

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, 2007, 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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or smaller reporting company (as defined 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)

132,804,839
Outstanding at February 1, 2008

AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
December 31, 2007

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I — FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Financial Statements — Unaudited</u>
a)	<u>Consolidated Condensed Balance Sheets as of June 30, 2007 and December 31, 2007</u>
b)	<u>Consolidated Condensed Statements of Operations for the three and six months ended December 31, 2006 and 2007 and for the period from March 24, 1989 (Inception) to December 31, 2007</u>
c)	<u>Consolidated Condensed Statements of Cash Flows for the six months ended December 31, 2006 and 2007 and for the period from March 24, 1989 (Inception) to December 31, 2007</u>
d)	<u>Notes to Consolidated Condensed Financial Statements</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>
<u>PART II — OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>
<u>Item 1A.</u>	<u>Risk Factors</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>
<u>Item 5.</u>	<u>Other Information</u>
<u>Item 6.</u>	<u>Exhibits</u>
<u>SIGNATURES</u>	
<u>EXHIBIT INDEX</u>	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	
<u>EXHIBIT 32.2</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, 2007	December 31, 2007
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 13,439	\$ 16,259
Short-term investments	14,886	14,930
Receivables, net	78	107
Inventories	8	—
Other current assets	1,766	2,135
Total current assets	<u>30,177</u>	<u>33,431</u>
PROPERTY AND EQUIPMENT, NET	<u>2,671</u>	<u>2,464</u>
Total assets	<u>\$ 32,848</u>	<u>\$ 35,895</u>
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 1,823	\$ 916
Accrued employee benefits	1,238	809
Current portion of long-term debt	439	431
Total current liabilities	<u>3,500</u>	<u>2,156</u>
LONG-TERM DEBT	1,097	1,011
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized — 250,000,000; shares issued and outstanding — 120,012,869 and 132,791,284, respectively	187,995	202,694
Deficit accumulated during the development stage	(159,744)	(169,966)
Total shareholders' equity	<u>28,251</u>	<u>32,728</u>
Total liabilities and shareholders' equity	<u>\$ 32,848</u>	<u>\$ 35,895</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)

	Three months ended December 31,		Six months ended December 31,		March 24, 1989 (Inception) to December 31, 2007
	2006	2007	2006	2007	
REVENUES:					
Product sales and rentals	\$ 6	\$ 24	\$ 18	\$ 36	\$ 1,407
Research and development agreements	—	—	—	—	2,105
Grants	152	60	244	135	9,478
Total revenues	<u>158</u>	<u>84</u>	<u>262</u>	<u>171</u>	<u>12,990</u>
COSTS AND EXPENSES:					
Cost of product sales and rentals	3	1	3	1	595
Cost of product sales and rentals - - provision for obsolete and excess inventory	—	—	—	—	2,239
Research and development	2,563	3,895	4,867	7,768	129,338
Selling, general and administrative	2,332	1,725	4,716	3,339	60,611
Total costs and expenses	<u>4,898</u>	<u>5,621</u>	<u>9,586</u>	<u>11,108</u>	<u>192,783</u>
LOSS FROM OPERATIONS	<u>(4,740)</u>	<u>(5,537)</u>	<u>(9,324)</u>	<u>(10,937)</u>	<u>(179,793)</u>
OTHER INCOME (EXPENSE):					
Other income	—	—	—	—	1,249
Interest income	515	386	1,042	751	9,849
Interest expense	—	(21)	—	(36)	(303)
Other income	<u>515</u>	<u>365</u>	<u>1,042</u>	<u>715</u>	<u>10,795</u>
NET LOSS	<u>\$ (4,225)</u>	<u>\$ (5,172)</u>	<u>\$ (8,282)</u>	<u>\$ (10,222)</u>	<u>\$ (168,998)</u>
COMPUTATION OF NET LOSS PER SHARE APPLICABLE TO COMMON SHARES:					
NET LOSS	<u>\$ (4,225)</u>	<u>\$ (5,172)</u>	<u>\$ (8,282)</u>	<u>\$ (10,222)</u>	
NET LOSS PER SHARE (Basic and Diluted)	<u>\$ (.04)</u>	<u>\$ (.04)</u>	<u>\$ (.07)</u>	<u>\$ (.08)</u>	
Weighted average number of shares outstanding (Basic and Diluted)	<u>119,516</u>	<u>130,467</u>	<u>119,347</u>	<u>125,537</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)

	Six months ended December 31,		March 24, 1989 (Inception) to December 31, 2007
	2006	2007	2007
OPERATING ACTIVITIES:			
Net loss	\$ (8,282)	\$ (10,222)	\$ (168,998)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	205	370	4,934
Loss on property held for resale	—	—	110
Amortization of discounts and premiums on investments	(277)	(292)	(1,585)
Stock compensation expense	1,445	1,107	6,531
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	18	(29)	(356)
Inventories	(11)	8	(2,335)
Other current assets	10	(487)	(1,455)
Accounts payable and accrued expenses	(164)	(858)	859
Accrued employee benefits	(58)	(429)	809
Net cash used for operating activities	<u>(7,114)</u>	<u>(10,832)</u>	<u>(155,743)</u>
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73)
Purchase of short-term investments	(29,593)	(24,752)	(206,090)
Maturities of short-term investments	41,500	25,000	192,745
Property and equipment purchases	(266)	(163)	(5,674)
Proceeds from sale of property held for resale	—	—	400
Net cash provided by (used for) investing activities	<u>11,641</u>	<u>85</u>	<u>(18,692)</u>
FINANCING ACTIVITIES:			
Net proceeds from issuance of preferred stock	—	—	51,647
Net proceeds from issuance of common stock and warrants	418	13,592	136,790
Repurchase of common stock	—	—	(49)
Payments received for stock purchase rights	—	—	3,500
Payments received under shareholder notes	—	—	31
Restricted cash used as compensating balance	—	118	(659)
Proceeds from long-term debt	—	—	751
Principal payments under long-term obligations	—	(143)	(1,317)
Net cash provided by financing activities	<u>418</u>	<u>13,567</u>	<u>190,694</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	4,945	2,820	16,259
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	<u>9,034</u>	<u>13,439</u>	<u>—</u>
CASH AND CASH EQUIVALENTS AT END OF PERIOD	<u>\$ 13,979</u>	<u>\$ 16,259</u>	<u>\$ 16,259</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

Astrom Biosciences, Inc. was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the clinical development stage. The Company operates its business in one reportable segment — research and product development involving the development of autologous cell products for use in regenerative medicine.

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

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. The Company will need to raise additional funds or pursue strategic transactions in order to complete its product development programs, complete clinical trials needed to market its products, and commercialize these products. If the Company decides to pursue additional financing, it cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and its overall success include: the rate and degree of progress for its product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the U.S., EU and other countries, the liquidity and market volatility of the Company's equity securities, the overall economic environment, 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, enhance or commercialize products, take advantage of future opportunities, including possible acquisition or development of complementary business activities, 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. The Company does not expect to generate positive cash flows from its consolidated operations for at least the next several years and then only if significant TRC-based cell product sales commence.

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 three and six months ended December 31, 2007, are not necessarily indicative of the results to be expected for the full year or for any other period.

These financial statements should be read in conjunction with the audited financial statements and the notes thereto included in the Company's 2007 Annual Report on Form 10-K for the year ended June 30, 2007, as filed with the Securities and Exchange Commission.

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

3. Share-Based Compensation

Service-Based Options

During the six months ended December 31, 2007, the Company granted 2,635,900 service-based options to purchase common stock. These were granted with exercise prices equal to the fair value of the Company's stock at the grant date, vest over four years (other than non-employee director options which vest over one year) and have lives of 10 years. 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, 2006 and 2007 was \$1.36 and \$0.67, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors were approximately \$538,000 and \$1,054,000 for the three and six months ended December 31, 2007, respectively, compared to \$487,000 and \$1,311,000 for the same periods in fiscal year 2007.

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,	
	2006	2007
Stock Option Plans:		
Expected dividend rate	0%	0%
Expected stock price volatility	67%	61%
Risk free interest rate	4.9%	4.2%
Estimated forfeiture rate	10%	10%
Expected life (years)	6.6	6.6

[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, 2007	8,357,536	\$ 1.46		
Granted	2,635,900	\$ 1.05		
Exercised	—	—		\$ —
Forfeited or expired	(457,050)	\$ 1.52		
Outstanding at December 31, 2007	<u>10,536,386</u>	<u>\$ 1.36</u>	<u>7.9</u>	<u>\$ 25,000</u>
Exercisable at December 31, 2007	<u>4,479,219</u>	<u>\$ 1.56</u>	<u>6.3</u>	<u>\$ 25,000</u>

As of December 31, 2007 there was approximately \$2,184,000 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 3.1 years.

Performance-Based Stock Options

During the six months ended December 31, 2007, the Board of Directors granted 69,400 performance-based stock options to a key employee in three equal tranches of 23,133 options. The weighted average grant-date fair value of performance-based options granted under the Company's Option Plans during the six months ended December 31, 2007 was \$0.67. These performance options have a 10 year life and an exercise price that exceeded the fair value of the Company's common stock at the grant date. Vesting of these performance options is dependent on (i) the passage of time subsequent to the grant date and (ii) meeting certain performance conditions, which relate to the Company's progress in its clinical trial programs, which were established by the Board of Directors. The Board of Directors will determine if the performance conditions have been met. Stock-based compensation expense for these options will be recorded when the Company believes that the vesting of these options is probable based on the progress of its clinical trial programs and other relevant factors.

As of December 31, 2007, there are 2,549,800 performance-based options outstanding. There are three tranches of performance-based options that vest upon the satisfaction of performance conditions, all of which vest based on progress toward clinical trial or product successes within a certain timeframe.

For the six months ended December 31, 2007, 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.

Table of Contents

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, 2007	2,480,400	\$ 1.50		
Granted	69,400	\$ 1.53		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at December 31, 2007	<u>2,549,800</u>	<u>\$ 1.50</u>	<u>8.8</u>	<u>\$ 0</u>

The aggregate estimated fair value of these awards that are outstanding as of December 31, 2007 is approximately \$2,542,000.

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 \$20,000 and \$54,000 for the three and six months ended December 31, 2007, respectively, compared to \$47,000 and \$131,000 for the same periods in fiscal year 2007.

A summary of the Company's restricted stock activity for the six months ended December 31, 2007 is presented below:

<u>Non-vested Restricted Shares</u>	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Non-vested at June 30, 2007	220,063	\$2.19
Granted	—	—
Vested	(63,380)	\$2.19
Forfeited	(14,925)	\$2.38
Non-vested at December 31, 2007	<u>141,758</u>	<u>\$2.16</u>

As of December 31, 2007 there was approximately \$87,000 of total unrecognized compensation cost related to non-vested restricted stock awards granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 2.0 years.

4. Shareholders' Equity

During the six months ended December 31, 2007, the Company issued 142,411 shares of common stock as part of the Direct Stock Purchase Plan and 808,824 shares of common stock in connection with the exercise of certain warrants previously issued to investors, for cash proceeds of \$1,160,000. The Company also closed its previously announced registered direct offering of

Table of Contents

11,842,105 shares of common stock and warrants to purchase up to 5,921,053 shares of common stock to certain institutional investors at a price of \$1.14 per unit, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock at an exercise price of \$1.5875 per share of common stock. The net cash proceeds, after deducting the placement agent's fee and other offering expenses, were approximately \$12,432,000. The estimated fair market value of the warrants at the date of issuance was \$2,698,000. This value was calculated using the Black-Scholes option-pricing model.

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 nonvested restricted shares of common stock, are not included in the per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares that have been excluded from the computations of net loss per common shares as of December 31, 2006 and 2007 is approximately 16,318,000 and 23,388,000, respectively.

6. Recent Accounting Pronouncement

In December 2007, the FASB issued Statement No. 141 (revised), *Business Combinations* (SFAS No. 141(R)). The standard changes the accounting for business combinations including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for pre-acquisition gain and loss contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company is currently assessing the impact of the pending adoption of FAS 141(R) on the accounting and financial statements for any potential future business combinations entered into by the Company.

In June 2007, the FASB ratified Emerging Issues Task Force (EITF) 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The Company is currently assessing the impact of the pending adoption of EITF 07-3 on its results of operations and financial condition.

In December 2007, the SEC issued Staff Accounting Bulletin No. 110, *Year-End Help for Expensing Employee Stock Option* (SAB 110). SAB 110 states that the SEC will continue to accept, under certain circumstances, when a company elects to use the "simplified" method after December 31, 2007 for determining expected term for "plain vanilla" share option grants in accordance with SFAS 123(R) *Share-Based Payment*. SAB 110 updates guidance provided in SAB 107 *Share-Based Payment*, that previously stated that the Staff would not expect a company to use the simplified method for share option grants after December 31, 2007. The Company is currently assessing the impact of SAB 110 on its share options and other items on its financial statements.

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

Overview of Aastrom

We are a regenerative medicine company (*a medical area that focuses on developing therapies that regenerate damaged or diseased tissues or organs*) focused on the clinical development of autologous cell products (*cells collected from a patient and returned to that same patient*) for the repair or regeneration of multiple human tissues, based on our proprietary Tissue Repair Cell (TRC) technology. Our preclinical and clinical product development programs utilize patient-derived bone marrow stem and early progenitor cell populations, and are being investigated for their ability to aid in the regeneration of tissues such as vascular, bone, cardiac and neural. TRC-based products have been used in over 250 patients, and are currently in the following stages of development:

- Vascular regeneration — Vascular Repair Cells (VRCs):
 - Critical limb ischemia:
 - U.S.: RESTORE-CLI Phase IIb clinical trial enrolling patients
 - Germany: Phase I/II clinical trial enrolling patients; positive interim data reported in October 2007
- Bone regeneration — Bone Repair Cells (BRCs):
 - Osteonecrosis of the femoral head:
 - U.S.: ON-CORE Phase III clinical trial enrolling patients; Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head
 - Spain: Pivotal clinical trial enrolling patients
 - Non-union fractures:
 - U.S.: Positive final patient results from Phase I/II clinical trial reported in October 2007
- Cardiac regeneration — Cardiac Repair Cells (CRCs):
 - Chronic heart disease:
 - Compassionate-use, clinical treatments underway in Europe
 - Orphan Drug Designation from the FDA for use in the treatment of dilated cardiomyopathy, a severe chronic disease of the heart
 - Clinical trial program under development
- Neural regeneration — Neural Repair Cells (NRCs):
 - Spinal cord injury:
 - Preclinical research underway; clinical program under development

Our platform TRC technology is based on:

- Autologous cell products which are a unique cell mixture containing large numbers of stem and early progenitor cells produced outside of the body from a small amount of bone marrow taken from the patient, and
- The means to produce these products in an automated process.

Table of Contents

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

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

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf. Our initial business plan was to pursue our targeted markets by commercializing our cell manufacturing system and supplies. Since that time we have phased out our marketing efforts promoting the cell manufacturing system as a commercial product. Currently, we have product sales consisting of limited sales of manufacturing supplies to academic collaborators for research and limited revenue related to cell-based products.

Our current focus is on utilizing our TRC technology to produce autologous cell-based products for use in regenerative medicine. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC-based products to constitute nearly all of our product sales revenues.

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

We are beginning to explore the possibility of entering into complementary regenerative medicine business activities, whether through acquisition or otherwise.

We expect that we will need to raise additional funds or pursue strategic transactions or other strategic alternatives in order to complete our product development programs, complete clinical trials needed to market our products, and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue obtaining required capital in a similar manner. As a development stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. With respect to our current activities, this is not likely to occur until we obtain significant additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through December 31, 2007, we have accumulated a net loss of approximately \$169 million. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

Clinical Development

Currently, our active clinical development programs are focused on the utilization of our TRC technology in cardiac regeneration, as well as vascular and bone regeneration, and we anticipate beginning clinical activities in the neural regeneration therapeutic area during fiscal year 2008.

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

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

Clinical Trials Summary

Vascular Tissue Regeneration

Critical Limb Ischemia:

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

In April 2007, we initiated patient enrollment in our RESTORE-CLI trial, a U.S. Phase IIb prospective, controlled, randomized, double-blind, multi-center clinical trial to treat patients suffering from critical limb ischemia, the end stage of peripheral arterial disease. This study is expected to enroll 120 patients at up to 20 sites, randomized into two patient groups, to evaluate the safety and efficacy of VRCs in the treatment of critical limb ischemia. Currently, 15 clinical sites have been initiated, and our website will be updated as sites are open for patient enrollment. Patients will be followed for a period of twelve months post-treatment. In addition to assessing the safety of the VRCs, secondary objectives include assessing major amputation rates, wound healing and blood flow in the affected limbs, patient quality of life, pain scores and analgesic use. Patient enrollment began in June 2007, when the first patient was randomized and treated.

[Table of Contents](#)

In October 2007, positive interim results from the first 13 patients treated in a multi-arm Phase I/II single-center clinical trial to evaluate the safety of VRCs and normal bone marrow cells in the treatment of chronic diabetic foot wounds associated with CLI were reported by an investigator from the Heart & Diabetes Center located in Bad Oeynhausen, Germany at the 2nd Congress of the German Society for Stem Cell Research in Würzburg, Germany. Results reflect treatment experience from: four diabetic patients with ischemia-related chronic tissue ulcers who were treated with our VRCs; seven patients who were treated with normal bone marrow cells; and two standard of care patients who received no cells. All patients received standard wound care as described by the American Diabetes Association. Twelve months post-treatment, all patients in the interim analysis who were treated with VRCs reported no major amputations, no cell-related adverse events, and healing of all open wounds. Of the seven patients treated with normal bone marrow cells, five reported results similar to the VRC-treated patients 12 months post-treatment, one reported similar results to the VRC-treated patients 18 months post-treatment, and one patient received a major amputation. For the two standard of care patients who only received wound care (no cells), one patient received a major amputation and one patient experienced no improvement in wound healing after 12 months. Patient accrual is ongoing.

Bone Regeneration

Osteonecrosis of the Femoral Head:

In October 2007, early clinical results from four compassionate use patients were presented by an investigator from the Orthopaedic Institute, König-Ludwig-Haus, University of Würzburg, Germany, involving the first use of our BRCs to treat patients suffering from osteonecrosis of the femoral head. Osteonecrosis of the femoral head involves the death of cells in the bone and marrow within the femur head and in many cases leads to total hip replacement. All patients tolerated the procedure well, have reported a reduction in hip pain with no signs of disease progression (as determined by MRI and X-ray) and were back to work within 6 months after treatment. In addition, no cell-related adverse events were reported and none of these patients have required hip replacement surgery.

In May 2007, the FDA approved our Investigational New Drug (IND) application which allowed us to proceed with our ON-CORE trial, a U.S. Phase III clinical trial, to use our Bone Repair Cells (BRCs) based on our TRC technology in the treatment of osteonecrosis (also known as avascular necrosis) of the femoral head. Currently, five clinical sites have been initiated, and our website will be updated as sites are open for patient enrollment. This trial will seek to enroll 120 patients, randomized into two patient groups, at up to 20 clinical sites. The primary efficacy variable of this trial is to delay disease progression to a more severe stage in patients treated with BRCs by at least 24 months post-treatment. Disease progression will be measured by a blinded third party review of X-ray and MRI results. We intend this to be a pivotal trial with the goal of demonstrating clinical safety and efficacy for the submission of a Biologics License Application (BLA). We may have to provide or generate further patient data to support a U.S. BLA submission. In March 2006, we received an Orphan Drug Designation from the FDA to use our BRCs in the treatment of osteonecrosis of the femoral head.

[Table of Contents](#)

In January 2007, we initiated patient enrollment and treatment in a pivotal clinical trial in Spain utilizing BRCs for the treatment of osteonecrosis of the femoral head. The trial protocol was approved by the Spanish Drug Agency (AEMPS) and Centro Medico Teknon's (Teknon) Ethics Committee for our Investigational Medicinal Product Dossier (IMPD), and is being conducted at Teknon located in Barcelona, Spain. Patient recruitment is ongoing for up to 10 patients.

Fractures, Spine and Jaw:

In October 2007, positive final results from our U.S. Phase I/II clinical trial for the treatment of severe long bone non-union fractures were reported at the Orthopedic Trauma Association Annual Meeting in Boston, MA by the lead clinical investigator. In the study, patients with non-union tibia, humerus or femur fractures that had failed to heal after one or more medical procedures (average 1.75) showed an overall healing rate of 91% after one year. Overall, 34 patients completed the six-month post-treatment follow-up and 33 completed the 12-month follow-up. The 33 patients followed for 12 months showed an overall healing rate of 91%, as determined by bone bridging observed with radiographic imaging or computed tomography. Final results showed healing in 91% (21 of 23) of tibia fractures, 100% (3 of 3) of humerus fractures, and 86% (6 of 7) of femur fractures. In addition to the 91% healing rate observed after 12 months, results at six months showed that early bone bridging successfully occurred in 85% (29 of 34) of patients and that signs of early healing (callus formation) were present in 97% (33 of 34) of patients. Three patients failed to complete the required follow-up visits. Though final data could not be collected from these three patients, two showed healing by 18 weeks. No cell-related adverse events were reported. The following centers participated in the multi-center, prospective, open-label clinical trial: Lutheran General Hospital, Park Ridge, IL; the University of Michigan Health System, Ann Arbor, MI; William Beaumont Hospital, Royal Oak, MI; and Lutheran Medical Center, Brooklyn, NY.

An initial bone regeneration study was conducted at three centers in Spain under Ethical Committee approvals. Results from this feasibility study conducted at Hospital General de l'Hospitalet, Teknon and Hospital de Barcelona-SCIAS in Spain were disclosed in May 2005. All five patients, with a total of 6 treated fractures, have been reported as healed by a third party independent reviewer using radiographic images, or by clinical observation. No cell-related adverse events were observed. Following the feasibility trial, an IMPD was approved by the AEMPS to commence a 10-patient Phase II non-union fracture trial. The Phase II study has completed enrollment and BRC treatment of all 10 patients, and we are continuing the specified 24-months follow-up of these patients.

A Phase I/II spine fusion clinical trial is currently open at William Beaumont Hospital, Royal Oak, MI that may enroll up to 25 patients. No cell-related adverse events have been reported to date. With the FDA approval of the Phase III ON-CORE Trial we believe this trial is no longer necessary to demonstrate the feasibility of using BRCs for bone regeneration. We are continuing regular patient follow-up for treated patients, however, no further patients have been enrolled.

[Table of Contents](#)

In addition to the long bone and spine fusion studies a clinical feasibility study for jaw bone regeneration was completed in Barcelona, Spain. Five edentulous patients, with severe bone loss who needed a sinus lift procedure so that dental implants could be placed, were treated with BRCs and no cell-related adverse events were reported over a 24-month follow-up period.

Cardiac Regeneration

Dilated cardiomyopathy (DCM) is a chronic cardiac disease that leads to enlargement of the heart and is associated with the reduced pump function to a point that blood circulation is impaired. Typically patients with DCM present with symptoms of congestive heart failure, including limitations in their physical activity and shortness of breath. DCM often represents the end stage of chronic ischemic heart disease in patients who have experienced multiple heart attacks. Patient prognosis depends on the stage of the disease but is characterized by a high mortality rate. Other than heart transplantation, there are no curative treatment options for end stage patients with this disease. The New England Journal of Medicine estimates that in the U.S. alone 120,000 people currently suffer from this disease; other sources report estimates of up to 150,000.

In November 2007, the first patient was treated using our Cardiac Repair Cells (CRCs) based on our TRC technology for DCM in a European compassionate-use case. CRCs were administered to the patient via direct injection into the heart. The compassionate use of CRCs is ongoing and we expect that these patient treatments will provide clinical experience that will assist us in the development of the clinical protocols we are preparing for a U.S. IND and an EU IMPD submission targeting DCM.

In February 2007, our CRCs based on our TRC technology received an Orphan Drug Designation from the FDA for use in the treatment of DCM.

Neural Regeneration

We have begun the process of developing a proprietary Neural Repair Cell (NRC) product for the treatment of spinal cord injuries. Preclinical work has been initiated and we are in the process of preparing for clinical activities in the EU. We expect that these patient treatments will provide clinical experience that will assist us in the development of future clinical protocols.

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 patient and physician see a potential benefit from using TRC-based products. We do not anticipate generating significant sales outside of the U.S. until we have sufficient evidence of clinical efficacy to ensure physician acceptance and product reimbursement, and to justify the investment in manufacturing, sales and marketing infrastructure. However, we are currently generating limited, nominal sales of TRC-based products and expect to continue this level of activity. As a result of these compassionate use and other patient treatment activities, it is possible that we, or third parties, may make case studies

[Table of Contents](#)

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 suggest that any future clinical trials will demonstrate that TRC-based products are effective in any specific medical application.

Critical Accounting Policies

The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosures. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

There are several accounting policies that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting policy relates to stock-based compensation expense.

Performance-Based Stock Options — See the footnotes in our financial statement as well as our Critical Accounting Policies discussion in our 2007 Annual Report on Form 10-K for information with respect to key terms and provisions of our performance-stock options.

During the six months ended December 31, 2007, 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 has been recorded. However, it is not likely that the performance conditions for the first tranche of options will be met. If management had determined that as of December 31, 2007 the first tranche of 849,933 options was probable of vesting, compensation expense of approximately \$832,000 would have been recorded in the quarter (which would represent the accumulated compensation expense from the grant dates of these options through December 31, 2007).

Due to the complexity of measuring the performance conditions, the Compensation Committee of the Board of Directors is considering offering employees with performance-based stock options the opportunity to convert them to a reduced number of service-based stock options.

Results of Operations

Total revenues for the quarter and six months ended December 31, 2007 were \$84,000 and \$171,000, respectively, which consisted of grant revenues and product sales, compared to total revenues of \$158,000 and \$262,000, respectively, for the same periods in fiscal year 2007. Product sales for the quarter and six months ended December 31, 2007 were \$24,000 and \$36,000, respectively, compared to \$6,000 and \$18,000 for the same periods in fiscal 2007. Grant revenues decreased to \$60,000 and \$135,000, respectively, for the quarter and six months ended December 31, 2007 compared to \$152,000 and \$244,000, respectively, for the same periods in fiscal year 2007. The decrease in grant revenues is the result of decreased activities on grants from the National Institutes of Health. Grant revenues are recorded on a cost-reimbursement basis and accounted for 79% of total revenues for the six months ended December 31, 2007 and 93% of total revenues for the same period in fiscal year 2007.

[Table of Contents](#)

Total costs and expenses increased to \$5,621,000 for the quarter ended December 31, 2007, compared to \$4,898,000 for the quarter ended December 31, 2006.

Costs and expenses include an increase in research and development expenses to \$3,895,000 for the quarter ended December 31, 2007 from \$2,563,000 for the quarter ended December 31, 2006. This increase reflects continued expansion of our research and development and manufacturing activities to support future regulatory submissions and on-going and planned tissue regeneration clinical trials and activities in the U.S. and EU that include: additional headcount and increases in contract services from fees associated with Clinical Research Organizations. Research and development expenses also included a non-cash charge relating to share-based compensation expense of \$214,000 for the quarter ended December 31, 2007 compared to \$181,000 for the quarter ended December 31, 2006.

Selling, general and administrative expenses decreased for the quarter ended December 31, 2007 to \$1,725,000 from \$2,332,000 for the quarter ended December 31, 2006. This decrease is primarily due to the additional one-time, non-cash charge relating to the former Chief Executive Officer's stock options upon the termination of his service as a director that was recorded in the quarter ended December 31, 2006 and an adjustment that reduced supplemental compensation relating to fiscal year 2007 management bonuses that were paid in December 2007. Selling, general and administrative expenses for the quarter ended December 31, 2007, included a non-cash charge relating to share-based compensation expense of \$344,000 compared to \$690,000 for the quarter ended December 31, 2006.

Total costs and expenses increased to \$11,108,000 for the six months ended December 31, 2007, compared to \$9,586,000 for the six months ended December 31, 2006.

Research and development expenses increased for the six months ended December 31, 2007 to \$7,768,000 from \$4,867,000 for the six months ended December 31, 2006, reflecting continued expansion of our research and development programs to support regulatory and clinical trial activities in the U.S. and EU. Research and development expenses also included a non-cash charge relating to stock-based compensation expense of \$437,000 for the quarter ended December 31, 2007 compared to \$290,000 for the quarter ended December 31, 2006.

Selling, general and administrative expenses decreased for the six months ended December 31, 2007 to \$3,339,000 from \$4,716,000 for the six months ended December 31, 2006. This decrease is primarily due to additional employee costs for the six months ended December 31, 2006, that included: the one-time, non-cash charge for the former CEO's stock options upon the termination of his service as a director, accruals and severance payments relating to the former CEO's and former President and Chief Operating Officer's employment agreements. This decrease also includes an adjustment that reduced supplemental compensation relating to fiscal year 2007 management bonuses that were paid in December 2007. Selling, general and administrative expenses for the the six months ended December 31, 2007, included a non-cash charge relating to share-based compensation expense of \$670,000 compared to \$1,152,000 for the six months ended December 31, 2006.

[Table of Contents](#)

Interest income was \$386,000 and \$751,000, respectively, for the quarter and six months ended December 31, 2007 compared to \$515,000 and \$1,042,000, respectively, for the same periods in fiscal 2007. 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 improved yields from our investments.

Interest expense was \$21,000 and \$36,000 for the quarter and six months ended December 31, 2007 related to the secured loan with Key Equipment Finance Inc.

Our net loss was \$5,172,000, or \$.04 per common share for the quarter ended December 31, 2007 compared to \$4,225,000, or \$.04 per common share for the quarter ended December 31, 2006. For the six months ended December 31, 2007, our net loss increased to \$10,222,000, or \$.08 per common share compared to a net loss of \$8,282,000, or \$.07 per common share for the six months ended December 31, 2006. The increase in net loss is primarily the result of increased costs and expenses offset on a per share basis by an increase in the weighted average number of common shares outstanding.

Our major ongoing research and development programs are focused on the development of TRC-based products, bone marrow-derived adult stem and early progenitor cells, for use in vascular, bone and cardiac regeneration, as well as neural regeneration. Clinical trials using TRC-based products are open for patient enrollment in the U.S. and EU for the treatment of critical limb ischemia resulting from peripheral vascular disease and for the treatment of osteonecrosis of the femoral head. Compassionate-use clinical activities have been initiated in Europe to evaluate the treatment of dilated cardiomyopathy using our TRC-based product. All of these potential product applications use TRC technology, our proprietary cells and platform manufacturing technologies. We are also completing other research and development activities using our TRC-based products that are intended to improve the functionality for certain clinical indications, to improve shelf life, and to decrease the cost of manufacturing our TRC-based products. Research and development expenses outside of the TRC-based product development consist primarily of immunotherapy programs, engineering and cell manufacturing.

[Table of Contents](#)

The following table summarizes our research and development expenses for the quarter and six months ended December 31, 2006 and December 31, 2007:

R&D Project	Quarter Ended December 31,		Six Months Ended December 31,	
	2006	2007	2006	2007
TRC-based product	\$ 2,352,000	\$ 3,631,000	\$ 4,378,000	\$ 7,242,000
Other	211,000	264,000	489,000	526,000
Total	<u>\$ 2,563,000</u>	<u>\$ 3,895,000</u>	<u>\$ 4,867,000</u>	<u>\$ 7,768,000</u>

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, 2007, have totaled approximately \$203 million and, to a lesser degree, through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments, and funding under equipment leasing agreements. These financing sources have generally allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash, cash equivalents and short-term investments totaled \$31,189,000 at December 31, 2007, an increase of \$2,864,000 from June 30, 2007. During the six months ended December 31, 2007, the primary source of cash, cash equivalents and short-term investments was from equity transactions from a registered direct placement of common stock to a select group of investors, from the Direct Stock Purchase Plan and the exercise of certain warrants previously issued to investors, with net proceeds of \$13,592,000. The primary uses of cash, cash equivalents and short-term investments during the six months ended December 31, 2007 included \$10,832,000 to finance our operations and working capital requirements, and \$163,000 in capital additions for leasehold improvements and equipment.

Table of Contents

We expect our monthly cash utilization to average approximately \$1.8 million for the remainder of fiscal year 2008.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of possible acquisition or development of complementary business activities and the cost of product commercialization. We do not expect to generate a positive cash flow from operations for at least the next several years due to the expected spending for research and development programs and the cost of commercializing our product candidates. We intend to seek additional funding through public or private debt or equity financing transactions, research and development agreements or grants and distribution and marketing agreements. Successful future operations are subject to several technical and risk factors, including our continued ability to obtain future funding, satisfactory product development, obtaining regulatory approval and market acceptance for our products.

In order to grow and expand our business, to introduce our product candidates into the marketplace and to possibly acquire or develop complementary business activities, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. We expect that our primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of our equity or debt securities. There can be no assurance that such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. In addition, we may also pursue strategic transactions or other strategic alternatives in order to complete our product development programs, complete clinical trials needed to market our products, and commercialize our products. Several factors will affect our ability to raise additional funding or enter into strategic transactions or other strategic alternatives, including, but not limited to, market volatility of our common stock, continued stock market listing and economic conditions affecting the public markets generally or some portion or the entire technology sector. If our common stock is delisted from the Nasdaq Stock Market, the liquidity of our common stock could be impaired, and prices paid by investors to purchase our shares of our common stock could be lower than might otherwise prevail.

On December 20, 2007, we received a deficiency letter from the Nasdaq Stock Market indicating that for 30 consecutive trading days our common stock had a closing bid price below the \$1.00 minimum closing bid as required for continued listing set forth in Nasdaq Marketplace Rule 4310(c)(4). In accordance with Nasdaq Marketplace Rule 4310(c)(8)(D), we were provided a compliance period of 180 calendar days, or until June 17, 2008, to regain compliance with this requirement. We can regain compliance with the minimum closing bid price rule if the bid price of our common stock closes at \$1.00 or higher for a minimum of ten consecutive business days during the initial 180-day compliance period, although Nasdaq may, in its discretion, require us to maintain a minimum closing bid price of at least \$1.00 per share for a period in excess of ten consecutive business days (but generally no more than 20 consecutive business days) before determining that we have demonstrated the ability to maintain long-term compliance. If compliance is not achieved by June 17, 2008, we will be eligible for an additional 180-day compliance period, or until December 14, 2008, if we meet all other Nasdaq Capital Market initial listing criteria as set forth in

[Table of Contents](#)

Marketplace Rule 4310(c) other than the minimum closing bid price requirement. If we are not eligible for an additional compliance period, or do not regain compliance during any additional compliance period, Nasdaq will provide written notice that our securities will be delisted from the Nasdaq Capital Market. At such time, we would be able to appeal the delisting determination to a Nasdaq Listing Qualifications Panel.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material adverse affect on our business. See “Risk Factors” and “Notes to Consolidated Financial Statements” in our 2007 Annual Report on Form 10-K and “Notes to Consolidated Financial Statements” and “Risk Factors” included herein.

Risk Factors

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

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

We were incorporated in 1989 and have experienced substantial operating losses since inception. As of December 31, 2007, we have incurred a cumulative net loss totaling approximately \$169 million and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development of our cell culture technologies and our cell manufacturing system, general and administrative expenses, and the prosecution of patent applications. We expect to continue to incur significant operating losses over the next several years and at least until, and probably after, product sales increase, primarily owing to our research and development programs, including preclinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. We cannot predict with any certainty the amount of future losses. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, timely initiation and completion of clinical trials, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components, acquisition and development of complementary activities and raising sufficient cash to fund our operating activities. In addition, we may not ever be able to achieve or sustain profitability.

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

We are required to meet certain qualitative and financial tests (including a minimum bid price for our common stock of \$1.00) to maintain the listing of our common stock on the Nasdaq Capital Market. On December 20, 2007, we received a deficiency letter from the Nasdaq Stock Market indicating that for 30 consecutive trading days our common stock had a closing bid price

Table of Contents

below the \$1.00 minimum closing bid as required for continued listing set forth in Nasdaq Marketplace Rule 4310(c)(4). In accordance with Nasdaq Marketplace Rule 4310(c)(8)(D), we were provided a compliance period of 180 calendar days, or until June 17, 2008, to regain compliance with this requirement. We can regain compliance with the minimum closing bid price rule if the bid price of our common stock closes at \$1.00 or higher for a minimum of ten consecutive business days during the initial 180-day compliance period, although Nasdaq may, in its discretion, require us to maintain a minimum closing bid price of at least \$1.00 per share for a period in excess of ten consecutive business days (but generally no more than 20 consecutive business days) before determining that we have demonstrated the ability to maintain long-term compliance. If compliance is not achieved by June 17, 2008, we will be eligible for an additional 180-day compliance period, or until December 14, 2008, if we meet all other Nasdaq Capital Market initial listing criteria as set forth in Marketplace Rule 4310(c) other than the minimum closing bid price requirement. If we are not eligible for an additional compliance period, or do not regain compliance during any additional compliance period, Nasdaq will provide written notice that our securities will be delisted from the Nasdaq Capital Market. At such time, we would be able to appeal the delisting determination to a Nasdaq Listing Qualifications Panel.

In May 2003 and in July 2004, we received notification from Nasdaq of potential delisting as a result of our stock trading below \$1.00 for more than thirty consecutive business days. While in each case our stock price recovered within the permitted grace periods and Nasdaq notified us that we were again in full compliance, we cannot provide any assurance that our stock price will again recover within the permitted grace period. The qualitative tests we must meet address various corporate governance matters, including Audit Committee and Board composition. If we do not maintain compliance with the Nasdaq requirements within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file). 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 would 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.

We will require substantial capital resources in order to conduct our operations and develop and commercialize our products and cell manufacturing facilities. However, 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 additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our cell product candidates for additional indications. Accordingly, we are continuing to pursue additional sources of financing.

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

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

[Table of Contents](#)

Because of our long-term funding requirements, we intend 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.

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 certain countries in the EU. If we cannot demonstrate the safety and efficacy of our cell product candidates, or of the cells produced in our manufacturing system, we may not be able to obtain required regulatory approvals. If we cannot demonstrate the safety and efficacy of our technologies and product candidates, or if one or more patients die or suffer severe complications, 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 mixtures (such as our TRC-based products) is, under current regulations, regulated as a biologic product, which requires a Biological License Application (BLA).

[Table of Contents](#)

EU Directives and regulations (laws) have become effective, and have influenced the requirements for manufacturing cell products and the conduct of clinical trials. Recent changes to the EU Medicinal Products Prime Directive (including added annexes and new regulations) shifted patient-derived cells to the medicinal products category, which will require Marketing Authorizations in order to market and sell these products. These new requirements have delayed some of our current planned clinical trials with TRC-based products in the EU, and will require clinical trials with data submission and review by one or more European regulatory bodies. There is uncertainty about which clinical trial activities and data are required, and because of the recent nature of these new directives, laws and regulations, there is no established precedent to understand the timeline or other requirements for Marketing Authorization.

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

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

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

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

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

[Table of Contents](#)

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 are sufficient for a marketable or regulatory approvable product.

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

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

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

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

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

[Table of Contents](#)

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 market place at a level that would allow us to operate profitably. Our products may be unable to achieve commercial acceptance for a number of reasons such as the availability of alternatives that are less expensive, more effective, or easier to use, the perception of a low cost-benefit ratio for the product amongst physicians and hospitals, or an inadequate level of product support from ourselves or a commercial partner. Our technologies or product candidates may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technologies and product candidates, and our potential revenues.

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

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

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

Some of the manufacturing materials and/or components we use in, and are critical to, implementation of our TRC technology involve the use of animal-derived products, including fetal bovine serum. Suppliers or regulatory changes may limit or restrict the availability of such materials for clinical and commercial use. We currently purchase all of our fetal bovine sera from protected herds in Australia and New Zealand. These sources are considered to be the safest and raise the least amount of concern from the global regulatory agencies. If, for example, the so-called "mad cow and disease" occurs in New Zealand or in Australia, it may lead to a restricted supply of the serum currently required for the TRC-based product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture TRC-based cell products. Regulatory authorities in the EU are reviewing the safety issues related to the use of animal-derived materials, which we currently use in our production process. The FDA has issued draft regulations for controls over bovine materials. These proposed regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may issue final regulations that could affect our operations. We do not

Table of Contents

know what actions, if any, the authorities may take as to animal derived materials specific to medicinal products distributed in the EU. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts. There are certain limitations in the supply of certain animal-derived materials, which may lead to delays in our ability to complete clinical trials or eventually to meet the anticipated market demand for our cell products.

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

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

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

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

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

The market price of shares of our common stock has been volatile, ranging in closing price between \$0.52 and \$1.58 during the twelve month period ended December 31, 2007. 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

Table of Contents

- 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

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.

We have experienced significant management turnover, and if we cannot attract and retain key personnel, then our business will suffer.

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other companies, research and academic institutions and other entities. Further, in an effort to conserve financial resources, we have implemented reductions in our work force on two 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.

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. Certain of these foreign patents are due expire beginning in 2008. Furthermore, we rely on exclusive, world-wide licenses relating to the production of human cells granted to us by the University of Michigan for certain of our patent rights. If we materially breach such agreements or otherwise fail to materially comply with such agreements, or if such agreements expire or are otherwise terminated by us, we may lose our rights under the patents held by the University of Michigan. At the latest, each of these licenses will terminate when the patent underlying the license expires. The first of these underlying patents will expire on March 21, 2012. We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

Intellectual property litigation could harm our business.

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

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

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

[Table of Contents](#)

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

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

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

Our Board of Directors has the authority, without shareholder approval, to issue additional shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders. This authority, together with certain provisions of our charter documents, may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire control of our Company. This effect could occur even if our shareholders consider the change in control to be in their best interest.

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

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

Forward-looking statements

This report, including the documents that we incorporate by reference, contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “trends,” “opportunity,” “comfortable,” “current,” “intention,” “position,” “assume,” “potential,” “outlook,” “remain,” “continue,” “maintain,”

Table of Contents

“sustain,” “seek,” “achieve,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “could,” “may,” or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this report, and in particular those factors listed under the section “Risk Factors.”

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These forward-looking statements include statements regarding:

- potential strategic collaborations with others
- future capital needs
- adequacy of existing capital to support operations for a specified time
- product development and marketing plan
- clinical trial plans and anticipated results
- anticipation of future losses
- replacement of manufacturing sources
- commercialization plans
- revenue expectations and operating results

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2007, our cash and cash equivalents included money market securities and short-term investments included short-term corporate debt securities (Standard & Poor's Corporation: A1/A1+; Moody's Investor Service, Inc.: P1) with original maturities of less than twelve months. Due to the short duration and credit quality of our investment portfolio, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio, 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 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 in connection with our internal controls and policies. We do not enter into hedging transactions and do not purchase derivative instruments.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of management, including the Chief Executive Officer ("CEO") and the Chief Financial Officer ("CFO"), 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 and CFO have concluded that the Company's disclosure controls and procedures were effective as of December 31, 2007, 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 and 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 and 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 the quarter ended December 31, 2007, no changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) occurred that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II — OTHER INFORMATION*Item 1. Legal Proceedings*

From time to time we receive threats or may be subject to litigation matters incidental to our business. However, we are not currently a party to any material pending legal proceedings.

Item 1A. Risk Factors

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

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

- (a) The Annual Meeting of Shareholders of Aastrom Biosciences, Inc. was held on November 7, 2007.
- (b) At the 2007 Annual Meeting of Shareholders, votes were cast on matters submitted to the shareholders, as follows:
 - Proposal 1: Election of three Class I directors whose terms expire at the 2010 Annual Meeting of Shareholders.

NOMINEE	FOR	WITHHELD
George W. Dunbar	93,012,581	2,797,879
Susan L. Wyant	91,810,655	3,999,805
Robert L. Zerbe	92,757,368	3,053,092

In addition to the election of the above referenced directors, the following individuals continue as directors; Timothy M. Mayleben and Stephen G. Sudovar, as Class II directors, whose terms expire at the 2008 Annual Meeting of Shareholders; and Alan L. Rubino and Nelson M. Sims, as a Class III director, whose term expires at the 2009 Annual Meeting of Shareholders.

[Table of Contents](#)

Proposal 2: Ratification of the selection of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the year ending June 30, 2008.

<u>FOR</u>	<u>AGAINST</u>	<u>ABSTAIN</u>
93,011,582	1,743,883	1,054,993

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 8, 2008

/s/ George W. Dunbar, Jr.

George W. Dunbar, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 8, 2008

/s/ Gerald D. Brennan, Jr.

Gerald D. Brennan, Jr.
Vice President, Administrative & Financial Operations
and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

CERTIFICATION

I, George W. Dunbar, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aastrom Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 8, 2008

/s/ George W. Dunbar, Jr.

George W. Dunbar, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Gerald D. Brennan, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aastrom Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 8, 2008

/s/ Gerald D. Brennan, Jr.

Gerald D. Brennan, Jr.

Vice President, Administrative & Financial
Operations and 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 December 31, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George W. Dunbar, Jr., President and Chief Executive 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 8, 2008

/s/ George W. Dunbar, Jr.

George W. Dunbar, Jr.

President and Chief Executive Officer

(Principal Executive 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.

**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, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerald D. Brennan, Jr., Vice President, Administrative & Financial Operations 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 8, 2008

/s/ Gerald D. Brennan, Jr.

Gerald D. Brennan, Jr.

Vice President, Administrative & Financial
Operations and 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.