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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2008,

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

Large accelerated filer - o	Accelerated filer - ☑	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	145,131,900
(Class)	Outstanding at February 5, 2009

AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
December 31, 2008

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED CONDENSED BALANCE SHEETS
(Unaudited)
(In thousands)

	June 30, 2008	December 31, 2008
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,492	$ 16,326
Short-term investments	5,970	—
Receivables, net	18	70
Other current assets	1,583	1,372
Total current assets	24,063	17,768
PROPERTY AND EQUIPMENT, NET	2,154	1,832
Total assets	$ 26,217	$ 19,600
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 907	$ 1,085
Accrued employee benefits	747	388
Current portion of long-term debt	446	463
Total current liabilities	2,100	1,936
LONG-TERM DEBT	783	548
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized — 250,000,000; shares issued and outstanding — 132,858,736 and 138,146,908, respectively	203,211	205,009
Deficit accumulated during the development stage	(179,877)	(187,893)
Total shareholders' equity	23,334	17,116
Total liabilities and shareholders' equity	$ 26,217	$ 19,600

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

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

	Three months ended December 31,		Six months ended December 31,		March 24, 1989 (Inception) to December 31, 2008
	2007	2008	2007	2008	
REVENUES:					
Product sales and rentals	$ 24	$ 28	$ 36	$ 55	$ 1,634
Research and development agreements	—	—	—	—	2,105
Grants	60	—	135	—	9,657
Total revenues	84	28	171	55	13,396
COSTS AND EXPENSES:					
Cost of product sales and rentals	1	18	1	22	672
Cost of product sales and rentals — provision for obsolete and excess inventory	—	—	—	—	2,239
Research and development	3,895	2,829	7,768	5,555	142,374
Selling, general and administrative	1,725	1,333	3,339	2,649	66,357
Total costs and expenses	5,621	4,180	11,108	8,226	211,642
LOSS FROM OPERATIONS	(5,537)	(4,152)	(10,937)	(8,171)	(198,246)
OTHER INCOME (EXPENSE):					
Other income	—	—	—	—	1,249
Interest income	386	69	751	196	10,464
Interest expense	(21)	(20)	(36)	(41)	(392)
Other income	365	49	715	155	11,321
NET LOSS	$ (5,172)	$ (4,103)	$ (10,222)	$ (8,016)	$ (186,925)
COMPUTATION OF NET LOSS PER SHARE APPLICABLE TO COMMON SHARES:					
NET LOSS	$ (5,172)	$ (4,103)	$ (10,222)	$ (8,016)	
NET LOSS PER SHARE (Basic and Diluted)	$ (.04)	$ (.03)	$ (.08)	$ (.06)	
Weighted average number of shares outstanding (Basic and Diluted)	130,467	134,575	125,537	133,686	

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

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

	Six months ended December 31,		March 24, 1989 (Inception) to December 31, 2008
	2007	2008	
OPERATING ACTIVITIES:			
Net loss	$ (10,222)	$ (8,016)	$ (186,925)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	370	350	5,646
Loss on property held for resale	—	—	110
Amortization of discounts and premiums on investments	(292)	(30)	(1,704)
Stock compensation expense	1,107	756	7,783
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	(29)	(52)	(319)
Inventories	8	—	(2,335)
Other current assets	(487)	84	(942)
Accounts payable and accrued expenses	(858)	178	1,028
Accrued employee benefits	(429)	(359)	388
Net cash (used for) operating activities	(10,832)	(7,089)	(171,527)
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73)
Purchase of short-term investments	(24,752)	—	(212,041)
Maturities of short-term investments	25,000	6,000	213,745
Property and equipment purchases	(163)	(28)	(5,754)
Proceeds from sale of property held for resale	—	—	400
Net cash provided by (used for) investing activities	85	5,972	(3,723)
FINANCING ACTIVITIES:			
Net proceeds from issuance of preferred stock	—	—	51,647
Net proceeds from issuance of common stock and warrants	13,592	1,042	137,853
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	118	127	(409)
Proceeds from long-term debt	—	—	751
Principal payments under long-term obligations	(143)	(218)	(1,748)
Net cash provided by financing activities	13,567	951	191,576
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,820	(166)	16,326
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	13,439	16,492	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 16,259	$ 16,326	$ 16,326

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. Organization

Aastrom Biosciences, Inc. was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. The Company operates its business in one reportable segment — research and product development involving the development of 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 for 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. Management believes, based on its current projections of the Company's cash utilization (which is expected to approximate between $1.4 — $1.5 million per month) and taking into consideration the $2.3 million of additional cash raised in January (as described in Note 5), available cash and cash equivalents on hand as of January 31, 2009 (which equaled approximately $17.5 million) are adequate to finance the Company's planned operations at least until December 31, 2009. However, the Company will need to raise 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 for its product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the 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, the U.S. economic conditions regarding the availability of investment capital 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 three and six months ended December 31, 2008, 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 financial statements and the notes thereto included in the Company's 2008 Annual Report on Form 10-K for the year ended June 30, 2008, as filed with the Securities and Exchange Commission.

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.

In June 2007, the Financial Accounting Standards Board ("FASB") ratified Emerging Issues Task Force (EITF) 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities" (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. The Company's adoption of EITF 07-3 on July 1, 2008, did not have a material impact on its consolidated financial position and results of operations.

3. Fair Value Measurements

Effective July 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" (SFAS 157) for assets and liabilities measured at fair value on a recurring basis. In addition to expanding the disclosures surrounding fair value measurements, SFAS 157 clarifies that fair value represents the amount that would be received to sell 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, SFAS 157 establishes 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 December 31, 2008, the Company had $16.3 million invested in one money market fund, which is included within the “Cash and cash equivalents” line on the balance sheet. Because there is an active market for shares of this money market fund, the Company considers its fair value measure of this investment to be based on Level 1 inputs. The adoption of SFAS 157 did not change the way in which the Company records this investment at fair value.

4. Share-Based Compensation

The Company has various stock incentive plans and agreements (Option Plans) that provide for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company’s Board of Directors to certain of the Company’s employees, directors and consultants. Options granted under these plans expire no later than ten years from the date of grant, and other than those granted to non-employee directors, generally become exercisable over a four-year period, under a graded-vesting methodology, following the date of grant.

Service-Based Options

During the six months ended December 31, 2008, the Company granted 3,827,500 service-based options to purchase common stock. These were granted with exercise prices equal to the fair value of the Company’s stock at the grant date, vest over four years (other than 3,545,000 of options granted in October 2008 that vest over 3 years) and have lives of 10 years. Non-employee director options vest over one year. The weighted average grant-date fair value of service-based options granted under the Company’s Option Plans during the six months ended December 31, 2007 and 2008 was $0.67and $0.39, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors were approximately $365,000 and $708,000 for the three and six months ended December 31, 2008, respectively, compared to $538,000 and $1,054,000 for the same periods in fiscal year 2008.

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

	Six Months Ended December 31,	
	2007	2008
Stock Option Plans:		
Expected dividend rate	0%	0%
Expected stock price volatility	61%	70%
Risk free interest rate	4.2%	3.3%
Estimated forfeiture rate	10%	10%
Expected life (years)	6.6	6.6

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

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at June 30, 2008	8,535,181	$ 1.31		
Granted	3,827,500	$ 0.39		
Exercised	—	—		$ —
Forfeited or expired	(907,484)	$ 1.39		
Outstanding at December 31, 2008	11,455,197	$ 1.00	8.2	$ 420,000
Exercisable at December 31, 2008	4,581,726	$ 1.37	7.1	$ 9,000

As of December 31, 2008, there was approximately $1,467,000 of total unrecognized compensation cost related to non-vested service-based stock options granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 1.5 years.

Performance-Based Stock Options

There were no grants of performance-based stock options for the six months ended December 31, 2008.

The vesting of performance options is dependent on both of the following conditions occurring: (i) the passage of a certain amount of time subsequent to the grant date and (ii) meeting certain performance conditions which relate to our progress in our clinical trial programs. The Board of Directors will determine if the performance conditions have been met. Stock-based compensation expense for these options will be recorded when the Company believes that the vesting of these options is probable based on the progress of its clinical trial programs and other relevant factors.

For the performance-based options outstanding at December 31, 2008, there are two tranches of performance-based options that vest upon the satisfaction of performance conditions, all of which vest based on progress toward clinical trial or product successes within a certain timeframe.

The first tranche would vest if performance conditions are met by June 2011; and, the second tranche would vest if performance conditions are met by June 2012. Each tranche of options is forfeited if its performance conditions are not met by the required timeframe, and vesting for any tranche of options is not dependent on the vesting of the other tranches of options.

For the six months ended December 31, 2008, management reviewed the progress toward the performance conditions necessary for these options to vest and concluded that it was not yet probable that the performance conditions of any of the tranches of options would be met and, accordingly, no compensation expense has been recorded.

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

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at June 30, 2008	1,287,868	$ 1.49		
Granted	—	—		
Exercised	—	—		
Forfeited or expired	(233,200)			
Outstanding at December 31, 2008	1,054,668	$ 1.48	7.8	$ 0

The aggregate estimated fair value of these awards that are outstanding as of December 31, 2008 is approximately $1,054,000.

Restricted Stock Awards

Restricted stock awards generally vest over a four year period and entitle the recipient to receive common stock upon vesting. The compensation costs charged as operating expenses for restricted stock were approximately $28,000 and $48,000 for the three and six months ended December 31, 2008, respectively, compared to $20,000 and $54,000 for the same periods in fiscal year 2008.

A summary of the Company's restricted stock activity for the six months ended December 31, 2008 is presented below:

Non-vested Restricted Shares	Shares	Weighted Average Grant Date Fair Value
Non-vested at June 30, 2008	88,825	$ 1.68
Granted	155,200	$ 0.29
Vested	(55,475)	$ 1.40
Forfeited	(6,950)	$ 1.72
Non-vested at December 31, 2008	181,600	$ 0.58

As of December 31, 2008, there was approximately $48,000 of total unrecognized compensation cost related to non-vested restricted stock awards granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 0.7 years.

5. Shareholders' Equity

In October 2008, the Company entered into a $15 million common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), an Illinois limited liability company. Concurrently with entering into the common stock purchase agreement, the Company entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, Aastrom agreed to file a registration statement related to the transaction with the U.S. Securities & Exchange Commission ("SEC") covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. The SEC declared this registration statement to be effective on November 26, 2008. The Company has the right over a 25-month period (beginning on the date the SEC declared the registration statement to be effective) to sell shares of Aastrom common stock to Fusion Capital from time to time in amounts between $60,000 and $2 million, depending on certain conditions as set forth in the agreement, up to an aggregate of $15 million. The number of shares to be issued to Fusion Capital during each sale will be 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 (3) lowest closing sale prices of common stock during the twelve (12) consecutive business days (ten (10) 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). The Company will control the timing and amount of any sales of shares to Fusion Capital. In order to comply with Nasdaq Capital Market rules, Aastrom cannot issue to Fusion Capital more than 19.99% of outstanding common stock shares as of October 27, 2008 without shareholder approval, which Aastrom does not intend to seek.

Pursuant to the common stock purchase agreement with Fusion Capital, there are certain events of default which, if such an event would occur, would eliminate the obligation of Fusion Capital to purchase shares from the Company. Such events include, but are not limited to, (i) shares of the Company's common stock not being listed on any one of several stock exchanges outlined in the agreement and (ii) a "material adverse change" in the Company's business or operations. In addition, Fusion Capital shall not have the obligation to purchase any shares of the Company's common stock on any business day that the Purchase Price of the Company's common stock is below $0.10. The common stock purchase agreement may be terminated by Aastrom at any time at the Company's discretion without any cost to Aastrom. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement. The proceeds received by the Company under the common stock purchase agreement will be used to conduct operations and continue to conduct the Company's clinical development programs.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement in October 2008, Aastrom issued to Fusion Capital 1,936,317 shares of the Company's common stock as a commitment fee. Also, Aastrom will issue to Fusion Capital an additional 1,936,317 shares as a commitment fee pro rata as the Company receives up to the $15 million of future funding.

Through December 31, 2008, 5,117,694 shares of the Company's common stock (including 2,074,440 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $1,035,000.

During the month ended January 31, 2009, 6,026,202 shares of the Company's common stock (including 296,900 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $2,300,000.

In October 2008, warrants to purchase up to 1,838,843 shares of common stock pursuant to previous warrant agreements expired unexercised.

6. 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 nonvested 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 shares as of December 31, 2007 and 2008 is approximately 23,388,000 and 21,013,000, respectively.

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

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 repair or regeneration of multiple human tissues, based on our proprietary Tissue Repair Cell (TRC) technology. Our preclinical and clinical product development programs utilize patient-derived bone marrow stem and early progenitor cell populations, and are being investigated for their ability to aid in the regeneration of tissues such as cardiac, vascular, bone and neural. TRC-based products have been used in over 300 patients, and are currently in the following stages of development:

- Cardiac regeneration — Cardiac Repair Cells (CRCs):
  - Dilated cardiomyopathy (DCM) (severe chronic disease of the heart):
    - U.S.: IMPACT-DCM Phase II clinical trial began treating patients in November 2008; to date, 9 patients enrolled at three clinical sites (The Methodist Hospital, Houston, TX, Baylor University Medical Center, Dallas, TX, and The University of Utah School of Medicine, Salt Lake City, UT); initiation of two other clinical sites is in progress; Orphan Drug Designation from the FDA for use in treatment of DCM; the IMPACT-DCM trial is currently on clinical hold due to a serious adverse event associated with anesthesia management during treatment of one patient at one of the active clinical sites; an internal review at the clinical site and a second review by the trial's independent Data Safety Monitoring Board (DSMB) determined that this event was not related to the surgical procedure or our CRCs (see Page 15 for additional details related to the clinical hold)
    - Germany: Encouraging data reported April 2008 from compassionate use treatment in two patients
- Vascular regeneration — Vascular Repair Cells (VRCs):
  - Critical limb ischemia (CLI):
    - U.S.: RESTORE-CLI Phase IIb clinical trial has enrolled 51 patients; interim analysis of 12-month data for the first 30 patients expected to occur during the 4th quarter of calendar year 2009; patient enrollment continues
    - Germany: Phase I/II investigator-sponsored clinical trial completed enrollment and patient follow-up ongoing; positive interim data reported October 2007; report of final data expected during the first half of calendar year 2009
- Bone regeneration — Bone Repair Cells (BRCs):
  - Osteonecrosis of the femoral head:
    - U.S.: ON-CORE Phase III clinical trial active; not enrolling additional patients; Orphan Drug Designation from the FDA for use in treatment of osteonecrosis of the femoral head
    - Spain: 9 of 10 patients treated in clinical trial; 24 month follow-up for all patients
    - Germany: Encouraging data reported October 2007 from compassionate use treatment cases; follow-up ongoing

- Non-union fractures:
  - U.S.: Final clinical study report issued in December 2008; TRC product showed an excellent safety profile and the efficacy data indicated a high non-union healing rate, with bridging callus formation rates reported in over 90% of patients 12 months post-surgery compared to 50% historically
  - Spain: Final 24-month follow-up complete for 10-patient investigator-sponsored Phase II clinical trial; report of final data expected during the first half of calendar year 2009

- Neural regeneration — Neural Repair Cells (NRCs):
  - Spinal cord injury:
    - Plans for clinical program on hold

Our platform TRC technology is based on 1) autologous cell products which are a unique cell mixture containing large numbers of stem and early progenitor cells produced outside of the body from a small amount of bone marrow taken from the patient, and 2) the ability to produce these products in an automated process that meets Good Manufacturing Practice (GMP) requirements.

We have developed a manufacturing system to produce human cells for clinical use. This automated cell manufacturing system enables the “single-pass perfusion” cell culture process. Single-pass perfusion is our patented manufacturing technology for growing large numbers of human cells. The cell component of TRC-based products include adult stem and early progenitor cell populations, which are capable of forming tissues such as cardiac, vascular, bone, neural, and the hematopoietic and immune system.

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 in Ann Arbor, MI and three contract facilities in the EU located in Stuttgart, Germany (Fraunhofer Institute for Interfacial Engineering and Biotechnology), Bad Oeynhausen, Germany (Institute of Laboratory and Transfusion Medicine at the Heart Center) and Barcelona, Spain (Tissue and Cell Therapy Center at the Blood and Tissue Bank).

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. 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.

Our current focus is on utilizing our TRC technology to produce autologous cell-based products for use in regenerative medicine applications. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our 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 or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential. We are also exploring the possibility of entering into complementary regenerative medicine business activities, whether through acquisition or otherwise. In addition to reprioritizing our development and clinical programs, we also made reductions in our staff and reduced our overhead expenses.

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 obtaining 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 December 31, 2008, we have accumulated a net loss of approximately $187 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.

Clinical Development

Currently, our clinical development programs are focused primarily on the utilization of our TRC technology for cardiac and vascular regeneration. In May 2008, we 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, reactivating the Phase III ON-CORE trial or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential.

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

In November 2008, the first patient was treated in our 40-patient U.S. Phase II clinical trial (called IMPACT-DCM) to study 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 form of chronic heart failure. The U.S. Food & Drug Administration (FDA) approved our Investigational New Drug (IND) application in June 2008. 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. To date, 9 patients have been enrolled in the IMPACT-DCM trial at the first three clinical sites (The Methodist Hospital, Houston, TX, Baylor University Medical Center, Dallas, TX, and The University of Utah School of Medicine, Salt Lake City, UT). Two other sites have been identified and are completing the various steps necessary to begin patient enrollment, including clinical trial agreements, Investigational Review Board (IRB) review and approval, and clinical site training.

On February 2, 2009, we reported that one patient enrolled in the IMPACT-DCM clinical trial experienced a serious adverse event associated with anesthesia management during treatment at one of the active clinical sites. According to the results of an internal review conducted at the clinical site, and a second review by the trial’s DSMB, this event has been attributed to anesthesia administration and management in this single patient. Furthermore, these two reviews separately determined that this event was not related to the surgical approach or the use of our CRCs in this procedure. This patient has received appropriate treatment, has fully recovered from this isolated event and continues to be monitored in accordance with the study protocol. In compliance with regulatory requirements and standard operating procedures, this event was reported directly to the FDA and we immediately took the initiative to suspend patient enrollment at the clinical site where the event took place, pending an internal review and the implementation of a corrective action plan. In accordance with our commitment to the highest safety standards for participants in this trial, we have complied with a subsequent verbal communication from the FDA that the IMPACT-DCM trial

be placed on clinical hold at all trial sites pending completion of a more comprehensive review of this event. We are working closely with the FDA to provide any information required in order to expedite this review and to resolve this matter so that patient enrollment into the IMPACT-DCM trial can resume as soon as possible. Notwithstanding the hold, the FDA authorized us to proceed with the CRC treatment for one patient previously enrolled in the IMPACT-DCM clinical trial. This patient was treated at the end of January 2009. In addition, follow-up monitoring of patients who have previously been treated in the IMPACT-DCM trial is continuing in accordance with the study protocol.

Once the IMPACT-DCM trial is able to resume patient enrollment, participants must have a left ventricular ejection fraction 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 left ventricular ejection fraction and other cardiac function parameters as well as heart failure stage will be monitored. Patients will be followed for 12 months post treatment.

CRCs, manufactured using Aastrom's TRC technology, received an Orphan Drug Designation from the FDA for the treatment of DCM in February 2007.

In April 2008, we reported data from two compassionate use patients treated 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 a left ventricular ejection fraction (LVEF) of approximately 10% (the percentage of blood pumped out of the heart with each contraction) 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 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 often represents the end stage of chronic ischemic heart disease in patients who have experienced multiple heart attacks. Patient prognosis depends on the stage of the disease but is typically characterized by a high mortality rate. Other than heart transplantation, there are 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

Based on our laboratory observations that TRC-based products have the ability to form small blood vessels *in vitro* and results from third party trials involving the use of bone marrow cells for peripheral vascular disease, we are conducting trials to evaluate the safety and efficacy of Vascular Repair Cells (VRCs) based on TRC technology in the treatment of diabetics with open foot wounds and patients diagnosed with critical limb ischemia (CLI).

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, the end stage of peripheral arterial disease. This study is allowed 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, 51 patients have been enrolled in the RESTORE-CLI trial and 21 clinical sites are open for patient enrollment. Our website will be updated as additional sites are open for patient enrollment. Patients will be followed for a period of twelve months post-treatment. In addition to assessing the safety of the VRCs, secondary objectives include assessing major amputation rates, level of amputation, wound healing and blood flow in the affected limbs, patient quality of life, pain scores and analgesic use. During the 4th quarter of calendar year 2009, we expect to unblind and analyze the clinical data from the first 30 patients enrolled in the study.

In October 2007, positive interim results from the first 13 patients treated 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 seven patients treated with unexpanded bone marrow cells, five reported results similar to the VRC-treated patients 12 months post-treatment, one reported similar results to the VRC-treated patients 18 months post-treatment, and one patient underwent a major amputation. For the two 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 is complete and final data is expected to be reported during the first half of calendar year 2009.

Bone Regeneration

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. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential.

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 Bone Repair Cells (BRCs) based on our TRC technology in the treatment of osteonecrosis (also known as avascular necrosis) of the femoral head. 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. 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. 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 ongoing with 9 of 10 planned patients currently 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 three centers in Spain under Ethical Committee approval; positive results were disclosed in May 2005. Following this trial, a ten patient Phase II non-union fracture trial was initiated. The Phase II study has completed enrollment and BRC treatment of all 10 patients, and we are continuing the specified 24 months follow-up of these patients. Final data is expected to be reported during the first half of calendar year 2009.

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 in this indication. We will continue to focus primarily on the utilization of our TRC technology for cardiac and vascular regeneration.

Neural Regeneration

In May 2008, we reprioritized our clinical development programs to primarily focus on cardiovascular applications. We do not anticipate initiating formal clinical trials in the neural area using our proprietary Neural Repair Cells (NRCs) without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential.

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 and expect to continue this level of activity. 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 grant revenues and product sales, for the quarter and six months ended December 31, 2008 were $28,000 and $55,000, respectively, compared to $84,000 and $171,000, respectively, for the same periods in fiscal year 2008. Product sales for the quarter and six months ended December 31, 2008 were $28,000 and $55,000, respectively, compared to $24,000 and $36,000 for the same periods in fiscal 2008. No grant revenues were recorded for the quarter and six months ended December 31, 2008 as there were no active grants with the National Institutes of Health. Grant revenues for the quarter and six months ended December 31, 2007 were $60,000 and $135,000, respectively. Grant revenues may vary in any period based on timing of grant awards, grant-funded activities, level of grant funding and number of grant awards received.

Total costs and expenses decreased to $4,180,000 for the quarter ended December 31, 2008, compared to $5,621,000 for the quarter ended December 31, 2007.

Costs and expenses include a decrease in research and development expenses to $2,829,000 for the quarter ended December 31, 2008 from $3,895,000 for the quarter ended December 31, 2007. This decrease reflects the changes we implemented in May 2008, when we reprioritized our clinical development programs to focus primarily on cardiovascular applications. The reprioritization reduced our overall research and development expenses, including salaries and benefits and other purchased services. Research and development expenses also included a non-cash charge relating to share-based compensation expense of $174,000 for the quarter ended December 31, 2008 compared to $214,000 for the quarter ended December 31, 2007.

Selling, general and administrative expenses decreased for the quarter ended December 31, 2008 to $1,333,000 from $1,725,000 for the quarter ended December 31, 2007. This decrease is primarily due to lower salaries and benefits and other purchased services that are the result of the reduction in force that was part of our reprioritzation of our clinical programs. Selling, general and administrative expenses for the quarter ended December 31, 2008, included a non-cash charge relating to share-based compensation expense of $219,000 compared to $344,000 for the quarter ended December 31, 2007.

Total costs and expenses decreased to $8,226,000 for the six months ended December 31, 2008, compared to $11,108,000 for the six months ended December 31, 2007.

Research and development expenses decreased for the six months ended December 31, 2008 to $5,555,000 from $7,768,000 for the six months ended December 31, 2007, reflecting the changes we implemented in May 2008, when we reprioritized our clinical development programs to focus primarily on cardiovascular applications. The reprioritization reduced our overall research and development expenses, including salaries and benefits and other purchased services. Research and development expenses also included a non-cash charge relating to stock-based compensation expense of $335,000 for the six months ended December 31, 2008 compared to $437,000 for the six months ended December 31, 2007.

Selling, general and administrative expenses decreased for the six months ended December 31, 2008 to $2,649,000 from $3,339,000 for the six months ended December 31, 2007. This decrease is primarily due to to lower salaries and benefits that is the result of the reduction in force that was part of our reprioritzation of our clinical programs. Selling, general and administrative expenses for the six months ended December 31, 2008, included a non-cash charge relating to share-based compensation expense of $421,000 compared to $670,000 for the six months ended December 31, 2007.

Interest income was $69,000 and $196,000, respectively, for the quarter and six months ended December 31, 2008 compared to $386,000 and $751,000, respectively, for the same periods in fiscal 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 $20,000 and $41,000, respectively, for the quarter and six months ended December 31, 2008 compared to $21,000 and $36,000, respectively, for the same periods in fiscal 2008. Interest expense is related to the secured loan with Key Equipment Finance Inc.

Our net loss was $4,103,000, or $.03 per common share for the quarter ended December 31, 2008 compared to $5,172,000, or $.04 per common share for the quarter ended December 31, 2007. For the six months ended December 31, 2008, our net loss decreased to $8,016,000, or $.06 per common share compared to a net loss of $10,222,000, or $.08 per common share for the six months ended December 31, 2007.

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 and 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, reactivating the Phase III ON-CORE trial or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential. Compassionate-use clinical activities have been initiated in Europe to evaluate the treatment of dilated cardiomyopathy using our TRC-based product. 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. Research and development expenses outside of the TRC-based product development consist primarily of immunotherapy programs, engineering and cell manufacturing.

The following table summarizes our research and development expenses for the quarter and six months ended December 31, 2007 and December 31, 2008:

R&D Project	Quarter Ended December 31, 2007	Quarter Ended December 31, 2008	Six Months Ended December 31, 2007	Six Months Ended December 31, 2008
TRC-based product	$3,631,000	$2,829,000	$7,242,000	$5,555,000
Other	264,000	—	526,000	—
Total	$3,895,000	$2,829,000	$7,768,000	$5,555,000

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 December 31, 2008, have totaled approximately $205 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, cash equivalents and short-term investments totaled $16,326,000 at December 31, 2008, a decrease of $6,136,000 from June 30, 2008. The primary uses of cash, cash equivalents and short-term investments during the six months ended December 31, 2008 included $7,089,000 to finance our operations and working capital requirements, and $28,000 in capital equipment additions. The primary source of cash, cash equivalents and short-term investments was from equity transactions, of which net proceeds of $1,042,000 was raised during the six months ended December 31, 2008, principally through our agreement with Fusion Capital.

Pursuant to the agreement with Fusion Capital, 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 $60,000 and $2 million, depending on certain conditions as set forth in the agreement, up to an aggregate of $15 million. The number of shares to be issued to Fusion Capital during each sale will be 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 (3) lowest closing sale prices of common stock during the twelve (12) consecutive business days (ten (10) 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 will control the timing and amount of any sales of shares to Fusion Capital. In order to comply with Nasdaq Capital Market rules, we cannot issue to Fusion Capital more than 19.99% of outstanding common stock shares as of October 27, 2008 without shareholder approval, which we do not intend to seek.

There are certain events of default which, if such an event would 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 obligation to purchase any shares of our common stock on any business day that the Purchase Price of our common stock is below $0.10. 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 continue to conduct our clinical development programs.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement in October 2008, we issued to Fusion Capital 1,936,317 shares of our common stock as a commitment fee. Also, we will issue to Fusion Capital an additional 1,936,317 shares as a commitment fee pro rata as we receive the up to $15 million of future funding.

Through December 31, 2008, 5,117,694 shares of our common stock (including 2,074,440 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $1,035,000. During the month ended January 31, 2009, 6,026,202 shares of our common stock (including 296,900 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $2,300,000.

Assuming the Purchase Price for future shares issued to Fusion Capital remain at the same average price as the January 2009 transactions, we would be able to raise an additional $5.6 million of cash proceeds per our agreement with Fusion Capital (through the issuance of the remaining 15,421,402 shares of our common stock, which includes 1,501,294 shares related to the commitment fee).

Our monthly cash utilization has average approximately $1.2 million for the six months ended December 31, 2008. We expect our monthly cash utilization for the remainder of fiscal year 2009 to average approximately $1.5 million due to increased expenses to conduct our cardiac trial. Our cash and cash equivalents at January 31, 2009 were $17.5 million.

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 public or private debt or equity financing transactions, research and development agreements or grants and distribution and marketing agreements. 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.

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. In addition, we may also 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. Several factors will affect our ability to raise additional funding or enter into strategic transactions or other strategic alternatives, 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.

Management believes, based on its current projections of our cash utilization (which is expected to approximate between $1.4 — $1.5 million per month) and taking into consideration the $2.3 million of additional cash raised in January (as described in Note 5), available cash and cash equivalents on hand as of January 31, 2009 (which equaled approximately $17.5 million) are adequate to finance our planned operations at least until December 31, 2009. However, we will need to raise additional funds in order to complete our product development programs, complete clinical trials needed to market its products, and commercialize these products. 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 substantial additional funds. We will also need significant 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.

On January 7, 2009, we received notification from the Listings Qualifications Department of The Nasdaq Stock Market LLC ("NASDAQ") that, given the continued extraordinary market conditions, NASDAQ had extended the suspension enforcing the rules requiring a minimum $1.00 per share closing bid price and a minimum market value of publicly held shares through April 19, 2009. As a result of the extension of NASDAQ's suspension and the 60 days left on our previously granted compliance period, we have 60 days after April 19, 2009 to regain compliance with the $1.00 minimum closing bid price rule in order to remain listed on the Nasdaq Capital Market. We must demonstrate a closing bid price of $1.00 or more for a minimum of ten consecutive business days to regain compliance. 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.

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 2008 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 December 31, 2008, we have incurred a cumulative net loss totaling approximately $187 million, and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development 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. In addition, we may not be able to achieve or sustain profitability.

The global economy and capital markets have been challenging for the small cap biotech sector for the past year or so. 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 December 20, 2007, we received a deficiency letter from NASDAQ indicating that for 30 consecutive trading days our common stock had a closing bid price below the $1.00 per share minimum closing bid as required for continued listing set forth in NASDAQ Marketplace Rule 4310(c)(4). In accordance with NASDAQ Marketplace Rule 4310(c)(8)(D), we were provided a compliance period of 180 calendar days, or until June 17, 2008, to regain compliance with this requirement. On June 17, 2008, we had not yet regained compliance with the requirement and were granted an additional 180-day compliance period, or until December 15, 2008 to regain compliance. On October 22, 2008, we received notice from NASDAQ that the period during which we were granted to gain compliance with the bid price requirement had been suspended and that, upon completion of the suspension period, we would have until March 20, 2009 to regain compliance with the requirement. On January 7, 2009, we received notification from the Listings Qualifications Department of NASDAQ that, given the continued extraordinary market conditions, NASDAQ had extended the suspension of enforcing the rules requiring a minimum $1.00 per share closing bid price and a minimum market value of publicly held shares through April 19, 2009. As a result of the extension of NASDAQ's suspension and the 60 days left on our previously granted compliance period, we have 60 days after April 19, 2009 to regain compliance with the $1.00 minimum closing bid price rule in order to remain listed on the Nasdaq Capital Market. 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. If we do not regain compliance during the additional compliance period, NASDAQ will provide written notice that our securities will be delisted from the NASDAQ Capital Market. At such time, we would be able to appeal the delisting determination to a NASDAQ Listing Qualifications Panel.

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 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; and
- complementary business acquisition or development opportunities.

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 is expected to 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 Capital 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 and if there is a material adverse change to our business, properties, operations, financial condition or results of operations. In addition, our ability to raise the entire $15 million will be dependent on the stock price of our common stock as we will not be able to sell greater than 19.99% of our outstanding shares of common stock as of the date of the Purchase Agreement without obtaining shareholder approval.

We only have the right to receive $60,000 every two business days 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. Since we will be limited to 22,692,664 shares sold to Fusion Capital, the selling price of our common stock to Fusion Capital will have to average at least $0.66 per share for us to receive the maximum proceeds of $15.0 million. Assuming a purchase price of $0.40 per share (the closing sale price of the common stock

on October 23, 2008) and the purchase by Fusion Capital of the full 22,692,664 shares under the Purchase Agreement, proceeds to us would only be $9,077,066 unless we choose to register more than 22,692,664 shares, which we have the right, but not the obligation, to do. Subject to approval by our board of directors, we have the right but not the obligation to sell more than 22,692,664 shares to Fusion Capital. In the event we elect to sell more than 22,692,664 shares offered hereby, we will be required to file a new registration statement covering resale of the incremental shares and have it declared effective by the U.S. Securities & Exchange Commission. In addition, in the event that we decide to issue more than 26,565,299, i.e. greater than 19.99% of our outstanding shares of common stock as of the date of the Purchase Agreement, we would first be required to seek shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

The extent 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 $15.0 million under the Purchase Agreement with Fusion Capital, we will need 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 be a material adverse effect on our business, operating results, financial condition and prospects.

We have experienced significant management turnover, and 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.

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. If we cannot demonstrate the safety and efficacy of our product candidates produced in our manufacturing system, 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 Biological 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. Recent changes to the EU Medicinal Products Prime Directive (including added annexes and new regulations) shifted patient-derived cells to the medicinal products category which will require Marketing Authorizations in order to market and sell these products. These new requirements will require clinical trials with data submission and review by one or more European regulatory bodies. There is uncertainty about which clinical trial activities and data are required, and because of the recent nature of these new directives, laws and regulations, there is no established precedent to understand the timeline or other requirements for 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 or other considerations.

On February 2, 2009, we reported that one patient enrolled in the IMPACT-DCM clinical trial experienced a serious adverse event associated with anesthesia management during treatment at one of the active clinical sites. According to the results of an internal review conducted at the clinical site, and a second review by the trial's independent Data Safety Monitoring Board (DSMB), this event has been attributed to anesthesia administration and management in this single patient. Furthermore, these two reviews separately determined that this event was not related to the surgical approach or the use of our CRCs in this procedure. This patient has received appropriate treatment, has fully recovered from this isolated event and continues to be monitored in accordance with the study protocol. In compliance with regulatory requirements and standard operating procedures, this event was reported directly to the FDA and we immediately took the initiative to suspend patient enrollment at the clinical site where the event took place, pending an internal review and the implementation of a corrective action plan. In accordance with our commitment to the highest safety standards for participants in this trial, we have complied with a subsequent verbal communication from the FDA that the IMPACT-DCM trial be placed on clinical hold at all trial sites pending completion of a more comprehensive review of this event. We are working closely with the FDA to provide any information required in order to expedite this review and to resolve this matter so that patient enrollment into the IMPACT-DCM trial can resume as soon as possible. Notwithstanding the hold, the FDA authorized us to proceed with the CRC treatment for one patient previously enrolled in the IMPACT-DCM clinical trial. This patient was treated at the end of January 2009. In addition, follow-up monitoring of patients who have previously been treated in the IMPACT-DCM trial is continuing in accordance with the study protocol.

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 component parts or provide limited source supplies, or the imposition of additional regulation, would impair our new product development and our sales activities.

We rely solely on third parties such as Astro, Ethox, Moll and Lonza 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, the Institute of Laboratory and Transfusion Medicine at the Heart Center in Bad Oeynhausen, Germany, and the Tissue and Cell Therapy Center at the Blood and Tissue Bank in Barcelona, Spain, 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 could be subject to ongoing, periodic, unannounced inspection by regulatory agencies to ensure strict compliance with GMP 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 in 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 transaction 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 $0.76 during the twelve month period ended December 31, 2008. 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. 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, contain 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 December 31, 2008, 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

The Company conducted an evaluation, under the supervision and with the participation of management, including the Chief Executive Officer ("CEO")/Chief Financial Officer ("CFO"), who currently is the same individual, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). Based on that evaluation, the CEO/CFO has concluded that the Company's disclosure controls and procedures were effective as of December 31, 2008 to ensure that information related to the Company required to be disclosed in reports the Company files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to the Company's management, including the CEO/CFO, to allow timely decisions regarding required disclosure. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that the Company's disclosure controls and procedures will detect or uncover every situation involving the failure of persons within the Company to disclose material information otherwise required to be set forth in the Company's periodic reports; however, the Company's disclosure controls are designed to provide reasonable assurance that they will achieve their objective of timely alerting the CEO/CFO to the information relating to the Company required to be disclosed in the Company's periodic reports required to be filed with the SEC.

Changes in Internal Control over Financial Reporting

During our second quarter of fiscal 2009, there were no changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) occurred 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

On October 27, 2008, the Company entered into common stock purchase agreement with Fusion Capital Fund II, LLC (“Fusion Capital”), an Illinois limited liability company, to sell to Fusion Capital up to $15.0 million in its common stock, pursuant to Section 4(2) of the Securities Act, as amended. Concurrently with entering into the common stock purchase agreement, the Company entered into a registration rights agreement with Fusion Capital. The Company has the right over a 25-month period to sell shares of its common stock to Fusion Capital from time to time in amounts between $60,000 and $2 million, depending on certain conditions as set forth in the agreement, up to an aggregate of $15.0 million. The Company will control the timing and amount of any sales of shares to Fusion Capital. In order to comply with Nasdaq Capital Market rules, the Company cannot issue to Fusion Capital more than 20% of outstanding common stock shares as of October 27, 2008, without shareholder approval, which Aastrom does not intend to seek.

The purchase price of the shares related to the $15.0 million of future funding is based on the prevailing market prices of the Company’s shares at the time of sales without any fixed discount. Fusion Capital does not have the right or the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below $0.10. The proceeds received by the Company under the common stock purchase agreement will be used to conduct operations and continue to conduct our clinical development programs.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement Aastrom issued to Fusion Capital 1,936,317 shares of our common stock as a commitment fee. Also, Aastrom will issue to Fusion Capital an additional 1,936,317 shares as a commitment fee pro rata as the Company receives the up to $15.0 million of future funding.

Item 3. Defaults Upon Senior Securities

None.

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

(a) The Annual Meeting of Shareholders of Aastrom Biosciences, Inc. was held on October 17, 2008.

(b) At the 2008 Annual Meeting of Shareholders, votes were cast on matters submitted to the shareholders, as follows:

Proposal 1: Amendment to the Company Bylaws to eliminate the classification of the Board of Directors.

FOR	AGAINST	ABSTAIN
98,278,901	7,545,103	1,175,987

Proposal 2: As a result of shareholder approval of Proposal 1, the election of six directors to serve for one-year terms expiring at the 2009 Annual Meeting of Shareholders or until his successor shall have been elected and qualified.

NOMINEE	FOR	WITHHELD
George W. Dunbar	96,486,225	10,513,766
Timothy M. Mayleben	96,490,645	10,509,346
Alan L. Rubino	96,486,994	10,512,997
Nelson M. Sims	96,552,726	10,447,265
Stephen G. Sudovar	96,377,829	10,622,162
Robert L. Zerbe	96,521,593	10,478,398

Proposal 3: Amendment to the Company's Restated Articles of Incorporation to eliminate the supermajority vote requirements.

FOR	AGAINST	ABSTAIN
91,966,757	13,810,473	1,222,760

Proposal 4: Ratification of the selection of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the year ending June 30, 2009.

FOR	AGAINST	ABSTAIN
103,200,555	2,474,093	1,325,343

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.

AASTROM BIOSCIENCES, INC.

Date: February 6, 2009

/s/ George W. Dunbar, Jr.
George W. Dunbar, Jr.
President and Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
10.1	Common Stock Purchase Agreement, dated October 27, 2008, between Aastrom Biosciences, Inc. and Fusion Capital Fund II, LLC, attached as Exhibit 10.1 to Aastrom's Current Report on Form 8-K filed on October 29, 2008, incorporated herein by reference.
10.2	Registration Rights Agreement, dated October 27, 2008, between Aastrom Biosciences, Inc. and Fusion Capital Fund II, LLC, attached as Exhibit 10.2 to Aastrom's Current Report on Form 8-K filed on October 29, 2008, incorporated herein by reference.
31.1	Certification of Chief Executive Officer and 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 Regulatory 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.

TERM	DEFINITION
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.
LVEF — Left Ventricle Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heart beat.
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).
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

TERM	DEFINITION
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.

TERM	DEFINITION
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 biological drug that, if approved, 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.
Non-union Fractures	Broken bones that have failed to unite and heal
NRC — Neural Repair Cell	Aastrom's proprietary Tissue Repair Cells for Neural indications (Also see TRC — Tissue Repair Cell)
ON — Osteonecrosis	A progressive bone disease characterized by death of bony tissue due to insufficient blood flow within the bone.

TERM	DEFINITION
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/placebo treatment.
Orphan Drug Designation	"Orphan drug" refers to a drug or biologic that is intended for use in the treatment of a rare disease or condition. Orphan drug designation from the U.S. Food and Drug Association (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for developing the drug for a rare disease or condition. The drug must then go through the FDA marketing approval process like any other drug or biologic which evaluates for safety and efficacy. Usually a sponsor receives a quicker review time and lower application fees for an orphan product.
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.

TERM	DEFINITION
Somatic Cell	Any of the cells that are 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. In culture, these undifferentiated cells possesse 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, George W. Dunbar, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aastrom Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(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.

Date: February 6, 2009

/s/ George W. Dunbar, Jr.
George W. Dunbar, Jr.
President and Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Aastrom Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended December 31, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George W. Dunbar, Jr., President, Chief Executive Officer and Chief Financial Officer 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"), that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 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.

February 6, 2009

/s/ George W. Dunbar, Jr.
George W. Dunbar, Jr.
President and Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial and Accounting Officer)

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