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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, 2009

OR

o **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	94-3096597
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
24 Frank Lloyd Wright Dr. P.O. Box 376 Ann Arbor, Michigan	48106
(Address of principal executive offices)	(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 — o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes — o No — o

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

Large accelerated filer — o	Accelerated filer — o	Non-accelerated filer — o (Do not check if a smaller reporting company)	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 — o 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	173,971,085
(Class)	Outstanding at November 5, 2009

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, 2009, which was filed with the Securities and Exchange Commission ("SEC") on November 6, 2009 (the "Original Filing"), to amend and restate our unaudited consolidated condensed financial statements and related disclosures for the three months ended September 30, 2008 and September 30, 2009, and the period from inception to September 30, 2009, 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 3.7% decrease in the deficit accumulated during the development stage in the amount of $7.3 million as of September 30, 2009. 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 December 31, 2009, March 31, 2010 and September 30, 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, 2009 was to reduce previously reported shareholders' equity at that time by $0.5 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, 2009

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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)
(In thousands, except share amounts)

	June 30, 2009 (Restated)	September 30, 2009 (Restated)
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,000	$ 17,357
Receivables, net	58	519
Inventory	1	—
Other current assets	732	902
Total current assets	17,791	18,778
PROPERTY AND EQUIPMENT, NET	1,485	1,388
Total assets	$ 19,276	$ 20,166
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 853	$ 1,335
Accrued employee benefits	355	334
Current portion of long-term debt	479	418
Warrant liabilities	532	523
Total current liabilities	2,219	2,610
LONG-TERM DEBT	305	249
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized — 250,000,000; shares issued and outstanding — 160,222,644 and 171,774,132, respectively	205,286	209,633
Deficit accumulated during the development stage	(188,534)	(192,326)
Total shareholders' equity	16,752	17,307
Total liabilities and shareholders' equity	$ 19,276	$ 20,166

The accompanying notes are an integral part of these financial statements.

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

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

	Quarter ended September 30,		March 24, 1989 (Inception) to September 30, 2009 (Restated)
	2008 (Restated)	2009 (Restated)	
REVENUES:			
Product sales and rentals	$ 27	$ 73	$ 1,834
Research and development agreements	—	—	2,105
Grants	—	—	9,657
Total revenues	27	73	13,596
COSTS AND EXPENSES:			
Cost of product sales and rentals	4	32	794
Cost of product sales and rentals — provision for obsolete and excess inventory	—	—	2,239
Research and development	2,726	2,911	151,019
Selling, general and administrative	1,316	946	69,604
Total costs and expenses	4,046	3,889	223,656
LOSS FROM OPERATIONS	(4,019)	(3,816)	(210,060)
OTHER INCOME (EXPENSE):			
Decrease in fair value of warrants	243	9	7,298
Other income	—	—	1,249
Interest income	127	28	10,592
Interest expense	(21)	(13)	(437)
Total other income, net	349	24	18,702
NET LOSS	$ (3,670)	$ (3,792)	$ (191,358)
COMPUTATION OF NET LOSS PER SHARE APPLICABLE TO COMMON SHARES:			
NET LOSS	$ (3,670)	$ (3,792)	
NET LOSS PER COMMON SHARE (Basic and Diluted)	$ (0.03)	$ (0.02)	
Weighted average number of common shares outstanding (Basic and Diluted)	132,796	165,433	

The accompanying notes are an integral part of these financial statements.

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

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Quarter ended September 30,		March 24, 1989 (Inception) to September 30, 2009 (Restated)
	2008 (Restated)	2009 (Restated)	
OPERATING ACTIVITIES:			
Net loss	$ (3,670)	$ (3,792)	$ (191,358)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	175	151	6,151
Loss on property held for resale	—	—	110
Amortization of discounts and premiums on investments	(30)	—	(1,704)
Stock compensation expense	363	47	8,436
Decrease in fair value of warrants	(243)	(9)	(7,298)
Inventory write downs and reserves	—	—	2,239
Stock issued pursuant to license agreement	—	—	3,300
Provision for losses on accounts receivable	—	—	204
Changes in assets and liabilities:			
Receivables	(48)	(461)	(768)
Inventories	—	1	(2,335)
Other current assets	(61)	(238)	(672)
Accounts payable and accrued expenses	43	482	1,278
Accrued employee benefits	(277)	(21)	334
Net cash used for operating activities	(3,748)	(3,840)	(182,083)
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73)
Purchase of short-term investments	—	—	(212,041)
Maturities of short-term investments	6,000	—	213,745
Property and equipment purchases	(4)	(54)	(5,815)
Proceeds from sale of property held for resale	—	—	400
Net cash provided by (used for) investing activities	5,996	(54)	(3,784)
FINANCING ACTIVITIES:			
Net proceeds from issuance of preferred stock	—	—	51,647
Net proceeds from issuance of common stock	5	4,300	149,645
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	63	68	(209)
Proceeds from long-term debt	—	—	751
Principal payments under long-term obligations	(108)	(117)	(2,092)
Net cash provided by (used for) financing activities	(40)	4,251	203,224
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,208	357	17,357
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	16,492	17,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 18,700	$ 17,357	$ 17,357
SUPPLEMENTAL CASH FLOW INFORMATION:			
Interest paid	$ 21	$ 13	$ 437

The accompanying notes are an integral part of these financial statements.

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

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. Organization

Aastrom Biosciences, Inc. (the "Company") 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. While management believes available cash, cash equivalents and short-term investments are adequate to finance its operations at least through September 30, 2010, in part due to the fact that many of the Company's expenditures are discretionary in nature and could, if necessary, be delayed, the Company will need to raise a substantial amount of additional funds in order to 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 of 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 U.S., EU and other countries, the liquidity and market volatility of the Company's equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If the Company cannot raise such funds, it may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would likely have a material adverse impact on the Company's business, financial condition and results of operations.

2. Basis of Presentation

The consolidated condensed financial statements included herein have been prepared by us without audit according to 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 quarter ended September 30, 2009, are not necessarily indicative of the results to be expected for the full year or for any other period.

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 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 Aastrom Biosciences, S.L., located in Barcelona, Spain (collectively, the "Company"). All significant inter-company transactions and accounts have been eliminated in consolidation. These subsidiaries have limited operations and are not significant to the consolidated financial statements.

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 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. 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 $7.4 million and $0.4 million, respectively, as of the beginning of the quarter ended September 30, 2008. 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.

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 Previoulsy Reported	Adjustments	As Restated
As of June 30, 2009			
Warrant liabilities	$ —	$ 532	$ 532
Total current liabilities	$ 1,687	$ 532	$ 2,219
Common stock	$ 213,107	$ (7,821)	$ 205,286
Deficit accumulated during the development stage	$ (195,823)	$ 7,289	$ (188,534)
Total shareholders' equity	$ 17,284	$ (532)	$ 16,752
As of September 30, 2009			
Warrant liabilities	$ —	$ 523	$ 523
Total current liabilities	$ 2,087	$ 523	$ 2,610
Common stock	$ 217,454	$ (7,821)	$ 209,633
Deficit accumulated during the development stage	$ (199,624)	$ 7,298	$ (192,326)
Total shareholders' equity	$ 17,830	$ (523)	$ 17,307

	Consolidated Condensed Statements of Operations		
	As Previously Reported	Adjustments	As Restated
For the quarter ended September 30, 2008:			
Decrease in fair value of warrants	$ —	$ 243	$ 243
Total other income	$ 106	$ 243	$ 349
Net loss	$ (3,913)	$ 243	$ (3,670)
Net loss per share (basic and diluted)	$ (0.03)	$ —	$ (0.03)
For the quarter ended September 30, 2009:			
Decrease in fair value of warrants	$ —	$ 9	$ 9
Total other income	$ 15	$ 9	$ 24
Net loss	$ (3,801)	$ 9	$ (3,792)
Net loss per share (basic and diluted)	$ (0.02)	$ —	$ (0.02)
March 24, 1989 (Inception) to September 30, 2009:			
Decrease in fair value of warrants	$ —	$ 7,298	$ 7,298
Total other income	$ 11,404	$ 7,298	$ 18,702
Net loss	$ (198,656)	$ 7,298	$ (191,358)

	Consolidated Condensed Statements of Cash Flows		
	As Previously Reported	Adjustments	As Restated
For the quarter ended September 30, 2008:			
Net loss	$ (3,913)	$ 243	$ (3,670)
Decrease in fair value of warrants	$ —	$ (243)	$ (243)
For the quarter ended September 30, 2009:			
Net loss	$ (3,801)	$ 9	$ (3,792)
Decrease in fair value of warrants	$ —	$ (9)	$ (9)
March 24, 1989 (Inception) to September 30, 2009:			
Net loss	$ (198,656)	$ 7,298	$ (191,358)
Decrease in fair value of warrants	$ —	$ (7,298)	$ (7,298)

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, 2009, the Company had $17.4 million invested in two money market funds, which is 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, 2009 that are measured at fair value.

5. Shareholders’ Equity

On June 12, 2009, the Company entered into a $30.0 million common stock purchase agreement with Fusion Capital Fund II, LLC, (“Fusion Capital”) an Illinois limited liability company. The terms of the arrangement with Fusion Capital are disclosed in the Company’s Annual Report on Form 10-K for the year ended June 30, 2009 and there have been no changes to the terms of this arrangement during the quarter ended September 30, 2009.

During the quarter ended September 30, 2009, 11,551,486 shares of the Company’s common stock (including 346,923 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $4,300,000.

During October 2009, 2,196,953 shares of the Company’s common stock (including 64,544 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $800,000.

6. Stock Purchase Warrants

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

(i) warrants to purchase an aggregate of 300,000 shares of the Company’s common stock, issued on April 5, 2004 in connection with the Company’s registered direct offering, exercisable for a five year period commencing on April 5, 2004 at an exercise price of $13.20 per share, all of which expired unexercised;

(ii) warrants to purchase an aggregate of 320,248 shares of the Company’s common stock, issued on October 27, 2004 in connection with the Company’s registered direct offering, exercisable from April 28, 2005 through October 27, 2008 at an exercise price of $13.92 per share, 229,855 of which expired unexercised; and

(iii) 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.

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:

October 2007 Warrants	June 30, 2009	September 30, 2009
Closing stock price	$ 3.36	$ 3.44
Expected dividend rate	0%	0%
Expected stock price volatility	70.8%	71.8%
Risk free interest rate	1.6%	1.5%
Expected life (years)	3.75	3.50

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

Warrant Liabilities	
Balance at June 30, 2009	$ 532
Decrease in fair value	(9)
Balance at September 30, 2009	$ 523

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, consisting of options, warrants for the purchase of common stock and unvested restricted shares of common stock are not included in the per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares that have been excluded from the computations of net loss per common share for the quarters ended September 30, 2008 and 2009 is approximately 19,145,017 and 20,793,971, respectively.

8. Recent Accounting Pronouncements

In July 2009, the Financial Accounting Standards Board (FASB) issued the FASB Accounting Standards Codification (ASC) as the only authoritative source of generally accepted accounting principles. The ASC is effective for interim and annual reporting periods ending after September 15, 2009. The Company implemented use of the ASC without a significant impact on its consolidated financial statements.

In September 2006, the FASB issued ASC 820 (SFAS No. 157, *Fair Value Measurements*. SFAS No. 157). This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. It emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value measurements should be determined based on the assumptions that market participants would use in pricing an asset or liability. The Company adopted the disclosure and recognition provisions for non-financial assets and liabilities, for interim and annual periods effective July 1, 2009 and it had no effect on the consolidated financial statements.

9. Subsequent Events

On October 23, 2009, Aastrom Biosciences, Inc. entered into an Amendment to its Employment Agreement with George W. Dunbar, Jr. dated July 17, 2006 (the "Amendment"), a Consulting Agreement with Timothy M. Mayleben and an Employment Agreement with Mr. Mayleben. These agreements were entered into in connection with the management transition whereby, immediately after the upcoming Annual Meeting of Shareholders scheduled for December 14, 2009, Mr. Dunbar will step down as Chief Executive Officer, President and Chief Financial Officer and Mr. Mayleben will assume such responsibilities.

Under the Amendment, Mr. Dunbar will terminate his employment with the Company and resign from all positions with the Company and its affiliates, other than his membership on the Board of Directors. Other than 500,000 stock options granted to Mr. Dunbar in October 2008, Mr. Dunbar will forfeit all of his vested and unvested stock options upon the termination of his employment with the Company. Because Mr. Dunbar will remain a member of the Company's Board of Directors upon his termination of employment with the Company, he will continue to vest in his remaining 500,000 stock options under the original terms of the stock option agreement.

During this period, Mr. Mayleben will continue as an independent contractor to the Company and not as an employee.

Under the agreements entered into with Mr. Mayleben, he will be granted an initial stock option to purchase 3,000,000 shares of the Company's common stock (with an exercise price equal to the fair market value of the stock on the date of grant) immediately following the upcoming Annual Meeting of the Shareholders on December 14, 2009. All 3,000,000 options will be service-based options and will vest in 48 equal monthly installments commencing on the first day of the calendar month following the date of grant.

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, 2009.

Overview of Aastrom

We are a regenerative medicine company *(a medical area that focuses on developing therapies that regenerate damaged or diseased tissues or organs)* that incorporated in 1989 and focuses on the clinical development of autologous cell products *(cells collected from a patient and returned to that same patient)* for the treatment of chronic cardiovascular diseases. Our proprietary Tissue Repair Cell (TRC) technology expands the numbers of stem and early progenitor cells from a small amount of bone marrow collected from the patient. Bone marrow provides a rich source of diverse cell populations, is easily accessible and allows us to produce a personalized cell product for site-specific delivery to the patient's diseased tissues. We have treated more than 350 patients in various clinical trials over 10 years without any product safety issues, and are currently in the following stages of development (see "Clinical Development" for additional development information):

- Cardiac regeneration — Cardiac Repair Cells (CRCs):
  - Dilated cardiomyopathy (DCM — a severe condition associated with chronic heart failure):
    - FDA has granted Orphan Drug Designation to CRCs for use in treatment of DCM
    - U.S.: Phase II IMPACT-DCM surgical clinical trial
      - Surgical clinical trial began treating patients in November 2008
      - To date, 29 patients enrolled in trial
      - Five clinical sites are open for patient enrollment (Methodist DeBakey Heart &Vascular Center, Houston, TX, Baylor University Medical Center, Dallas, TX, The University of Utah School of Medicine, Salt Lake City, UT, Cleveland Clinic Heart & Vascular Institute, Cleveland, OH, and Emory University Hospital Midtown, Atlanta, GA)
      - All 40 patients expected to be enrolled by December 31, 2009 and will be followed for 1 year
      - Expected to report clinical trial interim data during 1st quarter of calendar year 2010
      - Report of preliminary interim data expected once all patients have completed 6 month follow-up visits
    - U.S.: Phase II cardiac catheter clinical trial
      - Designed to explore a catheter-based approach for the delivery of CRCs to treat DCM patients
      - Expected to initiate clinical site training during 4th quarter of calendar year 2009
- Vascular regeneration — Vascular Repair Cells (VRCs):

- Critical limb ischemia (CLI — the most severe form of peripheral arterial disease):
  - U.S.: Phase IIb RESTORE-CLI clinical trial
    - To date, 76 patients enrolled in trial
    - Unblind clinical data for planned interim analysis expected to occur during the 4th quarter of calendar year 2009
    - Expected to report interim clinical data during 1st quarter of calendar year 2010

Our platform TRC technology is based on a manufacturing system we developed to produce human cells for clinical use. This automated cell manufacturing system enables 1) the “single-pass perfusion” cell culture process which is our patented manufacturing technology for growing large numbers of human stem and early progenitor cells, and 2) the ability to produce these products in an automated process that meets Good Manufacturing Practice (GMP) guidelines.

Our cell products have three features that we believe are critical for future success in regenerative medicine. Our products are:

- **autologous** which helps to ensure the product is not immuno-rejected by the patient and has the potential to engraft, differentiate and integrate long-term into functional tissues and organs,
- **expanded** which allows for higher numbers of stem and progenitor cells than would be obtainable with a product harvested directly from a patient and then returned to the patient without a culturing step, and
- composed of a **mixed population of cells** which includes all constituents of the original bone marrow and ensures that if multiple cell types are needed to regenerate the target tissue or a specific cell type is required, the product can directly address the need.

The cellular components of TRC-based products include adult stem and early progenitor cell populations which are capable of forming tissues such as cardiac, vascular, bone and neural and can reconstitute the hematopoietic and immune systems.

All TRC-based products are produced using our cell manufacturing system in centralized manufacturing facilities. We have one manufacturing site in the U.S. located at our headquarters in Ann Arbor, MI, and two contract facilities in the EU located in Stuttgart, Germany (Fraunhofer Institute for Interfacial Engineering and Biotechnology) and Bad Oeynhausen, Germany (Institute of Laboratory and Transfusion Medicine at the Heart Center).

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf. Our initial business plan was to pursue our targeted markets by commercializing our cell manufacturing system and supplies; however, since 2004, we have phased out our marketing efforts promoting the cell manufacturing system as a commercial product. Currently, we have minimal product sales consisting of manufacturing supplies to academic collaborators in the U.S. and cell-based products to EU-based physicians.

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

In May 2008, we reprioritized our clinical development programs to focus primarily on cardiovascular applications, including dilated cardiomyopathy and critical limb ischemia. We have discontinued further patient enrollment into our Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate initiating new clinical bone activity, reactivating the Phase III ON-CORE trial without additional financial resources.

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 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, 2009, we have accumulated a net loss of approximately $199 million. 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.

On September 3, 2009, we announced that our President, Chief Executive Officer and Chief Financial Officer, George W. Dunbar, Jr., will be stepping down from those positions immediately after our annual meeting in December 2009. At that time, Mr. Dunbar will be succeeded in those positions by Timothy Mayleben, currently a director of the Company.

Clinical Development

Currently, our clinical development programs are focused primarily on the utilization of our TRC technology for cardiac and vascular regeneration. An improved formulation for storage of our TRC-based cell product has been developed to extend the shelf-life of our product. The extended shelf-life provides additional flexibility in transport of the product and in scheduling of patient administration. The extended shelf-life product has been qualified and implemented at our centralized manufacturing sites in the U.S. and EU. It is used for all cardiac and vascular regeneration clinical trials in the U.S. and is available for supply to all active EU treatment sites.

The preclinical data for our TRC-based products have shown that the large numbers of the stem and early progenitor cells obtained through application of our TRC technology can develop into a variety of tissues including blood, bone, vascular and fat, as well as the potential to form tissues characteristic of certain internal organs. We have demonstrated in the laboratory that TRC-based products can differentiate into both endothelial (blood vessel) and osteoblast (bone cell) lineages. Based on these preclinical observations, clinical trials have been initiated in the U.S. and European Union (EU) for cardiac tissue regeneration in patients with dilated cardiomyopathy, for vascular tissue regeneration in patients with critical limb ischemia and for bone regeneration in patients with osteonecrosis of the femoral head and severe long bone fractures.

The preliminary results of our current clinical trials may not be indicative of results that will be obtained from subsequent patients in those trials or from future clinical trials. Further, our future clinical trials may not be successful, and we may not be able to obtain the required Biologic License Application (BLA) registration in the U.S. or required foreign regulatory approvals for our TRC-based products in a timely fashion, or at all. See “Risk Factors.”

Clinical Trials Summary

Cardiac Regeneration

Dilated Cardiomyopathy — Surgical

To date, 29 patients have been enrolled in our U.S. Phase II surgical clinical trial (called IMPACT-DCM) and the five clinical sites are open for patient enrollment (Methodist DeBakey Heart &Vascular Center, Houston, TX, Baylor University Medical Center, Dallas, TX, The University of Utah School of Medicine, Salt Lake City, UT, Cleveland Clinic Heart & Vascular Institute, Cleveland, OH, and Emory University Hospital Midtown, Atlanta, GA). In November 2008, the first patient was treated in the 40-patient IMPACT-DCM trial to evaluate the use of Cardiac Repair Cells (CRCs), a mixture of stem and progenitor cells derived from a patient’s own bone marrow, for the treatment of dilated cardiomyopathy (DCM), a severe condition associated with chronic heart failure. This randomized, controlled, prospective, open-label, Phase II study seeks to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM at up to 5 clinical sites in the U.S. CRCs, manufactured using Aastrom’s TRC technology, received an Orphan Drug Designation from the U.S. Food & Drug Administration (FDA) for the treatment of DCM in February 2007. The FDA approved our Investigational New Drug (IND) application for this clinical trial in May 2008.

We anticipate that all 40 patients will be enrolled into the IMPACT-DCM trial by December 31, 2009, and we expect to report interim data during the first quarter of calendar year 2010. In addition, we anticipate reporting preliminary 6-month interim data after all 40 patients have completed their 6-month follow-up visits.

Participants in the IMPACT-DCM clinical trial must have a left ventricular ejection fraction (LVEF), the perctage of blood pumped out of the heart with each contraction, of less than or equal to 30% (60-75% is typical for a healthy person) and meet certain other eligibility criteria. All patients in each group will receive standard medical care and approximately 75% of the patients in each group will be treated with CRCs through direct injection into the heart muscle during open heart surgery. While the primary objective of this study is to assess the safety of CRCs in patients with DCM, efficacy measures including LVEF and other cardiac function parameters as well as heart failure stage will be monitored. Patients will be followed for 12 months post treatment.

Dilated Cardiomyopathy — Catheter

We are expanding our ongoing clinical program to evaluate CRCs in the treatment of severe heart failure patients. We have submitted an IND application with the FDA to initiate a second clinical trial to treat DCM patients. The second cardiac regeneration trial is designed to explore a catheter-based approach for the delivery of CRCs to treat DCM patients, in addition to the ongoing surgical delivery approach in the IMPACT-DCM trial. It is anticipated that we will initiate clinical site training for a U.S. Phase II clinical trial for DCM patients with catheter delivery of CRCs during the 4th quarter of calendar year 2009.

Dilated Cardiomyopathy — Background

In April 2008, we reported data from two compassionate use patients treated in Germany with our autologous stem cell therapy for DCM. A cardiothoracic surgeon experienced with cell therapy at the University Hospital in Dusseldorf, Germany performed the first human application of our CRC product through direct injection into the heart muscle during open heart surgery for these two patients in late 2007. The data from these two critically ill patients upon discharge from the surgical center was encouraging. Per typical treatment practices in Germany, once these patients were released from the surgical center, they were followed by regional rehabilitation hospitals or local physicians. Patient #1 had an LVEF of approximately 10% prior to the CRC treatment in November 2007. Over the course of two months, this patient's LVEF improved to 25-30% and clinical improvement of his heart failure stage was noted. As reported to us by the surgeon, during his stay at a rehabilitation hospital, this critically ill patient refused all further medical treatment and discharged himself from the hospital against medical advice. This patient's subsequent death due to natural causes was unrelated to the cell therapy treatment. Patient #2 had an LVEF of 25-30% prior to being treated with CRCs in December 2007. Upon discharge from the surgical center in February 2008, her LVEF had improved to 45%. In September 2008, at a 7 month follow-up visit with the treating surgeon, this patient's LVEF was again measured at 45% and the patient reported further improvement in her heart failure symptoms. These EU compassionate use treatments provided supporting information considered critical to the success of the U.S. Phase II IMPACT-DCM IND application.

DCM is a chronic cardiac disease that leads to enlargement of the heart and is associated with reduced pump function to the point that blood circulation is impaired. Typically patients with DCM present with symptoms of congestive heart failure, including limitations in their physical activity and shortness of breath. DCM generally occurs in patients who have ischemic heart failure due to multiple heart attacks, though it can also be found in patients with non-ischemic heart failure caused by hypertension, viral infection or alcoholism. Patient prognosis depends on the stage of the disease but is typically characterized by a high mortality rate. Other than heart transplantation, there are currently no curative treatment options for end-stage patients with this disease. The New England Journal of Medicine estimates that in the U.S. alone 120,000 people currently suffer from this disease; other sources report estimates of up to 150,000.

Vascular Tissue Regeneration

Critical Limb Ischemia

Laboratory observations have shown that TRC-based products have the ability to form small blood vessel-like structures *in vitro*. Based on these encouraging data, we are conducting clinical trials to evaluate the safety and efficacy of Vascular Repair Cells (VRCs), based on TRC technology, in the treatment of patients suffering from diabetes with open foot wounds and in patients diagnosed with critical limb ischemia (CLI), which represents the end stage of peripheral arterial disease. These patients suffer from chronic rest pain, ulcers or gangrene in their limbs.

In October 2008, the first 30 patients (treatment and placebo control) completed enrollment in our RESTORE-CLI trial, a U.S. Phase IIb prospective, controlled, randomized, double-blind, multi-center clinical trial to treat patients suffering from CLI.. This study is designed to enroll up to 150 patients at up to 30 sites. Patients are randomized into two patient groups (treatment or placebo control), to evaluate the safety and efficacy of VRCs in the treatment of CLI. To date, 76 patients have been enrolled in the RESTORE-CLI trial and 18 clinical sites are open for patient enrollment. Please see our website for the most updated list of sites that are open for patient enrollment. Patients will be followed for a period of 12 months post-treatment. In addition to assessing the safety of the VRCs, secondary objectives include the measurement of major amputation rates, the level of amputation, wound healing and blood flow in the affected limbs, patient quality of life, pain scores and analgesic use. During the fourth quarter of calendar year 2009, we expect to unblind and analyze interim clinical data from a subset of patients enrolled in the study that includes the first 30 patients who have completed their entire 12 month follow-up. Interim clinical data is expected to be reported during the first quarter of calendar year 2010.

In October 2007, positive interim results from the first 13 patients treated in Germany in a 30-patient multi-arm Phase I/II single-center clinical trial to evaluate the safety of VRCs and unexpanded bone marrow cells in the treatment of chronic diabetic foot wounds associated with CLI were reported by an investigator from the Heart & Diabetes Center located in Bad Oeynhausen, Germany, at the 2nd Congress of the German Society for Stem Cell Research in Würzburg, Germany. Results reflect treatment experience from: four diabetic patients with ischemia-related chronic tissue ulcers who were treated with our VRCs; seven patients who were treated with normal unexpanded marrow cells; and two standard of care patients who did not receive cells. All patients received standard wound care as described by the American Diabetes Association. Twelve months post-treatment, all patients in the interim analysis who were treated with VRCs reported no major amputations, no cell-related adverse events, and healing of all open wounds. Of the 7 patients treated with unexpanded bone marrow cells, 5 reported results similar to the VRC-treated patients 12 months post-treatment, 1 reported similar results to the VRC-treated patients 18 months post-treatment, and 1 patient underwent a major amputation. For the 2 standard of care patients who only received wound care (no cells), one patient received a major amputation and one patient experienced no improvement in wound healing after 12 months. Patient follow-up has been completed and final data is expected to be reported by the investigator before the end of calendar year 2009.

In Spain, two compassionate use cases have been treated for critical limb ischemia to date and patient follow-up is ongoing. These cases were conducted under approval from the AEMPS (Spanish Drug Agency).

Bone Regeneration

Maxillofacial

In the U.S., an investigator-sponsored controlled study in the treatment of alveolar bone defects is enrolling patients. The primary objective of this investigator-sponsored study is to determine whether the placement of Bone Repair Cells (BRCs) at the time of tooth extraction can safely and effectively promote bone regeneration in alveolar bone defects created by tooth extraction.

A second U.S. investigator-sponsored controlled study is anticipated to begin patient enrollment for the treatment of sinus floor bone augmentation. The primary objective of this study is to determine whether the placement of BRCs during bone regenerative sinus augmentation can safely and effectively promote bone regeneration in the resorbed posterior maxilla.

In Spain, 3 patients with craniofacial defects have been treated under compassionate use. The investigator reported early bone formation resulted in healing, including peripheral nerve regeneration or repair, new skin formation, and proliferation of blood vessels in the ischemic areas.

Osteonecrosis of the Femoral Head

In May 2008, we reprioritized our clinical development programs to primarily focus on cardiovascular applications. We have discontinued further patient enrollment into our U.S. Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate new clinical bone activity or reactivating the Phase III ON-CORE trial without additional financial resources.

In May 2007, the FDA approved our Investigational New Drug (IND) application which allowed us to proceed with our ON-CORE trial, a U.S. Phase III clinical trial, to use our BRCs based on our TRC technology in the treatment of osteonecrosis (also known as avascular necrosis) of the femoral head. Osteonecrosis of the femoral head involves the death of cells in the bone and marrow within the femur head and in many cases leads to total hip replacement. While the 7 treated patients will continue to be monitored for the full 24-month follow-up period, no additional patients are being enrolled at this time. Our website will be updated if we resume patient enrollment in this trial. In March 2006, we received an Orphan Drug Designation from the FDA to use our BRCs in the treatment of osteonecrosis of the femoral head.

In October 2007, early clinical results from 4 compassionate use patients were presented by an investigator from the Orthopedic Institute, König-Ludwig-Haus, University of Würzburg, Germany, involving the first use of our Bone Repair Cells (BRCs) to treat patients suffering from osteonecrosis of the femoral head. After 6 months of follow-up all patients tolerated the procedure well. Three patients reported a reduction in hip pain, there were no signs of disease progression for any of the four patients (as determined by MRI and X-ray) and all were back to work within 6 months after treatment. In addition, no cell-related adverse events were reported and none of these patients have required hip replacement surgery. Follow-up for these compassionate use patients is ongoing.

In January 2007, we opened patient enrollment and treatment in a clinical trial in Spain utilizing BRCs for the treatment of osteonecrosis of the femoral head. The trial protocol was approved by the Spanish Drug Agency (AEMPS) and Centro Medico Teknon's (Teknon) Ethics Committee for our Investigational Medicinal Product Dossier (IMPD), and is being conducted at Teknon located in Barcelona, Spain. Patient recruitment is complete with 9 hips (7 patients) treated. All patients will be followed for 24 months post-treatment.

Other Bone

In December 2008, the final Aastrom clinical study report from our U.S. Phase I/II clinical trial for the treatment of severe long bone non-union fractures was completed. This trial demonstrated that the TRC product had an excellent safety profile. The overall number of adverse events reported was low in comparison to historical data, and no adverse events were considered related to the TRC product. The efficacy data indicated a high non-union fracture healing rate, with bridging callus formation rates in over 90% of patients 12 months post-surgery compared to 50% historically.

An initial 5 patient bone regeneration (post-fracture) study was conducted at 3 centers in Spain under Ethical Committee approval; positive results were disclosed in May 2005. Following this trial, a physician-sponsored 10 patient Phase II non-union fracture trial was initiated. The Phase II study has completed BRC treatment of all 10 patients. The final physician report indicates that 7 of 10 cases resulted in healing at 24 months with no adverse events related to bone marrow aspiration or TRC administration.

The Phase I/II spine fusion clinical trial at William Beaumont Hospital, Royal Oak, MI has been closed and no further patients will be enrolled. While the 2 patients who were treated in this trial did not experience any cell-related adverse events and there were no safety issues, there was no conclusive evidence of efficacy with the current formulation for ectopic bone formation in this indication. A final clinical study report on this trial will be finalized in fourth quarter 2009.

Additional Activity

In certain non-U.S. regions, autologous cells, such as our TRC-based products, do not require a marketing authorization for commercial distribution. This enables us to gain product use experience and refine our clinical development strategies through compassionate use and standard patient treatment in countries where it is allowed and where both the patient and the physician see a potential benefit from using TRC-based products.

Through limited commercial use of TRC-based products, we are also able to obtain a privileged regulatory position in some regions. In the EU, the Advanced Therapies and Medicinal Products (ATMP) regulation went into effect January 1, 2009 requiring cell products such as ours to obtain a marketing authorization from the European Medicines Agency (EMEA) before they can be marketed in EU member states. However, the ATMP includes a grandfathering provision that allows products on the market in one or more EU member states on December 31, 2008 to remain on the market in those EU member states for a period of four years before EMEA market authorization must be obtained. With the activities completed to date in Germany, we believe TRC-based products meet the requirements for the ATMP transition period in this member state.

In any event, we do not anticipate generating significant sales in any geographic region until we have sufficient evidence of clinical safety and efficacy to ensure marketplace acceptance and product reimbursement and to justify the investment in manufacturing, sales and marketing infrastructure. However, we are currently generating limited, nominal sales of TRC-based products. As a result of these limited, commercial treatment activities, it is possible that we, or third parties, may make case studies and other data generated outside of a clinical trial program available on websites, in publications or in presentations. Such data should be considered anecdotal; it is not intended to represent evidence of clinical efficacy or to suggest that any future clinical trials will demonstrate that TRC-based products are effective in any specific medical application.

Results of Operations

Total revenues, consisting of product sales, for the quarter ended September 30, 2009 were $73,000 compared to total revenues of $27,000 for the same period in fiscal year 2009. The fluctuations in product sales is due to the changes in volume of cell production sales for investigator-sponsored clinical trials in Spain and limited cell manufacturing supplies to a research institute in the U.S. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC cell-based products will constitute nearly all of our product sales revenues.

Cost of product sales and rentals were $32,000 for the quarter ended September 30, 2009 compared to $4,000 for the same period in fiscal year 2009. The fluctuations in the cost of product sales and rentals are due to the changes in the volume of product sales.

Total costs and expenses decreased to $3,889,000 for the quarter ended September 30, 2009, compared to $4,046,000 for the quarter ended September 30, 2008.

Costs and expenses include an increase in research and development expenses to $2,911,000 for the quarter ended September 30, 2009 from $2,726,000 for the quarter ended September 30, 2008. This increase reflects continued expansion of our clinical development activities including the costs associated with recruitment and treatment of patients in our IMPACT-DCM clinical trial. Research and development expenses also included a non-cash charge relating to share-based compensation expense of $186,000 for the quarter ended September 30, 2009 compared to $162,000 for the quarter ended September 30, 2008.

Selling, general and administrative expenses decreased for the quarter ended September 30, 2009 to $946,000 from $1,316,000 for the quarter ended September 30, 2008. This decrease is primarily due to an offset to the stock compensation expense for the quarter ended September 30, 2009 for a reversal of $279,000 of previously recognized expense for certain options held by George W. Dunbar that will be forfeited when he steps down as Chief Executive Officer, President and Chief Financial Officer on December 14, 2009. This expense was reversed in the quarter ended September 30, 2009 as these options are no longer expected to vest due to the management transition that was announced on September 3, 2009. Selling, general and administrative expenses for the quarters ended September 30, 2009 and 2008 also include a non-cash charge of $140,000 and $201,000, respectively, relating to share-based compensation expense.

Income from the change in fair value of warrants was $9,000 for the quarter ended September 30, 2009 compared to $243,000 for the quarter ended September 30, 2008. The fluctuation is due primarily to changes in the fair value of our common stock and the related impact on our warrant liabilities.

Interest income was $28,000 for the quarter ended September 30, 2009 compared to $127,000 for the quarter ended September 30, 2008. The fluctuations in interest income are due primarily to corresponding changes in the level of cash, cash equivalents and short-term investments during the periods.

Interest expense was $13,000 for the quarter ended September 30, 2009 compared to $21,000 for the quarter ended September 30, 2008. The interest expense is related to the secured loan with Key Equipment Finance Inc.

Our net loss was $3,792,000, or $0.02 per common share for the quarter ended September 30, 2009 compared to $3,670,000, or $0.03 per common share for the quarter ended September 30, 2008. The changes in net loss are primarily due to the fluctuations in spending of research and development expenses and the increase in the weighted average shares outstanding. We expect to report additional significant net losses until such time as substantial TRC-based product sales commence.

Our major ongoing research and development programs are focused on the clinical development of TRC-based products, bone marrow-derived adult stem and early progenitor cells, for use in cardiac regeneration, as well as vascular regeneration. We have reprioritized our clinical development programs to focus on cardiovascular applications including our Phase II IMPACT-DCM (dilated cardiomyopathy) trial and our Phase IIb RESTORE-CLI (critical limb ischemia) trial. We have discontinued further patient enrollment into our Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate initiating new clinical bone activity or reactivating the Phase III ON-CORE trial without additional financial resources. All of these potential product applications use TRC technology, our proprietary cells and platform manufacturing technologies. We are also completing other research and development activities using our TRC-based products that are intended to improve the functionality for certain clinical indications, to improve shelf life, and to decrease the cost of manufacturing our TRC-based products.

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to TRC-based products, estimating the completion dates or cost to complete our major research and development program 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 in the "Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products," "Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations," and "We must successfully complete our clinical trials to be able to market certain of our products" sections under the heading "Risk Factors" of this report. The potentially 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, 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 have financed our operations since inception primarily through public and private sales of our equity securities, which, from inception through September 30, 2009, have totaled approximately $210 million 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 and cash equivalents totaled $17,357,000 at September 30, 2009, an increase of $357,000 from June 30, 2009. During the quarter ended September 30, 2009, the primary source of cash and cash equivalents was from equity transactions, of which net proceeds of $4,300,000 were raised principally through sales of our equity securities pursuant to the June 2009 agreement with Fusion Capital. The primary uses of cash and cash equivalents during the quarter ended September 30, 2009 included $3,840,000 to finance our operations and working capital requirements, and $54,000 in capital equipment additions.

We expect our monthly cash utilization to average approximately $1.4 million per month through September 30, 2010.

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 a positive cash flow 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. We expect that our available cash and expected interest income will be sufficient to finance current planned activities at least through September 30, 2010, in part due to the fact that many of our expenditures are discretionary in nature and could, if necessary, be delayed. 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 this report. In order to grow and expand our business, to introduce our product candidates into the marketplace and to possibly acquire or develop complementary business activities, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product

candidates for the expansion of additional cell types. We expect that our primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of our equity or debt securities. There can be no assurance that such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. Several factors will affect our ability to raise additional funding, including, but not limited to, market volatility of our common stock, continued stock market listing and economic conditions affecting the public markets generally or some portion or the entire technology sector. If our common stock is delisted from the NASDAQ Stock Market, the liquidity of our common stock could be impaired, and prices paid by investors to purchase our shares of our common stock could be lower than might otherwise prevail.

On June 12, 2009, we entered into a $30.0 million common stock purchase agreement with Fusion Capital. Concurrently with entering into the common stock purchase agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we filed a registration statement related to the transaction with the U.S. SEC covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. The SEC declared the registration statement effective on June 29, 2009.

As of the commencement date, July 1, 2009, we have the right over a 25-month period to sell shares of our common stock to Fusion Capital from time to time in amounts between $100,000 and $4 million, depending on certain conditions as set forth in the agreement, up to an aggregate of $30.0 million. The number of shares that could be issued to Fusion Capital during each sale is determined based on a stock price (“Purchase Price”) that is the lower of the (a) the lowest sale price of common stock on the purchase date or (b) the arithmetic average of the three lowest closing sale prices of common stock during the twelve consecutive business days (ten days in certain circumstances) ending on the business day immediately preceding the purchase date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction). We control the timing and amount of any sales of shares to Fusion Capital.

Pursuant to the common stock purchase agreement with Fusion Capital, there are certain events of default which, if such an event were to occur, would eliminate the obligation of Fusion Capital to purchase shares from us. Such events include, but are not limited to, (i) shares of our common stock not being listed on any one of several stock exchanges outlined in the agreement and (ii) a “material adverse change” in our business or operations. In addition, Fusion Capital shall not have the right or the obligation to purchase any shares of our common stock on any business day that the price of the common stock is below $0.36. The common stock purchase agreement may be terminated by us at any time at our discretion without any cost to us. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement. The proceeds received by us under the common stock purchase agreement will be used to conduct operations and to continue to conduct our clinical development programs.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement, we issued 1,452,238 shares of our common stock to Fusion Capital as an initial commitment fee. We will also issue from time to time up to an additional 2,420,396 shares to Fusion Capital as a commitment fee pro rata as we receive the $30.0 million of future funding.

Through November 5, 2009, 13,748,439 shares of our common stock (including 411,467 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $5,100,000.

Assuming the stock price remains at the same average price as November 2009 prices to date, additional proceeds related to the Fusion Capital transaction would not be able to be raised without shareholder approval. If the stock price increases to at least $0.36 per share, we would be able to raise an additional $8.1 million of cash proceeds per our agreement with Fusion Capital (through the issuance of the remaining 24,671,957 shares of our common stock, which includes 2,008,929 shares related to the commitment fee) assuming the average Purchase Price of future purchases was $0.36 per share.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material adverse affect on our business. See “Risk Factors” and “Notes to Consolidated Financial Statements” in our 2009 Annual Report on Form 10-K and “Notes to Consolidated Financial Statements” and “Risk Factors” included herein.

Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described below, that could adversely affect our business, financial condition, results of operations, cash flows, and trading price of our common stock. The risks and uncertainties described below are not the only ones we face. There may be additional risks and uncertainties that are not known to us or that we do not consider to be material at this time. If the events described in these risks occur, our business, financial condition, and results of operations would likely suffer.

Our past losses and expected future losses cast doubt on our ability to operate profitably.

We were incorporated in 1989 and have experienced substantial operating losses since inception. As of September 30, 2009, we have incurred a cumulative net loss totaling approximately $191 million, and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development (including clinical trials) of our cell culture technologies and our cell manufacturing system, general and administrative expenses, and the prosecution of patent applications. We expect to continue to incur significant operating losses over the next several years and at least until, and probably after, product sales increase, primarily owing to our research and development programs, including preclinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. We cannot predict with any certainty the amount of future losses. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, timely initiation and completion of clinical trials, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components, acquisition and development of complementary activities and raising sufficient cash to fund our operating activities. Therefore, we may not be able to achieve or sustain profitability.

The global economy and capital markets are challenging for the small cap biotech sector. This situation makes the timing and potential for future equity financings uncertain.

Our stock may be delisted from NASDAQ, which could affect its market price and liquidity.

We are required to meet certain qualitative and financial tests (including a minimum bid price for our common stock of $1.00 per share) to maintain the listing of our common stock on the NASDAQ Capital Market. On October 2, 2009, we received a Staff Determination letter from the NASDAQ Stock Market (NASDAQ) indicating that we had not regained compliance with the $1.00 minimum closing bid price requirement for continued listing set forth in NASDAQ Listing Rule 5550(a)(2). As a result, our common stock would be subject to delisting from the NASDAQ Capital Market on October 13, 2009 unless we requested a hearing before a NASDAQ Hearings Panel (the “Panel”). We requested an oral hearing before the Panel within the timeframe provided by NASDAQ, which will stay the delisting of our securities. The oral hearing with the NASDAQ Panel is scheduled for November 12, 2009. At the hearing, we intend to request continued listing on the NASDAQ Capital Market based upon our plan for regaining compliance with the minimum bid price requirement. The Panel has the authority, if it deems appropriate, to grant us up to an additional 180 days from the date of the Staff Determination letter of October 2, 2009, or until March 31, 2010, to implement our plan of compliance. We have presented a plan that the Panel that includes a discussion of the events that we believe enables us to regain compliance in this time frame, along with a commitment to effect a reverse stock split, if necessary.

We can regain compliance with the minimum closing bid price rule if the bid price of our common stock closes at $1.00 per share or higher for a minimum of ten consecutive business days during the 180-day compliance period, although NASDAQ may, in its discretion, require us to maintain a minimum closing bid price of at least $1.00 per share for a period in excess of ten consecutive business days (but generally no more than 20 consecutive business days) before determining that we have demonstrated the ability to maintain long-term compliance.

In the event that our common stock is delisted from the NASDAQ Capital Market there are alternative listing options, as follows:

- We may be eligible for quotation on FINRA’s Over-the-Counter Bulletin Board (OTCBB) if a market maker makes an application to register and quote our common stock in accordance with SEC Rule 15c2-11, and such application, Form 211, is cleared. Only a market maker is able to file Form 211.
- If we do not qualify for quotation on the OTCBB, we could apply to other unregulated markets.

We cannot provide any assurance that our stock price will recover within the permitted grace period. If our common stock were delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital.

We may not be able to raise the required capital to conduct our operations and develop and commercialize our products.

In addition to our current financing with Fusion Capital, we will require substantial additional capital resources in order to conduct our operations and develop and commercialize our products and cell manufacturing facilities. In order to grow and expand our business, to introduce our new product candidates into the marketplace and to acquire or develop complementary business activities, we will need to raise a significant amount of additional funds. We will also need significant additional funds or a collaborative partner, or both, to finance the research and development activities of our cell product candidates for additional indications. Accordingly, we are continuing to pursue additional sources of financing.

Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research, clinical and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals;
- competing technological and market developments;
- our ability to establish additional collaborative relationships;
- the effect of commercialization activities and facility expansions, if and as required;
- complementary business acquisition or development opportunities; and
- an increase in our shares of authorized common stock.

Because of our long-term funding requirements, we intend to try to access the public or private equity markets if conditions are favorable to complete a financing, even if we do not have an immediate need for additional capital at that time, or whenever we require additional operating capital. This additional funding may not be available to us on reasonable terms, or at all. If adequate funds are not available in the future, we may be required to further delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities.

The transaction with Fusion Capital, described above under “Recent Financing”, may provide us with some of the required capital to conduct our operations; however, we expect that we will need additional capital. In addition, under certain conditions, Fusion will not be required to purchase our shares, including if the market price of our common stock is less than $0.10, if we are not listed on a national exchange or the OTC Bulletin Board or if there is a material adverse change to our business, properties, operations, financial condition or results of operations.

Additionally, in order to be in compliance with NASDAQ Capital Market rules, we cannot be required to sell, and Fusion Capital shall not have the right or the obligation to purchase shares of our common stock at a price below $0.36, which represents the greater of the book value per share of our common stock as of March 31, 2009 or the closing sale price per share of our common stock on June 11, 2009, the business day before we entered into the Purchase Agreement, plus $0.01. If we elect to sell our shares of common stock to Fusion Capital at a price per share below $0.36, we may be required to obtain shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

We only have the right to receive $100,000 every other business day under the Purchase Agreement unless our stock price equals or exceeds $0.25, in which case we can sell greater amounts to Fusion Capital as the price of our common stock increases. The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business days that the market price of our common stock is less than $0.10.

Even if we are able to access the full $30.0 million under the Purchase Agreement with Fusion Capital, we will need significant additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.

In connection with entering into the Purchase Agreement, we authorized the sale to Fusion Capital of up to 36,000,000 shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the Purchase Agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the Purchase Agreement will fluctuate based on the price of our common stock. All 39,872,634 shares registered with the SEC are expected to be freely tradable. The registered shares may be sold over a period of up to 25 months from the commencement date of July 1, 2009. Depending upon market liquidity at the time, a sale of shares to Fusion Capital at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, or some of the 36,000,000 shares of common stock registered in the offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to Fusion Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

If we cannot attract and retain key personnel, then our business will suffer.

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other companies, research and academic institutions and other entities. Further, in an effort to conserve financial resources, we have implemented reductions in our work force on three previous occasions. As a result of these and other factors, we may not be successful in hiring or retaining key personnel. Our inability to replace any key employee could harm our operations.

On September 3, 2009, we announced that our President, Chief Executive Officer and Chief Financial Officer, George W. Dunbar, Jr., will be stepping down from those positions immediately after our annual meeting in December 2009. At that time, Mr. Dunbar will be succeeded in those positions by Timothy Mayleben, currently a director of the Company. If we are unable to integrate our new leadership, our operations may be harmed.

Failure to obtain and maintain required regulatory approvals would severely limit our ability to sell our products.

We must obtain the approval of the FDA before commercial sales of our cell product candidates may commence in the U.S., which we believe will ultimately be the largest market for our products. We will also be required to obtain additional approvals from various foreign regulatory authorities to initiate sales activities of cell products in those jurisdictions, including the EU under regulation of the EMEA. If we cannot demonstrate the safety and efficacy of our cell product candidates produced in our manufacturing system, we may not be able to obtain required regulatory approvals or the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

Finally, even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility, may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products.

The FDA establishes regulatory requirements based on the classification of a product. Because our product development programs are designed to satisfy the standards applicable to biological licensure for our cellular products, any change in the regulatory classification or designation would affect our ability to obtain FDA approval of our products. Each of these cell products (such as our TRC-based products) is, under current regulations, regulated as a biologic, which requires a Biologic License Application (BLA).

EU Directives and regulations (laws) have become effective, and have influenced the requirements for manufacturing cell products and the conduct of clinical trials. For products that are regulated as an ATMP, the EU Directive requires: (i) preclinical laboratory and animal testing; (ii) submission of an IMPD to the Competent Authorities of the Member State where the clinical trial will be conducted, which must be approved prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to EMEA for a Marketing Authorization (MA); and, (v) review and approval of the MA. Under the newly approved ATMP regulation for cellular products only the EMEA will be allowed to approve cell-based medicinal products (a "centralized" review of the submission) after December 31, 2008.

The regulatory requirements to market somatic cellular and ATMP products have changed significantly with the approval of the EU ATMP regulation. Beginning January 1, 2008, a one year transition time was put into effect. After December 31, 2008, any product that is considered "tissue engineered" under the definitions provided in the ATMP regulation was granted a four year "grandfather" marketing allowance if that product has been on the market on or before the end of the transition period.

Germany had not required marketing authorization to distribute cultured expanded autologous tissue products for tissue regeneration when the newly revised law became effective. We had introduced a product into the German market by that time and we fall under the "grandfathered" regulations for some period of time before we will need to apply for a centralized marketing authorization.

Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations.

In order to commercialize our cell product candidates in the U.S. and the EU, we must complete substantial clinical trials and obtain sufficient safety and efficacy results to support required registration approval and market acceptance of our cell product candidates. We may not be able to successfully complete the development of our product candidates, or successfully market our technologies or product candidates. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technologies and product candidates. Our research and development programs may not be successful, and our cell culture technologies and product candidates may not facilitate the production of cells outside the human body with the expected result. Our technologies and cell product candidates may not prove to be safe and efficacious in clinical trials, and we may not obtain the requisite regulatory approvals for our technologies or product candidates and the cells produced in such products. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of that issue.

We must successfully complete our clinical trials to be able to market certain of our products.

To be able to market therapeutic cell products in the U.S. and across the EU, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates. If our clinical trials are not successful, our products may not be marketable.

Our ability to complete our clinical trials in a timely manner depends on many factors, including the rate of patient enrollment. Patient enrollment can vary with the size of the patient population, the proximity of suitable patients to clinical sites, perceptions of the utility of cell therapy for the treatment of certain diseases, and the eligibility criteria for the study. We have experienced delays in patient accrual in our previous and current clinical trials. If we experience future delays in patient accrual, we could experience increased costs and delays associated with clinical trials, which would impair our product development programs and our ability to market our products. Furthermore, the FDA monitors the progress of clinical trials and it may suspend or terminate clinical trials at any time due to patient safety, demonstrated lack of efficacy or other considerations.

Our research programs are currently directed at improving TRC-based product functionality for certain clinical indications, improving product shelf life, and decreasing the cost of manufacturing our TRC-based products. These production process changes may alter the functionality of our cells and require various additional levels of experimental and clinical testing and evaluation. Any such testing could lengthen the time before these products would be commercially available.

Even if successful clinical results are reported for a product from a completed clinical trial, this does not mean that the results will be sustained over time, or will be sufficient for a marketable or regulatory approvable product.

Failure of third parties to manufacture or supply certain components, equipment, disposable devices and other materials used our cell manufacturing process, would impair our TRC-based cell product development.

We rely solely on third parties such as BioLife and Invitrogen to manufacture and/or supply certain components, equipment, disposable devices and other materials used our cell manufacturing process to develop our TRC-based cell products.

It would be difficult to obtain alternate sources of supply for many of these items on a short-term basis. If any of our key manufacturers or suppliers fails to perform their respective obligations or if our supply of certain components, equipment, disposable devices and other materials is limited or interrupted, it would impair our ability to manufacture our TRC-based cell products which would delay our ability to conduct our clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

Failure of third parties to manufacture component parts or provide limited source supplies, or the imposition of additional regulation, would impair our new product development.

We rely solely on third parties such as Sparton (formerly Astro), Ethox, Moll, Lonza and Genpore to manufacture or supply certain of our devices/manufacturing equipment, as well as component parts and other materials used in the cell product manufacturing process. We would not be able to obtain alternate sources of supply for many of these items on a short-term basis. If any of our key manufacturers or suppliers fails to perform their respective obligations or if our supply of components or other materials is limited or interrupted, we would not be able to conduct clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

Finally, we may not be able to continue our present arrangements with our suppliers, supplement existing relationships, establish new relationships or be able to identify and obtain the ancillary materials that are necessary to develop our product candidates in the future. Our dependence upon third parties for the supply and manufacture of these items could adversely affect our ability to develop and deliver commercially feasible products on a timely and competitive basis.

Manufacturing our cell products in centralized facilities may increase the risk that we will not have adequate quantities of our cell products for clinical programs.

We rely on third party manufacturers, Fraunhofer Institute for Interfacial Engineering and Biotechnology in Stuttgart, Germany and the Institute of Laboratory and Transfusion Medicine at the Heart Center in Bad Oeynhausen, Germany, to supply our TRC-based cell products for certain EU clinical activities. Reliance on third party manufacturers entails risks including regulatory compliance and quality assurance and the possible breach of the manufacturing agreement by the third party. We are subject to similar regulatory and compliance risks at our site in Ann Arbor, Michigan. All sites are subject to ongoing, periodic, unannounced inspection by regulatory agencies to ensure strict compliance with GMP and GCP regulations and other governmental regulations and corresponding foreign standards. Our present and future manufacturers might not be able to comply with these regulatory requirements. We do not have redundant cell manufacturing sites in the U.S. In the event our cell manufacturing facilities are damaged or destroyed or are subject to regulatory restrictions, our clinical trial programs and other business prospects would be adversely affected.

Even if we obtain regulatory approvals to sell our products, lack of commercial acceptance could impair our business.

We will be seeking to obtain regulatory approvals to market our TRC-based cell products for tissue repair and regeneration treatments. Even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be accepted in the marketplace at a level that would allow us to operate profitably. Our products may be unable to achieve commercial acceptance for a number of reasons, such as the availability of alternatives that are less expensive, more effective, or easier to use; the perception of a low cost-benefit ratio for the product amongst physicians and hospitals; or an inadequate level of product support from ourselves or a commercial partner. Our technologies or product candidates may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technologies and product candidates, and our potential revenues.

The market for our products will be heavily dependent on third party reimbursement policies.

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payors will pay for our products and related treatments. Reimbursement by third party payors depends on a number of factors, including the payor's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the U.S. or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement from third party payors may reduce the demand for, or negatively affect the price of, our products. For example, in the past, published studies suggested that stem cell transplantation for breast cancer, which constituted a significant portion of the overall stem cell therapy market at the time, may have limited clinical benefit. The lack of reimbursement for these procedures by insurance payors has negatively affected the marketability of our products for this indication in the past.

Use of animal-derived materials could harm our product development and commercialization efforts.

Some of the manufacturing materials and/or components we use in, and are critical to, implementation of our TRC technology involve the use of animal-derived products, including fetal bovine serum. Suppliers or regulatory changes may limit or restrict the availability of such materials for clinical and commercial use. We currently purchase all of our fetal bovine sera from protected herds in Australia and New Zealand. These sources are considered to be the safest and raise the least amount of concern from the global regulatory agencies. If, for example, the so-called "mad cow disease" occurs in New Zealand or in Australia, it may lead to a restricted supply of the serum currently required for the TRC-based product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture TRC-based cell products. Regulatory authorities in the EU are reviewing the safety issues related to the use of animal-derived materials, which we currently use in our production process. The FDA has issued draft regulations for controls over bovine materials. These proposed regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may issue final regulations that could affect our operations. We do not know what actions, if any, the authorities may take as to animal derived materials specific to medicinal products distributed in the EU. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts. There are certain limitations in the supply of certain animal-derived materials, which may lead to delays in our ability to complete clinical trials or eventually to meet the anticipated market demand for our cell products.

Given our limited internal manufacturing, sales, marketing and distribution capabilities, we need to develop increased internal capability or collaborative relationships to manufacture, sell, market and distribute our products.

We have only limited internal manufacturing, sales, marketing and distribution capabilities. As market needs develop, we intend to establish and operate commercial-scale manufacturing facilities, which will need to comply with all applicable regulatory requirements. We will also need to develop new configurations of our cell manufacturing system for these facilities to enable processes and cost efficiencies associated with large-scale manufacturing. Establishing these facilities will require significant capital and expertise. We may need to make such expenditures when there are significant uncertainties as to the market opportunity. Any delay in establishing, or difficulties in operating, these facilities will limit our ability to meet the anticipated market demand for our cell products. We intend to get assistance to market some of our future cell products through collaborative relationships with companies with established sales, marketing and distribution capabilities. Our inability to develop and maintain those relationships would limit our ability to market, sell and distribute our products. Our inability to enter into successful, long-term relationships could require us to develop alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand. We may market one or more of our TRC-based products through our own sales force. Our inability to develop and retain a qualified sales force could limit our ability to market, sell and distribute our cell products.

The issuance of additional common stock for funding has the potential for substantial dilution.

As noted above, we will need significant additional equity funding, in addition to the transactions with Fusion Capital, to provide us with the capital to reach our objectives. We may enter into financing transactions at prices which are at a substantial discount to market. Such an equity issuance would cause a substantially larger number of shares to be outstanding and would dilute the ownership interest of existing stockholders.

Our stock price has been volatile and future sales of substantial numbers of our shares could have an adverse affect on the market price of our shares.

The market price of shares of our common stock has been volatile, ranging in closing price between $0.16 and $0.73 during the twelve month period ended September 30, 2009. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

- clinical trial results
- the amount of our cash resources and our ability to obtain additional funding
- announcements of research activities, business developments, technological innovations or new products by us or our competitors
- entering into or terminating strategic relationships
- changes in government regulation
- disputes concerning patents or proprietary rights
- changes in our revenues or expense levels
- public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing
- news or reports from other stem cell, cell therapy or regenerative medicine companies
- reports by securities analysts
- status of the investment markets
- concerns related to management transitions
- delisting from the NASDAQ Capital Market

Any of these events may cause the price of our shares to fall, which may adversely affect our business and financing opportunities. In addition, the stock market in general and the market prices for biotechnology companies in particular have experienced significant volatility recently that often has been unrelated to the operating performance or financial conditions of such companies. These broad market and industry fluctuations may adversely affect the trading price of our stock, regardless of our operating performance or prospects.

If we do not keep pace with our competitors and with technological and market changes, our products will become obsolete and our business may suffer.

The markets for our products are very competitive, subject to rapid technological changes, and vary for different candidates and processes that directly compete with our products. Our competitors may have developed, or could in the future develop, new technologies that compete with our products or even render our products obsolete. As an example, in the past, published studies have suggested that hematopoietic stem cell therapy use for bone marrow transplantation, following marrow ablation due to chemotherapy, may have limited clinical benefit in the treatment of breast cancer, which was a significant portion of the overall hematopoietic stem cell transplant market. This resulted in the practical elimination of this market for our cell-based product for this application.

Our cell manufacturing system is designed to improve and automate the processes for producing cells used in therapeutic procedures. Even if we are able to demonstrate improved or equivalent results, the cost or process of treatment and other factors may cause researchers and practitioners to not use our products and we could suffer a competitive disadvantage. Finally, to the extent that others develop new technologies that address the targeted application for our products, our business will suffer.

If our patents and proprietary rights do not provide substantial protection, then our business and competitive position will suffer.

Our success depends in large part on our ability to develop or license and protect proprietary products and technologies. However, patents may not be granted on any of our pending or future patent applications. Also, the scope of any of our issued patents may not be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. Certain patent equivalents to the U.S. patents have also been issued in other jurisdictions including Australia, Japan, the Republic of Korea, Canada and under the European Convention. Furthermore, we rely on exclusive, world- wide licenses relating to the production of human cells granted to us by the University of Michigan for certain of our patent rights. If we materially breach such agreements or otherwise fail to materially comply with such agreements, or if such agreements expire or are otherwise terminated by us, we may lose our rights under the patents held by the University of Michigan. At the latest, each of these licenses will terminate when the patent underlying the license expires. The first of these underlying patents will expire on March 21, 2012. We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

Intellectual property litigation could harm our business.

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. Although we have not been subject to any filed infringement claims, other patents could exist or could be filed which would prohibit or limit our ability to market our products or maintain our competitive position. In the event of an intellectual property dispute, we may be forced to litigate. Intellectual property litigation would divert management’s attention from developing our products and would force us to incur substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties, and force us to curtail or cease the development and sale of our products and processes.

The government maintains certain rights in technology that we develop using government grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established government guidelines.

Certain of our and our licensors’ research have been or are being funded in part by government grants. As a result of such funding, the U.S. Government has established guidelines and have certain rights in the technology developed with the grant. If we fail to meet these guidelines, we would lose our exclusive rights to these products, and we would lose potential revenue derived from the sale of these products.

Potential product liability claims could affect our earnings and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the manufacture and/or use of TRC-based products during clinical trials, or after commercialization, results in adverse events. As a result, we may incur significant product liability exposure, which could exceed existing insurance coverage. We may not be able to maintain adequate levels of insurance at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would increase our operating loss and affect our financial condition.

Our corporate documents and Michigan law contain provisions that may make it more difficult for us to be acquired.

Our Board of Directors 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 are required to evaluate our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 and any adverse results from such evaluation could have a negative market reaction.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we are required to furnish a report by our management on our internal control over financial reporting. That report must contain, among other matters, an assessment of the design and operating effectiveness of our internal controls over financial reporting as of the end of the fiscal year. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. That report must also contain a statement that our independent registered public accounting firm has issued an attestation report on the design and operating effectiveness of our system of internal accounting controls over financial reporting. If in the future we are unable to assert that our internal control over financial reporting is effective as of the end of the then current fiscal year (or, if our independent registered public accounting firm is unable to express an unqualified opinion on the design and operating effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports, which would have a negative effect on our stock price and our ability to raise capital.

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 and Section 21E of the Securities 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. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this report, and in particular those factors listed under the section “Risk Factors.”

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
- 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
- replacement of manufacturing sources
- commercialization plans
- revenue expectations and operating results

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of September 30, 2009, our cash and cash equivalents included money market securities, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio.

Our sales to customers in foreign countries are denominated in U.S. dollars or Euros. Our vendors, employees and clinical sites in countries outside the U.S. are typically paid in Euros. However, such expenditures have not been significant to date. Accordingly, we are not directly exposed to significant market risks from currency exchange rate fluctuations. We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectibility and establishment of appropriate allowances. We do not enter into hedging transactions and do not purchase derivative instruments.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2009. 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, 2009 was filed on November 6, 2009, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2009. 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, 2009 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.

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, 2009 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

We have provided updated risk factors in the section labeled “Risk Factors” in Part I, Item 2 to allow readers to understand the material risks and uncertainties affecting our businesses and to qualify forward-looking statements we make.

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

None.

ltem 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. Maylebend
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

Exhibit Number	Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

GLOSSARY

TERM	DEFINITION
Adult Stem Cell	A cell present in adults that can generate a limited range of cell types as well as renew itself.
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.
AEMPS — Agencia Española de Medicamentos y Productos Sanitarios	Spanish Drug Agency
Allogeneic	Originating from someone other than the patient receiving treatment. (Aastrom does NOT use allogeneic cells)
ATMP — Advanced Therapy Medicinal Product	New medical products in the European Union based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering).
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 (equivalent to NDA)
BRC — Bone Repair Cell	Aastrom’s proprietary Tissue Repair Cells for bone indications. (Also see TRC — Tissue Repair Cell)
CBER — Center for Biologics Evaluation and Research	Branch of the FDA that regulates biological products for disease prevention and treatment that are inherently more complex than chemically synthesized pharmaceuticals.
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.
CRC — Cardiac Repair Cell	Aastrom’s proprietary Tissue Repair Cells for cardiac indications. (Also see TRC — Tissue Repair Cell)
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.
EMEA — European Medicines Agency	European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products. The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products. EMEA is similar in function to the US FDA (see FDA below).

TERM	DEFINITION
EU — European Union	The economic and political union of 27 member states, located primarily in Europe, for which the EMEA holds the medical regulatory power.
Ex vivo	Outside the body
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.
GTP — Good Tissue Practice	GTP regulations help ensure that donors of human cellular and tissue-based products are free of communicable diseases and that the cells and tissues are not contaminated during manufacturing and maintain their integrity and function. Key elements of the proposed rule are: Establishment of a quality program, which would evaluate all aspects of the firm's operations, to ensure compliance with GTP; Maintenance of an adequate organizational structure and sufficient personnel; Establishment of standard operating procedures for all significant steps in manufacturing; Maintenance of facilities, equipment and the environment; Control and validation of manufacturing processes; Provisions for adequate and appropriate storage; Record keeping and management; Maintenance of a complaint file; Procedures for tracking the product from donor to recipient, and from recipient to donor.
Hematopoietic Stem Cells	Stem cells that give rise to all the blood cell types including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells).
IMPACT-DCM	Aastrom's U.S. Phase II dilated cardiomyopathy clinical trial.
IMPD — Investigational Medicinal Product Dossier	An IMPD is now required to accompany an application to perform clinical trials in any European Member State. It provides a summary of information on the quality of the product being evaluated in a clinical trial planned to occur in a European Member State, including reference products and placebos. It also provides data from non-clinical studies and available previous clinical experience with the use of the investigational medicinal product.
In vitro	In a laboratory dish or test tube; in an artificial environment
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.
IRB — Institutional Review Board	A committee designated to formally approve, monitor, and review biomedical research at an institution involving humans. Institutional Review Boards aim to protect the rights and welfare of the research subjects. For Aastrom-sponsored clinical trials, IRB approval must be obtained at each individual clinical site in order for patient recruitment and treatment to commence at that site.

TERM	DEFINITION
LVEF — Left Ventricular Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heart beat.
Non-union Fractures	Broken bones that have failed to unite and heal
ON — Osteonecrosis	A progressive bone disease characterized by death of bony tissue due to insufficient blood flow within the bone.
ON-CORE	Aastrom's U.S. Phase III osteonecrosis of the femoral head clinical trial
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 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.
Osteoblast	A bone forming cell
Phase I Clinical Trial	A Phase I trial represents an initial study in a small group of patients to test for safety and other relevant factors
Phase II Clinical Trial	A Phase II trial represents a study in a moderate number of patients to assess the safety and efficacy of a product
Phase IIb Clinical Trial	A Phase IIb trial is a moderately-sized Phase II study that is more specifically designed assess the efficacy of a product than a Phase IIa trial
Phase III Clinical Trial	Phase III studies are initiated to establish safety and efficacy in an expanded patient population at multiple clinical study 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 for a period of time during and after the conclusion of a clinical trial.
Randomized Clinical Trial	A clinical trial in which the participants are assigned randomly to different treatment groups.
Somatic Cell	Any of the cells responsible for forming the body of an organism such as internal organs, bones, skin, connective tissues and blood.
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.
Standard of care treatment	The treatment normally prescribed in medical practice for a particular illness, injury or procedure.
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.

TERM	DEFINITION
	In culture, these undifferentiated cells possess the ability to divide for indefinite periods in culture and may give rise to highly specialized cells.
TRC — Tissue Repair Cell	Aastrom's cell manufacturing process begins with the collection of a small aspirate of bone marrow from the patient's hip in an outpatient procedure. The sample of bone marrow is shipped to a manufacturing facility, and transferred into Aastrom's cell manufacturing system. In this fully automated, sterile process, the stem and progenitor cell populations present in the bone marrow are greatly expanded to yield cellular products based on Aastrom's Tissue Repair Cell (TRC) technology. The finished TRC-based product is shipped back to the physician who administers it to the original patient as an autologous cell therapy.
VRC — Vascular Repair Cell	Aastrom's proprietary Tissue Repair Cells for Vascular indications. (Also see TRC — Tissue Repair Cell)

EXHIBIT 31.1

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, 2009;

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; and

(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; and

(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.

/s/ Timothy M. Mayleben

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

Date: February 24, 2011

EXHIBIT 31.2

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, 2009;

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; and

(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; and

(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.

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

Date: February 24, 2011

EXHIBIT 32.1

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, 2009, 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.

/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)

Date: February 24, 2011

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.