

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 MARCH 31, 2010, OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number 0-22025

AASTROM BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction of incorporation or organization)

94-3096597

(I.R.S. employer identification no.)

24 Frank Lloyd Wright Dr.
P.O. Box 376
Ann Arbor, Michigan

(Address of principal executive offices)

48106

(Zip code)

(734) 930-5555

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes — No —

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes — No —

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

Large accelerated filer — Accelerated filer — Non-accelerated filer — Smaller reporting company —
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes — No —

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date.

COMMON STOCK, NO PAR VALUE
(Class)

28,255,889
Outstanding at May 4, 2010

AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
March 31, 2010

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I — FINANCIAL INFORMATION</u>	
<i>Item 1. Financial Statements — Unaudited</i>	
a) <u>Consolidated Condensed Balance Sheets as of June 30, 2009 and March 31, 2010</u>	3
b) <u>Consolidated Condensed Statements of Operations for the quarter and nine months ended March 31, 2009 and 2010 and for the period from March 24, 1989 (Inception) to March 31, 2010</u>	4
c) <u>Consolidated Condensed Statements of Cash Flows for the nine months ended March 31, 2009 and 2010 and for the period from March 24, 1989 (Inception) to March 31, 2010</u>	5
d) <u>Notes to Consolidated Condensed Financial Statements</u>	6
<i>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</i>	12
<i>Item 3. Quantitative and Qualitative Disclosures About Market Risk</i>	24
<i>Item 4. Controls and Procedures</i>	24
<u>PART II — OTHER INFORMATION</u>	
<i>Item 1. Legal Proceedings</i>	26
<i>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</i>	26
<i>Item 6. Exhibits</i>	26
<u>SIGNATURES</u>	27
<u>EXHIBIT INDEX</u>	28
<u>GLOSSARY</u>	29
<u>EX-31.1 Rule 13a-14(a)/15d-14(a) Certification</u>	
<u>EX-32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906</u>	

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	March 31, 2010
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 17,000	\$ 17,844
Short-term investments	—	5,000
Receivables, net	58	—
Inventory	1	—
Other current assets	732	591
Total current assets	<u>17,791</u>	<u>23,435</u>
PROPERTY AND EQUIPMENT, NET	1,485	1,134
Total assets	<u>\$ 19,276</u>	<u>\$ 24,569</u>
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 853	\$ 1,161
Accrued employee benefits	355	358
Current portion of long-term debt	479	291
Total current liabilities	<u>1,687</u>	<u>1,810</u>
LONG-TERM DEBT	305	137
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized — 31,250,000 and 62,500,000, respectively; shares issued and outstanding — 20,027,830 and 28,255,889, respectively	213,107	231,059
Deficit accumulated during the development stage	(195,823)	(208,437)
Total shareholders' equity	<u>17,284</u>	<u>22,622</u>
Total liabilities and shareholders' equity	<u>\$ 19,276</u>	<u>\$ 24,569</u>

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 March 31,		Nine months ended March 31,		March 24, 1989 (Inception) to March 31, 2010
	2009	2010	2009	2010	2010
REVENUES:					
Product sales and rentals	\$ 58	\$ —	\$ 113	\$ 89	\$ 1,850
Research and development agreements	—	—	—	—	2,105
Grants	—	—	—	—	9,657
Total revenues	<u>58</u>	<u>—</u>	<u>113</u>	<u>89</u>	<u>13,612</u>
COSTS AND EXPENSES:					
Cost of product sales and rentals	25	—	47	34	796
Cost of product sales and rentals — provision for obsolete and excess inventory	—	—	—	—	2,239
Research and development	2,785	2,845	8,340	9,039	157,147
Selling, general and administrative	1,260	1,418	3,909	3,680	72,338
Total costs and expenses	<u>4,070</u>	<u>4,263</u>	<u>12,296</u>	<u>12,753</u>	<u>232,520</u>
LOSS FROM OPERATIONS	<u>(4,012)</u>	<u>(4,263)</u>	<u>(12,183)</u>	<u>(12,664)</u>	<u>(218,908)</u>
OTHER INCOME (EXPENSE):					
Other income	—	—	—	—	1,249
Interest income	57	34	253	83	10,647
Interest expense	(17)	(9)	(58)	(33)	(457)
Other income	40	25	195	50	11,439
NET LOSS	<u>\$ (3,972)</u>	<u>\$ (4,238)</u>	<u>\$ (11,988)</u>	<u>\$ (12,614)</u>	<u>\$ (207,469)</u>
COMPUTATION OF NET LOSS PER SHARE APPLICABLE TO COMMON SHARES:					
NET LOSS	<u>\$ (3,972)</u>	<u>\$ (4,238)</u>	<u>\$ (11,988)</u>	<u>\$ (12,614)</u>	
NET LOSS PER SHARE (Basic and Diluted)	<u>\$ (.24)</u>	<u>\$ (.16)</u>	<u>\$ (.72)</u>	<u>\$ (.55)</u>	
Weighted average number of shares outstanding (Basic and Diluted)	<u>16,821</u>	<u>26,737</u>	<u>16,711</u>	<u>23,016</u>	

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)

	Nine months ended March 31,		March 24, 1989 (Inception) to March 31, 2010
	2009	2010	2010
OPERATING ACTIVITIES:			
Net loss	\$ (11,988)	\$ (12,614)	\$ (207,469)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	522	454	6,454
Loss on property held for resale	—	—	110
Amortization of discounts and premiums on investments	(30)	—	(1,704)
Stock compensation expense	1,129	426	8,815
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	(236)	58	(249)
Inventories	—	1	(2,335)
Other current assets	432	(66)	(500)
Accounts payable and accrued expenses	(23)	308	1,104
Accrued employee benefits	(392)	3	358
Net cash (used for) operating activities	<u>(10,586)</u>	<u>(11,430)</u>	<u>(189,673)</u>
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73)
Purchase of short-term investments	—	(5,000)	(217,041)
Maturities of short-term investments	6,000	—	213,745
Property and equipment purchases	(34)	(103)	(5,864)
Proceeds from sale of property held for resale	—	—	400
Net cash provided by (used for) investing activities	<u>5,966</u>	<u>(5,103)</u>	<u>(8,833)</u>
FINANCING ACTIVITIES:			
Net proceeds from issuance of preferred stock	—	—	51,647
Net proceeds from issuance of common stock and warrants	7,343	17,526	162,871
Repurchase of common stock	—	—	(49)
Payments received for stock purchase rights	—	—	3,500
Payments received under shareholder notes	—	—	31
Restricted cash used as compensating balance	192	207	(70)
Proceeds from long-term debt	—	—	751
Net cash provided by financing activities	<u>7,204</u>	<u>17,377</u>	<u>216,350</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,584	844	17,844
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	<u>16,492</u>	<u>17,000</u>	<u>—</u>
CASH AND CASH EQUIVALENTS AT END OF PERIOD	<u>\$ 19,076</u>	<u>\$ 17,844</u>	<u>\$ 17,844</u>

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” or “Aastrom”) was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. The Company operates its business in one reportable segment — research and product development 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 March 31, 2011, 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,

[Table of Contents](#)

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 nine months ended March 31, 2010, 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 SEC 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.

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

3. Fair Value Measurements

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

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

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

At March 31, 2010, the Company had \$17.8 million invested in three money market funds and \$5.0 million invested in certificates of deposit, that are included within the "Cash and cash equivalents" and "Short-term investments" lines on the balance sheet, respectively. Because there is an active market for shares of these money market funds and the certificates of deposit, the

[Table of Contents](#)

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 March 31, 2010 are measured at fair value.

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 nine months ended March 31, 2010, the Company granted 1,268,525 service-based options to purchase common stock. These options were granted with exercise prices equal to the closing price of the Company's stock on the grant date, vest over four years (other than non-employee director options which vest over one to three years) 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 nine months ended March 31, 2009 and 2010 was \$2.08 and \$1.54, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors were approximately \$75,000 and \$415,000 for the quarter and nine months ended March 31, 2010, respectively, compared to \$352,000 and \$1,060,000 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.

	Nine months ended March 31,	
	2009	2010
Stock Option Plans:		
Expected dividend rate	0%	0%
Expected stock price volatility	73%	70.2% - 72.8%
Risk free interest rate	2.1%	2.49% - 3.09%
Estimated forfeiture rate	10%	10%
Expected life (years)	6.6	5.5 - 6.25

Table of Contents

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

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at June 30, 2009	1,365,353	\$ 7.76		
Granted	1,268,525	\$ 2.33		
Exercised	—	—		\$ —
Forfeited or expired	(355,931)	\$ 9.58		
Outstanding at March 31, 2010	<u>2,277,947</u>	<u>\$ 4.45</u>	<u>8.4</u>	<u>\$ 58,000</u>
Exercisable at March 31, 2010	<u>715,046</u>	<u>\$ 7.88</u>	<u>6.5</u>	<u>\$ —</u>

As of March 31, 2010, there was approximately \$1,391,000 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 1.7 years.

Performance-Based Stock Options

There were no grants of performance-based stock options during the nine months ended March 31, 2010. There have been no changes to the terms of the performance-based stock options from those disclosed in our Annual Report on Form 10-K for the year ended June 30, 2009.

For the nine months ended March 31, 2010, management reviewed the progress toward the performance conditions necessary for these options to vest and concluded that it was not yet probable that the performance conditions of any of the tranches of options would be met and, accordingly, no compensation expense has been recorded.

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

<u>Options</u>	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at June 30, 2009	110,162	\$ 11.76		
Granted	—	—		
Exercised	—	—		
Forfeited or expired	(49,999)	\$ 11.24		
Outstanding at December 31, 2009	<u>60,163</u>	<u>\$ 12.19</u>	<u>6.6</u>	<u>\$ 0</u>

The aggregate estimated fair value of these awards that are outstanding as of March 31, 2010 is approximately \$493,000.

Restricted Stock Awards

[Table of Contents](#)

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 \$11,000 for the quarter and nine months ended March 31, 2010, respectively, compared to \$21,000 and \$69,000 for the same periods in fiscal year 2009.

A summary of the Company's restricted stock activity for the nine months ended March 31, 2010, is presented below:

Non-vested Restricted Shares	Shares	Weighted Average Grant Date Fair Value
Non-vested at June 30, 2009	12,515	\$ 5.92
Granted	—	—
Vested	(12,359)	\$ 5.86
Forfeited	—	—
Non-vested at March 31, 2010	<u>156</u>	<u>\$10.53</u>

As of March 31, 2010, there was approximately \$800 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 0.4 years.

4. 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 March 31, 2010.

During the nine months ended March 31, 2010, 1,718,538 shares of the Company's common stock (including 51,432 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of \$5,100,000.

On January 21, 2010, the Company also completed the sale of 6,509,637 units (including 740,387 units sold to the underwriter pursuant to the exercise of its over-allotment option) at a public offering price of \$2.08 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 \$2.97 per share and (iii) a Class B warrant to purchase 0.50 of a share of common stock at an exercise price of \$2.08 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 total fair market value of the warrants at the date of issuance was approximately \$4,375,000. This total fair market value was determined as a proportional amount of the gross proceeds received for the sale of the common stock, class A and class B warrants. The proportional amount for the warrants was determined through the use of the

[Table of Contents](#)

Black-Scholes option-pricing model and the common stock was determined using the market price of common stock on the sale date.

The 6,509,637 units consist of an aggregate of 6,509,637 shares of the Company's common stock, Class A Warrants to purchase an aggregate of 4,882,228 shares of common stock and Class B Warrants to purchase an aggregate of 3,254,818 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.

5. 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 March 31, 2009 and 2010 is approximately 2,555,000 and 11,215,000, respectively.

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 number 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. Nearly 400 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

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 TRCs 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 TRCs in the treatment of DCM.

The first U.S. patient was treated with TRCs in our Phase II IMPACT-DCM surgical clinical trial in November 2008. The trial was fully enrolled in January 2010 with 40 patients and the last patient was treated in March 2010. 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 the 6-month follow-up visits for all patients during the third quarter of calendar year 2010. We are planning to report interim analysis results 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 TRCs to treat DCM patients. Clinical site training for this trial was initiated during the fourth quarter of calendar year 2009, and we enrolled our first patient in April 2010.

Vascular Regeneration

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 safety and efficacy of TRCs in the treatment of patients with this severe, chronic disease compared with placebo; neither patients nor physicians know the treatment received during the study.

Table of Contents

In February 2010 a planned interim analysis was performed for this study on 46 patients having completed at least 6 months of the study. According to the interim analysis, the safety profile was similar between the treatment and placebo patients. Based on a composite efficacy endpoint assessing time to treatment failure (including major amputations, doubling of wound size and new gangrene), our autologous TRCs were more effective than placebo ($p < 0.05$). Other clinically meaningful endpoints (e.g., major amputation rate, complete wound healing) individually showed encouraging trends, but have not yet reached statistical significance at the interim analysis.

The interim analysis was planned to assess performance of TRCs and to help plan further studies. Based on the interim findings, we concluded enrollment of new patients in order to complete the study as soon as possible, and to begin planning and discussions with the FDA for pivotal clinical trials in CLI. The last patient enrolled in this trial was treated on March 23, 2010, for a total of 86 patients who will be followed for 12 months per protocol.

The TRC Technology Platform

TRCs are a cellular therapy 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.

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 means we start with the patient’s own cells, which are accepted by the patient’s immune system allowing the cells to differentiate and integrate into existing functional tissues and organs, and provide long-term engraftment and repair;
- **expanded**, resulting in significantly higher concentrations of stem and progenitor cells than occur naturally, especially for older patients; and,
- **a mixed population of cells**, which includes all of the most important cell types required for tissue regeneration and found in natural bone marrow and are required for tissue regeneration.

All TRC-based products are manufactured at centralized facilities. We have our primary cell processing 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. We are focused 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.

[Table of Contents](#)

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 March 31, 2010, we have accumulated a net loss of approximately \$207 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 TRCs for cardiac and vascular regeneration. Our TRC-based cell therapies have a 72-hour shelf-life which we believe provides additional flexibility in transport and scheduling treatment for patients.

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, TRC 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 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.

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.

Early clinical data in the treatment of DCM with TRCs was obtained from two DCM patients treated in 2007 at the University Hospital in Düsseldorf, Germany. These two patients showed 15-20% improvement in their left ventricular ejection fraction approximately 2 months after treatment with TRCs. One patient maintained this improvement after 7 months of follow-up; however, the other died due to natural causes after declining further medical treatment. These data provided supportive information 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 TRCs 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. TRCs, manufactured using our TRC technology, received Orphan Drug Designation from the 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.

Full IMPACT-DCM enrollment of 40 patients was completed in January 2010 with the final patient treated in March 2010 and with patients enrolled at 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 versus the control group within each stratum. All patients receive optimal medical therapy and patients in the treatment group are treated with TRCs 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 TRCs in patients with DCM (including the incidence of ectopy and arrhythmia as well as major adverse cardiac events),

Table of Contents

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 TRCs 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 TRCs to treat DCM patients. The first patient was enrolled into the trial in April 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 TRCs via catheter injection. The catheter trial will randomize patients in an approximate 2:1 ratio to the treatment versus control group within each ischemic/non-ischemic stratum. While the primary objective of this study is to assess the safety of TRCs 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

Peripheral Arterial Disease (PAD) is a chronic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other clinical conditions, including hypertension, cardiovascular disease, hyperlipidemia, diabetes, obesity and stroke. CLI is used to describe patients with the most severe forms of PAD: those with chronic ischemia-induced pain (even at rest), ulcers, tissue loss or gangrene in the limbs. CLI is typically the end stage of PAD 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*. TRC 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 where we are exploring the use of TRC therapies to regenerate vascular tissue in patients with CLI.

[Table of Contents](#)

Initial results from the first clinical trial of TRCs in CLI were reported in October 2007. The trial examined the safety of TRCs and unexpanded bone marrow cells relative to standard of care in treatment of chronic diabetic foot wounds. Initial results from 13 patients after 12 month follow-up indicated similar safety profiles, with no cell-related adverse events reported. No major amputations were reported in the TRC group (N=4), one in the unexpanded bone marrow cell group (N=7), and one in the standard of care group (N=2). Patients in the TRC group and in the unexpanded bone marrow group reported healing of all open wounds; this was not observed in the standard of care group.

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 evaluate the safety and efficacy of TRCs in the treatment of CLI. Patients are being followed for a period of 12 months post-treatment. In addition to assessing the safety of TRCs, secondary endpoints include the measurement of time to treatment failure, major amputation rates, level of amputation, complete wound healing, blood flow in affected limbs, patient quality of life, pain scores and analgesic use.

In February 2010 a planned interim analysis was performed for this study on 46 patients having completed at least 6 months of the study. We reported the safety profile was similar between the treatment and control patients. Importantly, we reported that our autologous TRCs were more effective than placebo ($p \geq .0090$), based on a composite efficacy endpoint assessing time to treatment failure (including major amputations, doubling of wound size or new gangrene). Other clinically meaningful endpoints (e.g., major amputation rate, complete wound healing) individually showed encouraging trends, but have not yet reached statistical significance at the interim analysis.

The interim analysis was planned to assess performance of TRCs in the CLI patient population and to help plan further studies. Based on the interim findings, we concluded enrollment of new patients in February 2010 in order to complete the study as rapidly as possible, and to begin

planning and discussions with the FDA for pivotal clinical trials in CLI. The last patient enrolled in this trial was treated on March 23, 2010.

Results of Operations

Total revenues, consisting of product sales, for the quarter and nine months ended March 31, 2010 were \$0 and \$89,000, respectively, compared to \$58,000 and \$113,000, 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 \$4,263,000 for the quarter ended March 31, 2010, compared to \$4,070,000 for the quarter ended March 31, 2009.

Costs and expenses include an increase in research and development expenses to \$2,845,000 for the quarter ended March 31, 2010 from \$2,785,000 for the quarter ended March 31, 2009. 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 \$146,000 for the quarter ended March 31, 2010 compared to \$100,000 for the quarter ended March 31, 2009. A reversal of \$171,000 was recorded for the quarter ended March 31, 2010, in share-based compensation expense for certain stock options no longer expected to vest related to employee terminations and forfeitures.

Selling, general and administrative expenses increased for the quarter ended March 31, 2010 to \$1,418,000 from \$1,260,000 for the quarter ended March 31, 2009. This increase is primarily the result of increased legal fees and contract services. Selling, general and administrative expenses for the quarter ended March 31, 2010, included a non-cash charge relating to share-based compensation expense of \$225,000 compared to \$273,000 for the quarter ended March 31, 2009. A reversal of \$125,000 was recorded for the quarter ended March 31, 2010, in share-based compensation expense for certain stock options no longer expected to vest related to employee terminations and forfeitures.

Total costs and expenses increased to \$12,753,000 for the nine months ended March 31, 2010, compared to \$12,296,000 for the nine months ended March 31, 2009.

Research and development expenses increased for the nine months ended March 31, 2010 to \$9,039,000 from \$8,340,000 for the nine months ended March 31, 2009. 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 \$506,000 for the nine months ended March 31, 2010 compared to \$435,000 for the nine months ended March 31, 2009. A reversal of \$125,000 was recorded for the nine months ended March 31, 2010, in share-based compensation expense for certain stock options no longer expected to vest related to employee terminations and forfeitures.

[Table of Contents](#)

Selling, general and administrative expenses decreased for the nine months ended March 31, 2010 to \$3,680,000 from \$3,909,000 for the nine months ended March 31, 2009. This decrease is primarily due to an offset of \$404,000 in share-based compensation expense recorded for certain stock options no longer expected to vest related to employee terminations and forfeitures. Selling, general and administrative expenses for the nine months ended March 31, 2010, included a non-cash charge relating to share-based compensation expense of \$494,000 compared to \$694,000 for the nine months ended March 31, 2009.

Interest income was \$34,000 and \$83,000, respectively, for the quarter and nine months ended March 31, 2010 compared to \$57,000 and \$253,000, 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 \$9,000 and \$33,000, respectively, for the quarter and nine months ended March 31, 2010 compared to \$17,000 and \$58,000, respectively, for the same periods in fiscal 2009. Interest expense is related to the secured loan with Key Equipment Finance Inc.

Our net loss was \$4,238,000, or \$.16 per common share for the quarter ended March 31, 2010 compared to \$3,972,000, or \$.24 per common share for the quarter ended March 31, 2009. For the nine months ended March 31, 2010, our net loss increased to \$12,614,000, or \$.55 per common share compared to a net loss of \$11,988,000, or \$.72 per common share for the nine months ended March 31, 2009.

On April 27, 2010, Moll Industries, a supplier of the cell culture cassettes used in the production of TRC-based products, filed for bankruptcy protection in a Delaware court. Although we believe we have adequate supplies of these materials for our anticipated uses, there can be no assurance that we will be able to continue our present arrangements with Moll or, if necessary, establish new relationships on the same or similar terms as we have with Moll. Although we anticipate that the cell culture cassettes will be able to be manufactured for us on the same or similar terms as Moll is currently providing, any increase in the cost of these cassettes could increase our research and development expense which may have a material adverse affect on our business, financial condition and results of operations. See Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended June 30, 2009.

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" in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended June 30, 2009. The potentially lengthy process of seeking regulatory approvals for our

[Table of Contents](#)

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 March 31, 2010, have totaled approximately \$231 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 and short-term investments totaled \$22,844,000 at March 31, 2010, an increase of \$5,844,000 from June 30, 2009. During the nine months ended March 31, 2010, the primary source of cash and cash equivalents was from equity transactions, of which net proceeds of \$17,500,000 were raised through sales of our equity securities pursuant to the June 2009 agreement with Fusion Capital and an underwritten public offering of public offering of our common stock and warrants. The primary uses of cash and cash equivalents during the nine months ended March 31, 2010 included \$11,430,000 to finance our operations and working capital requirements, and \$103,000 in capital equipment additions. Our combined cash and cash equivalents at April 30, 2010 was approximately \$21,556,000.

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. 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 \$2.88.

Our monthly cash utilization has average approximately \$1.3 million for the nine months ended March 31, 2010. 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

Table of Contents

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 March 31, 2011, 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 “Results of Operations” above. 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 6,509,637 units (including 740,387 units sold to the underwriter pursuant to the exercise of its over-allotment option) at a public offering price of \$2.08 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 \$2.9744 per share and (iii) a Class B warrant to purchase 0.50 of a share of common stock at an exercise price of \$2.08 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 6,509,637 units consist of an aggregate of 6,509,637 shares of our common stock, Class A Warrants to purchase an aggregate of 4,882,228 shares of common stock and Class B Warrants to purchase an aggregate of 3,254,818 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 Part I, Item 1. “Financial Statements — Notes to Consolidated Financial Statements” 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.

Off-Balance Sheet Arrangements

At March 31, 2010, we were not party to any off-balance sheet arrangements.

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. The factors described in Part I, Item 1A, “Risk Factors,” in our Annual Report on Form 10-K for the year-ended June 30, 2009 Such factors, among others, could have a material adverse effect upon our business, results of operations and financial conditions.

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation, unless required by law, 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 and expected cash flows;
- 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;
- enrollment in and results of our 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;
- the continued listing of our securities on the NASDAQ Capital Market;
- regulatory and manufacturing requirements and uncertainties;
- technological developments by competitors;
- anticipation of future losses;

[Table of Contents](#)

- replacement of manufacturing sources;
- our products and commercialization plans; and
- revenue expectations and operating results.

For further information on factors which could impact us and the statements contained herein, see Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended June 30, 2009.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

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 March 31, 2010 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.

[Table of Contents](#)

Changes in Internal Control over Financial Reporting

During our third 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.

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 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 March 31, 2010.

The Company did not issue any unregistered securities during the three months ended March 31, 2010. During the nine months ended March 31, 2010, 1,769,970 shares of the Company's common stock, including 51,432 shares issued as payment of the Company's commitment fee were issued to Fusion Capital for net proceeds of \$5,100,000. 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 6. Exhibits

The Exhibits listed in the Exhibit Index immediately following the Signatures, are filed as a part of this Quarterly Report on Form 10-Q.

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: May 10, 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

<u>Exhibit Number</u>	<u>Description</u>
4.1	Class A Warrant Agreement, dated as of January 21, 2010, by and between the Registrant and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on January 27, 2010)
4.2	Class B Warrant Agreement dated as of January 21, 2010, by and between the Registrant and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on January 27, 2010)
10.1	Underwriting Agreement, dated as of January 15, 2010, and between the Registrant and Oppenheimer & Co. Inc. (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on January 15, 2010)
31.1	Rule 13a-14(a)/15d-14(a) Certification (furnished herewith)
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)

GLOSSARY

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.

Table of Contents

<u>TERM</u>	<u>DEFINITION</u>
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.
EMA — 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. EMA 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 EMA holds the medical regulatory power.
<i>Ex vivo</i>	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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.
<i>In vitro</i>	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.

[Table of Contents](#)

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.

[Table of Contents](#)

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	<p>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.</p> <p>In culture, these undifferentiated cells possess the ability to divide for indefinite periods in culture and may give rise to highly specialized cells.</p>
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)

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;
 - (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;
 - (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; and
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: May 10, 2010

/s/ Timothy M. Mayleben

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

**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 March 31, 2010, 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.

May 10, 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.