could, if necessary, delay or forego certain budgeted discretionary expenditures such as anticipated hiring plans or certain non-critical research and development expenditures. In addition, we could slow down or delay certain clinical trial activity (without jeopardizing our pursuit of a Phase 3 clinical trial for CLI) such that we will have sufficient cash on hand through June 30, 2011. The Company will need to raise additional funds in order to complete its product development programs, complete clinical trials needed to market its products (including for a Phase 3 clinical trial for CLI), 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 may 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. These estimates are based on certain assumptions which could be negatively impacted by the matters discussed under this heading and under the caption "Risk Factors," in Item 1A of our 2010 Annual Report on Form 10-K/A filed with the SEC.

### **Off-Balance Sheet Arrangements**

At September 30, 2010, 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. 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/A for the year-ended June 30, 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;
- 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.

**Item 4. Controls and Procedures**

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2010. The term “disclosure controls and procedures” is defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934 (“the Exchange Act”). Management recognizes that any disclosure controls and procedures no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

At the time that our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 was filed on November 8, 2010, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2010. Subsequent to that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were not effective to provide reasonable assurance as of September 30, 2010 because of a material weakness in our internal control over financial reporting described below.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. We did not maintain effective controls relating to accounting for warrants. Specifically, we did not maintain effective controls over the identification and proper accounting treatment of certain terms and conditions in our warrant agreements. This material weakness resulted in a material misstatement of our liabilities, non-cash expense relating to the changes in fair value of common stock warrants and accumulated deficit accounts and related financial disclosures and the restatement of our consolidated financial statements for the years ended June 30, 2008, 2009 and 2010, the period from Inception to June 30, 2010, and each of the quarterly periods (including the period from Inception) from September 30, 2008 through September 30, 2010 (the “Affected Periods”) as discussed below and in Note 3 to the consolidated financial statements included in this Quarterly Report on Form 10-Q/A. Additionally, this deficiency could result in misstatements of the aforementioned accounts and disclosures that would result in a material misstatement of the consolidated financial statements that would not be prevented or detected.

Restatement of Consolidated Financial Statements

On February 11, 2011, in connection with responding to certain comments raised by the Staff of the SEC in its periodic review of the Company’s SEC filings, the Company in consultation with its Audit Committee, concluded that its previously issued consolidated financial statements for the Affected Periods should be restated because of a misapplication in the guidance around accounting for warrants and should no longer be relied upon. However, the non-cash adjustments to the financial statements, in all of the Affected Periods, do not impact the amounts previously reported for the Company’s cash and cash equivalents, operating expenses or cash flows.

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### Remediation Plan

Management has been actively engaged in developing a remediation plan to address the material weakness. Implementation of the remediation plan is in process and consists of the hiring of new accounting/finance personnel and their revisiting the original accounting assessment for each of their historical warrants and assessing the original accounting and the on-going accounting impact. Management has completed this assessment during February 2011 and the results of this analysis have been used to adjust the Affected Periods in the restated documents.

Management believes the foregoing efforts will effectively remediate the material weakness. As the Company continues to evaluate and work to improve its internal control over financial reporting, management may execute additional measures to address potential control deficiencies or modify the remediation plan described above. Management will continue to review and make necessary changes to the overall design of the Company's internal control.

### Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## **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*

See "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K/A for the year ended June 30, 2010 filed concurrently with this report.

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

None.

### *Item 3. Defaults Upon Senior Securities*

None.

### *Item 4. Submission of Matters to a Vote of Security Holders*

None.

### *Item 5. Other Information*

None.

### *Item 6. Exhibits*

See Exhibit Index.

**SIGNATURES**

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

Date: February 24 , 2011

AASTROM BIOSCIENCES, INC.

/s/ TIMOTHY M. MAYLEBEN

Timothy M. Mayleben  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ SCOTT C. DURBIN

Scott C. Durbin  
*Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
10.1	Form of indemnification agreement entered into between the Company and each of its directors, including Timothy M. Mayleben, a director and the Company's President and Chief Executive Officer, attached as Exhibit 10.1 to Aastrom's Current Report on Form 8-K filed on August 31, 2010, 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 Financial 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).

**GLOSSARY**

<b>TERM</b>	<b>DEFINITION</b>
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	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.
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	A 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 supplying it.
LVEF — Left Ventricular Ejection Fraction	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.

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<b>TERM</b>	<b>DEFINITION</b>
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.
Progenitor Cells	A “parent” cell that gives rise to a distinct cell lineage by a series of cell divisions.
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.
SPP — Single-Pass Perfusion	SPP is Aastrom’s proprietary technology that controls gas and cell culture media exchange to enable the replication of early-stage stem and progenitor cells while preventing their differentiation into mature cells.
Stem Cell	Unspecialized (undifferentiated) cells that retain the ability to divide throughout a lifetime and give rise to more specialized (differentiated) cells which take the place of cells that die or are lost. In culture, these undifferentiated cells possess the ability to divide for indefinite periods in culture and may give rise to highly specialized cells.

## CERTIFICATION

I, Timothy M. Mayleben, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q/A of Aastrom Biosciences, Inc. for the quarter ended September 30, 2010;
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(s) 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(s) 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: February 24, 2011

/s/ TIMOTHY M. MAYLEBEN

Timothy M. Mayleben

*President and Chief Executive Officer*  
*(Principal Executive Officer)*

**CERTIFICATION**

I, Scott C. Durbin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q/A of Aastrom Biosciences, Inc. for the quarter ended September 30, 2010;
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(s) 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(s) 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: February 24, 2011

/s/ SCOTT C. DURBIN

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Scott C. Durbin

*Chief Financial Officer*

*(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/A for the quarter ended September 30, 2010, 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: February 24, 2011

/s/ TIMOTHY M. MAYLEBEN

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Timothy M. Mayleben  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ SCOTT C. DURBIN

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Scott C. Durbin  
*Chief Financial Officer*  
*(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.