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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED September 30, 2014,

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission file number 0-22025

AASTROM BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Michigan	**94-3096597**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
24 Frank Lloyd Wright Dr. — Lobby K Ann Arbor, Michigan	**48105**
(Address of principal executive offices)	(Zip code)

(800) 556-0311
(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 - x No - o

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

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

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

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

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	**23,785,653**
(Class)	Outstanding at October 31, 2014

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AASTROM BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash	$ 37,578	$ 8,059
Accounts receivable	3,959	8
Inventory	1,711	—
Other current assets	1,468	409
Total current assets	44,716	8,476
Property and equipment, net	2,398	739
Intangible assets	3,267	—
Total assets	$ 50,381	$ 9,215
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,390	$ 2,676
Accrued employee benefits	2,176	620
Verigen payment liability	3,158	—
Restructuring reserve and asset retirement obligation	2,511	—
Current portion of long-term debt	38	6
Warrant liabilities	1,209	2,019
Total current liabilities	12,482	5,321

Long term debt:	115	—
Total liabilities	12,597	5,321
COMMITMENTS AND CONTINGENCIES (Note 14)		
Shareholders' equity:		
Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved — 39, shares issued and outstanding — 12	38,389	38,389
Common stock, no par value; shares authorized — 75,000 and 15,000; shares issued and outstanding — 23,786 and 4,723, respectively	304,780	253,270
Other comprehensive income	(70)	—
Accumulated deficit	(305,315)	(287,765)
Total shareholders' equity	37,784	3,894
Total liabilities and shareholders' equity	$ 50,381	$ 9,215

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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AASTROM BIOSCIENCES, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Product sales	$ 9,658	$ 0	$ 14,090	$ 11
Total revenues	**9,658**	**0**	**14,090**	**11**
Costs and expenses:				
Cost of product sales	5,532	0	10,541	3
Gross profit	**4,126**	**0**	**3,549**	**8**
Research and development	7,835	2,575	15,470	11,789
Selling, general and administrative	4,313	1,066	9,267	4,259
Total operating expenses	12,148	3,641	24,737	16,048
Loss from operations	**(8,022)**	**(3,641)**	**(21,188)**	**(16,040)**
Other income (expense):				
(Increase) decrease in fair value of warrants	949	1,367	(155)	3,331
Bargain purchase gain	—	—	3,634	—
Foreign currency translation gain	154	—	154	—
Interest income	3	4	9	12
Interest expense	(1)	(3)	(4)	(9)
Total other income (expense)	1,105	1,368	3,638	3,334
Net loss	**$ (6,917)**	**$ (2,273)**	**$ (17,550)**	**$ (12,706)**
Net loss per share attributable to common shareholders (Basic and Diluted) (see note 11)	$ (0.82)	$ (1.20)	$ (2.90)	$ (6.60)
Weighted average number of common shares outstanding (Basic and Diluted)	10,273	3,042	7,569	2,526

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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AASTROM BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited, amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss	**$ (6,917)**	**$ (2,273)**	**$ (17,550)**	**$ (12,706)**
Other comprehensive income				
Foreign currency translation	(75)	—	(70)	—
Comprehensive loss	**$ (6,992)**	**$ (2,273)**	**$ (17,620)**	**$ (12,706)**

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

AASTROM BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, amounts in thousands)

	Nine Months Ended September 30,	
	2014	2013
Operating activities:		
Net loss	$ (17,550)	$ (12,706)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	496	387
Stock compensation expense	653	528
Change in fair value of warrants	155	(3,331)
Bargain purchase gain	(3,634)	—
Foreign currency translation gain	(154)	—
Changes in operating assets and liabilities:		
Inventory	489	—
Accounts receivable	(3,930)	—
Other current assets	(855)	(65)
Accounts payable and accrued expenses	(69)	(329)
Accrued employee benefits	1,071	(84)
Verigen payment liability	3,158	—
Restructuring reserve and asset retirement obligation	1,004	—
Net cash used for operating activities	(19,166)	(15,600)
Investing activities:		
Acquisition of CTRM business, net of cash acquired	(1,450)	—
Property and equipment purchases	(82)	(40)
Net cash used for investing activities	(1,532)	(40)
Financing activities:		
Net proceeds from issuance of common stock and warrants	50,236	12,848
Pay downs of debt	(6)	(30)
Net cash provided by financing activities	50,230	12,818
Effect of exchange rate changes on cash	(13)	—
Net increase (decrease) in cash	29,519	(2,822)
Cash at beginning of period	8,059	13,638
Cash at end of period	$ 37,578	$ 10,816
Supplemental cash flow information (non-cash):		
Accretion of convertible preferred stock	$ —	$ 1,263
Warrants exchanged for common stock	$ 965	$ —
Equipment acquired under capital lease obligations	$ 153	—

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE QUARTER ENDED SEPTEMBER 30, 2014 (UNAUDITED)

NOTE 1— ORGANIZATION:

Aastrom Biosciences, Inc. (the Company or Aastrom) was incorporated in March 1989 and began employee-based operations in 1991. On May 30, 2014 Aastrom completed the acquisition of certain assets of Sanofi, a French société anonyme (Sanofi), including all of the outstanding equity interests of Genzyme Biosurgery ApS (Genzyme Denmark), a wholly-owned subsidiary of Sanofi, and over 250 patents and patent applications of Sanofi and certain of its subsidiaries and assumed certain liabilities for purposes of acquiring the portion of the cell therapy and regenerative medicine business (the CTRM Business), which researches, develops, manufactures, markets and sells Carticel, MACI and Epicel (the CTRM Transaction). The CTRM Business researches, develops, manufactures, markets and sells the Carticel®, MACI™ and Epicel® products. As a result, the Company exited the development stage, and is now a fully integrated, commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of innovative therapies that enable the body to repair and regenerate damaged tissues and organs to restore normal structure and function. Aastrom has marketed products as well as

developmental stage product candidates and the Company's goal is to become the leader in cell therapy and regenerative medicine by developing, manufacturing and marketing best-in-class therapies for patients with significant unmet medical needs.

The Company operates its business in one reportable segment — the research, product development, manufacture and distribution of patient-specific, expanded cellular therapies for use in the treatment of specific diseases.

Successful future operations are subject to several technical hurdles and risk factors, including satisfactory product development, timely initiation and completion of clinical trials, regulatory approval and market acceptance of the Company's products, and the successful integration and profitability of the CTRM Business.

NOTE 2 — BASIS OF PRESENTATION:

The condensed consolidated financial statements included herein have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). The preparation of condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States of America (U.S. GAAP) requires management to make estimates, judgments, and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the nine months ended September 30, 2014, are not necessarily indicative of the results to be expected for the full year or for any other period. The December 31, 2013 condensed consolidated balance sheet data was derived from the Company's audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the period ended December 31, 2013, as filed with the SEC on March 13, 2014 (Annual Report).

The consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany, Marrow Donation, LLC, located in San Diego, California, and Aastrom Biosciences DK ApS, in Kastrup, Demark (collectively, the Company). All inter-company transactions and accounts have been eliminated in consolidation. Aastrom Biosciences GmbH has ceased operations.

NOTE 3 —SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND NEWLY ISSUED ACCOUNTING STANDARDS:

During the nine months ended September 30, 2014, the Company added certain policies and procedures as a result of its acquisition of the commercialized CTRM Business. There were no other changes to the significant accounting policies described in the Company's audited financial statements as of and for the year ended December 31, 2013, and the notes thereto, which are included in the Annual Report.

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Inventory

Inventories are measured at the lower of cost or market value. Cost is calculated using the first-in, first-out method. Utilization reserves are established for estimated obsolescence or un-marketable inventory in an amount equal to the cost of inventory.

Accounts Receivable

Accounts receivable is initially recorded at the contractual amount owed by the customer. Allowances for doubtful accounts are established when the facts and circumstances indicate that a receivable may not be collectible.

Property, Plant and Equipment

Property, plant and equipment are initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use or, in the case of assets acquired in a business combination, at fair value as at the date of the combination.

After initial measurement, property, plant and equipment are carried at cost less accumulated depreciation and impairment.

Repair and maintenance costs of property, plant and equipment are expensed as incurred.

The depreciable value of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The useful lives of property, plant and equipment are as follows:

- Equipment and computers: 3 to 5 years
- Furniture and fixtures: 5 years
- Building improvements and leasehold improvements: Shorter of the remaining life of the lease or 15 years

Useful lives and residual values of property, plant and equipment are reviewed periodically. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change of accounting estimate.

Intangible Assets

Intangible assets are initially measured at acquisition cost, including any directly attributable costs of preparing the asset for its intended use or, in the case of assets acquired in a business combination at fair value as at the date of the combination. Identifiable intangible assets related to product rights are amortized on a straight line basis over their expected useful lives.

The useful lives of intangible assets are reviewed periodically. The effect of any adjustment to useful lives is recognized prospectively as a change of accounting estimate.

Amortization of intangible assets is recognized in these financial statements under Costs of product sales.

Intangible assets are carried at cost less accumulated amortization and impairment.

Impairment of Intangible Assets and Other Long-Lived Assets

Intangible assets and long-lived assets are assessed for potential impairment when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. An impairment loss would be recognized when an asset's fair value, determined based on undiscounted cash flows expected to be generated by the asset, is less than its carrying amount. The impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and recognized in these financial statements.

Foreign Currency Translation

Assets and liabilities of Genzyme Denmark are translated from Danish Krone into U.S. dollars using the applicable exchange rates in effect at the period end. Expenses of the operations in Denmark are translated from the applicable currencies into U.S. dollars using average exchange rates for the reported period.

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Revenue Recognition

Total revenues are comprised of product sales of Carticel, Epicel, MACI, bone marrow, and surgical kits. Revenue is recognized when persuasive evidence of an arrangement exists, the goods are shipped or delivered, depending on shipping terms, title and risk of loss pass to the customer and collectability is reasonably assured.

Revenue is recorded net of a provision, made at the time of sale, for rebates and cash discounts. These revenue reductions are established by the Company at the time of sale, based on historical experience adjusted to reflect known changes in the factors that impact such reserves. Distributors are entitled to chargeback incentives for services that are provided for based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Research and Development Expense

Research and development activities represent a significant part of the Company's business. These expenditures relate to the development of new products, improvement of existing products, technical support of products and compliance with governmental regulations for the protection of consumers and patients. Research and development expenses are expensed as incurred.

Newly issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, Revenue from Contracts with Customers. ASU 2014-09 merges revenue recognition standards of the FASB and International Accounting Standards Board (IASB). The FASB and IASB initiated a joint project to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP and International Financial Reporting Standards (IFRS) that would: (1) remove inconsistencies and weaknesses in revenue requirements; (2) provide a more robust framework for addressing revenue issues; (3) improve comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets; (4) provide more useful information to users of financial statements through improved disclosure requirements; and (5) simplify the preparation of financial statements by reducing the number of requirements to which an entity must refer. The standard is required to be adopted by public business entities in annual periods beginning on or after December 15, 2016, and interim periods within those annual periods. The Company is currently evaluating the potential impact of this new guidance on its consolidated financial statements.

NOTE 4—ACQUISITIONS:

CTRM Business acquisition

On May 30, 2014, Aastrom completed its acquisition of certain assets of Sanofi, including all of the outstanding equity interests of Genzyme Denmark, a wholly-owned subsidiary of Sanofi, and over 250 patents and patent applications and assumed certain liabilities for purposes of acquiring portions of the CTRM Business. Aastrom is a leading developer of patient-specific, expanded multicellular therapies for the treatment of severe, chronic cardiovascular diseases. The CTRM Business, also a leading developer of patient-specific expanded cellular therapies, expands the Company's portfolio of cellular therapies to include products which treat severe burns and as well as cartilage defects. The CTRM Business is a commercial business, with manufacturing, marketing and sales capabilities. Pursuant to the terms of the asset purchase agreement, the Company paid a total purchase price of $6.5 million, including $4.0 million in cash and a $2.5 million promissory note which was repaid on July 30, 2014.

The total purchase price consideration is as follows:

Acquisition consideration (in 000's):	Fair Value
Cash payment	$ 4,000
Promissory note	2,500
Total acquisition consideration	$ 6,500

The Company recognized tangible and intangible assets and liabilities acquired based upon their respective estimated fair values as of the acquisition date. The table below shows the preliminary fair values assigned to the assets acquired and liabilities assumed. Based on this analysis, the transaction resulted in a

bargain purchase gain. We may make additional adjustments to the fair values, and these valuations could change significantly from those used to determine certain adjustments in the pro forma condensed combined financial statements.

The preliminary purchase price allocation is as follows:

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Purchase price allocation (in 000's):	Fair Value
Cash	$ 5,050
Accounts receivable	53
Inventory	2,200
Other current assets	192
Accounts payable and accrued expenses	(939)
Asset retirement obligation	(1,600)
Property and equipment	1,818
Intangible assets	3,360
Bargain purchase gain	(3,634)
Total consideration	$ 6,500

As part of the acquisition, $5.0 million in cash was received from Sanofi in order to fund the restructuring of the Denmark operations and close the facility. To date we have recorded restructuring charges of $3.1 million and may incur additional costs in the fourth quarter of 2014. See Note 5 "Restructuring" below for additional information.

The intangible assets acquired represent commercial use rights for certain products acquired in the transaction. This estimated fair value was determined using the income approach based on projected cash flows attributed to the commercial rights. The calculated value of the commercial rights intangible assets are amortized using the straight line method over an estimated useful life of twelve years.

The identifiable intangible assets acquired and their estimated useful lives are summarized as follows:

(in 000's)	Fair Value	Useful Life
Commercial rights	$ 3,360	12 years

Revenue and net loss included in the condensed consolidated financial statements include four months of operations related to the CTRM Business since the May 30, 2014 acquisition and are $13.8 million and $(1.7 million), respectively. The net loss related to the CTRM Business includes the restructuring costs of $3.1 million described below as well as $0.8 million of expenses from the Denmark subsidiary that the Company is in the process of shutting down.

The following unaudited pro forma condensed combined information for the nine month periods ended September 30, 2014, and 2013, respectively are presented as if the acquisition of the CTRM Business had occurred on January 1, 2013.

These unaudited pro forma condensed combined statements should be read in connection with the Company's historical combined financial statements and notes thereto filed with the SEC. In management's opinion, all adjustments necessary to reflect the significant effects of this transaction have been made. These statements are based on assumptions and estimates considered appropriate by our management; however, they are not necessarily, and should not be assumed to be, an indication of our financial position or results of operations that would have been achieved had the acquisitions been completed as of the dates indicated or that may be achieved in the future.

	Nine Months Ended	
(in 000's)	September 30, 2014	September 30, 2013
Pro forma revenue	$ 30,200	$ 30,362
Pro forma net loss	(27,745)	(34,414)
Pro forma net loss per share — basic and diluted	$ (4.26)	$ (15.20)

NOTE 5—RESTRUCTURING:

On June 16, 2014, the Company announced a strategic plan to maximize the profitability and growth potential of the CTRM Business (the Plan). Under the Plan, the Company discontinued manufacturing MACI in Denmark, temporarily ceased sales of MACI in Europe, and significantly reduced research and development expenses associated with MACI. Furthermore, the Company has eliminated approximately 80 full time employee positions, which represented approximately 30% of the Company's current total workforce. Employees terminated as part the Plan were provided with severance payments and outplacement assistance.

As a result of the Plan, the Company recorded a restructuring charge of $0.1 million and $3.1 million in the three and nine months ended September 30, 2014, respectively, related to the operations in the United States and Denmark, primarily representing cash

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payments for severance and other personnel-related expenses. Of the total restructuring charge, $2.5 million was recorded in cost of product sales, and $0.6 million was recorded in selling, general and administrative expenses. The restructuring reserve decreased to $0.9 million as of September 30, 2014 as a result of cash payments made for severance and other personnel-related expenses. In addition to restructuring charges recorded thus far, the Company may incur additional lease termination costs and stay-on bonuses associated with future restructuring actions. The Company currently expects to complete the Plan by the end of the fourth quarter of 2014. The Company acquired an asset retirement obligation of $1.6 million related to the obligation to restore the Denmark

facility to its original state. The Company is currently attempting to sell the leasehold improvement and transfer the lease obligation in order to avoid incurring the restoration costs.

Any additional restructuring costs will be recognized when management finalizes and approves the additional restructuring activities. These costs will be recognized when appropriate.

NOTE 6 — STOCK—BASED COMPENSATION

The Company issues nonqualified and incentive stock options as well as other equity awards pursuant to its Amended and Restated 2009 Omnibus Incentive Plan, (Option Plan). Such awards pursuant to the Option Plan may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants.

During the three and nine months ended September 30, 2014, the Company granted zero and 242,025, respectively, service-based options to purchase common stock. These options were granted with exercise prices equal to the fair market value of the Company's stock at the grant date, generally vest over four years and expire after ten years. The weighted average grant-date fair value of service-based options granted under the Option Plan during the three month period ended September 30, 2013 was $5.11. The weighted average grant-date fair value of service-based options granted under the Option Plan during the nine month periods ended September 30, 2014 and 2013 was $2.85 and $14.07, respectively.

The net compensation expense recorded for the service-based stock options related to employees and directors was $0.2 million and $0.7 million for the three and nine months ended September 30, 2014, respectively, compared to $0.1 million and $0.5 million for the three and nine month periods ended September 30, 2013, respectively. The compensation cost includes forfeiture adjustments.

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 weighted average assumptions noted in the following table.

	Nine Months Ended September 30,	
Service-Based Stock Options	2014	2013
Expected dividend rate	0%	0%
Expected stock price volatility	82.4 – 88.2%	74.0-87.9%
Risk-free interest rate	1.66 – 2.2%	0.1- 2.1%
Expected life (years)	5.5 – 6.25	5.0 - 6.3

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

Service-Based Stock Options	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2013	297,860	$ 39.53	7.90	$ —
Granted	242,025	$ 3.91		
Exercised	—	$ —		$ —
Expired	(22,537)	$ 42.20		
Forfeited	(28,214)	$ 31.98		
Outstanding at September 30, 2014	489,134	$ 22.22	8.19	$ —
Exercisable at September 30, 2014	199,781	$ 38.35	6.83	$ —

As of September 30, 2014 there was approximately $1.1 million 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 2.92 years.

The total fair value of options vested during the nine months ended September 30, 2014 and 2013 was $1.3 million and $1.9 million, respectively.

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NOTE 7—BALANCE SHEET COMPONENTS:

Inventory:

(in 000's)	September 30, 2014
Raw materials	$ 916
Work-in-process	433
Finished goods	362
Inventory	$ 1,711

Property and equipment, net:

(in 000's)	September 30, 2014	December 31, 2013
Equipment and computers	$ 3,970	$ 3,024
Furniture and fixtures	722	706
Building improvements and leasehold improvements	1,691	1,018
Construction in progress	504	77
Total property and equipment, gross	6,887	4,825
Less: Accumulated depreciation	(4,489)	(4,086)
Total, net	$ 2,398	$ 739

Intangible assets, net:

(in 000's)	As of September 30, 2014 Gross Amount	Accumulated Amortization	Net Amount
Commercial rights	$ 3,360	$ (93)	$ 3,267

Amortization expenses were $0.07 million and $0.1 million for the three and nine month periods ended September 30, 2014, respectively. There was no amortization expense in the three and nine month periods ending September 30, 2013. The increase in intangible assets, net from December 31, 2013 to September 30, 2014 is due to the acquisition of the CTRM Business.

Estimated future amortization expense is as follows:

Calendar Years Ending December 31, (in 000's)	
2014	$ 70
2015	280
2016	280
2017	280
2018	280
Thereafter	2,077
Total	$ 3,267

Accounts payable and accrued expenses:

(in 000's)	September 30, 2014	December 31, 2013
Accounts payable to vendors	$ 2,504	$ 2,382
Accrued accounts payable	886	294
Total	$ 3,390	$ 2,676

Restructuring reserve and asset retirement obligation:

(in 000's)	September 30, 2014
Asset retirement obligation	$ 1,600
Restructure reserve	911
Total	$ 2,511

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Accumulated other comprehensive income:

Accumulated other comprehensive income consists entirely of foreign currency translation activity. There were no reclassifications out of other comprehensive income during the three or nine months ending September 30, 2014.

NOTE 8—FAIR VALUE MEASUREMENTS:

The Company's fair value measurements are classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following table summarizes the valuation of the Company's investments and financial instruments that are measured at fair value on a recurring basis:

	September 30, 2014				December 31, 2013			
		Fair value measurement category				Fair value measurement category		
(In 000's)	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Liabilities:								
Warrant liabilities	$ 1,209	$ —	$ 1,108	$ 101	$ 2,019	$ —	$ 1,934	$ 85

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The following table summarizes the change in the estimated fair value of the Company's warrant liabilities:

Warrant Liabilities (in 000's)	
Balance at December 31, 2013	$ 2,019

Warrant exercise	(965)
Increase in fair value	155
Balance at September 30, 2014	$ 1,209

A reconciliation of beginning and ending balances for the Company's fair value measurements using Level 3 inputs is as follows:
Warrants:

(in 000's)	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014
Beginning balance	$ 208	$ 85
(Decrease)/Increase in fair value	(107)	16
Ending balance	$ 101	$ 101

NOTE 9—STOCK PURCHASE WARRANTS:

The Company has historically issued warrants to purchase shares of the Company's common stock in connection with certain of its common stock offerings. The following warrants were outstanding at September 30, 2014, and include provisions that could require cash settlement of the warrants or have anti-dilution price protection provisions requiring each to be recorded as liabilities of the Company at the estimated fair value at the date of issuance, with changes in estimated fair value recorded as non-cash income or expense in the Company's statement of operations in each subsequent period:

	January 2010 Class A Warrants	December 2010 Warrants	August 2013 Warrants
Exercise price	$ 7.86	$ 2.55	$ 4.80
Expiration date	July 21, 2015	December 15, 2015	August 16, 2018
Total shares issuable on exercise	226,299	15,405	724,950

The fair value of the Class A warrants and the December 2010 warrants are measured using the Monte Carlo valuation model. The methodology is based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates, however; these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liabilities and the change in estimated fair value of the warrants could be materially different. The August 2013 warrants are valued using a Black-Scholes valuation model.

Inherent in the Monte Carlo and Black-Scholes valuation models are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The Monte Carlo model is used for the Class A warrants and the December 2010 warrants to value the potential future exercise price adjustments triggered by the anti-dilution provisions as well as the value of the put feature of the December 2010 warrants. These require Level 3 inputs which are based on the Company's estimates of the probability and timing of potential future financings and fundamental transactions. The other assumptions used by the Company are summarized in the following tables:

The assumptions used by the Company are summarized in the following tables:

January 2010 Class A Warrants	September 30, 2014	December 31, 2013
Closing stock price	$ 2.85	$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	104.7%	84.6%
Risk-free interest rate	0.1%	0.3%
Expected life (years)	0.75	1.50

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December 2010 Warrants	September 30, 2014	December 31, 2013
Closing stock price	$ 2.85	$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	124.7%	80.4%
Risk-free interest rate	0.2%	0.4%
Expected life (years)	1.21	1.96

August 2013 Warrants	September 30, 2014	December 31, 2013
Closing stock price	2.85	$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	90.4%	77.5%
Risk-free interest rate	1.4%	1.6%
Expected life (years)	3.88	4.63

NOTE 10—SERIES B CONVERTIBLE PREFERRED STOCK:

On March 9, 2012, the Company completed the sale of 12,308 shares of Series B-1 Non-Voting Convertible Preferred Stock (Series B-1 preferred stock) at an offering price of $3,250 per share. In addition to the Series B-1 preferred stock, which was issued at the closing, the Company also authorized Series B-2 Voting Convertible Preferred Stock (Series B-2 preferred stock). The Series B-1 preferred stock and Series B-2 preferred stock collectively are referred to as the Series B preferred stock. The Series B preferred stock is convertible, at the option of the holder thereof at any time after the five year anniversary of the

closing of the offering, (the Conversion date) into shares of common stock at a conversion price of $3.25 per share of common stock. At any time after the Conversion date, the Company may elect to convert any or all outstanding shares of Series B preferred stock into shares of common stock, subject to certain limitations. Stock dividends on the Series B preferred stock will be cumulative and compound daily, at a rate of 11.5% per annum, payable upon conversion, liquidation, redemption or other similar events, and payable in cash or Series B-1 preferred stock until the Conversion date. As of September 30, 2014, there are approximately 210,782 shares of accumulated but undeclared Series B-1 Stock dividends. Unless prohibited by Michigan law governing distributions to shareholders, the Series B-1 preferred stock shall be redeemable at the option of holder of the Series B-1 preferred stock commencing at any time after the Conversion date, liquidation, winding up, dissolution or other similar events, subject to certain terms and limitations.

The Series B preferred stock does not, in its entirety, require liability classification and was evaluated for embedded features to determine if those features require bifurcation and separate classification as derivative liabilities. The Series B preferred stock host contract was evaluated for equity or mezzanine classification based upon the nature of the redemption and conversion features. Generally, any feature that could require cash redemption for matters not within the Company's control, irrespective of probability of the event occurring, requires classification outside of shareholders' equity. The Series B preferred stock was initially recorded as mezzanine in the Condensed Consolidated Balance Sheets and was accreted to its redemption value through charges to accumulated deficit using the effective interest method.

On August 12, 2013, the Company amended the Series B preferred stock agreement to remove the cash redemption provision, modify the liquidation preferences for the Series B-2 preferred stock and to increase the redemption price for the Series B-1 preferred stock. The redemption price, prior to the five year anniversary, is now equal to $7,430 multiplied by the number of Series B-1 preferred shares redeemed minus the Company's closing stock price multiplied by the number of common shares into which the outstanding Series B-2 preferred stock are convertible. The redemption price, after the five year anniversary, is the amount equal to the greater of the Series B offering price plus accrued dividends or the conversion value in common stock. As a result of the amendment to the agreement, the total amount of $38.4 million Series B preferred stock was reclassified from mezzanine into shareholders' equity.

NOTE 11—NET LOSS PER COMMON SHARE:

Basic earnings (loss) per share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (loss) per share for the holders of the Company's common shares and holders of the Series B preferred stock. The Series B preferred stock shares contain participation rights in undistributed earnings, but do not share in the losses of the Company. The dividends on the Series B preferred stock are treated as a reduction of earnings attributable to common shareholders.

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The following reflects the net loss attributable to common shareholders and share data used in the basic and diluted earnings per share computations using the two class method:

(Amounts in 000's except per share amounts)	Three Months Ended September30, 2014	Three Months Ended September30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Numerator:				
Net loss	$ 6,917	$ 2,273	$ 17,550	$ 12,706
Less: dividends accumulated on convertible preferred stock	1,534	1,368	4,426	3,945
Numerator of basic and diluted EPS	$ 8,451	$ 3,641	$ 21,976	$ 16,651
Denominator:				
Denominator for basic and diluted EPS:				
Weighted-average common shares outstanding	10,273	3,042	7,569	2,526
Net loss per share attributable to common shareholders (basic and diluted)	$ (0.82)	$ (1.20)	$ (2.90)	$ (6.60)

Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares (related to options, warrants and preferred stock) that have been excluded from the computations of diluted net loss per common share at September 30, 2014 and 2013 were 2.3 million and 2.4 million, respectively.

NOTE 12—SHAREHOLDERS' EQUITY:

On September 17, 2014, the Company closed on a public equity offering whereby it sold 15,784,313 shares of common stock at an offering price of $2.55 per share (the 2014 offering). The proceeds of $37.5 million, net of $2.4 million of underwriters' discount and $0.3 million of issuance costs consisting primarily of legal and accounting fees, were recorded as a common stock issuance.

On July 9, 2014, the Company entered into a Warrant Exercise Agreement with one holder of warrants issued by the Company on August 16, 2013 (the 2013 Warrants) to purchase an aggregate of 362,500 shares of the Company's common stock, no par value. Pursuant to the Warrant Exercise Agreement, the holder agreed to exercise the 2013 Warrants at the existing exercise price of $4.80. The net proceeds to the Company in connection with the exercise of the 2013 Warrants, after deducting a warrant inducement payment and expenses, were approximately $1.5 million.

On January 21, 2014, the Company entered into a purchase agreement (Purchase Agreement), together with a registration rights agreement, for the sale of up to $15.0 million of shares of its common stock to Lincoln Park, subject to certain limitations, from time to time over a 30-month period, which began on April 3, 2014 and ends on October 3, 2016.

The Company may direct Lincoln Park, at its sole discretion, to purchase up to 50,000 shares of common stock in regular purchases, increasing to amounts of up to 100,000 shares depending upon the closing sale price of the common stock. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock equals or exceeds $3.00 per share. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 10 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price of $2.50, subject to adjustment. The Company controls the timing and amount of any sales of common stock to Lincoln Park. The

Company's sales of shares of common stock to Lincoln Park under the Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the common stock.

In connection with the Purchase Agreement, in the nine months ended September 30, 2014, the Company issued to Lincoln Park 935,499 shares of common stock and raised gross proceeds of $3.7 million (with a remaining balance of $11.3 million). Additionally, during the nine months ended September 30, 2014, the Company raised net proceeds of $7.1 million utilizing the At-the-Market Sales Agreement (ATM) with MLV & Co. LLC (formerly McNicoll, Lewis & Vlak). At September 30, 2014 there was approximately $7.8 million of net capacity remaining on the ATM.

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NOTE 13—CONCENTRATION OF CREDIT RISK

Revenue from one customer, a distributor in the U.S., represented approximately 75% of total revenue during the three and nine months ended September 30, 2014. Excluding that distributor, the largest customer represented approximately 10% of revenue for the three month period ended September 30, 2014 and no other customer accounted for more than 10% of revenue Reported revenue primarily reflects sales related to the acquisition of the CTRM Business from Sanofi since May 30, 2014.

NOTE 14 — COMMITMENTS AND CONTINGENCIES

During 2013, the Company amended its operating lease with Domino's Farms Office Park, LLC to extend the term of the lease for an additional five years, which began on May 1, 2013. The Company now has a right to terminate on the third anniversary of the renewal, and has two five-year market value renewal options. The Company's leased facility includes a Class 100,000 modular manufacturing clean room, laboratories and office space. The lease also provides the Company a right of first refusal on certain additional space.

In conjunction with the acquisition of the CTRM Business, the company assumed the leases for facilities in Cambridge, MA and Kastrup, Denmark. The leases for the facilities in Cambridge and Kastrup are non-cancelable leases expiring at various dates through February 2017.

As of September 30, 2014, future minimum payments related to leases are as follows:

(in 000's)	2014	2015	2016	2017	2018	More than 5	Total
Leased office space	$ 751	$ 4,101	$ 4,069	$ 1,209	$ 338	—	$ 10,468
Sales force leased auto fleet	47	194	169	68	5	—	483
Leased computer equipment	11	43	43	43	32		172
Total	$ 809	$ 4,338	$ 4,281	$ 1,320	$ 375	$ —	$ 11,123

Rent expense for the three and nine months ended September 30, 2014 was approximately $1.4 million and $2.2 million, respectively, compared to $0.3 million and $0.9 million for those same periods in 2013.

As part of its acquisition of Verigen AG (Verigen), Genzyme Corporation, a subsidiary of Sanofi, agreed to make cash payments to Verigen upon the achievement of developmental milestones relating to regulatory and commercialization of MACI in the United States. In connection with the acquisition of the CTRM Business, the Company agreed that if it further developed MACI in the U.S., it would be obligated to pay these milestone payments, which the Company determined was remote. During the three months ended September 30, 2014, at the request of the Company, Sanofi entered into a settlement agreement with the former shareholders of Verigen whereby these shareholders agreed to discharge all obligations related to these MACI milestone payments in exchange for a one-time cash payment of €2.5 million (approximately $3.2 million) due within two months from the date when all parties sign the settlement agreement. The Company is a third-party beneficiary of the settlement agreement and, as agreed in connection with the acquisition of the CTRM Business, the Company was responsible to reimburse Sanofi for this €2.5 million payment.

At September 30, 2014, the $3.2 million was accrued and recorded as research and development expense in the Company's financial statements in recognition of this agreement. The amount was subsequently paid on October 17, 2014. This agreement was reached in full settlement of any and all potential obligations to Verigen related to future MACI developmental milestones.

NOTE 15— LIQUIDITY:

As of September 30, the Company had $37.6 million of cash which is substantially higher than the $7.3 million of cash the Company had at June 30, 2014. This increase is primarily due to the 2014 Offering which raised $37.5 million, net of the underwriting discount and offering costs. The Company believes this amount of cash will be sufficient to sustain operations for at least one year. In addition to the existing cash balance, the Company also has access to certain amounts of financing through an agreement with Lincoln Park Capital Fund, LLC (Lincoln Park). The Company may direct Lincoln Park to purchase up to $15.0 million worth of shares of its common stock over a 30-month period generally in amounts up to 50,000 shares on certain business days under a Purchase Agreement (the Purchase Agreement) entered into with Lincoln Park on January 21, 2014 (the Lincoln Park Equity Line). As of September 30, 2014, the Company has issued to Lincoln Park 935,499 shares of common stock and raised $3.7 million. However, there are certain factors, such as volume of trading in the Company's common stock, its stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time through the Lincoln Park Equity Line. The extent to which the Company can rely on the Lincoln Park Equity Line as sources of funding will depend on a number of factors, including the prevailing market price of the common stock and the extent to which the Company is able to secure working capital from other sources. Additionally, during the nine months ended September 30, 2014, the Company raised net proceeds of $7.1 million utilizing its at the market sales agreement (ATM) with MLV & Co., LLC. The ATM, which as of September 30, 2014 had remaining capacity of approximately $7.8 million, allowed the Company to sell its common stock from time to time under a registration statement on

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Form S-3 filed in June 2011, pursuant to which the Company registered $100 million of its securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014.

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

Overview

We are a fully integrated, commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of innovative therapies that enable the body to repair and regenerate damaged tissues and organs to restore normal structure and function. Our product portfolio is comprised of patient-specific (autologous) cell therapies utilizing proprietary manufacturing processes and systems. We have marketed products as well as developmental stage product candidates and our goal is to become the leading cell therapy and regenerative medicine company by developing, manufacturing and marketing best-in-class therapies for patients with significant unmet medical needs.

Acquisition of Sanofi's CTRM Business

On May 30, 2014 we completed the acquisition of certain assets of Sanofi, a French société anonyme (Sanofi), including all of the outstanding equity interests of Genzyme Biosurgery ApS (Genzyme Denmark), a wholly-owned subsidiary of Sanofi, and over 250 patents and patent applications of Sanofi and certain of its subsidiaries and assumed certain liabilities for purposes of acquiring the portion of the cell therapy and regenerative medicine business (the CTRM Business), which researches, develops, manufactures, markets and sells Carticel®, MACI™ and Epicel® (the CTRM Transaction).

In consideration for the acquisition of the CTRM Business, we paid a total purchase price of approximately $6.5 million, as follows: (a) $4.0 million was paid in cash on the closing date of the CTRM Transaction, and (b) a $2.5 million promissory note was paid on July 30, 2014. In accordance with generally accepted accounting principles in the United States of America (U.S. GAAP), we recorded the assets and liabilities of the CTRM Business at fair value. The net assets of the CTRM Business were preliminarily valued at $10.1 million, which is in excess of the $6.5 million purchase price, which resulted in a $3.6 million bargain purchase gain. The primary driving factor for the bargain purchase gain was the structure of the CTRM Transaction. As part of the CTRM Transaction, Sanofi funded Genzyme Denmark with $5.0 million in cash in order to fund the restructuring of the Denmark operations and close the facility. Under U.S. GAAP, no restructuring actions were taken by Sanofi prior to our purchase of the CTRM Business, and accordingly, there were no restructuring related accruals in the opening balance sheet. Additionally, there were no restrictions on the use of the cash in Genzyme Denmark. We implemented our restructuring plans for Genzyme Denmark after the consummation of the CTRM Transaction, and accordingly, have recorded restructuring charges in our current period results of operations. To date we have recorded restructuring charges of $3.1 million and expect to incur additional costs in the last quarter of 2014. See Note 5, "Restructuring" for additional information.

Manufacturing

We acquired two cell-manufacturing facilities as part of the acquisition of the CTRM Business in Cambridge, Massachusetts and Copenhagen, Denmark. The Cambridge facility, which is approved by the U.S. Food and Drug Administration (FDA), is used for U.S. manufacturing and distribution of Carticel, Epicel manufacturing and also manufactured MACI for the SUMMIT study conducted for approval in Europe. The Copenhagen manufacturing facility, which was approved by the Danish Medicines Agency (DKMA), was responsible for MACI manufacturing and distribution in Europe. As part of the June 2014 restructuring, MACI manufacturing at the Copenhagen manufacturing facility has been discontinued. Going forward, any clinical and commercial production of MACI will occur at our Cambridge facility. We also operate a centralized cell manufacturing facility in Ann Arbor, Michigan. The facility supports the current ixCELL-DCM clinical trial being conducted in the United States and Canada and has sufficient capacity, with minor modifications, to supply our early commercialization requirements.

Product Portfolio

Our approved and marketed products were acquired through the CTRM Transaction and include three approved autologous cell therapy products, each of which are further described below: Carticel (autologous cultured chondrocytes), a first-generation product for autologous chondrocyte implantation (ACI) currently marketed in the U.S., MACI (matrix-applied characterized autologous cultured chondrocytes), a third-generation ACI product, and Epicel (cultured epidermal autografts), a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area. Our product candidate portfolio also includes ixmyelocel-T, a patient-specific multicellular therapy currently in development for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM).

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Carticel

Carticel, a first-generation ACI product for the treatment and repair of cartilage defects in the knee, is the first and only FDA-approved autologous cartilage repair product. Carticel is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure such as debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft. Carticel received a Biologics License Application (BLA) approval in 1997 and is currently marketed in the U.S. It is generally used on patients with larger lesions (greater than 3 cm^2). In the year ended December 31, 2013, net revenues were $35.2 million for Carticel.

In the U.S., we focus net sales of Carticel on the sports-injury-targeted orthopedic physician target audience, which is very concentrated, with 60% of the current Carticel business originating from 25% of this audience, or approximately 110 physicians. We currently have a 20-person field force calling on these sports-injury targeted orthopedic physician audience.

Epicel

Epicel is a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area (TBSA). Epicel is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was approved in the United States as a humanitarian use device (HUD) under a Humanitarian Device Exemption (HDE). Devices eligible for an HDE are intended for diseases or conditions that occur in a maximum

of 4,000 individuals annually in the United States. Currently, approximately 100 patients are treated with Epicel in the U.S. each year. In the year ended December 31, 2013, net revenues were $7.1 million for Epicel.

Under the original HDE approval and pursuant to the Pediatric Medical Device Safety and Improvement Act of 2007 (PMDSIA), Epicel could not be sold for an amount that exceeds the costs of research and development, fabrication, and distribution and the number of patients treated could not exceed 4,000. In 2012, the PMDSIA was modified so that under a HDE program, a manufacturer would be allowed to sell for a profit devices intended for a condition or disease that does not occur (or only rarely occurs) in pediatric patients, so long as it meets certain other specified conditions. In addition, the modified PMDSIA does not cap the number of devices for which the manufacturer may obtain a profit per year at 4,000 devices, but rather assigns an "annual distribution number." We are currently investigating the potential impact of this change on our ability to sell Epicel for a profit. Prior to July 1, 2014, Epicel was being sold below standard costs and those costs allowed under the modified PMDSIA regulations. As of July 1, 2014, we have increased the price of Epicel to reflect the full costs allowed under those regulations.

Up until July, 2014, we had one sales representative selling Epicel and two partially dedicated Medical Scientific Liaisons supporting Epicel inquiries. We have recently expanded the Epicel sales force to three representatives and will expect to increase the number of burn centers called upon.

MACI

MACI is a third-generation ACI product for the treatment of focal chondral cartilage defects in the knee. MACI received marketing authorization in Europe in July 2013 by meeting the requirements of the Advanced Therapy and Medicinal Product (ATMP) guidelines. MACI has been commercially available in the EU since 1998. Sales of MACI have been temporarily discontinued as part of a restructuring of the business in August 2014, primarily due to low utilization and an unfavorable pricing environment. We believe that MACI, which is a Phase 3 product candidate in the U.S., has significant revenue potential in the U.S., and we are planning to discuss approval requirements with the FDA. The timing and process to gain approval in the U.S. and a possible reintroduction in select EU countries have not yet been determined.

MACI was obtained via the acquisition by Genzyme Corporation, a subsidiary of Sanofi of Verigen AG (Verigen) in 2005. As part of its acquisition of Verigen , Genzyme Corporation agreed to make cash payments to Verigen upon the achievement of developmental milestones relating to regulatory and commercialization of MACI in the United States. In connection with our acquisition of the CTRM Business, we agreed that if we further developed MACI in the U.S., we would be obligated to pay these milestone payments. During the three months ended September 30, 2014, Sanofi entered into an agreement with the former shareholders of Verigen whereby those shareholders agreed to discharge all obligations related to the MACI milestone payments in exchange for a one-time cash payment of €2.5 million (approximately $3.2 million) due within two months from the date when all parties sign the settlement agreement.

We are a third-party beneficiary of the settlement agreement and, as we agreed in connection with the acquisition of the CTRM Business, we were responsible to reimburse Sanofi for this €2.5 million payment. At September 30, 2014, $3.2 million was accrued on

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our financial statements in recognition of this liability. The amount was paid on October 17, 2014. This agreement was reached in full settlement of any and all potential obligations to Verigen related to future MACI developmental milestones.

Ixmyelocel-T

Our preapproval stage portfolio also includes ixmyelocel-T, a unique patient-specific multicellular therapy derived from an adult patient's own bone marrow which utilizes our proprietary, highly automated and scalable manufacturing system. Our proprietary cell manufacturing process significantly expands the mesenchymal stromal cells (MSCS) and M2-like anti-inflammatory macrophages in the patient's bone marrow mononuclear cells while retaining many of the hematopoietic cells. These cell types are known to regulate the immune response and play a key role in tissue repair and regeneration by resolving pathologic inflammation, promoting angiogenesis, and remodeling ischemic tissue. The novelty and advantage of using ixmyelocel-T is the expansion of a unique combination of cell populations, including MSCS and M2-like macrophages, which secrete a distinct combination of angiogenic and regenerative factors, and possess the ability to remain anti-inflammatory in the face of inflammatory challenge.

Our lead clinical development program for ixmyelocel-T is focused on severe, chronic ischemic cardiovascular diseases. We are currently enrolling our Phase 2b ixCELL-DCM study, which is a randomized, double-blind, placebo-controlled clinical trial for patients with advanced heart failure due to ischemic DCM. Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM. We also have an ongoing ixmyelocel-T clinical program for the treatment of craniofacial reconstruction and have conducted clinical studies for the treatment of critical limb ischemia.

The ongoing Phase 2b ixCELL-DCM clinical study is designed to treat 108 patients at approximately 35 sites in the U.S. and Canada. Patients will be followed for 12 months for the primary efficacy endpoint of MACE events, defined as all-cause deaths, all-cause hospitalizations, and unplanned outpatient or emergency department visits for IV treatment of acute worsening heart failure. Secondary endpoints include clinical, functional, structural, symptomatic, quality of life, and biomarker measures at 3, 6 and 9 months. Patients will be followed for an additional 12 months for safety. We expect to complete enrollment of the ixCELL-DCM study in 2014, and have top-line efficacy results approximately 12 months later.

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Results of Operations

NET LOSS

Our Net loss for the three and nine months ended September 30, 2014 totaled ($6.9 million) or ($0.82) per share and ($17.6 million) or ($2.90) per share. Results for the nine months ended September 30, 2014 include four months of operating results of the CTRM Business including restructuring charges of $3.1 million, expenses for the exited Denmark business of $0.8 million and a bargain purchase gain of approximately $3.6 million.

The following table summarizes the effect of the CTRM Transaction on our results of operations for the three and nine months ended September 30, 2014 (in thousands):

	For the Three Months Ended September 30, 2014			For the Nine Months Ended September 30, 2014		
	Legacy Business	Acquired Business	Consolidated Business	Legacy Business	Acquired Business	Consolidated Business
Total revenues	**$ 244**	**$ 9,414**	**$ 9,658**	**$ 303**	**$ 13,787**	**$ 14,090**
Cost of product sales	222	5,310	5,532	309	10,232	10,541
Gross profit (loss)	**22**	**4,104**	**4,126**	**(6)**	**3,555**	**3,549**
Total operating expenses	9,028	3,120	12,148	19,525	5,212	24,737
Income (loss) from operations	**(9,006)**	**984**	**(8,022)**	**(19,531)**	**(1,657)**	**(21,188)**
Other income (expense)	1,105	—	1,105	4	—	4
Bargain purchase gain.	—			3,634		3,634
Total other income	**1,105**	**—**	**1,105**	**3,638**	**—**	**3,638**
Net income (loss)	**$ (7,901)**	**$ 984**	**$ (6,917)**	**$ (15,893)**	**$ (1,657)**	**$ (17,550)**

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For the three and nine months ended September 30, 2014, the CTRM Business results include a charge to earnings of $3.2 million for the Verigen payment. Additionally, restructuring charges of $0.1 million and $3.1 million are included in the CTRM Business results for those same periods.

We have exited the “Developmental Stage” and are a “Commercial Stage” company following the acquisition of the CTRM Business on May 30, 2014 and the initiation of commercial sales of bone marrow from our wholly owned subsidiary Marrow Donation LLC (Marrow Donation) in June 2014.

REVENUES

Net revenues for the three and nine months ending September 30, 2014 are shown below.

Revenue by product (in 000’s)	Three months ended September 30, 2014	Nine months ended — September 30, 2014
Carticel	$ 7,459	$ 10,904
Epicel	1,769	2,697
Bone Marrow	244	303
MACI	186	186
	$ 9,658	$ 14,090

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in 000’s)	2014	2013	2014	2013
Segment:				
Cell Therapy	$ 9,658	$ —	$ 14,090	$ 11
Geographic Region				
United States of America	$ 9,472	$ —	$ 13,904	$ 11
Europe	$ 186	$ —	$ 186	$ —

Net revenues for the three and nine months ended September 30, 2014 reflect three and four months of results, respectively, from commercial operations of the acquired CTRM Business.

GROSS PROFIT AND GROSS PROFIT RATIO

	Three Months Ended September 30		Nine Months Ended September 30,	
(in 000’s)	2014	2013	2014	2013
Gross profit	$ 4,126	$ —	$ 3,549	$ 8
Gross profit %	43%	0%	25%	73%

Period comparisons for gross profit are not yet meaningful due to the acquisition of the CTRM Business. Gross Profit for the three and nine month periods ending September 30, 2014 included $0.2 million and $2.5 million, respectively, of restructuring expenses which reduced the gross profit margin by18 percentage points for the nine months ended September 30, 2014.

RESEARCH AND DEVELOPMENT COSTS

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in 000’s)	2014	2013	2014	2013
Research and development costs	$ 7,835	$ 2,575	$ 15,470	$ 11,789

Research and development expenses for the three months ended September 30, 2014 were $7.8 million versus $2.6 million for the same period a year ago. The increase in research and development expenses is due to a $3.2 million accrued expense for the Verigen agreement which eliminated all future milestones related to the development and commercialization of MACI in the United States, $0.8 million of additional expenses from the CTRM business, and a $1.3 million increase in clinical trial expenses resulting from increased enrollment in the Phase 2b ixCELL-DCM clinical trial of ixmyelocel-T for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM). Neither the CTRM Business nor the Denmark operations were part of our business a year ago.

Research and development expenses for the nine months ended September 30, 2014 were $15.5 million versus $11.8 million for the same period a year ago. The increase in R&D costs results from: $3.2 million accrued expense for the Verigen agreement, $1.3 million of expenses from the CTRM Business, $4.8 million of increased costs in the ixCELL-DCM clinical trial, offset by a $5.5 million reduction in the CLI clinical trial costs. DCM trial costs have increased as we are at the stage of the trial where more patients are being treated. For CLI, we are nearing the end of the life cycle of the trial, and as a result, expenses tend to reduce.

Our major ongoing research and development program is focused on the clinical development of ixmyelocel-T for treatment of advanced heart failure due to ischemic DCM. The following table summarizes the approximate allocation of cost for our research and development projects:

	Three Months September 30,		Nine Months Ended September30,	
(In 000's)	2014	2013	2014	2013
Dilated Cardiomyopathy	$ 3,634	$ 1,860	$ 10,232	$ 5,428
Critical Limb Ischemia	261	715	805	6,353
MACI	3,158	—	3,158	—
Other	782	—	1,275	8
Total research and development expenses	$ 7,835	$ 2,575	$ 15,470	$ 11,789

SELLING, GENERAL AND ADMINSTRATIVE COSTS

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in 000's)	2014	2013	2014	2013
Selling, general and administrative costs	$ 4,313	$ 1,066	$ 9,267	$ 4,259

Selling, general and administrative expenses for the three months ended September 30, 2014 were $4.3 million compared to $1.1 million for the same period a year ago. The increase in SG&A expenses is due to approximately $1.9 million in sales and marketing expenses from the CTRM Business, approximately $0.8 million in increased IT, legal, consulting and personnel costs related to integrating and managing the CTRM Business in the U.S., and $0.6 million in SG&A costs from Denmark operations, which is expected to be shut down by the end of the year. Neither the CTRM Business nor the Denmark operations were part of our business a year ago.

Selling, general and administrative expenses for the nine months ended September 30, 2014 were $9.3 million compared to $4.3 million for the same period a year ago. The increase in SG&A expenses is due to approximately $2.6 million in sales and marketing expenses from the CTRM Business, approximately $1.0 million in increased IT, legal, consulting and personnel costs related to integrating and managing the CTRM Business in the U.S., an increase of approximately $0.6 million in restructuring charges, and $0.8 million in SG&A costs from the Denmark opeartions, which is expected to be shut down by the end of the year. Neither the CTRM Business nor the Denmark operations were part of our business a year ago.

OTHER INCOME (EXPENSE)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in 000's)	2014	2013	2014	2013
(Increase) decrease in fair value of warrants	$ 949	$ 1,367	$ (155)	$ 3,331
Bargain purchase gain	—	—	3,634	—
Foreign currency translation gain	154	—	154	—
Net interest income	2	1	5	3
TOTAL	$ 1,105	$ 1,368	$ 3,638	$ 3,334

The decrease in warrant value was primarily due to the decline in our stock price, the reduction in the time to maturity and the reduction of warrants outstanding due to the exercise of warrants in the three months ended September 30, 2014. Fluctuations in the fair value of the warrants in the future periods could result in significant non-cash adjustments to the condensed combined

consolidated financial statements, however, any income or expense recorded will not impact our cash, operating expenses, or cash flow.

The bargain purchase gain of approximately $3.6 million for the nine months ended September 30, 2014 represents the bargain purchase gain associated with the acquisition of the CTRM Business on May 30, 2014.

The foreign currency translation gain was the result of the strengthening U.S. dollar and its impact on intercompany balances with the Denmark unit.

STOCK COMPENSATION

Non-cash stock-based compensation expense included in research and development expenses and selling, general and administrative expenses is summarized in the following table:

	Three Months Ended September 30,	Nine Months Ended September 30,

(in 000's)	2014	2013	2014	2013
Research and development	$ 64	$ 66	$ 129	$ (92)
Selling, general and administrative	138	79	524	620
Total non-cash stock-based compensation expense (income)	$ 202	$ 145	$ 653	$ 528

The increase in stock-based compensation expense in both periods is due primarily to the restructuring that was announced on March 27, 2013, and the forfeiture adjustment that resulted from the related reduction in workforce, as it did not recur in 2014.

Liquidity and Capital Resources

We are currently focused on utilizing our technology to identify, develop and commercialize innovative therapies that enable the body to repair and regenerate damaged tissues and organs to restore normal structure and function. Until such time as we satisfy, if at all, applicable regulatory approval requirements for ixmyelocel-T and MACI, we expect the sales of Carticel and Epicel therapies to constitute nearly all of our product sales revenues. Additionally, we are focusing significant resources geared towards successfully integrating and growing our CTRM Business.

We do not expect to generate positive cash flows from our consolidated operations for at least the a year and then only if we achieve some combination of significant product sales growth, improved product margins, and lower SG&A and R&D expenses.

We have raised significant funds in order to complete our product development programs, and complete clinical trials needed to market and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities. On September 17, 2014, we completed the sale of 15,784,313 shares of common stock at an offering price of $2.55 per share, and received net proceeds of $37.5 million. The Company believes this amount of cash will be sufficient to sustain operations for at least the next year. We also have access to certain amounts of financing through an agreement with Lincoln Park Capital Fund, LLC (Lincoln Park). We may direct Lincoln Park to purchase up to $15.0 million worth of shares of our common stock over a 30-month period generally in amounts up to 50,000 shares of our common stock on certain business days under a Purchase Agreement (the Purchase Agreement) we entered into with Lincoln Park on January 21, 2014 (the Lincoln Park Equity Line). As of September 30, 2014, we issued to Lincoln Park 935,499 shares of common stock and raised $3.7 million. However, there are certain factors, such as volume of trading in our common stock, our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time. The extent to which we rely on the Lincoln Park Equity Line as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Additionally, during the nine months ended September 30, 2014, the Company raised net proceeds of $7.1 million utilizing our at the market sales agreement (ATM) with MLV & Co., LLC. The ATM, which as of September 30, 2014 had remaining capacity of approximately $7.8 million, allowed the Company to sell its common stock from time to time under a registration statement on Form S-3 filed in June 2011, pursuant to which the Company registered $100 million of its securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014.

Our cash totaled $37.6 million at September 30, 2014, an increase of $29.5 million from December 31, 2013. During the nine months ended September 30, 2014, the primary uses of cash included $19.2 million for our operations and working capital requirements. This use of funds was fueled largely by the operating loss recorded by the Company. Cash used in investing activities is

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the result of the acquisition of the CTRM business. Cash provided from investing activities is the result of the September equity raise as well as Lincoln Park and ATM activity.

As of September 30, 2014 we had $35.6 million of cash deposited into an Insured Cash Sweep (ICS) program which is administered by Bank of New York Mellon. This program maximizes our Federal Deposit Insurance Company (FDIC) coverage by dividing our ICS funds into amounts under the standard FDIC maximum and places these amounts with other ICS Network member banks (each an FDIC-insured institute). These funds are placed in savings accounts at the member banks earning interest while still maintaining insurance coverage.

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 the cost of successfully integrating the CTRM Business and the cost of product commercialization. We do not expect to generate positive cash flows from operations for at least a year due to the expected spending for research and development programs and the cost of marketing and commercializing our products and product candidates.

Off-Balance Sheet Arrangements

At September 30, 2014, we were not party to any off-balance sheet arrangements.

Significant Accounting Policies

During the nine months ended September 30, 2014, we added certain policies and procedures as a result of our acquisition of the CTRM Business. There were no other changes to the significant accounting policies described in our audited financial statements and notes thereto as of and for the year ended December 31, 2013, which are included in our Annual Report on Form 10-K filed with the SEC on March 13, 2014.

Inventory

Inventories are measured at the lower of cost or market value. Cost is calculated using the first-in, first-out method. Utilization reserves are established for estimated obsolescence or un-marketable inventory in an amount equal to the cost of inventory.

Accounts Receivable

Accounts receivable is initially recorded at the contractual amount owed by the customer. Allowances for doubtful accounts are established when the facts and circumstances dictate that the receivable may not be collectible.

Property, Plant and Equipment

Property, plant and equipment are initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use or, in the case of assets acquired in a business combination, at fair value as at the date of the combination.

After initial measurement, property, plant and equipment are carried at cost less accumulated depreciation and impairment.

Repair and maintenance costs of property, plant and equipment are expensed as incurred.

The depreciable value of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The useful lives of property, plant and equipment are as follows:

- Equipment and computers: 3 to 5 years
- Furniture and fixtures: 5 years
- Building improvements and leasehold improvements: Shorter of the remaining life of the lease or 15 years

Useful lives and residual values of property, plant and equipment are reviewed periodically. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change of accounting estimate.

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Intangible Assets

Intangible assets are initially measured at acquisition cost, including any directly attributable costs of preparing the asset for its intended use or, in the case of assets acquired in a business combination at fair value as at the date of the combination. Identifiable intangible assets related to product rights are amortized on a straight line basis over their expected useful lives.

The useful lives of intangible assets are reviewed at each reporting date. The effect of any adjustment to useful lives is recognized prospectively as a change of accounting estimate.

Amortization of intangible assets is recognized in these financial statements under costs of product sales.

Intangible assets are carried at cost less accumulated amortization and impairment.

Impairment of Intangible Assets and Other Long-Lived Assets

Intangible assets and long-lived assets are assessed for potential impairment when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. An impairment loss would be recognized when an asset's fair value, determined based on undiscounted cash flows expected to be generated by the asset, is less than its carrying amount. The impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and recognized in these financial statements.

Foreign Currency Translation

Assets and liabilities of Genzyme Denmark are translated from Danish Krone into U.S. dollars using the applicable exchange rates in effect at the period end. Expenses of the operations in Denmark are translated from the applicable currencies into U.S. dollars using average exchange rates for the reported period.

Revenue Recognition

Total revenues are comprised of product sales of Carticel, Epicel, MACI, bone marrow, and surgical kits. Revenue is recognized when persuasive evidence of an arrangement exists, the goods are shipped or delivered, depending on shipping terms, title and risk of loss pass to the customer and collectability is reasonably assured.

Revenue is recorded net of a provision, made at the time of sale, for rebates, and cash discounts. These revenue reductions are established by us at the time of sale, based on historical experience adjusted to reflect known changes in the factors that impact such reserves. Distributors are entitled to chargeback incentives for services that are provided for based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Because Epicel is a humanitarian use device, Aastrom does not sell Epicel for a profit. The amount charged does not exceed the costs of the research, development, fabrication and distribution of the product.

Research and Development Expense

Research and development activities represent a significant part of our business. These expenditures relate to the development of new products, improvement of existing products, technical support of products and compliance with governmental regulations for the protection of consumers and patients. Research and development expenses are expensed as incurred.

Newly issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, Revenue from Contracts with Customers. ASU 2014-09 merges revenue recognition standards of the FASB and International Accounting Standards Board (IASB). The FASB and IASB initiated a joint project to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP and International Financial Reporting Standards (IFRS) that would: (1) remove inconsistencies and weaknesses in revenue requirements; (2) provide a more robust framework for addressing revenue issues; (3) improve comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets; (4) provide more useful information to users of financial statements through improved disclosure requirements; and (5) simplify the preparation of financial statements by reducing the number of requirements to which an entity must refer. The standard is required to be adopted by public business entities in annual periods beginning on or after December 15, 2016, and interim periods within those annual periods. We are currently evaluating the potential impact of this new guidance on our consolidated financial statements.

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Forward-Looking Statements

This report, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “trends,” “opportunity,” “comfortable,” “current,” “intention,” “position,” “assume,” “potential,” “outlook,” “remain,” “continue,” “maintain,” “sustain,” “seek,” “achieve,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “could,” “may,” or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. The factors described in Part 1, Item 1A, “Risk Factors,” and in our Annual Report on Form 10-K filed with the SEC on March 13, 2014, among others, could have a material adverse effect upon our business, results of operations and financial conditions.

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation 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 and financing sources;
- adequacy of existing capital to support operations for a specified time;
- product development and marketing plan;
- features and successes of our cellular therapies;
- manufacturing and facility capabilities;
- clinical trial plans and anticipated results; including publication thereof:
- anticipation of future losses;
- replacement of manufacturing sources;
- integration of the CTRM business and assets;
- commercialization plans; or
- revenue expectations and operating results.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of September 30, 2014, 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.

We operate in the United States of America and in Denmark and are exposed to the risk that our earnings, cash flows and equity could be adversely impacted by fluctuations in foreign exchange. We are primarily exposed to foreign exchange risk with respect to recognized assets and liabilities. Our vendors in countries outside the United States are typically paid in Euro and/or Danish Krone. We do not enter into hedging transactions and do not purchase derivative instruments.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (Certifying Officers), as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of management, including our Certifying Officers, of the effectiveness of the design and operation of the Company’s disclosure controls and procedures as of the end of the period

covered by this quarterly report. As of September 30, 2014, our Certifying Officers concluded that our disclosure controls and procedures were not effective because of a material weakness in our internal control over financial reporting described below.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the preparation of our consolidated financial statements for the period ended June 30, 2014, we identified a material weakness in the design of our internal control over financial reporting. The material weakness relates to the evaluation of significant transactions and the financial close process. Specifically, we did not have a sufficient level of accounting and supervisory personnel nor did we have the appropriate level of technical accounting experience and training necessary for our financial reporting requirements during this period. This material weakness contributed to adjustments identified by our independent registered public accounting firm during the quarter ended June 30, 2014. Although management has taken some steps to remediate the material weakness, it still exists at September 30, 2104.

Notwithstanding the material weakness described above, we believe the Company's financial statements included in this Quarterly Report on Form 10-Q present fairly, in all material respects, the Company's financial position, results of operations and cash flows for the periods presented. The Certifying Officers have certified to their knowledge that this Quarterly Report on Form 10-Q does not contain any untrue statements of material fact or omit to state any 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 periods covered in this quarterly report.

Plan for Remediation of Material Weakness

With the oversight of senior management and our audit committee, we have taken steps to remediate the material weakness noted above. We initiated a plan to remediate the weakness, but have not yet fully eliminated this weakness. During the second quarter, we hired a Chief Financial Officer (CFO), who has extensive finance experience. On a temporary basis we have hired experienced accounting consultants to supplement our existing accounting staff while we search for additional experienced finance and accounting personnel to augment our accounting staff and to provide more resources to support effective internal controls. Those consultants remained with the organization through the third quarter, and recently one of the consultants agreed to join Aastrom as a permanent member of the Finance team. The CFO hired in June remains with the organization and is leading our financial reporting activities. We continue to search for permanent employees to replace the remaining accounting consultants. Management believes that hiring qualified accounting personnel will increase the level of technical accounting knowledge and improve the overall system of internal controls and will fully remediate this material weakness.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2014, there were no changes made in our internal control over financial report (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonable likely to material affect, our internal control over financial reporting, other than the previously discussed material weakness and the related remediation plan.

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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

In addition to the cautionary information included in this report, including the section of this report captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, you should carefully consider the information regarding our risk factors set forth in Part 1, Item 1A, "Risk Factors," on our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 13, 2014, and the additional risk factors below. If any of the events described in the following risk factors and the risk described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. Except as described in the risk factor below, there have been no material changes in our risk factors from those disclosed in Part 1, Item 1A, "Risk Factors" on our Annual Report on Form 10-K. This report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Those risk factors below denoted with a "" are newly added or have been materially updated from our Annual Report on Form 10-k filed with the SEC on March 13, 2014.*

Risks Related to our Business

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

While we are a commercial-stage biopharmaceutical company following our acquisition of the CTRM business, we have not yet generated significant revenues. We have incurred net losses each year since our inception in 1989, including net losses of $15.6 million and $29.5 million for the years ended December 31, 2013 and 2012, respectively, and $17.6 million for the nine months ended September 30, 2014. As of September 30, 2014, we had $37.6 million of cash. We expect that this will be sufficient to sustain our operations for at least a year. While we have access to certain amounts of financing through an agreement with Lincoln Park Capital Fund, LLC (Lincoln Park) and the at the market sales agreement (ATM) with MLV & Co., LLC, there are certain factors, such as volume of trading in our common stock, our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time through our agreement with Lincoln Park and the ATM. We anticipate that we will incur certain non-recurring charges in connection with the integration; however, we cannot identify the timing, nature and amount of all such charges. These costs along with the transaction costs that we incurred in connection with the negotiation and completion of the acquisition of the acquired business could materially affect our

results of operations in the period in which such charges are recorded. In the longer term, we may need to raise additional funds in order to continue commercializing the products we acquired in connection with the acquisition of the acquired business, complete product development programs and complete clinical trials needed to market and commercialize our current product candidates. In addition, we expect to continue to incur significant operating expenses in connection with the operation of the acquired business, as we seek to, among other things, continue to develop our sales and marketing for the commercialization of our products and product candidates and expand and protect our intellectual property portfolio for our products. We cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact our ability to raise additional capital and our overall success include:

· Our ability to successfully integrate the acquired business with our existing business and streamline its operations;
· The rate and degree of progress for our product development;
· Our ability to maintain our facility as an FDA compliant and validated product manufacturing facility;
· 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 United States and other countries;
· The liquidity and market volatility of our equity securities;
· Regulatory and manufacturing requirements and uncertainties; and
· Technological developments by competitors.

If we cannot raise such funds, we will not be able to develop, manufacture or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on our business, financial condition and results of operations. As a result of the potential need to raise additional capital, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively past the year. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We were incorporated in 1989 and have experienced substantial operating losses since inception. As of September 30, 2014, we had accumulated a deficit of approximately $305 million. These losses have resulted principally from costs incurred in the research and development (including clinical trials) of our cell culture technologies and our cell manufacturing system, general and

administrative expenses, the prosecution of patent applications, and more recently, acquisition-related costs. We expect to continue to incur significant operating losses over the next several years and at least until, and probably after, streamlining the manufacturing and commercialization of the products we recently acquired and 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 product candidates and continuing the commercialization of 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 commercializing our products, completing the development of our product candidates, timely initiation and completion of clinical trials, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components, acquisition and development of complementary activities and raising sufficient cash to fund our operating activities. Therefore, we may not be able to achieve or sustain profitability.

**** We received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2013 with respect to our ability to continue as a going concern. The existence of such a report may adversely affect our stock price and our ability to raise capital.***

In their report dated March 13, 2014, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern as we have suffered recurring losses from operations and have insufficient liquidity to fund our future operations. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, obtaining loans and grants from various financial institutions where possible. On September 17, 2014, we sold 15,784,313 shares of our common stock under a Form S-1 registration statement with net proceeds of approximately $37.5 million. As a result, we expect that this will be sufficient to sustain our operations for at least a year.

**** The failure to successfully integrate the acquired business and operations in the expected time frame may adversely affect the combined company's future results.***

We believe that the acquisition of the acquired business will result in certain benefits, including certain manufacturing, sales and distribution and operational efficiencies. However, to realize these anticipated benefits, Aastrom's existing business and the acquired business must be successfully combined. We may be unable to effectively integrate the acquired business into our organization, make the acquired business profitable, and may not succeed in managing the acquired business or the larger company that results from this acquisition. The process of integration of an acquired business may subject us to a number of risks, including:

· Failure to successfully manage relationships with clients, distributors and suppliers;
· Demands on management related to the increase in size of the company after the acquisition;
· Diversion of management attention;
· Potential difficulties integrating and harmonizing financial reporting systems;
· Difficulties in the assimilation and retention of employees;
· Inability to retain the management, key personnel and other employees of the acquired business;
· Inability to establish uniform standards, controls, systems, procedures and policies;
· Inability to retain the customers of the acquired business;
· Exposure to legal claims for activities of the acquired business prior to acquisition; and
· Incurrence of additional expenses in connection with the integration process.

If the acquired business is not successfully integrated into our company, our business, financial condition and results of operations could be materially adversely affected, as well as our professional reputation. Furthermore, if we are unable to successfully integrate the acquired business and operations, or if there are delays in combining the businesses, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer

to realize than expected. Successful integration of the acquired business will depend on our ability to manage these operations, to realize opportunities for revenue growth presented by our products and eliminate certain excess costs of the acquired business.

**** The acquisition will result in the expansion of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

As a result of the acquisition, our employee base increased significantly from 38 employees as of March 31, 2014 to over 150 full-time employees as of September 30, 2014. We expect that such growth will impose significant additional responsibilities on our management. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business

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opportunities, loss of employees and reduced productivity among remaining employees. The effective management of the acquired business could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. In connection with the operation of the acquired business we expect to expand our internal sales and marketing capabilities as we build an internal sales and marketing organization and hire additional manufacturing, quality control, pharmacovigilance, regulatory affairs, quality assurance, and management personnel as necessary to maintain or expand our processing operations. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our products and our other product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage our current growth.

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

Notwithstanding the net proceeds of approximately $37.5 million we received from our offering in September, we may require substantial additional capital resources in order to complete our product development programs and complete our clinical trials needed to market and commercialize our product candidates (including the Phase 2b clinical trial of ixmyelocel-T for the treatment of advanced heart failure due to ischemic DCM). In order to grow and expand our business, to introduce our new product candidates into the marketplace, we may need to raise additional funds. We may also need significant additional funds or a collaborative partner, or both, to finance the research and development activities of our cell therapy 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;
- Avoiding infringement and misappropriation of third-party intellectual property;
- Obtaining valid and enforceable patents that give us a competitive advantage;
- Our ability to establish additional collaborative relationships;
- Our ability to scale up our production capabilities for larger quantities of our products;
- The effect of commercialization activities and facility expansions, if and as required; and
- Complementary business acquisition or development opportunities.

We may direct Lincoln Park to purchase up to $15 million worth of shares of our common stock over a 30-month period generally in amounts up to 50,000 shares of our common stock on certain business days under a Purchase Agreement (the Purchase Agreement) we entered into with Lincoln Park on January 21, 2014 (the Lincoln Park Equity Line). As of September 30, 2014, we had sold $3.7 million worth of shares to Lincoln Park. However, there are certain factors, such as volume of trading in our common stock, our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time. The extent to which we rely on the Lincoln Park Equity Line as sources of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove impracticable or prohibitively dilutive, we may need to secure other sources of funding in order to satisfy our working capital needs. Even if we sell the maximum amount we are eligible to sell to Lincoln Park under the purchase agreements with Lincoln Park, respectively, we may need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive should we require it, the consequences may have a material adverse effect on our business, operating results, financial condition and prospects. Additionally, during the nine months ended September 30, 2014, the Company raised net proceeds of $7.1 million utilizing our at the market sales agreement (ATM) with MLV & Co., LLC. The ATM, which as of September 30, 2014 had remaining capacity of approximately $7.8 million, allowed the Company to sell its common stock from time to time under a registration statement on Form S-3 filed in June 2011, pursuant to which the Company registered $100 million of its securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014.

We may try to access the public or private equity markets if conditions are favorable to complete a financing, even if we do not have an immediate need for additional capital at that time, or whenever we require additional operating capital. In addition, we may seek collaborative relationships, incur debt and access other available funding sources. This additional funding may not be available to us on reasonable terms, or at all. Some of the factors that will impact our ability to raise additional capital and our overall success include:

- Our ability to successfully integrate the acquired business and further commercialize our products;
- The rate and degree of progress for our product development;
- The rate of regulatory approval to proceed with clinical trial programs;

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- The level of success achieved in clinical trials;
- The requirements for marketing authorization from regulatory bodies in the United States and other countries;
- The liquidity and market volatility of our equity securities; and
- Regulatory and manufacturing requirements and uncertainties, and technological developments by competitors.

If adequate funds are not available in the future, we may not be able to develop or enhance our products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements and we may be required to delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

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

We must maintain our domestic and foreign regulatory approvals to continue to commercialize our products. In addition, we must obtain the approval of the FDA before commercial sales of our cell therapy product candidates may commence in the United States, which we believe will ultimately be the largest market for our products. We anticipate that we will also be required to obtain additional approvals from various foreign regulatory authorities to initiate sales activities of cell therapy product candidates in those jurisdictions. If we cannot demonstrate the safety, purity and potency of our product candidates, including our cell therapy product candidates, produced in our production system, the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

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 product candidates or adversely affect the regulatory approvals of our products.

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

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 cell therapy products, any change in the regulatory classification or designation would affect our ability to obtain FDA approval of our products and product candidates. As each of our cell therapy products is, under current regulations, regulated as a biologic, a Biologics License Application (BLA) is required to be submitted and approved by the FDA prior to the marketing of any of our product candidates.

**** Our product candidate, ixmyelocel-T, is still in clinical development. If we do not successfully continue or complete the clinical development of ixmyelocel-T, our ability to finance our operations may be adversely affected.***

Our near-term prospects depend in part upon our ability to successfully continue and complete clinical trials of our product candidate, ixmyelocel-T, and to demonstrate its safety and effectiveness, as well as its superiority over existing therapies and standards of care, if any. We are currently enrolling and treating patients with ischemic DCM for the Phase 2b ixCELL-DCM clinical trial. Our ability to finance our company and to generate revenues will depend in part on our ability to obtain favorable results in the ongoing and planned clinical trials of ixmyelocel-T, including the ongoing ixCELL-DCM Phase 2b clinical trial, and to successfully develop and commercialize ixmyelocel-T. Ixmyelocel-T could be unsuccessful if it:

- Does not demonstrate acceptable safety and efficacy in clinical trials, or otherwise does not meet applicable regulatory standards for approval;
- Does not offer sufficient, clinically meaningful therapeutic or other improvements over existing or future drugs used to Treat the ischemic DCM indication for which it is being tested;
- Is not capable of being produced in commercial quantities at acceptable costs; or
- Is not accepted as safe, efficacious, cost-effective, less costly and preferable to current therapies in the medical community and by third-party payers.

If we are not successful in developing and commercializing ixmyelocel-T or are significantly delayed in doing so, our financial condition and future prospects may be adversely.

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**** Our products and product development programs are based on novel technologies and are inherently risky.***

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, if regulatory agencies have limited experience in approving cellular therapies for commercialization, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

Further, when manufacturing autologous cell therapies, the number and the composition of the cell population varies from patient to patient, in part due to the age of the patient, since the therapy is dependent on patient specific physiology. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective manner and meet acceptable product release specifications for use in a clinical trial or, if approved, for commercial sale. As a consequence, the development and regulatory approval process for autologous cell therapy products could be delayed or may never be completed

**** Our products represent new classes of therapy that the marketplace may not understand or accept. Furthermore, the success of our products is dependent on wider acceptance by the medical community.***

While our acquired products have had some commercial success to date, the broader market may not understand or accept our products. Our products represent new treatments or therapies and compete with a number of more conventional products and therapies manufactured and marketed by others. The new nature of our products creates significant challenges in regards to product development and optimization, manufacturing, government regulation, and third-party reimbursement. As a result, the commercialization of our current products and development pathway for our potential products may be subject to increased scrutiny, as compared to the pathway for more conventional products.

The degree of market acceptance of any of our marketed or potential products will depend on a number of factors, including:

- The clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods;
- Our ability to convince health care providers that the use of our products in a particular procedure is more beneficial than The standard of care or other available methods;
- Our ability to explain clearly and educate others on the autologous use of patient-specific human tissue, to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue and engineered human tissue;
- Adverse reactions involving our products or the products or product candidates of others that are human tissue based;
- Our ability to supply a sufficient amount of our product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and
- The cost of our products and the reimbursement policies of government and third-party payers.

If patients or the medical community do not accept our potential products as safe and effective for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations. While acceptance by the medical community may be fostered by broad evaluation via peer-reviewed literature, we may not have the resources to facilitate sufficient publication.

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

In order to commercialize our cell product candidates in the United States, we must complete substantial clinical trials and obtain sufficient safety, purity and potency results to support required regulatory 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 results. Our technologies and cell product candidates may not prove to be safe and effective 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 any issues delaying commercialization and we may not be able to raise capital to finance our continued operations during the period required for resolution of any such issues.

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**** We must successfully complete our clinical trials to be able to market certain of our products and product candidates. Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent the continued commercialization of our products or future therapeutic product candidates.***

To be able to market therapeutic cell products in the United States, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and effectiveness of our processes and product candidates. If our clinical trials are not successful, our products may not be marketable. The results of early stage clinical trials do not ensure success in later clinical trials, and interim results are not necessarily predictive of final results.

With respect to any clinical trials affecting our products or product candidates, failures or delays can occur at any stage of the trials, and may be directly or indirectly caused by a variety of factors, including but not limited to:

- Delays in securing clinical investigators or trial sites for our clinical trials;
- Delays in obtaining Institutional Review Board (IRB) and other regulatory approvals to commence a clinical trial;
- Slower than anticipated rates of patient recruitment and enrollment in our clinical trials, or failing to reach the targeted number of patients due to competition for patients from other trials;
- Limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payers for the use of biological products supplied for use in our clinical trials;
- Negative or inconclusive results from clinical trials;
- Unforeseen side effects interrupting, delaying, or halting clinical trials of any future therapeutic product candidates, and possibly resulting in the FDA or other regulatory authorities denying approval of any future therapeutic product candidates;
- Unforeseen safety issues;
- Approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- Inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- Inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- Inability or unwillingness of medical investigators to follow our clinical protocols; and
- Unavailability of clinical trial supplies.

Moreover, our ability to complete the clinical trials for our product candidates in a timely manner depends on additional factors such as 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. For example, patients enrolling in our studies of ixmyelocel-T need to provide an adequate amount of bone marrow to process and expand for injection and some patients may not be able to provide sufficient starting material despite our study inclusion and exclusion criteria designed to prevent this. Bone marrow is an inherently variable starting material. We have experienced delays in patient accrual in our previous clinical trials. On March 27, 2013, we announced that we were stopping enrollment in the Phase 3 REVIVE clinical trial due to the slow patient accrual rate for the study and to optimize the use of our financial resources. If we experience similar delays in

patient enrollment for other clinical trials, we could experience increased costs and delays associated with these 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.

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

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

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We may rely on third parties to conduct some of our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We may use clinical research organizations (CROs) to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion, or if we are forced to change service providers. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented. In addition, we and any provider that we retain will be subject to Good Clinical Practice (GCP) requirements. If GCP and other regulatory requirements are not adhered to by us or our third-party providers, the development and commercialization of our product candidates could be delayed.

Any failure of such CRO to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services it provides for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our products and obtain regulatory approval. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

**** Failure of third parties, including Vention Medical, to manufacture or supply certain components, equipment, disposable devices and other materials used in our ixmyelocel-T cell manufacturing process would impair our cell product development.***

We rely on third parties, including Vention Medical, Inc. (Vention), to manufacture and/or supply certain of our devices/manufacturing equipment and to manufacture and/or supply certain components, equipment, disposable devices and other materials used in our cell manufacturing process to develop our marketed cell therapy products and our product candidates. Vention is our sole supplier of cell cassettes used in the ixmyelocel-T manufacturing process, and it would be difficult to obtain alternate sources of supply on a short-term basis. If any of our manufacturers or suppliers fails to perform its respective obligations, or if our supply of certain components, equipment, disposable devices and other materials is limited or interrupted, it could impair our ability to manufacture our products, which would delay our ability to conduct our clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

In addition, we may not be able to continue our present arrangements with our suppliers, supplement existing relationships, establish and maintain 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.

**** Failure by our third-party manufacturers, including Vention, to comply with the regulatory guidelines set forth by the FDA with respect to our products could delay or prevent the completion of clinical trials, the approval of any product candidates or the commercialization of our products.***

Third-party manufacturers, such as Vention, must be inspected by the FDA for current Good Manufacturing Practice, or cGMP, compliance before they can produce commercial product. We may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected.

Manufacturers are obligated to operate in accordance with FDA-mandated requirements. A failure of any of our third-party manufacturers to establish and follow cGMP requirements and to document their adherence to such practices may lead to significant delays in the availability of material for clinical trials, may delay or prevent filing or approval of marketing applications for our products, and may cause delays or interruptions in the availability of our products for commercial distribution following FDA approval. This could result in higher costs to us or deprive us of potential product revenues.

Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection may significantly delay FDA approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations may be materially harmed.

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The manufacture of cell therapy products is characterized by inherent risks and challenges and has proven to be a costly endeavor relative to manufacturing other therapeutics products. We have limited experience in manufacturing products for commercial purposes and we cannot assure you that we will be able to successfully and efficiently manage the manufacturing of our products, either ourselves or through third-party contractors with whom we may enter into strategic relationships.

The manufacture of cell therapy products, such as our products and product candidates, is highly complex and is characterized by inherent risks and challenges such as autologous raw material inconsistencies, logistical challenges, significant quality control and assurance requirements, manufacturing complexity, and significant manual processing. Unlike products that rely on chemicals for efficacy, such as most pharmaceuticals, cell therapy products are difficult to characterize due to the inherent variability of biological input materials. Difficulty in characterizing biological materials or their interactions creates greater risk in the manufacturing process. We attempt to mitigate risk associated with the manufacture of biologics by continuing to improve the characterization of all of our input materials, utilizing multiple vendors for supply of qualified biological materials, and manufacturing some of these materials ourselves. However, there can be no assurance that we will be able to maintain adequate sources of biological materials or that biological materials that we maintain in inventory will yield finished products that satisfy applicable product release criteria. Our inability to obtain necessary biological materials or to successfully manufacture cell therapy products that incorporate such materials could have a material adverse effect on our results of operations.

Additionally, we have limited experience in manufacturing products for commercial purposes and could experience difficulties in the continued manufacturing of our products. Because our experience in manufacturing, sales, marketing and distribution is limited, we may encounter unforeseen difficulties in our efforts to efficiently manage the manufacturing, sale and distribution of our products or have to rely on third-party contractors over which we may not have direct control to manufacture our products. Moreover, there can be no assurance that we or any third-party contractors with whom we enter into strategic relationships will be successful in streamlining manufacturing operations and implementing efficient, low-cost manufacturing capabilities and processes that will enable us to meet the quality, price and production standards or production volumes to achieve profitability. Our failure to develop these manufacturing processes and capabilities in a timely manner could prevent us from achieving our growth and profitability objectives as projected or at all.

We intend to obtain assistance to market our products and 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 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.

**** We have limited manufacturing capacity and our commercial manufacturing operations in the U.S. depend on one facility. Similarly, manufacturing of our lead product candidate, ixmyelocel-T, is conducted at one facility. If either facility is destroyed or we experience any manufacturing difficulties, disruptions or delays, this could limit supply of our products or adversely affect our ability to conduct our clinical trials and our business would be adversely impacted.***

We presently conduct all of our commercial manufacturing operations in the U.S. at one facility located in Cambridge, Massachusetts. As a result, all of the commercial manufacturing of our marketed products, Epicel and Carticel, for the U.S. market takes place at a single U.S. facility. In addition, clinical trials for certain product candidates would primarily depend upon the manufacturing of such product candidates in the same Cambridge facility. Similarly, manufacturing of our lead product candidate, ixmyelocel-T, takes place at one facility located in Ann Arbor, Michigan. If regulatory, manufacturing or other problems require us to discontinue production at either facility, we will not be able to supply our products to our patients or have supplies for any clinical trials, which would adversely impact our business. If either facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace our facility at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing from one facility to the other or to a third party, the shift would likely be expensive and time-consuming, particularly since an alternative facility would need to comply with the applicable regulatory and quality standard requirements whereby validation and FDA approval would be required before any products manufactured at that facility could be made commercially available.

Currently, we maintain insurance coverage totaling $4.0 million in Denmark and $32.0 million in the U.S. against damage to our property and equipment, an additional $1.0 million to cover business interruption and extra expenses, and $1.0 million to cover R&D restoration expenses. If we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies.

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**** We are subject to significant regulation with respect to the manufacturing of our products.***

All of those involved in the preparation of a cellular therapy for clinical trials or commercial sale, including our existing supply contract manufacturers and clinical trial investigators, are subject to extensive and continuing government regulations by the FDA and comparable agencies in other jurisdictions. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors and suppliers must pass inspection for compliance with the applicable regulations as a condition of FDA approval of our products. The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third party contractors. In addition, the FDA may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted.

Our manufacturing facility in Cambridge, Massachusetts was inspected by the FDA. On March 19, 2014 the FDA issued a 483 List of Inspectional Observations, an inspection citing observations made during an FDA inspection of the manufacturing facility. We are undertaking remedial measures to improve our manufacturing process and communicate those measures to the FDA, but the FDA may decide that our remedial measures should be revised or expanded, or the FDA may not find our corrective actions to be adequate. Generally, if any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, recalls, warning letters, market withdrawals, seizures or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

**** We could incur significant costs complying with environmental and health and safety requirements, or as a result of liability for contamination or other harm caused by hazardous materials that we use.***

Our research and development and manufacturing processes involve the use of hazardous materials. We are subject to federal, state, local and foreign environmental requirements, including regulations governing the use, manufacture, handling, storage and disposal of hazardous materials, discharge to air and water, the cleanup of contamination and occupational health and safety matters. We cannot eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any contamination or injury. Under some environmental laws and regulations, we could also be held responsible for costs relating to any contamination at our past or present facilities and at third party waste disposal sites where we have sent wastes. These could include costs relating to contamination that did not result from any violation of law, and in some circumstances, contamination that we did not cause. We may incur significant expenses in the future relating to any failure to comply with environmental laws. Any such future expenses or liability could have a significant negative impact on our financial condition. The enactment of stricter laws or regulations, the stricter interpretation of existing laws and regulations or the requirement to undertake the investigation or remediation of currently unknown environmental contamination at our own or third party sites may require us to make additional expenditures, which could be material.

**** In order to market any of our product candidates, including MACI and ixmyelocel-T, in the United States, the FDA requires us to file a BLA.***

The FDA approved Carticel as a biological product, for which we currently hold a biologics license. MACI and ixmyelocel-T are also subject to the FDA's biological product requirements, which will require us to submit a new BLA for each product prior to being granted marketing approval. To the extent the FDA regulates each of MACI and ixmyelocel-T as a biological product and requires us to file a BLA, we would be unable to sell MACI or ixmyelocel-T unless and until we receive BLA approval from the FDA, which requires that we conduct clinical trials in support of approval of a BLA, which would be expensive and time consuming, and uncertain as to outcome. For example, the FDA may require that we conduct one or more clinical trials in support of approval of a BLA, which would result in the expenditure of additional financial resources and extended timelines to commercialization.

**** Our business, financial condition, results of operation and cash flows could be significantly and negatively affected by substantial governmental regulations.***

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Overall, there appears to be a trend toward more stringent regulation worldwide, and we do not anticipate this trend to dissipate in the near future.

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In general, the development, testing, labeling, manufacturing and marketing of our products are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. The regulatory process requires the expenditure of significant time, effort and expense to bring new products to market. For example, FDA approved Epicel as a Humanitarian Use Device (HUD), which is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. HUD treatment is subject to additional FDA requirements, such as recordkeeping, reporting, labeling, as well as limited use of a HUD when approved by an Institutional Review Board, or IRB, that oversees medical treatment. Failure to meet FDA requirements pertaining to a HUD could result in the suspension or revocation of the HUD. While Epicel has been approved as a HUD, oversight is conducted by the Center for Biologics Evaluation and Research (CBER), the branch of the FDA that regulates biologic products, as Epicel is a cell-based product.

If HUD approval is suspended or revoked, marketing approval for Epicel would require the submission and approval of a premarket approval application (or PMA) in order to be made commercially available, or an approved BLA. The PMA and BLA processes are costly, lengthy and uncertain. A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. A BLA must be supported by substantial evidence of clinical safety and effectiveness for its intended use as proven through clinical trials in a statistically significant patient population. If the HUD approval for Epicel was withdrawn, and we were unable to obtain approval of a PMA or BLA, we could not market Epicel for sale in the U.S.

We are also required to implement and maintain stringent reporting, labeling and record keeping procedures. More specifically, in the United States, both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. Compliance with the FDA's requirements, including the FDA's cGMP recordkeeping regulations, labeling and promotional requirements and adverse event reporting regulations, is subject to continual review and is monitored rigorously through periodic inspections by the FDA. Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

In addition, the pharmaceutical, biologic and medical industries also are subject to many complex laws and regulations governing Medicare and Medicaid reimbursement and targeting healthcare fraud and abuse, with these laws and regulations being subject to interpretation. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations. In certain public statements, governmental authorities have taken positions on issues for which little official interpretation was previously available. Some of these positions appear to be inconsistent with common practices within the industry but have not previously been challenged.

Various federal and state agencies have become increasingly vigilant in recent years in their investigation of various business practices, such as the federal Anti-kickback Statute and the federal False Claims Act. Governmental and regulatory actions against us can result in various actions that could adversely impact our operations, including:

- The recall or seizure of products;
- The suspension or revocation of the authority necessary for the production or sale of a product;
- The suspension of shipments from particular manufacturing facilities;
- The imposition of fines and penalties;
- The delay of our ability to introduce new products into the market;
- Our exclusion or the exclusion of our products from being reimbursed by federal and state healthcare programs (such as Medicare, Medicaid, Veterans Administration, or VA, health programs and Civilian Health and Medical Program Uniformed Service, or CHAMPUS); and
- Other civil or criminal prosecution or sanctions against us or our employees, such as fines, penalties or imprisonment.

Any of these actions, in combination or alone, or even a public announcement that we are being investigated for possible violations of these laws, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In the United States, if the FDA were to conclude that we are not in compliance with applicable laws or regulations or that any of our products are ineffective or pose an unreasonable health risk, the FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of payment of certain products, refuse to grant pending approval applications, refuse to provide certificates to foreign governments for exports, and/or require us to notify healthcare professionals and others that the products present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions on a companywide basis, enjoin and restrain certain violations of applicable law pertaining to our products and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the United States

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Department of Justice (DOJ). Adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products.

In many of the foreign countries in which our products are marketed, we are subject to regulations affecting, among other things, clinical efficacy, product standards, packaging requirements, labeling requirements, import/ export restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our products in these countries, such as the Medicinal Products Directive and the ATMP guidelines, governing products in the EU, are similar to those of the FDA. In addition, in many countries the national health or social security organizations require our products to be qualified before they can be marketed with the benefit of reimbursement eligibility. Failure to receive or delays in the receipt of relevant foreign qualifications also could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As both the U.S. and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Our products and our operations are also often subject to the rules of industrial standards bodies, such as the International Standards Organization, or ISO. If we fail to adequately address any of these regulations, our business will be harmed.

**** Changes to our products or product candidates may require new regulatory approvals or may require us to recall or cease marketing our products until approvals are obtained.***

Modifications to our products or product candidates may require new regulatory approvals, including supplements to any of our Investigational New Drug applications (IND) requesting FDA authorization to administer our investigational biological product to humans or supplements to our BLA or Humanitarian Device Exemption (HDE) application, or require us to recall or cease marketing the modified products until these approvals are obtained. We may not be able to obtain those additional approvals for the changes or additional indications in a timely manner, or at all. Obtaining approvals can be a time consuming process, and delays in obtaining required future approvals would adversely affect our ability to introduce new or improved products in a timely manner, which in turn would harm our future growth.

**** If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.***

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for each of our products is subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with cGMP and Good Tissue Practice (GTP) regulations for the manufacture of our products and other regulations which cover requirements such as the methods and documentation pertaining to production controls, labeling, packaging, storage and shipment of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the cGMP, GTP and other regulations through periodic inspections. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- Untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- Unanticipated expenditures to address or defend such actions;
- Client notifications for repair, replacement, refunds;
- Recall, detention or seizure of our products;
- Operating restrictions or partial suspension or total shutdown of production;
- Refusing or delaying our requests for approval of new products or modified products;
- Operating restrictions;

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- Withdrawing product approvals that have already been granted;

- Refusal to approve a pending marketing application, such as a BLA or supplements to a BLA submitted by us;
- Refusal to grant export approval for our products; or
- Criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, we may be required to conduct costly post-approval studies, and post-market surveillance to monitor the safety or effectiveness of our products. We also must comply with adverse event reporting requirements, which require that we report certain adverse events involving patient use or treatment with our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as cGMP or GTP, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

**** Our marketed products may be used by physicians for indications that are not approved by the FDA. If the FDA finds that we marketed our products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.***

Under the Federal Food, Drug and Cosmetic Act (FFDCA) and other laws, we are prohibited from promoting our products for off-label uses. This means, for example, that we may not make claims about the use of our marketed products, Carticel or Epicel, outside of their approved indications, and we may not proactively discuss or provide information on off-label uses of Carticel or Epicel, with very specific and limited exceptions. The FDA does not, however, restrict physicians from prescribing products for off-label uses in the practice of medicine. Should the FDA determine that our activities constitute the promotion of off-label use, the FDA could bring action to prevent us from distributing Carticel or Epicel for the off-label use and could impose fines and penalties on us and our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions.

**** If the Office of Inspector General within the Department of Health and Human Services, the DOJ, or another federal or state agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties, and the off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.***

In addition to the FDA restrictions on our marketed products, several other types of state and federal healthcare laws have been applied by DOJ and state attorneys general to restrict certain marketing practices in the pharmaceutical industry. While physicians may prescribe products for off-label uses and indications, if other federal or state regulatory authorities determine that we have engaged in off-label promotion through remuneration, kickbacks or other monetary benefits to prescribers, we may be subject to civil or criminal penalties and could be prohibited from participating in government healthcare programs such as Medicaid and Medicare. In addition, government agencies or departments could conclude that we have engaged in off-label promotion and, potentially, caused the submission of false claims. Even if we are successful in resolving such matters without incurring penalties, responding to investigations or prosecutions will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

**** The price and sale of any of our products may be limited by health insurance coverage and government regulation.***

Maintaining and growing sales of our products will depend in large part on the availability of adequate coverage and the extent to which third-party payers, including health insurance companies, health maintenance organizations (HMOs), and government health administration authorities such as Medicare and Medicaid, private insurance plans and managed care programs will pay for the cost of the products and related treatment. Hospitals and other healthcare provider clients that purchase our products typically bill various third-party payers to cover all or a portion of the costs and fees associated with the procedures in which such products are used, including the cost of the purchase of these products. Third-party payers are also increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage and the amounts that they will pay for certain products, and, as a result, they may not cover or continue to provide adequate payment for our products. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products and product candidates to such payers' satisfaction. Such studies

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might require us to commit a significant amount of management time and financial and other resources. Our products and future products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in our products and future product development. If coverage and adequate reimbursement are not available, reimbursement is available only to limited levels, or if our costs of production increase faster than increases in reimbursement levels, we may not be able to successfully grow the sales of our products or commercialize any product candidates for which marketing approval is obtained.

Coverage decisions and payment amounts are established at the discretion of the individual third-party payer, and the regulations that govern pricing, coverage and reimbursement vary widely from country to country. Many private payers in the United States, however, use coverage decisions and payment amounts determined by the Centers for Medicare & Medicaid Services (CMS), as guidelines in setting their coverage and reimbursement policies. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. While certain procedures using our products are currently covered by Medicare and other third-party payers, future action by CMS or other government agencies may diminish payments to physicians, outpatient centers and/or hospitals for covered services. As a result, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level or reimbursed at all.

Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payers using a methodology that sets amounts based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, will view the

cost of our products to be justified so as to incorporate such costs into the overall cost of the procedure. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payers in the future.

**** We face intense competition in the markets targeted by our products. Many of our competitors have substantially greater resources than we do, and we expect that all of our products will face intense competition from existing or future products.***

All of our products face intense competition from existing and future products marketed by large companies. These competitors may successfully market products that compete with our products, successfully identify product candidates or develop products earlier than we do, or develop products that are more effective or cost less than our products. These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to effectively commercialize products and achieve revenue and profits.

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

The markets for our products are highly competitive, subject to rapid technological changes, and vary for different candidates and processes that directly compete with our products. Our competitors in the medical and biotechnology industries may have superior products, research and development, manufacturing, and marketing capabilities, and financial resources or marketing positions. Furthermore, 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 for ixmyelocel-T 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. To the extent that others develop new technologies that address the targeted application for our products, our business will suffer. Finally, if we are unable to continue to develop and market new products and technologies in a timely manner, the demand for our products may decrease or our products could become obsolete, and our revenue may decline.

**** Ethical, legal, social and other concerns surrounding the use of human tissue in synthetic biologically engineered products may negatively affect public perception of us or our products, or may result in increased scrutiny of our products and any future product candidates from a regulatory perspective, thereby reducing demand for our products, restricting our ability to market our products, or adversely affecting the market price for our common stock.***

The commercial success of our products depends in part on general public acceptance of the use of human tissue for the treatment of human diseases and other conditions. While not as controversial as the use of embryonic stem cells and fetal tissue, the

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use of adult tissue has been the subject of substantial debate regarding related ethical, legal and social issues. We do not use embryonic stem cells or fetal tissue, but the public may not be able to, or may fail to, differentiate our autologous use of adult tissue from the use by others of embryonic stem cells or fetal tissue. This could result in a negative perception of our company or our products.

Future adverse events in the field of cellular based therapy or changes in public policy could also result in greater governmental regulation of our products and potential regulatory uncertainty or delay relating to any required testing or approval.

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

Some of the manufacturing materials and/or components that we use in, and which are critical to, implementation of our technology involve the use of animal-derived products, including fetal bovine serum. Supplier changes or regulatory actions may limit or restrict the availability of such materials for clinical and commercial use for a variety of reasons including contamination or perceived risk of contamination with an adventitious agent, such as bovine spongiform encephalopathy (BSE), in one of our suppliers' herds. This may lead to a restricted supply of the serum currently required for our product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture our cell products. The FDA has issued regulations for controls over bovine material in animal feed. These regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may propose new regulations that could affect our operations. 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.

**** Carticel, MACI or any other product candidate for which we seek approval as a biologic, may face competition sooner than anticipated.***

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, as part of the PPACA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCI Act, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCI Act may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products. While the BCPI Act provides for a twelve-year period of exclusivity, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any of our future product candidates to be a reference product for competing products, potentially creating the opportunity for competition sooner than anticipated.

Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still

developing.

**** Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of our products.***

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our potential customers.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (jointly, the PPACA), which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical industry are the following:

· An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
· Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid

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rebate liability;
· Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
· New requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in the PPACA and its implementing regulations, including reporting any "transfer of value" made or distributed to teaching hospitals, prescribers, and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required and reporting to the Centers for Medicare & Medicaid Services (CMS) required by the 90th day of each calendar year;
· Expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
· A licensure framework for follow-on biologic products;
· A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
· Creation of the Independent Payment Advisory Board which, beginning in 2014, has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription products and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
· Establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products and which suppliers will be included in their healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may harm our ability to market our products and generate revenues.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and effectiveness can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

**** Tissue-based products are regulated differently in different countries. These requirements may be costly and result in delay or otherwise preclude the distribution of our products in some foreign countries, any of which would adversely affect our ability to generate operating revenues.***

Tissue based products are regulated differently in different countries. Many foreign jurisdictions have a different and may have a more difficult regulatory pathway for human tissue based products, which may prohibit the distribution of these products until the applicable regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain, and we may never seek such approvals, or if we do, we may never gain those approvals. Any adverse events in our clinical trials for a future product under development could negatively impact our products.

**** Competitor companies or hospitals may be able to take advantage of the EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization.***

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility.

This may, in certain countries, also apply to products manufactured in a country outside the EU and imported to treat specific patients or small groups of patients. In addition, advanced therapy medicinal products do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient (named patient basis).

These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules. Because any such sales would be made without a marketing authorization, there would be no need for the competitor company or hospital to refer to the clinical data in our marketing authorization dossiers, and so any data exclusivity protection that we may obtain for our products would not prevent such competing sales.

**** The current credit and financial market conditions may exacerbate certain risks affecting our business.***

We rely upon third parties for certain aspects of our business, including collaboration partners, wholesale distributors, contract clinical trial providers, contract manufacturers and third-party suppliers. Because of the recent tightening of global credit and the volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

**** We are dependent on our key manufacturing, quality and other management personnel and the loss of any of these individuals could harm our business.***

Our success depends in large part upon the efforts of our key management and manufacturing and quality staff. The loss of any of these individuals, or our inability to attract and retain highly qualified scientific and management personnel in a timely manner, could materially and adversely affect our business and our future prospects. In the future, we may need to seek additional manufacturing and quality staff members. There is a high demand for highly trained manufacturing and quality personnel in our industry. We face competition for such personnel from other companies, research and academic institutions and other entities. We do not know whether we will be able to attract, train and retain highly qualified manufacturing and quality personnel in the future, which could have a material adverse effect on our business, financial condition and results of operations. A loss of one or more of our key personnel could severely and negatively impact our operations. Our key personnel are employed “at-will,” and any of them may elect to pursue other opportunities at any time. We have no present intention of obtaining key man life insurance on any of our key management, manufacturing, quality or other personnel.

Risks Related to Intellectual Property

**** We have no patent protection for Epicel.***

We have no issued patents or pending patent applications relating to Epicel. While we attempt to protect our proprietary information as trade secrets through certain agreements with our employees, consultants, agents and other organizations to which we disclose our proprietary information, we cannot give any assurance that these agreements will provide effective protection for our proprietary information in the event of unauthorized use or disclosure of such information. If other cultured epidermal autografts are approved and marketed, we will be unable to prevent them from competing with Epicel in the marketplace. We expect that the presence of one or more competing products would reduce our market share and could negatively impact price levels and third party reimbursement policies for Epicel, any of which would materially affect our business.

**** Our issued patents relating to Carticel and MACI will expire soon and may be insufficient to protect our business.***

We have issued patents in the United States and in certain foreign countries that relate to the combinations of chondrocytes and collagen membranes used in Carticel and MACI. However, the issued patents relating to Carticel are scheduled to expire by August of 2016 in the U.S. and by 2022 in Europe. Furthermore, the issued patents relating to MACI are scheduled to expire by August of 2016 in the U.S. and by August of 2017 in Europe. When these patents expire we may be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated.

The patents we own may not be of sufficient scope or strength to provide us with significant commercial protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes that are similar to ours without infringing on our intellectual property rights. In addition, we cannot be certain that any of our pending patent applications will be issued or that the scope of the claims in our pending patent applications will not be significantly narrowed or determined to be invalid

**** 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 intellectual property rights to protect our proprietary products and technologies. This involves complex legal, scientific, and factual questions and uncertainties. We rely upon patent, trade secret, copyright and contract laws to protect proprietary technology and trademark law to protect brand identities. However, we cannot assure you that any patent applications filed by, assigned to, or licensed to us will be granted, and that the scope of any of our issued or licensed patents will be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated, held to be unenforceable, or circumvented so that our patent rights would not create an effective competitive barrier. We also cannot assure you that the inventors of the patents and applications that we own or

license were the first to invent or the first to file on the inventions, or that a third party will not claim ownership in one of our patents or patent applications. We cannot assure you that a third party does not have or will not obtain patents that dominate the patents we own or license now or in the future.

Patent law relating to the scope of claims in the biotechnology field is evolving and our patent rights in this country and abroad are subject to this uncertainty. For example, from time to time, the U.S. Supreme Court (Supreme Court), other federal courts, the U.S. Congress or the United States Patent and Trademark Office (USPTO) may change the standards of patentability and any such changes could have a negative impact on our business. There have been several cases involving "gene patents" and diagnostic claims that have been considered by the Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union (ACLU) against Myriad Genetics (Myriad) and the USPTO, could impact biotechnology and diagnostic patents. That case involves certain of Myriad's U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit court issued a written decision on July 29, 2011 that reversed the decision of the U.S. District Court for the Southern District of New York that Myriad's composition claims to "isolated" DNA molecules cover unpatentable subject matter. The Federal Circuit court instead held that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in Mayo Collaborative v. Prometheus Laboratories (Prometheus) a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus' claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted certiorari in the Myriad case, vacated the judgment, and remanded the case back to the Federal Circuit court for further consideration in light of their decision in the Prometheus case. The Federal Circuit court heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit court reaffirmed its earlier decision and held that composition of matter claims directed to isolated nucleic acids are patent-eligible subject matter, but that method claims consisting of only abstract mental processes are not patent-eligible. On September 25, 2012, the ACLU filed a petition for a writ of certiorari asking the Supreme Court to review the Federal Circuit court's decision with respect to the composition of matter claims. On November 30, 2012, the Supreme Court granted the petition and agreed to review the case. On June 13, 2013, the Supreme Court issued a decision in the Myriad case. According to the decision, claims directed to genomic DNA cover unpatentable subject matter. However, claims directed to cDNA are patent eligible subject matter.

On March 4, 2014, the USPTO issued a memorandum entitled "2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products". This memorandum provides guidance to patent examiners for examining claims reciting laws of nature/natural principles, natural phenomena, and/or natural products for patent eligibility in view of the Supreme Court decisions in Prometheus and Myriad. The guidance indicates that claims reciting such natural subject matter, read as a whole, that do not significantly differ from such natural subject matter should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio or our efforts to seek patent protection for our technology and products will not be negatively impacted by the guidance issued by the USPTO, the decisions described above, rulings in other cases, or changes in guidance or procedures issued by the USPTO.

Congress directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter

stated in part: "Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress." The USPTO issued a Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing on January 25, 2012, and held additional public hearings in February and March 2013. It is unclear whether the results of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our present or future patent portfolio.

There can be no assurance that the Supreme Court's decision in either the Myriad or Prometheus case will not have a negative impact on biotechnology patents generally or the ability of biotechnology companies to obtain or enforce their patents in the future. Such negative decisions by the Supreme Court could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We also rely on trade secrets and un-patentable 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. Our competitors may also independently develop technologies substantially equivalent or superior to ours. If this were to occur, our business and competitive position would suffer.

**** Given our patent position in regard to our products, if we are unable to protect the confidentiality of our proprietary information and know-how related to these products, our competitive position would be impaired and our business, financial condition and results of operations could be adversely affected.***

Some of our technology, including our knowledge regarding the processing our products, is unpatented and is maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and could have a material adverse effect on our business, financial condition and results of operations.

**** Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or product candidates, our competitive position would be adversely affected.

**** With respect to MACI and ixmyelocel-T, if we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could limit opportunities for us to generate revenues by licensing our technology and selling products.***

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful in obtaining and enforcing patents, our competitors could use our technology and create products that compete with our products, without paying license fees or royalties to us.

The preparation, filing, and prosecution of patent applications can be costly and time consuming. Our limited financial resources may not permit us to pursue patent protection of all of our technology and products throughout the world.

Even if we are able to obtain issued patents covering our technology or products, we may have to incur substantial legal fees and other expenses to enforce our patent rights in order to protect our technology and products from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights.

**** A successful challenge to our trademarks could force us to rebrand Epicel, Carticel, or MACI.***

We rely on our trademarks to distinguish our products from the products of our competitors, and have registered or applied to register a number of these trademarks. Third parties may challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing these new brands.

**** Intellectual property litigation could harm our business. We may be subject to patent infringement claims that could be costly to defend, which may limit our ability to use disputed technologies, and which could prevent us from pursuing research and development or commercialization of some of our products, require us to pay licensing fees to have freedom to operate and/or result in monetary damages or other liability for us.***

The success of our business will depend significantly on our ability to operate without infringing patents and other proprietary rights of others. Our cell processing system and cell compositions utilize a wide variety of technologies and we can give no assurance that we have identified or can identify all inventions and patents that may be infringed by development and manufacture of our cell compositions. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of products that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a product with which any of our existing product candidates or our products would compete. If we could not obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in product development, or we could be forced to discontinue the development or marketing of any products that were developed using the technology covered by the patent.

Although we have not been subject to any filed infringement claims, 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. Such litigation is typically protracted and the results are unpredictable. 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 including treble damages and the opposing party’s attorney fees, and force us to pay significant license fees and royalties or cease the development and sale of our products and processes.

We have hired and expect to continue to hire individuals who have experience in cell culture and cell based therapeutics and may have confidential trade secret or proprietary information of third parties. We caution these individuals not to use or reveal this third-party information, but we cannot assure you that these individuals will not use or reveal this third-party information. Thus, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and could result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations.

**** We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.***

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to

challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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**** If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation***.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

**** Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are the same as or similar to our products or product candidates, but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- We might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

Others may challenge our patent or other intellectual property rights or sue us for infringement.

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 has been or is being funded in part by government grants. As a result of such funding, the United States government has established guidelines and has certain rights in the technology developed with the grant. These rights include a non-exclusive, fully paid-up, worldwide license under such inventions for any governmental purpose. In addition, the United States government has the right to require us to grant an exclusive license under any of such inventions to a third party if the United States government determines that: (i) adequate steps have not been taken to commercialize such inventions; (ii) such action is necessary to meet public health or safety needs; or (iii) such action is necessary to meet requirements for public use under federal regulations. Additionally, under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (x) products using the invention which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained; (y) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (z) the United States government may use the invention for its own needs. 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.

**** The use of our products and product candidates may expose us to product liability claims, and we may not be able to obtain adequate insurance. As a result, such 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 our products during clinical trials, or after commercialization, results in adverse events. Moreover, we derive the raw materials for our products from patients serving as their own donors, the production process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all. If we are unable to obtain insurance, or if claims

against us substantially exceed our coverage, then our business could be adversely impacted. Excessive insurance costs or uninsured claims would increase our operating loss and adversely affect our financial condition. Whether or not we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among other things:

- Significant awards against us;
- Substantial litigation costs;
- Recall of the product;
- Injury to our reputation;
- Withdrawal of clinical trial participants; or
- Adverse regulatory action.

Any of these results could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to an Investment in our Common Stock

**** We have identified a material weakness in our internal control over financial reporting. If we fail to remediate this material weakness and implement and maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.***

We identified a material weakness in the operation of our internal controls over financial reporting as of June 30, 2014. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness relates to the evaluation of significant transactions and the financial close process. Specifically, we did not have a sufficient level of accounting and supervisory personnel nor did we have the appropriate level of technical accounting experience and training necessary for our financial reporting requirements during this period. This material weakness contributed to adjustments identified by our independent registered public accounting firm during the quarter ended June 30, 2014. We have commenced efforts to remediate this material weakness through process and internal control improvements. However, if we cannot correct the material weakness we have identified, or if we experience other material weaknesses investor confidence and our stock price could be adversely affected. Further, if material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

**** The market price of the common stock of the combined company may be affected by factors different from those affecting the market price for our common stock in recent history.***

Our business in recent history differs from that of the CTRM business, and our current combined business differs from recent history, and accordingly, the results of operations for the combined company may be affected by factors different from those affecting our results of operation in recent history. As a result, the market price for our stock may be impacted differently in the future by those factors than it is currently.

**** Our common stock price has been volatile and future sales of shares of common stock could have an adverse effect on the market price of such shares.***

The market price of shares of our common stock has been volatile, ranging in closing price between $2.61 and $6.49 during the nine months ended September 30, 2014. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

- Clinical trial results;
- Our inability to successfully integrate the acquired business with our existing business;
- 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;
- Regulatory developments in both the United States and abroad;
- 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; and
- Delisting from The NASDAQ Capital Market.

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

**** Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a de-listing of our common stock.***

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow

our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

**** The sale of our common stock through future equity offerings may cause dilution and could cause the price of our common stock to decline.***

In the nine months ended September 30, 2014, we have sold (i) an aggregate gross amount of approximately $7.1 million worth of shares of common stock pursuant to our At-the-Market Sales Agreement (ATM) with MLV & Co. LLC (MLV) (formerly McNicoll, Lewis & Vlak) through September 30, 2014, (ii) an aggregate of approximately $3.7 million worth of shares of our common stock to Lincoln Park pursuant to the Lincoln Park Equity Line, and (iii) on September 17, 2014, we sold 15.8 million shares of common stock under a Form S-1 registration statement and pursuant to a prospectus first made available on September 11, 2014. During 2013, we sold (i) an aggregate of approximately $4.9 million of shares of common stock pursuant to our ATM through December 31, 2013, and (ii) in August 2013, we sold 1.5 million shares of common stock and warrants to purchase up to 1.5 million shares of common stock under a Form S-1 registration statement and pursuant to a prospectus supplement first made available on August 14, 2013. The ATM, which as of September 30, 2014 had remaining capacity of approximately $7.8 million, allowed us to sell our common stock from time to time under a registration statement on Form S-3 filed in June 2011, pursuant to which we registered $100 million of our securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014. Additionally, pursuant to the Lincoln Park Equity Line we may direct Lincoln Park to purchase up to $15 million worth of shares of our common stock over a 30-month period generally in amounts up to 50 thousand shares of our common stock. As of September 30, 2014, we had remaining capacity of approximately $11.3 million worth of shares under the Lincoln Park Equity Line. However, there are certain factors, such as volume of trading in our common stock, our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time through the Lincoln Park Equity Line.

Sales of our common stock offered through future equity offerings may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to investors, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

**** We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline.***

Our quarterly operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of our business involves variable factors, such as the timing of the research, development and regulatory pathways of our product candidates, which could cause our operating results to fluctuate.

Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance.

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**** Efforts to comply with recently enacted changes in securities laws and regulations will increase our costs and require additional management resources, and we still may fail to comply.***

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission (SEC) adopted rules requiring public companies to include a report of management on their internal controls over financial reporting in their annual reports on Form 10-K. In addition, in the event we are no longer a smaller reporting company, the independent registered public accounting firm auditing our financial statements would be required to attest to the effectiveness of our internal controls over financial reporting. If we are unable to conclude that we have effective internal controls over financial reporting or if our independent registered public accounting firm is required to, but is unable to provide us with a report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

**** If our common stock becomes subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.***

If at any time our securities are no longer listed on a national securities exchange, including The NASDAQ Stock Market, or we have net tangible assets of $5.0 million or less and our common stock has a market price per share of less than $5.00, transactions in our common stock will be subject to the SEC's "penny stock" rules. If our common stock becomes subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. For any transaction involving a penny stock, unless exempt, the rules require:

· That a broker or dealer approve a person's account for transactions in penny stocks; and
· The broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

· Obtain financial information and investment experience objectives of the person; and
· Make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form:

· Sets forth the basis on which the broker or dealer made the suitability determination; and
· That the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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

The Company did not repurchase any of its equity securities during the quarter ended September 30, 2014. All information regarding the unregistered sales of securities during the quarter ended September 30, 2014 has been previously disclosed in the Company's Current Reports on Form 8-K.

Item 6. Exhibits

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

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 13, 2014

AASTROM BIOSCIENCES, INC.

/s/ DOMINICK C. COLANGELO
Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

/s/ GERARD MICHEL
Gerard Michel
Chief Financial Officer and Vice President, Corporate Development
(Principal Financial Officer)

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EXHIBIT INDEX

Exhibit No.	Description
10.1	Employment Agreement, dated September 25, 2014, by and between the Company and Ross Tubo (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 25, 2014).
10.2	Employment Agreement, dated September 25, 2014, by and between the Company and David Recker (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 25, 2014).
10.3	Form of Warrant Exercise Agreement, dated July 9, 2014 (incorporated herein by reference to Exhibit 10 to the Company's Report on Form 8-K, filed on July 11, 2014).
31.1	Certification by Chief Executive Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (furnished herewith).
31.2	Certification by Chief Accounting Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (furnished herewith).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document

101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

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GLOSSARY

TERM	DEFINITION
Adverse Event	Any adverse change in health or "side-effect" that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.
Autologous (Patient Specific)	Originating from the patient receiving treatment. (Aastrom uses only autologous cells).
BLA — Biologics License Application	An application containing product safety, efficacy and manufacturing information required by the FDA to market biologics products in the U.S.
CLI — Critical Limb Ischemia	An atherosclerotic vascular disease characterized by insufficient blood flow in the lower extremities that causes severe pain, tissue loss or both.
Controlled Clinical Trial	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.
DCM — Dilated Cardiomyopathy	A chronic cardiac disease where expansion of the patient's heart reduces the pumping function to a point that the normal circulation of blood cannot be maintained.
Double-Blind Clinical Trial	Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo.
FDA — Food & Drug Administration	The U.S. FDA ensures that medicines, medical devices, and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of $1 trillion worth of goods annually.
GMP — Good Manufacturing Practice	GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
Hematopoietic Cells	All of the cells in the blood system including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells).
Ischemia	A shortage or inadequate flow of blood to a body part (commonly an organ or tissue) caused by a constriction or obstruction of the blood vessels supplying it.
LVEF — Left Ventricular Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heartbeat.
Mesenchymal stromal cells	Connective tissue cells that, in the case of bone marrow derived MSC, function to support blood forming cells and secrete anti-inflammatory factors.
M2 anti-inflammatory macrophages	Specialized blood cells that remove damaged tissue and bacteria and secrete anti-inflammatory factors.
Open-label Clinical Trial	A trial in which both the treating physician and the patient know whether they are receiving the experimental treatment or control/placebo treatment.
Orphan Drug Designation	"Orphan drug" refers to a drug or biologic that is intended for use in the treatment of a rare disease or condition. Orphan drug designation from the U.S. Food and Drug Association (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for developing the drug for a rare disease or condition. The drug must then go through the FDA marketing approval process like any other drug or biologic which evaluates for safety and efficacy. Usually a sponsor receives a quicker review time and lower application fees for an orphan product.
Phase 1 Clinical Trial	A Phase 1 trial represents an initial study in a small group of patients to test for safety and other relevant factors.
Phase 2 Clinical Trial	A Phase 2 trial represents a study in a moderate number of patients to assess the safety and efficacy of a product.
Phase 2b Clinical Trial	A Phase 2b trial is a moderately-sized Phase 2 trial that is more specifically designed assess the efficacy of a product than a Phase 2a trial.
Phase 3 Clinical Trial	Phase 3 studies are initiated to establish safety and efficacy in an expanded patient population at multiple clinical trial sites and are generally larger than trials in earlier phases of development.
Prospective Clinical Trial	A clinical trial in which participants are identified and then followed throughout the study going forward in time.
Randomized Clinical Trial	A clinical trial in which the participants are assigned randomly to different treatment groups.

EXHIBIT 31.1

CERTIFICATION

I, Dominick C. Colangelo, 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 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;

   (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;

   (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 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: November 13, 2014

/s/ DOMINICK C. COLANGELO
Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Gerard Michel, 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 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;

   (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;

   (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 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: November 13, 2014

/s/ GERARD MICHEL

Gerard Michel

Chief Financial Officer and Vice President, Corporate Development

(*Principal Financial Officer)*

EXHIBIT 32.1

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

In connection with the Quarterly Report of Aastrom Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

(1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2014

/s/ DOMINICK C. COLANGELO
Dominick C. Colangelo
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.

EXHIBIT 32.2

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 September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

(1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2014

/s/ GERARD MICHEL
Gerard Michel
Chief Financial Officer and Vice President, Corporate Development
(Principal Financial 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.