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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, 2009,

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number 0-22025

AASTROM BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

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

(734) 930-5555
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes - ☑ No - o

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

Yes - o No - o

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

Large accelerated filer - o	Accelerated filer - ☑	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	226,048,759
(Class)	Outstanding at February 2, 2010

AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
December 31, 2009

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

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

CONSOLIDATED CONDENSED BALANCE SHEETS
(Unaudited)
(In thousands)

	June 30, 2009	December 31, 2009
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,000	$ 14,739
Receivables, net	58	23
Inventory	1	—
Other current assets	732	622
Total current assets	17,791	15,384
PROPERTY AND EQUIPMENT, NET	1,485	1,240
Total assets	$ 19,276	$ 16,624
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 853	$ 1,366
Accrued employee benefits	355	352
Current portion of long-term debt	479	354
Total current liabilities	1,687	2,072
LONG-TERM DEBT	305	194
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized — 250,000,000 and 500,000,000, respectively; shares issued and outstanding — 160,222,644 and 173971,085, respectively	213,107	218,557
Deficit accumulated during the development stage	(195,823)	(204,199)
Total shareholders' equity	17,284	14,358
Total liabilities and shareholders' equity	$ 19,276	$ 16,624

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

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

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

	Quarter ended December 31,		Six months ended December 31,		March 24, 1989 (Inception) to December 31,
	2008	2009	2008	2009	2009
REVENUES:					
Product sales and rentals	$ 28	$ 16	$ 55	$ 89	$ 1,850
Research and development agreements	—	—	—	—	2,105
Grants	—	—	—	—	9,657
Total revenues	28	16	55	89	13,612
COSTS AND EXPENSES:					
Cost of product sales and rentals	18	2	22	34	796
Cost of product sales and rentals — provision for obsolete and excess inventory	—	—	—	—	2,239
Research and development	2,829	3,283	5,555	6,194	154,302
Selling, general and administrative	1,333	1,316	2,649	2,262	70,920
Total costs and expenses	4,180	4,601	8,226	8,490	228,257
LOSS FROM OPERATIONS	(4,152)	(4,585)	(8,171)	(8,401)	(214,645)
OTHER INCOME (EXPENSE):					
Other income	—	—	—	—	1,249
Interest income	69	21	196	49	10,613
Interest expense	(20)	(11)	(41)	(24)	(448)
Other income	49	10	155	25	11,414
NET LOSS	$ (4,103)	$ (4,575)	$ (8,016)	$ (8,376)	$ (203,231)
COMPUTATION OF NET LOSS PER SHARE APPLICABLE TO COMMON SHARES:					
NET LOSS	$ (4,103)	$ (4,575)	$ (8,016)	$ (8,376)	
NET LOSS PER SHARE (Basic and Diluted)	$ (.03)	$ (.03)	$ (.06)	$ (.05)	
Weighted average number of shares outstanding (Basic and Diluted)	134,575	173,707	133,686	169,570	

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

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

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

	Six months ended December 31,		March 24, 1989 (Inception) to December 31, 2009
	2008	2009	
OPERATING ACTIVITIES:			
Net loss	$ (8,016)	$ (8,376)	$ (203,231)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	350	301	6,301
Loss on property held for resale	—	—	110
Amortization of discounts and premiums on investments	(30)	—	(1,704)
Stock compensation expense	756	350	8,739
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	(52)	35	(272)
Inventories	—	1	(2,335)
Other current assets	84	(27)	(461)
Accounts payable and accrued expenses	178	513	1,309
Accrued employee benefits	(359)	(3)	352
Net cash (used for) operating activities	(7,089)	(7,206)	(185,449)
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73)
Purchase of short-term investments	—	—	(212,041)
Maturities of short-term investments	6,000	—	213,745
Property and equipment purchases	(28)	(56)	(5,817)
Proceeds from sale of property held for resale	—	—	400
Net cash provided by (used for) investing activities	5,972	(56)	(3,786)
FINANCING ACTIVITIES:			
Net proceeds from issuance of preferred stock	—	—	51,647
Net proceeds from issuance of common stock and warrants	1,042	5,100	150,445
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	127	137	(140)
Proceeds from long-term debt	—	—	751
Principal payments under long-term obligations	(218)	(236)	(2,211)
Net cash provided by financing activities	951	5,001	203,974
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(166)	(2,261)	14,739
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	16,492	17,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 16,326	$ 14,739	$ 14,739

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

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

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. Organization

Aastrom Biosciences, Inc. (the "Company") was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. The Company operates its business in one reportable segment — research and product development focused on innovative therapies to repair or regenerate damaged or diseased tissues or organs. Aastrom is developing autologous cellular therapies for the treatment of severe, chronic cardiovascular diseases.

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

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. While management believes available cash, cash equivalents and short-term investments are adequate to finance its operations at least through December 31, 2010, in part due to the fact that many of the Company's expenditures are discretionary in nature and could, if necessary, be delayed, the Company will need to raise a substantial amount of additional funds in order to complete its product development programs, complete clinical trials needed to market its products, and commercialize these products. The Company cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and its overall success include: the rate and degree of progress of its product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the U.S., E.U. and other countries, the liquidity and market volatility of the Company's equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If the Company cannot raise such funds, it may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would likely have a material adverse impact on the Company's business, financial condition and results of operations.

2. Basis of Presentation

The consolidated condensed financial statements included herein have been prepared by us without audit according to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America have been omitted pursuant to such rules and regulations. The financial statements reflect,

in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the six months ended December 31, 2009, are not necessarily indicative of the results to be expected for the full year or for any other period.

These financial statements should be read in conjunction with the audited financial statements and the notes thereto included in our 2009 Annual Report on Form 10-K for the year ended June 30, 2009, as filed with the Securities and Exchange Commission on September 14, 2009.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany, Aastrom Biosciences, Ltd., located in Dublin, Ireland and Aastrom Biosciences, S.L., located in Barcelona, Spain (collectively, the "Company"). All significant inter-company transactions and accounts have been eliminated in consolidation. These subsidiaries have limited operations and are not significant to the consolidated financial statements.

3. Fair Value Measurements

Effective July 1, 2008, the Company began measuring assets and liabilities at fair value on a recurring basis. In addition to expanding the disclosures surrounding fair value measurements, U.S. GAAP (Generally Accepted Accounting Principles) clarifies that fair value represents the amount that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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

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

At December 31, 2009, the Company had $14.7 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. No other assets or liabilities on the Balance Sheet as of December 31, 2009 are measured at fair value using Level 1, 2 or 3 inputs.

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.

Service-Based Options

During the six months ended December 31, 2009, the Company granted 6,542,200 service-based options to purchase common stock. These options were granted with exercise prices equal to the fair value of the Company's stock at the grant date, vest over four years (other than non-employee director options which vest over one year) and expire ten years from the grant date. 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, 2008 and 2009 was $0.39 and $0.23 respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors were approximately $301,000 and $340,000 for the quarter and six months ended December 31, 2009, respectively, compared to $365,000 and $708,000 for the corresponding periods in fiscal year 2009.

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,	
	2008	2009
Stock Option Plans:		
Expected dividend rate	0%	0%
Expected stock price volatility	70%	70.2% - 72.8%
Risk free interest rate	3.3%	2.49% - 2.98%
Estimated forfeiture rate	10%	10%
Expected life (years)	6.6	5.5 - 6.25

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, 2009	10,923,059	$ 0.97		
Granted	6,542,200	$ 0.35		
Exercised	—	—		$ —
Forfeited or expired	(2,480,300)	$ 1.31		
Outstanding at December 31, 2009	14,984,959	$ 0.64	8.4	$ 41,000
Exercisable at December 31, 2009	4,906,411	$ 1.06	6.5	$ 6,000

As of December 31, 2009, there was approximately $1,393,000 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 1.6 years.

Performance-Based Stock Options

There were no grants of performance-based stock options during the six months ended December 31, 2009. There have been no changes to the terms of the performance-based stock options from those disclosed in our Annual Report on Form 10-K for the year ended June 30, 2009.

For the six months ended December 31, 2009, 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, 2009	881,334	$ 1.47		
Granted	—	—		
Exercised	—	—		
Forfeited or expired	(333,333)	$ 1.38		
Outstanding at December 31, 2009	548,001	$ 1.52	6.8	$ 0

The aggregate estimated fair value of these awards that are outstanding as of December 31, 2009 is approximately $561,000.

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 $1,000 and $10,000 for the quarter and six months ended December 31, 2009, respectively, compared to $28,000 and $48,000 for the same periods in fiscal year 2009.

A summary of the Company's restricted stock activity for the six months ended December 31, 2009 is presented below:

Non-vested Restricted Shares	Shares	Weighted Average Grant Date Fair Value
Non-vested at June 30, 2009	100,150	$0.74
Granted	—	—
Vested	(98,725)	$0.73
Forfeited	—	—
Non-vested at December 31, 2009	1,425	$1.38

As of December 31, 2009, there was approximately $1,300 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

On June 12, 2009, the Company entered into a $30.0 million common stock purchase agreement with Fusion Capital Fund II, LLC, ("Fusion Capital") an Illinois limited liability company. The terms of the arrangement with Fusion Capital are disclosed in the Company's Annual Report on Form 10-K for the year ended June 30, 2009 and there have been no changes to the terms of this arrangement during the quarter ended December 31, 2009.

During the six months ended December 31, 2009, 13,748,439 shares of the Company's common stock (including 411,467 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of $5,100,000.

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 unvested restricted shares of common stock are not included in the per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares that have been excluded from the computations of net loss per common share for the quarters ended December 31, 2008 and 2009 is approximately 21,013,000 and 21,455,000, respectively.

7. Recent Accounting Pronouncements

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

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

8. Subsequent Events

On January 21, 2010, the Company completed the sale of 52,077,100 units (including 5,923,100 units sold to the underwriter pursuant to the exercise of its over-allotment option) at a public offering price of $0.26 per unit. Each unit consisted of (i) one share of common stock, (ii) a Class A warrant to purchase 0.75 of a share of common stock at an exercise price of $0.3718 per share and (iii) a Class B warrant to purchase 0.50 of a share of common stock at an exercise price of $0.26 per share. The Company received approximately $12.4 million in net proceeds from the sale of the units (including the partially exercised option of the over-allotment), after underwriting discounts and commissions and other offering expenses. The estimated fair market value was a proportional amount of the total proceeds received allocable to the warrants at the date of issuance that was approximately $4,375,000. The value was based on the Black-Scholes option-pricing model.

The 52,077,100 units consist of an aggregate of 52,077,100 shares of the Company’s common stock, Class A Warrants to purchase an aggregate of 39,057,825 shares of common stock and Class B Warrants to purchase an aggregate of 26,038,550 shares of common stock. The Class A Warrants are exercisable for a five year period commencing on July 21, 2010. The Class B Warrants are exercisable at any time from January 21, 2010 through July 21, 2010.

On January 29, 2010, the Company's Board of Directors approved a one-for-eight reverse stock split of the Company's common stock and for the Company to pursue an effective date of such reverse stock split during February 2010. As of February 9, 2010 (the date of this Form 10-Q), this reverse stock split is not yet effective. Unaudited pro forma information, as if the reverse stock split was effective, is presented below for each of the interim periods ended December 31, 2008 and 2009 *(in thousands, except per share amounts:*

	Quarter Ended December 31,		Six Months Ended December 31,	
	2008	2009	2008	2009
Net loss	$ (4,103)	$ (4,575)	$ (8,016)	$ (8,376)
Proforma net loss per share (Basic and Diluted)	$ (0.24)	$ (0.21)	$ (0.48)	$ (0.40)
Proforma weighted average number of shares outstanding (Basic and Diluted)	16,821	21,713	16,710	21,196

The Company has evaluated subsequent events through February 9, 2010, the date that these financial statements were issued.

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

Overview of Aastrom

We focus on the development of innovative therapies to repair or regenerate damaged or diseased tissues or organs. We are developing autologous cellular therapies for the treatment of severe, chronic cardiovascular diseases. Using our proprietary Tissue Repair Cell (TRC) technology, we are able to expand the numbers of stem and early progenitor cells from a small amount (approximately 50 ml) of bone marrow collected from the patient. Early stage and clinical research show that these cells may have efficacy in the repair of cardiac and other tissue.

With the use of our proprietary TRC technology, we produce personalized cell products developed for site-specific delivery to repair or regenerate diseased or damaged tissue in patients. More than 375 patients have been treated in clinical trials based on this therapeutic approach over the past 10 years with no reported incidence of product safety problems or tissue rejection.

Cardiac Regeneration and Cardiac Repair Cells (CRCs)

Our lead product is based on the application of autologous stem cells used to repair damaged cardiac tissue. The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to our investigational therapy involving the use of CRCs (TRC-based cell therapy for cardiac indications) in the treatment of dilated cardiomyopathy (DCM). DCM is a severe, chronic cardiac disease that leads to enlargement of the heart and is associated with reduced heart pumping function to the point that blood circulation is impaired. We have advanced this development program with two U.S. Phase II trials investigating both a surgical and a catheter-based delivery pathway for the use of CRCs in the treatment of DCM.

The first U.S. patients were treated with CRCs in our Phase II IMPACT-DCM surgical clinical trial in November 2008. As of January 31, 2010, the trial was fully enrolled with 40 patients who will be followed for one year. The study is being conducted at five cardiovascular treatment centers in the U.S. including: Methodist DeBakey Heart & Vascular Center in Houston, TX; Baylor University Medical Center in Dallas, TX; The University of Utah School of Medicine in Salt Lake City, UT; Cleveland Clinic Heart & Vascular Institute in Cleveland, OH; and Emory University Hospital Midtown in Atlanta, GA. We anticipate collecting 6-month interim data from this trial upon completion of 6-month follow-up visits for all patients during the third quarter of calendar year 2010; the interim analysis results are planned to be reported in the fourth quarter of calendar year 2010.

Our second cardiac trial, a U.S. Phase II cardiac catheter clinical trial has been designed to explore a catheter-based delivery of CRCs to treat DCM patients. Clinical site training for this trial was initiated during the fourth quarter of calendar year 2009, and we expect to begin enrolling patients in the first quarter of calendar year 2010.

Vascular Regeneration and Vascular Repair Cells (VRCs)

Our TRC technology has also shown promise in the treatment of an advanced stage of peripheral arterial disease (PAD) called critical limb ischemia (CLI). Patients with CLI generally have painful wounds on their feet (or hands) that do not heal due to poor blood circulation, often leading to amputation. More than 160,000 amputations per year are associated with CLI. Our U.S. Phase IIb RESTORE-CLI clinical trial is investigating the use of VRCs in the treatment of patients with this severe, chronic disease. To date, 82 patients have been enrolled in this trial. Analysis of interim data began during the fourth quarter of calendar year 2009, and we expect to report conclusions from the interim analysis in the first quarter of calendar year 2010.

The TRC Technology Platform

CRCs and VRCs are cellular therapies developed using our proprietary TRC technology, an automated processing system utilizing “single-pass perfusion” to manufacture human cell products for clinical use. The system meets all Good Manufacturing Practices (GMP) guidelines. TRC-based therapies begin with a small amount of the patient’s own bone marrow to produce large numbers of stem and early progenitor cells. This mixture of cell types is capable of developing into cardiac, vascular and other tissues and can potentially reconstitute the hematopoietic and immune systems.

Our cell products have three features that we believe are critical for success in regenerative medicine. Cellular therapies based on our TRC technology are:

- **autologous,** which helps to ensure the cells are not rejected by patient’s immune system allowing the cells to engraft, differentiate and integrate into functional tissues and organs to produce a long-term repair;
- **expanded,** resulting in significantly higher concentrations of stem and progenitor cells than occur naturally; and,
- **a mixed population of cells,** which includes most of the cell types found in natural bone marrow and are required for tissue regeneration.

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

Since our inception, we have been a development-stage company engaged in research and product development conducted principally on our own behalf. With an initial focus on broader development and commercialization of cell therapy processing systems and supplies, we are now focused on the development of products based on our TRC technology platform for use in cardiovascular indications. We currently generate minimal product sales involving cell-therapy based products to physicians in the United States. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of therapies based on our TRC technology platform to constitute nearly all of our revenue from product sales.

We do not expect to generate positive cash flows from our consolidated operations for at least the next several years and then only if we achieve significant TRC-based cell product sales. Until that time, we expect that revenue sources from our current activities will consist of only minor sales of our cell products to our academic collaborators, grant revenue, research funding and potential licensing fees or other financial support from potential future corporate collaborators.

We expect that we will need to raise significant additional funds or pursue strategic alliances or other operational strategies to advance our product development programs including completion of our clinical research programs and commercialization of our products. To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue to seek to obtain 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 are achieved. With respect to our current activities, profitability 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, 2009, we have accumulated a net loss of approximately $203 million. We cannot provide any assurance that we will achieve profitability or obtain the required funding, regulatory approvals or complete additional corporate partnering or acquisition transactions to advance our products to commercial-stage development.

Clinical Development

Our clinical development programs are focused on the utilization of our TRC technology for cardiac and vascular regeneration. We have also extended the shelf-life of our TRC-based cell therapies which provides additional flexibility in transport and scheduling treatment for patients. The extended shelf-life product has been qualified and implemented at our centralized facilities in the U.S. and E.U. It is used for all cardiac and vascular regeneration clinical trials in the U.S. and is available for E.U. treatment sites.

The mixture of cell types in TRC-based therapies is capable of developing into cardiac, vascular and other tissues. We have demonstrated in the laboratory that cells in TRC-based therapies can differentiate into endothelial (blood vessel) lineages. In addition, VRC treatment in both rat and mouse models of critical limb ischemia have shown evidence of angiogenesis and increased tissue perfusion, respectively. These preclinical observations support our current clinical-stage research at treatment centers in the U.S. and E.U. where we are exploring the use of TRC-based therapies to regenerate cardiac tissue in patients with dilated cardiomyopathy and vascular tissue in patients with critical limb ischemia.

Results to date in our current clinical trials may not be indicative of results 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 — Background

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

The earliest clinical data from DCM patients treated with CRCs was obtained from two compassionate-use patients treated during 2007 at the University Hospital in Düsseldorf, Germany. A cardiothoracic surgeon with previous cell therapy experience performed the first human application of our CRC product through direct injection into the heart muscle during open heart surgery. Patient #1 had a left ventricular ejection fraction (LVEF) of approximately 10% prior to the CRC treatment in November 2007. Over the course of two months, this patient's LVEF increased to 25-30% with improvement of heart failure stage also noted. As reported by the treating surgeon, during in-hospital rehabilitation the patient declined further medical treatment and chose to leave the hospital against medical advice. This patient's subsequent death due to natural causes was found to be 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 heart failure symptoms. These E.U. compassionate-use treatments provided supporting information considered critical to the success of the U.S. Phase II IMPACT-DCM IND application.

Dilated Cardiomyopathy — Surgical Trial

In November 2008, the first patient was treated in the 40-patient U.S. IMPACT-DCM surgical trial to evaluate CRCs in the treatment of DCM. This randomized, controlled, prospective, open-label, Phase II study was designed using two strata to include 20 patients with ischemic DCM and 20 patients with non-ischemic DCM. CRCs, manufactured using our TRC technology, received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of DCM in February 2007. The FDA activated our Investigational New Drug (IND) application for this clinical trial in May 2008.

To date, 40 patients have enrolled in our IMPACT-DCM clinical trial at the five U.S. clinical sites (Methodist DeBakey Heart & Vascular Center, Houston, TX, Baylor University Medical Center, Dallas, TX, The University of Utah School of Medicine, Salt Lake City, UT, Cleveland Clinic Heart & Vascular Institute, Cleveland, OH, and Emory University Hospital Midtown, Atlanta, GA). We anticipate collecting 6-month interim data from this trial upon completion of 6-month follow-up visits for all patients during the third quarter of calendar year 2010; the interim analysis results are planned to be reported in the fourth quarter of calendar year 2010.

Participants in the IMPACT-DCM clinical trial have to be in New York Heart Association (NYHA) functional class III or IV heart failure, must have an LVEF of less than or equal to 30% (60-75% is typical for a healthy person), and meet certain other eligibility criteria. The IMPACT-DCM trial is a controlled trial and patients are randomized in an approximate 3:1 ratio to the treatment vs. the control group within each stratum. All patients receive optimal medical therapy and patients in the treatment group are treated with CRCs through direct injection into the heart muscle during minimally invasive open heart surgery (involving an incision of approximately 2 inches). While the primary objective of this study is to assess the safety of CRCs in patients with DCM (including the incidence of ectopies and arrhythmia as well as major adverse cardiac events), efficacy measures including cardiac dimensions and tissue mass, cardiac function (e.g. cardiac output, LVEF, cardiopulmonary exercise testing parameters), cardiac perfusion and viability as well as other efficacy endpoints will be monitored. NYHA functional class and quality of life are also assessed. Patients will be followed for 12 months post-treatment.

Dilated Cardiomyopathy — Catheter Trial

We have expanded our ongoing clinical program to evaluate CRCs in the treatment of severe heart failure patients with a second U.S. Phase II cardiac regeneration trial designed to explore a catheter-based delivery of CRCs to treat DCM patients. The FDA activated our IND application for this clinical trial in November 2009. The first clinical site was trained in December 2009 and patient enrollment is expected to begin during the first quarter of calendar year 2010.

This randomized, controlled, prospective, open-label, Phase II study seeks to enroll 12 patients with ischemic DCM and 12 patients with non-ischemic DCM at four clinical sites in the U.S. Participants must be in NYHA functional class III or IV heart failure, must have an LVEF of less than or equal to 30% (60-75% is typical for a healthy person) and meet certain additional eligibility criteria. All 24 patients will receive optimal medical therapy and 16 of the patients (8 ischemic and 8 non-ischemic) will also be treated with CRCs via catheter injection. The catheter trial will randomize patients in an approximate 2:1 ratio to the treatment vs. control group within each stratum. While the primary objective of this study is to assess the safety of CRCs delivered by catheter injection in patients with DCM, efficacy measures including heart failure stage and cardiac function parameters will also be assessed. Patients will be followed for 12 months post-treatment.

Vascular Tissue Regeneration

Critical Limb Ischemia — Background

PAD is a chronic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other clinical conditions, including hypertension, cardiovascular disease, hyperlipidemia, diabetes, obesity and stroke. The term CLI is used to describe patients with chronic ischemia-induced pain (even at rest), ulcers, tissue loss or gangrene in the limbs. CLI is the most severe form of PAD, and is typically the end stage of the disease. Patients suffering from this condition are critically ill, with a high risk of amputation. These patients are extremely limited in their ambulatory capacity, experience constant and chronic ischemia-induced pain, ulcers, tissue loss or gangrene to the limbs, which lead to approximately 160,000 amputations per year.

Laboratory observations have shown that TRC-based products have the ability to form small blood vessel-like structures *in vitro*. VRC treatment in both rat and mouse models of critical limb ischemia have shown evidence of angiogenesis and increased tissue perfusion, respectively. These preclinical observations support our current clinical-stage research at treatment centers in the U.S. and E.U. where we are exploring the use of VRC therapies to regenerate vascular tissue in patients with CLI.

The first evaluation of VRCs was conducted in a small clinical trial in Germany. Initial results from this study were reported in October 2007 at the 2nd Congress of the German Society for Stem Cell Research in Würzburg, Germany, by the study's Principal Investigator from the Heart & Diabetes Center in Bad Oeynhausen, Germany. This interim report provided 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. As presented, results reflect treatment experience from 4 diabetic patients with ischemia-related chronic tissue ulcers who were treated with VRCs, 7 patients who were treated with normal unexpanded marrow cells, and two standard-of-care patients who did not receive cells. All patients received wound care according to treatment standards outlined by the American Diabetes Association. Twelve months post-treatment, all patients in the interim analysis who were treated with VRCs reported no major amputations, no cell-related adverse events, and healing of all open wounds. Of the 7 patients treated with unexpanded bone marrow cells, 5 reported results similar to the VRC-treated patients 12 months post-treatment, 1 reported similar results to the VRC-treated patients 18 months post-treatment, and 1 patient underwent a major amputation. For the 2 standard-of-care patients who only received wound care (no cells), 1 patient received a major amputation and 1 patient experienced no improvement in wound healing after 12 months. Patient follow-up has been completed and final data are expected to be reported by the investigator.

Critical Limb Ischemia Trial

Following the interim clinical results from Germany, we initiated the RESTORE-CLI trial, a U.S. Phase IIb prospective, controlled, randomized, double-blind, multi-center clinical trial to treat patients suffering from CLI. This trial is designed to enroll up to 150 patients at up to 30 sites. Patients are randomized into two groups (treatment or placebo control) to evaluate the safety and efficacy of VRCs in the treatment of CLI. To date, 82 patients have been enrolled in the RESTORE-CLI trial and 18 clinical sites are open for patient enrollment. Patients will be followed for a period of 12 months post-treatment. In addition to assessing the safety of VRCs, secondary objectives

include the measurement of major amputation rates, the level of amputation, wound healing and blood flow in affected limbs, patient quality of life, pain scores and analgesic use.

In the fourth calendar quarter of 2009, data were unblinded for the subset of patients enrolled in the RESTORE-CLI trial (treatment and placebo control) who had completed at least 6 months of follow-up, including the first 30 patients who had completed the entire 12-month follow-up period. The analysis of these interim data is ongoing and conclusions from the interim results will be reported during the first quarter of calendar year 2010.

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.

We are not currently treating patients in the E.U.; however, through limited commercial use of TRC-based products, we are able to obtain a privileged regulatory position in some regions. In the E.U., 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 E.U. member states. However, the ATMP includes a grandfathering provision that allows products on the market in one or more E.U. member states on December 31, 2008 to remain on the market in those E.U. member states for a period of four years before EMEA market authorization must be obtained. With the activities completed to date in Germany, we believe TRC-based products meet the requirements for the ATMP transition period in this member state.

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

Results of Operations

Total revenues, consisting of product sales, for the quarter and six months ended December 31, 2009 were $16,000 and $89,000, respectively, compared to $28,000 and $55,000, respectively, for the same periods in fiscal year 2009. The fluctuations in product sales is due to the changes in volume of cell production sales for investigator-sponsored clinical trials in Spain and limited cell manufacturing supplies to a research institute in the U.S. At such time as we satisfy applicable

regulatory approval requirements, we expect the sales of our TRC cell-based products will constitute nearly all of our product sales revenues.

Total costs and expenses increased to $4,601,000 for the quarter ended December 31, 2009, compared to $4,180,000 for the quarter ended December 31, 2008.

Costs and expenses include an increase in research and development expenses to $3,283,000 for the quarter ended December 31, 2009 from $2,829,000 for the quarter ended December 31, 2008. This increase reflects continued expansion of our clinical development activities including the costs associated with recruitment and treatment of patients in our IMPACT-DCM clinical trial. Research and development expenses also included a non-cash charge relating to share-based compensation expense of $175,000 for the quarter ended December 31, 2009 compared to $174,000 for the quarter ended December 31, 2008.

Selling, general and administrative expenses decreased for the quarter ended December 31, 2009 to $1,316,000 from $1,333,000 for the quarter ended December 31, 2008. Selling, general and administrative expenses for the quarter ended December 31, 2009, included a non-cash charge relating to share-based compensation expense of $127,000 compared to $219,000 for the quarter ended December 31, 2008.

Total costs and expenses increased to $8,490,000 for the six months ended December 31, 2009, compared to $8,226,000 for the six months ended December 31, 2008.

Research and development expenses increased for the six months ended December 31, 2009 to $6,194,000 from $5,555,000 for the six months ended December 31, 2008. This increase reflects continued expansion of our clinical development activities including the costs associated with recruitment and treatment of patients in our IMPACT-DCM clinical trial. Research and development expenses also included a non-cash charge relating to stock-based compensation expense of $361,000 for the six months ended December 31, 2009 compared to $335,000 for the six months ended December 31, 2008.

Selling, general and administrative expenses decreased for the six months ended December 31, 2009 to $2,262,000 from $2,649,000 for the six months ended December 31, 2008. This decrease is primarily due to an offset of $279,000 to the stock compensation expense that was recorded in the first quarter of fiscal year 2010. This offset reversed previously recognized stock compensation expense for certain options held by George W. Dunbar that were forfeited when he stepped down as Chief Executive Officer, President and Chief Financial Officer on December 14, 2009, as these options were no longer expected to vest. Selling, general and administrative expenses for the six months ended December 31, 2009, included a non-cash charge relating to share-based compensation expense of $268,000 compared to $421,000 for the six months ended December 31, 2008.

Interest income was $21,000 and $49,000, respectively, for the quarter and six months ended December 31, 2009 compared to $69,000 and $196,000, respectively, for the same periods in fiscal 2009. 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 and lower interest rates.

Interest expense was $11,000 and $24,000, respectively, for the quarter and six months ended December 31, 2009 compared to $20,000 and $41,000, 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 $4,575,000, or $.03 per common share for the quarter ended December 31, 2009 compared to $4,103,000, or $.03 per common share for the quarter ended December 31, 2008. For the six months ended December 31, 2009, our net loss decreased to $8,376,000, or $.05 per common share compared to a net loss of $8,016,000, or $.06 per common share for the six months ended December 31, 2008.

Our major ongoing research and development programs are focused on the clinical development of TRC-based products, bone marrow-derived adult stem and early progenitor cells, for use in cardiac regeneration, as well as vascular regeneration. We have reprioritized our clinical development programs to focus on cardiovascular applications including our Phase II IMPACT-DCM (dilated cardiomyopathy) trial and our Phase IIb RESTORE-CLI (critical limb ischemia) trial. 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 and to decrease the cost of manufacturing our TRC-based products.

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to TRC-based products, estimating the completion dates or cost to complete our major research and development program would be highly speculative and subjective. The risks and uncertainties associated with developing our products, including significant and changing governmental regulation and the uncertainty of future clinical study results, are discussed in greater detail in the “Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products,” “Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations,” and “We must successfully complete our clinical trials to be able to market certain of our products” sections under the heading “Risk Factors” of this report. The potentially lengthy process of seeking regulatory approvals for our product candidates, and the subsequent compliance with applicable regulations, will require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We cannot be certain when any net cash inflow from products validated under our major research and development project, if any, will commence.

Liquidity and Capital Resources

We have financed our operations since inception primarily through public and private sales of our equity securities, which, from inception through December 31, 2009, have totaled approximately $219 million and, to a lesser degree, through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments, and funding under equipment leasing agreements. These financing sources have generally allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash and cash equivalents totaled $14,739,000 at December 31, 2009, a decrease of $2,261,000 from June 30, 2009. During the six months ended December 31, 2009, the primary source of cash and cash equivalents was from equity transactions, of which net proceeds of $5,100,000 were raised principally through sales of our equity securities pursuant to the June 2009 agreement with Fusion Capital. The primary uses of cash and cash equivalents during the six months ended December 31, 2009 included $7,206,000 to finance our operations and working capital requirements, and $56,000 in capital equipment additions. After the completion of our underwritten public offering of common stock and warrants in January 2010, our combined cash and cash equivalents at January 31, 2010 was approximately $25,500,000.

In our underwriting agreement with Oppenheimer & Co. Inc., we have agreed not to issue or sell any securities under our existing financing agreement with Fusion Capital or otherwise enter into any similar equity financing program with any third party for a period of 180 days from the date of the prospectus supplement (January 15, 2010) without the prior written consent of Oppenheimer & Co. Inc. However, pursuant to our financing agreement with Fusion Capital we are not able to put shares to Fusion Capital for purchase so long as our stock price is below $0.36.

Our monthly cash utilization has average approximately $1.2 million for the six months ended December 31, 2009. We expect our monthly cash utilization for the remainder of fiscal year 2010 to average approximately $1.4 million per month due to increased expenses to conduct our IMPACT-DCM clinical trial.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of possible acquisition or development of complementary business activities and the cost of product commercialization. We do not expect to generate a positive cash flow from operations for at least the next several years due to the expected spending for research and development programs and the cost of commercializing our product candidates. We intend to seek additional funding through research and development agreements or grants, distribution and marketing agreements and through public or private debt or equity financing transactions. Successful future operations are subject to several technical and risk factors, including our continued ability to obtain future funding, satisfactory product development, obtaining regulatory approval and market acceptance for our products. We expect that our available cash and expected interest income will be sufficient to finance current planned activities at least through December 31, 2010, in part due to the fact that many of our expenditures are discretionary in nature and could, if necessary, be delayed. These estimates are based on certain assumptions. See “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Forward Looking Statements” and “Item 1A. Risk Factors.” In order to grow and expand our business, to introduce our product candidates into the marketplace and to possibly acquire or develop complementary business activities, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. We expect that our primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of our equity or debt securities. There can be no assurance that

such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. Several factors will affect our ability to raise additional funding, including, but not limited to, market volatility of our common stock, continued stock market listing and economic conditions affecting the public markets generally or some portion or the entire technology sector. If our common stock is delisted from the NASDAQ Stock Market, the liquidity of our common stock could be impaired, and prices paid by investors to purchase our shares of our common stock could be lower than might otherwise prevail.

On January 21, 2010, we completed the sale of 52,077,100 units (including 5,923,100 units sold to the underwriter pursuant to the exercise of its over-allotment option) at a public offering price of $0.26 per unit. Each unit consisted of (i) one share of common stock, (ii) a Class A warrant to purchase 0.75 of a share of common stock at an exercise price of $0.3718 per share and (iii) a Class B warrant to purchase 0.50 of a share of common stock at an exercise price of $0.26 per share. We received approximately $12.4 million in net proceeds from the sale of the units (including the partially exercised option of the over-allotment), after underwriting discounts and commissions and other offering expenses.

The 52,077,100 units consist of an aggregate of 52,077,100 shares of our common stock, Class A Warrants to purchase an aggregate of 39,057,825 shares of common stock and Class B Warrants to purchase an aggregate of 26,038,550 shares of common stock. The Class A Warrants are exercisable for a five year period commencing on July 21, 2010. The Class B Warrants are exercisable at any time from January 21, 2010 through July 21, 2010.

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 “Item 1. Financial Statements — Notes to Consolidated Financial Statements” and “Item 1A. Risk Factors” in this Quarterly Report on Form 10-Q and “Notes to Consolidated Financial Statements” in our Annual Report on Form 10-K for the year ended June 30, 2009.

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 of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “trends,” “opportunity,” “comfortable,” “current,” “intention,” “position,” “assume,” “potential,” “outlook,” “remain,” “continue,” “maintain,” “sustain,” “seek,” “achieve,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “could,” “may,” or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. 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 “Item 1A. 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.

Among the factors about which we have made assumptions are:

- potential strategic collaborations with others;
- future capital needs;
- adequacy of existing capital to support operations for a specified time;
- the rate and degree of progress on our product development and marketing plans;
- the rate of regulatory approval to proceed with clinical trial programs and the success achieved in clinical trials;
- the requirements for marketing authorization from regulatory bodies in the U.S., E.U. and other countries;
- the liquidity and market volatility of our equity securities;
- regulatory and manufacturing requirements and uncertainties;
- technological developments by competitors;
- anticipation of future losses;
- replacement of manufacturing sources;
- commercialization plans; and
- revenue expectations and operating results.

For further information on factors which could impact us and the statements contained herein, see “Item 1A: Risk Factors.”

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2009, our cash and cash equivalents included money market securities, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio.

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

The Company conducted an evaluation, under the supervision and with the participation of management, including the Chief Executive Officer/Chief Financial Officer (“CEO”)/(“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, 2009 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 2010, there were no changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

On December 15, 2009, George W. Dunbar stepped down as President, Chief Executive Officer and Chief Financial Officer and Timothy M. Mayleben assumed these roles. Mr. Dunbar's resignation did not have a material effect on the Company's internal controls over financial reporting for the quarter ended December 31, 2009.

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

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, 2009, we have incurred a cumulative net loss totaling approximately $203 million, and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development (including clinical trials) of our cell culture technologies and our cell manufacturing system, general and administrative expenses, and the prosecution of patent applications. We expect to continue to incur significant operating losses over the next several years and at least until, and probably after, product sales increase, primarily owing to our research and development programs, including preclinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. We cannot predict with any certainty the amount of future losses. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, timely initiation and completion of clinical trials, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components, acquisition and development of complementary activities and raising sufficient cash to fund our operating activities. Therefore, we may not be able to achieve or sustain profitability.

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

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

As a result of the hearing that we had with the NASDAQ Hearing panel (the “Panel”) on November 12, 2009, we have until March 31, 2010 to regain compliance with the minimum bid price requirement of NASDAQ. If we are unable to gain compliance, our common stock will be delisted from NASDAQ.

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 before March 31, 2010, 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.

On December 14, 2009, we received approval from our shareholders to conduct a reverse stock split at any time within four months at the Board's discretion at a ratio between one for five and one for eight. On January 29, 2010, the our Board of Directors approved a one-for-eight reverse stock split of our common stock and for us to pursue an effective date of such reverse stock split during February 2010. As of February 9, 2010 (the date of this Form 10-Q), this reverse stock split is not yet effective. We intend to attempt to regain compliance with the NASDAQ bid price requirement by effecting this reverse stock split as soon as possible, however there can be no assurance that the reverse stock split will be successful in achieving sustained compliance with the minimum bid price requirement of NASDAQ.

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

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

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

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

In addition to our recent public offering underwritten by Oppenheimer & Co. Inc. and our existing financing program with Fusion Capital, under which we may put shares to Fusion Capital for purchase so long as our stock price is not less than $0.36 (subject to any adjustment in such stock price that may be required by the NASDAQ Capital Market or our other principal market at such time on account of any reverse stock split or otherwise), we will require substantial additional capital resources in order to conduct our operations and develop and commercialize our products and cell manufacturing facilities. In our underwriting agreement with Oppenheimer & Co. Inc., we have agreed not to issue or sell any securities under our existing financing agreement with Fusion Capital or otherwise enter into any similar equity financing program with any third party for a period

of 180 days from the date of the prospectus supplement (January 15, 2010) without the prior written consent of Oppenheimer & Co. Inc.

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.

On January 21, 2010, we completed the sale of 52,077,100 units (including 5,923,100 units sold to the underwriter pursuant to the exercise of its over-allotment option) at a public offering price of $0.26 per unit. Each unit consisted of (i) one share of common stock, (ii) a Class A warrant to purchase 0.75 of a share of common stock at an exercise price of $0.3718 per share and (iii) a Class B warrant to purchase 0.50 of a share of common stock at an exercise price of $0.26 per share. We received approximately $12.4 million in net proceeds from the sale of the units (including the partially exercised option of the over-allotment), after underwriting discounts and commissions and other offering expenses.

The 52,077,100 units consist of an aggregate of 52,077,100 shares of our common stock, Class A Warrants to purchase an aggregate of 39,057,825 shares of common stock and Class B Warrants to purchase an aggregate of 26,038,550 shares of common stock. The Class A Warrants are exercisable for a five year period commencing on July 21, 2010. The Class B Warrants are exercisable at any time from January 21, 2010 through July 21, 2010.

Substantial future sales of our common stock in the public market may depress our stock price.

As of February 2, 2010, there were 226,048,759 shares of our common stock outstanding. The market price of our common stock could drop due to sales of a large number of shares or the perception that such sales could occur. These factors also could make it more difficult to raise funds through future offerings of common stock or warrants.

The exercise of our outstanding options and warrants will dilute shareholders and could decrease our stock price.

The existence of our outstanding options and warrants, including any warrants to be issued pursuant to the public offering underwritten by Oppenheimer & Co. Inc.,may adversely affect our stock price due to sales of a large number of shares or the perception that such sales could occur. These factors also could make it more difficult to raise funds through future offerings of common stock or warrants, and could adversely impact the terms under which we could obtain additional equity capital. Exercise of outstanding options and warrants, or any future issuance of additional shares of common stock or other equity securities, including but not limited to options, warrants or other derivative securities convertible into our common stock, may result in significant dilution to our shareholders and may decrease our stock price.

There is no public market for the Class A warrants or Class B warrants in the public offering underwritten by Oppenheimer & Co. Inc.

There is no established public trading market for the Class A warrants or Class B warrants being offered in the public offering underwritten by Oppenheimer & Co. Inc. and we do not expect a market to develop. In addition, we do not intend to apply for listing the Class A warrants or Class B warrants on any securities exchange or other trading market. Without an active market, the liquidity of the Class A warrants and Class B warrants will be limited.

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

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

On December 15, 2009, George W. Dunbar stepped down as our President, Chief Executive officer and Chief Financial Officer and Timothy M. Mayleben assumed these roles. If we are unable to integrate our new leadership, our operations may be harmed.

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

We must obtain the approval of the FDA before commercial sales of our cell product candidates may commence in the U.S., which we believe will ultimately be the largest market for our products. We will also be required to obtain additional approvals from various foreign regulatory

authorities to initiate sales activities of cell products in those jurisdictions, including the E.U. under regulation of the EMEA. If we cannot demonstrate the safety and efficacy of our cell product candidates produced in our manufacturing system, we may not be able to obtain required regulatory approvals or the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

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

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

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

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

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

Germany had not required marketing authorization to distribute cultured expanded autologous tissue products for tissue regeneration when the newly revised law became effective. We

had introduced a product into the German market by that time and we fall under the “grandfathered” regulations.

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 E.U., 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 E.U., we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates. If our clinical trials are not successful, our products may not be marketable.

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

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

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

Failure of third parties to manufacture 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 BioLife and Invitrogen to manufacture and supply certain components, equipment, disposable devices and other materials used our cell manufacturing process to develop our TRC-based cell products.

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

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

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

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

We will be seeking to obtain regulatory approvals to market our TRC-based cell products for tissue repair and regeneration treatments. Even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be accepted in the marketplace at a level that would allow us to operate profitably. Our products may be unable to achieve commercial acceptance for a number of reasons, such as the availability of alternatives that are less expensive, more effective or easier to use; the perception of a low cost-benefit ratio for the product amongst

physicians and hospitals; or an inadequate level of product support from us or a commercial partner. Our technologies or product candidates may not be employed in all potential applications being investigated and any reduction in applications would limit the market acceptance of our technologies and product candidates and our potential revenues.

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

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

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

Some of the manufacturing materials and 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 E.U. 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 E.U.. 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 public offering underwritten by Oppenheimer & Co. Inc. and the transactions with Fusion Capital, to provide us with the capital to reach our objectives. We may enter into financing transactions at prices which are at a substantial discount to market. Such an equity issuance would cause a substantially larger number of shares to be outstanding and would dilute the ownership interest of existing shareholders.

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 $0.26 and $0.73 during the twelve month period ended December 31, 2009. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

- clinical trial results
- the amount of our cash resources and our ability to obtain additional funding
- announcements of research activities, business developments, technological innovations or new products by us or our competitors
- entering into or terminating strategic relationships
- changes in government regulation
- disputes concerning patents or proprietary rights
- changes in our revenues or expense levels

- public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing
- news or reports from other stem cell, cell therapy or regenerative medicine companies
- reports by securities analysts
- status of the investment markets
- concerns related to management transitions
- delisting from the NASDAQ Capital Market

Any of these events may cause the price of our shares to fall, which may adversely affect our business and financing opportunities. In addition, the stock market in general and the market prices for biotechnology companies in particular have experienced significant volatility 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. Currently, 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 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 that 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 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 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 or on 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 shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders. Michigan law contains provisions that make it more

difficult for a 10% shareholder and its affiliates to acquire a Michigan corporation. These provisions 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 us. 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.

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

On June 12, 2009, the Company entered into a $30.0 million common stock purchase agreement with Fusion Capital, an Illinois limited liability company. The terms of the arrangement with Fusion Capital are disclosed in the Company's Annual Report on Form 10-K for the year ended June 30, 2009 and there have been no changes to the terms of this arrangement during the quarter ended December 31, 2009.

During the quarter and six months ended December 31, 2009, 2,196,953 and 13,748,439 shares of the Company's common stock, respectively, including 64,538 and 411,467 shares issued as payment of the Company's commitment fee, respectively, were issued to Fusion Capital for net proceeds of $800,000 and $5,100,000, respectively. The Company has an effective registration statement covering the resale by Fusion Capital of all of these shares under the Securities Act of 1933, as amended.

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 the Company was held on December 14, 2009.

(b) At the 2009 Annual Meeting of Shareholders, votes were cast on matters submitted to the shareholders, as follows:

Proposal 1: As a result of shareholder approval of Proposal 1, the election of six directors to serve for one-year terms expiring at the 2010 Annual Meeting of Shareholders or until his successor shall have been elected and qualified.

NOMINEE	FOR	WITHHELD
George W. Dunbar	118,262,910	15,960,579
Timothy M. Mayleben	120,867,252	13,356,237
Alan L. Rubino	118,456,071	15,767,418
Nelson M. Sims	120,984,833	13,238,656
Harold C. Urschel, Jr.	121,419,197	12,804,292
Robert L. Zerbe	119,262,585	14,960,904

Proposal 2: Approval to amend the Company's Restated Articles of Incorporation, as amended, to increase the number of authorized shares of common stock from 250,000,000 to 500,000,000.

FOR	AGAINST	ABSTAIN
89,418,787	42,742,896	2,061,806

Proposal 3: Approval to grant discretionary authority to Aastrom's Board of Directors to amend the Company's Restated Articles of Incorporation, as amended, to effect a reverse stock split of Aastrom's authorized, issued and outstanding common stock at any time within four months after the date shareholder approval is obtained regarding the reverse stock split, at any whole number ratio between one for five and one for eight, with the exact exchange ratio and timing of the reverse stock split (if at all) to be determined at the discretion of the Board of Directors (the "Reverse Stock Split"). The Reverse Stock Split will not occur unless the Board of Directors determines that it is in the best interests of Aastrom and its shareholders to implement the Reverse Stock Split.

FOR	AGAINST	ABSTAIN
90,845,921	41,609,387	1,768,181

Proposal 4: Approval of the 2009 Omnibus Incentive Plan.

FOR	AGAINST	ABSTAIN	BROKER NON-VOTES
18,825,885	10,645,704	1,519,788	103,232,112

Proposal 5: Ratification of the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the year ending June 30, 2010.

FOR	AGAINST	ABSTAIN
123,351,860	5,358,848	5,512,780

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 9, 2010

/s/ Timothy M. Mayleben
Timothy M. Mayleben
President and Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
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 Drug Agency
Allogeneic	Originating from a human donor other than the patient receiving treatment (Aastrom does NOT use allogeneic cells).
ATMP — Advanced Therapy Medicinal Product	New medicinal 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)
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 extremities that causes severe pain, tissue loss or both.
Controlled Clinical Trial	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.

TERM	DEFINITION
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 dilation of the patient's heart reduces its function to a point that the normal circulation of blood cannot be maintained.
Double-Blind Clinical Trial	Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo.
EMEA — European Medicines Agency	European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products. The Agency provides the Member States and the institutions of the E.U. 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 E.U. legislation relating to medicinal products. EMEA is similar in function to the US FDA (see FDA below).
E.U. — European Union	The economic and political union of 27 member states, located primarily in Europe, for which the EMEA holds the medical regulatory power.
Ex vivo	Outside the body
FDA — Food and 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.

TERM	DEFINITION
GCP — Good Clinical Practice	GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.
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 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 surgical clinical trial evaluating the use of CRCs in the treatment of dilated cardiomyopathy.
IMPD — Investigational Medicinal Product Dossier	An IMPD is now required to accompany an application to perform clinical trials in any European Member State. It provides a summary of information on the quality of the product being evaluated in a clinical trial planned to occur in a European Member State, including reference products and placebos. It also provides data from non-clinical studies and available previous clinical experience with the use of the investigational medicinal product.
In vitro	In a laboratory dish or test tube; in an artificial environment
IND — Investigational New Drug	An application submitted to the FDA for a new drug or biologic that, if allowed, will be used in a clinical trial.
IRB — Institutional Review Board	A committee designated to formally approve, monitor, and review biomedical research at an institution involving humans. Institutional Review Boards aim to protect the rights and welfare of the research subjects. For Aastrom-sponsored clinical trials, IRB approval must be obtained at each individual clinical site in order for patient recruitment and treatment to commence at that site.
LVEF — Left Ventricular Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heart beat.
Open-label Clinical Trial	A trial in which both the treating physician and the patient know whether they are receiving the experimental treatment or control treatment.

TERM	DEFINITION
Orphan Drug Designation	"Orphan drug" refers to a drug or biologic that is intended for use in the treatment of a rare disease or condition. Orphan drug designation from the U.S. Food and Drug Association (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for developing the drug for a rare disease or condition. The drug must then go through the FDA marketing approval process like any other drug or biologic which evaluates for safety and efficacy. Usually a sponsor receives a quicker review time and lower application fees for an orphan product.
Phase 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 small 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 the duration of the clinical trial.
Randomized Clinical Trial	A clinical trial in which the participants are assigned randomly to treatment and control groups.
Somatic Cell	Any of the cells responsible for forming the body of an organism such as internal organs, bones, skin, connective tissues and blood.

TERM	DEFINITION
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 possess the ability to divide for indefinite periods in culture and may give rise to highly specialized cells.
TRC — Tissue Repair Cell	Aastrom's cell manufacturing process begins with the collection of a small aspirate (approximately 50 ml) of bone marrow from the patient's hip in an outpatient procedure. The sample of bone marrow is shipped to a manufacturing facility, and transferred into Aastrom's cell manufacturing system. In this fully automated, sterile process, the stem and progenitor cell populations present in the bone marrow are greatly expanded to yield cellular products based on Aastrom's Tissue Repair Cell (TRC) technology. The finished TRC-based product is shipped back to the physician who administers it to the original patient as an autologous cell therapy.
VRC — Vascular Repair Cell	Aastrom's proprietary Tissue Repair Cells for Vascular indications. (Also see TRC — Tissue Repair Cell)

Exhibit 31.1

CERTIFICATION

I, Timothy M. Mayleben, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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. I am 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 my 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 my 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 my 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. I have disclosed, based on my 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 9, 2010

/s/ Timothy M. Mayleben

Timothy M. Mayleben
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, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy M. Mayleben, 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 9, 2010

/s/ Timothy M. Mayleben
Timothy M. Mayleben
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.