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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-Q

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED June 30, 2014,**

**OR**

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

**FOR THE TRANSITION PERIOD FROM TO**

**Commission file number 0-22025**

### **AASTROM BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Michigan**  
(State or other jurisdiction of  
incorporation or organization)

**94-3096597**  
(I.R.S. employer  
identification no.)

**24 Frank Lloyd Wright Dr. – Lobby K**  
**Ann Arbor, Michigan**  
(Address of principal executive offices)

**48105**  
(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 -  No -

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

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

Large accelerated filer -

Accelerated filer -

Non-accelerated filer -

Smaller reporting company -

(Do not check if a smaller reporting company)

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

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

**COMMON STOCK, NO PAR VALUE**  
(Class)

**8,001,340**  
Outstanding at July 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)**

	<u>June 30, 2014</u>	<u>December 31, 2013</u>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 7,263	\$ 8,059
Accounts receivable	4,317	8
Inventory	1,922	—
Other current assets	610	409
Total current assets	<u>14,112</u>	<u>8,476</u>
Property and equipment, net	2,387	739
Intangible assets	3,337	—
Total assets	<u>\$ 19,836</u>	<u>\$ 9,215</u>
<b>LIABILITIES AND SHAREHOLDERS’ EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,845	\$ 2,676
Accrued employee benefits	1,732	620
Short-term debt	2,500	6
Warrant liabilities	2,974	2,019
Total current liabilities	<u>17,051</u>	<u>5,321</u>
<b>COMMITMENTS AND CONTINGENCIES (Note 16)</b>		
Shareholders’ equity:		
Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved — 39, shares issued	38,389	38,389

and outstanding — 12		
Common stock, no par value; shares authorized — 75,000 and 15,000; shares issued and outstanding — 7,019 and 4,723, respectively	262,789	253,270
Other comprehensive income	5	—
Accumulated deficit	(298,398)	(287,765)
Total shareholders' equity	2,785	3,894
Total liabilities and shareholders' equity	\$ 19,836	\$ 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)

	Quarter Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
<b>Revenues:</b>				
Product sales	\$ 4,432	\$ 3	\$ 4,432	\$ 11
<b>Total revenues</b>	<b>4,432</b>	<b>3</b>	<b>4,432</b>	<b>11</b>
<b>Costs and expenses:</b>				
Cost of product sales	5,009	1	5,009	3
<b>Gross profit (loss)</b>	<b>(577)</b>	<b>2</b>	<b>(577)</b>	<b>8</b>
Research and development	4,364	3,676	7,635	9,214
Selling, general and administrative	3,581	1,560	4,954	3,193
Total operating expenses	7,945	5,236	12,589	12,407
<b>Loss from operations</b>	<b>(8,522)</b>	<b>(5,234)</b>	<b>(13,166)</b>	<b>(12,399)</b>
<b>Other income (expense):</b>				
(Increase) decrease in fair value of warrants	248	345	(1,104)	1,964
Bargain purchase gain	3,634	—	3,634	—
Interest income	4	3	6	8
Interest expense	(2)	(3)	(3)	(6)
Total other income (expense)	3,884	345	2,533	1,966
<b>Net loss</b>	<b>\$ (4,638)</b>	<b>\$ (4,889)</b>	<b>\$ (10,633)</b>	<b>\$ (10,433)</b>
Net loss per share attributable to common shareholders (Basic and Diluted) (see note 12)	\$ (0.94)	\$ (2.72)	\$ (2.18)	\$ (5.75)
Weighted average number of common shares outstanding (Basic and Diluted)	6,518	2,283	6,195	2,263

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)

	Quarter Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
<b>Net loss</b>	<b>\$ (4,638)</b>	<b>\$ (4,889)</b>	<b>\$ (10,633)</b>	<b>\$ (10,433)</b>
<b>Other comprehensive income</b>				
Foreign currency translation	5	—	5	—
<b>Comprehensive loss</b>	<b>\$ (4,633)</b>	<b>\$ (4,889)</b>	<b>\$ (10,628)</b>	<b>\$ (10,433)</b>

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 CASH FLOWS**  
(Unaudited, amounts in thousands)

	Six Months Ended June 30,	
	2014	2013
<b>Operating activities:</b>		
Net loss	\$ (10,633)	\$ (10,433)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	246	275
Stock compensation expense	451	383
Change in fair value of warrants	1,104	(1,964)
Bargain purchase gain	(3,634)	—
Unrealized currency translation gain	5	—
Changes in operating assets and liabilities:		
Inventories	278	—
Accounts receivable	(4,256)	24
Other current assets	(10)	92
Accounts payable and accrued expenses	4,594	87
Accrued employee benefits	1,112	75
Net cash used for operating activities	<u>(10,743)</u>	<u>(11,461)</u>
<b>Investing activities:</b>		
Acquisition of CTRM business, net of cash acquired	1,050	—
Property and equipment purchases	(14)	(40)
Net cash provided by (used for) investing activities	<u>1,036</u>	<u>(40)</u>
<b>Financing activities:</b>		
Net proceeds from issuance of common stock and warrants	8,917	2,378
Principal payments under long-term debt obligations	(6)	(21)
Net cash provided by financing activities	<u>8,911</u>	<u>2,357</u>
Net decrease in cash	(796)	(9,144)
Cash at beginning of period	8,059	13,638
Cash at end of period	<u>\$ 7,263</u>	<u>\$ 4,494</u>
<b>Supplemental cash flow information (non-cash):</b>		
Accretion of convertible preferred stock	\$ 2,891	\$ 2,577
Acquisition of business through issuance of promissory note	\$ 2,500	\$ —
Warrants exchanged for common stock	\$ 149	\$ —

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

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE QUARTER ENDED JUNE 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 its 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 and assumed certain liabilities for purposes of acquiring the portions of the cell therapy and regenerative medicine business (the CTRM Business). The CTRM Business researches, develops, manufactures, markets and sells the Carticel®, MACI™ and Epicel® products. As a result, the Company has 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, successful integration and profitability of the CTRM Business and the Company's continued ability to obtain future funding.

**NOTE 2— LIQUIDITY:**

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. As of June 30, 2014, the Company had \$7.3 million of cash. This is not sufficient to sustain operations for one year. In light of its financial position, the Company is evaluating strategic financial opportunities in the short-term in order to maintain adequate liquidity through December 31, 2014 and beyond. The Company could sell an additional net \$9.3 million worth of common shares through an At the Market Sales Agreement (ATM) or direct Lincoln Park Capital Fund, LLC (Lincoln Park) to purchase up to \$11.8 million worth of shares of common shares under the Purchase Agreement between the Company and Lincoln Park in order to raise additional capital, though there are certain factors, such as volume of trading in the stock, the stock price and the ability to terminate the agreement with notice, which could limit the amount the Company could raise in a short period of time. See Note 14, "Shareholders' Equity" for additional information. On a longer-term basis, the Company will need to raise additional funds in order to complete product development programs and complete clinical trials needed to market and commercialize its products. The Company cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and our overall success include: the degree of success achieved in integrating and the revenue produced by the newly acquired CTRM Business, the rate and degree of progress for product development, the Company's ability to maintain its facility as a U.S. Food and Drug Administration (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 the Company's equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If the Company cannot raise such funds, the Company will not be able to develop or enhance its products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on the business, financial condition and results of operations. As a result of the need to raise additional capital, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate the business effectively over at least the next twelve months, which raises substantial doubt as to the ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **NOTE 3 — 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 six months ended June 30, 2014, are not necessarily indicative of the results to be expected for the full year or for any other period. The

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## **NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS FOR THE QUARTER ENDED JUNE 30, 2014 (UNAUDITED) (CONTINUED)**

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 4 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND NEWLY ISSUED ACCOUNTING STANDARDS:**

During the six months ended June 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.

#### *Inventories*

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 asset has been impaired.

#### *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 at each reporting date. 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 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.

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### **NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS FOR THE QUARTER ENDED JUNE 30, 2014 (UNAUDITED) (CONTINUED)**

#### *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*

Revenue arising from the sale of products is presented in these financial statements in Total revenues. Total revenues were comprised of revenue from sales of Carticel, Epicel, bone marrow, and surgical kits. Revenue is recognized from product sales 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, chargebacks 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.

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 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 5—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 acquired 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 acquired business also transforms the company into a fully integrated commercial business, and brings with it manufacturing, marketing and sales capabilities. This transaction provides a platform to generate operating income to support the development of pipeline products and possible additional strategic transactions. Pursuant to the terms of the asset purchase agreement, in consideration for the sale of the CTRM Business, the Company paid a total purchase price of \$6.5 million, including \$4.0 million in cash and a \$2.5 million promissory note with interest accruing at the short term applicable federal rate in effect on the May 30, 2014, prepayable without prepayment penalty, and due upon the earliest to occur of (i) July 30, 2014, (ii) a liquidation, dissolution or winding up of the Company, or (iii) a sale of the Company.

The total purchase price consideration is as follows:

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

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

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:

<b>Purchase price allocation (in 000's):</b>	<b>Fair Value</b>
Cash	\$ 5,050
Accounts receivable	53
Inventory	2,200
Other current assets	192
Accounts payable and accrued expenses	(2,539)
Property and equipment	1,818
Intangible assets	3,360
Bargain purchase gain	(3,634)
<b>Total consideration</b>	<b>\$ 6,500</b>

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 \$3.0 million and expect to incur additional costs in the second half of 2014. See Note 6 "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:

<b>(in 000's)</b>	<b>Fair Value</b>	<b>Useful Life</b>
Commercial rights	\$ 3,360	12 years

The following unaudited pro forma condensed combined information for the three month period ending June 30, 2014, and 2013, respectively and the six month period ending June 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 transactions have been made. These statements are based on assumptions and estimates considered appropriate by our management; however, they are unaudited and 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.

<b>(in 000's)</b>	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30, 2014</b>	<b>June 30, 2013</b>	<b>June 30, 2014</b>	<b>June 30, 2013</b>
Pro forma revenue	\$ 10,096	\$ 10,610	\$ 20,542	\$ 20,948
Pro forma net loss	(9,032)	(11,255)	(20,460)	(25,251)
Pro forma net loss per share — basic and diluted	\$ (1.61)	\$ (5.50)	\$ (3.77)	\$ (12.30)

Revenue and net loss included in the condensed consolidated financial statements include one month of operations related to the CTRM Business since the May 30, 2014 acquisition and are \$4.4 million and \$(2.7 million), respectively. The net loss related to the CTRM business includes the restructuring costs described below as well as \$231 thousand of expenses from the Genzyme Denmark subsidiary that the Company is in the process of shutting down.

**NOTE 6—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 intends to discontinue manufacturing MACI® in Denmark, temporarily cease sales of MACI® in Europe, and significantly reduce 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 are being provided with severance payments and outplacement assistance.

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

As a result of the Plan, the Company recorded a restructuring charge of \$3.0 million in the three months ended June 30, 2014 related to the operations in the United States and Denmark, primarily representing cash payments for severance and other personnel-related expenses. Of the total restructuring charge, \$2.4 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 \$2.6 million as of June 30, 2014 as a result of cash payments made for severance and other personnel-related expenses. In addition to restructuring charges recorded in the second quarter, the Company may incur the following costs in the future: lease termination costs of approximately \$0.6 million, and stay-on bonuses of \$0.2 million. These costs will be recognized when appropriate. 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.

**NOTE 7 — STOCK—BASED COMPENSATION**

The Company issues nonqualified and incentive stock options as well as other equity awards pursuant to its 2009 Omnibus Incentive Plan, as amended (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 six months ended June 30, 2014, the Company granted 128,000 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 June 30, 2014 and 2013 was \$3.11 and \$6.78, respectively. The weighted average grant-date fair value of service-based options granted under the Option Plan during the six month period ended June 30, 2014 and 2013 was \$2.85 and \$15.00, respectively.

The net compensation expense recorded for the service-based stock options related to employees and directors was \$0.2 million and \$0.5 million for the three and six months ended June 30, 2014, respectively, compared to \$426 thousand and \$383 thousand for the three and six month periods ended June 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.

Service-Based Stock Options	Six Months Ended June 30,	
	2014	2013
Expected dividend rate	0%	0%
Expected stock price volatility	82.4 – 88.2%	74.0-80.7%
Risk-free interest rate	1.66 – 2.2%	0.1- 1.4%
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	7.9	\$ —
Granted	242,025	\$ 3.91		
Exercised	—	\$ —		\$ —
Expired	(9,676)	\$ 47.58		
Forfeited	(23,240)	\$ 32.44		
Outstanding at June 30, 2014	506,969	\$ 22.69	8.3	\$ 57,599
Exercisable at June 30, 2014	191,888	\$ 40.24	6.62	\$ —

As of June 30, 2014 there was approximately \$0.9 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 3.19 years.

The total fair value of options vested during the six months ended June 30, 2014 and 2013 was \$1.0 million and \$1.4 million, respectively.

**NOTE 8—BALANCE SHEET COMPONENTS:**



**Inventories:**

(in 000's)	June 30, 2014	
Raw materials	\$	867
Work-in-process		582
Finished goods		473
Inventories	\$	<u>1,922</u>

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

	June 30, 2014		December 31, 2013	
<b>Property and equipment, net: (in 000's)</b>				
Equipment and computers	\$	3,949	\$	3,024
Furniture and fixtures		722		706
Buildings, building improvements and leasehold improvements		1,656		1,018
Construction in progress		368		77
Total property and equipment, gross		<u>6,695</u>		<u>4,825</u>
Less: Accumulated depreciation		<u>(4,308)</u>		<u>(4,086)</u>
	\$	<u>2,387</u>	\$	<u>739</u>

Intangible assets, net (in 000's)	As of June 30, 2014		
	Gross Amount	Accumulated Amortization	Net Amount
Commercial rights	\$ 3,360	\$ (23)	\$ 3,337

Amortization expenses were \$0.02 million and \$0 for the three and six month periods ended June 30, 2014 and 2013, respectively. The increase in intangible assets, net from December 31, 2013 to June 30, 2014 is due to the acquisition of the CTRM Business.

Estimated future amortization expense, which includes the preliminary estimates of amortization for the assets acquired through the initial closing of the CTRM Business acquisition, is as follows:

Calendar Years Ending December 31, (in 000's)	
2014	\$ 163
2015	280
2016	280
2017	280
2018	280
Thereafter	2,077
<b>Total</b>	<u>\$ 3,360</u>

(in 000's)	June 30, 2014		December 31, 2013	
<b>Accounts payable and accrued expenses:</b>				
Accounts payable to vendors	\$	2,909	\$	2,355
Accrued accounts payable		2,505		294
Restructuring reserve		2,605		—
Asset retirement obligation		1,600		—
Other		226		27
Total accounts payable and accrued expenses	\$	<u>9,845</u>	\$	<u>2,676</u>

**Accumulated other comprehensive income**

The components of accumulated other comprehensive income, net of taxes were as follows:

	June 30, 2014	
	Foreign Currency translation adjustment, net of taxes	
Beginning balance	\$	—
Foreign currency translation		5
Net loss reclassified into earnings		—
<b>Total</b>	\$	<u>5</u>

**NOTE 9—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;

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

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:

(In 000's)	June 30, 2014				December 31, 2013				
	Total	Fair value measurement category			Total	Fair value measurement category			
		Level 1	Level 2	Level 3		Level 1	Level 2	Level 3	
<b>Liabilities:</b>									
Warrant liabilities	\$ 2,974	\$	2,766	\$ 208	\$ 2,019	\$	—	\$ 1,934	\$ 85

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

<b>Warrant Liabilities (in 000's)</b>	
Balance at December 31, 2013	\$ 2,019
Warrant exercise	(149)
Increase in fair value	1,104
Balance at June 30, 2014	<u>\$ 2,974</u>

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 June 30, 2014	Six Months Ended June 30, 2014
Beginning balance	\$ 196	\$ 85
Increase in fair value	12	123
Ending balance	<u>\$ 208</u>	<u>\$ 208</u>

**NOTE 10—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 June 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	\$ 18.09	\$ 3.30	\$ 4.80
Expiration date	July 21, 2015	December 15, 2015	August 16, 2018
Total shares issuable on exercise	226,299	15,405	1,087,450

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

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

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.

Inherent in the Monte Carlo valuation model 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:

<b>January 2010 Class A Warrants</b>	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Closing stock price	\$ 4.10	\$ 3.23

Expected dividend rate	0%	0%
Expected stock price volatility	130.4%	84.6%
Risk-free interest rate	0.2%	0.3%
Expected life (years)	1.00	1.50

<b>December 2010 Warrants</b>	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Closing stock price	\$ 4.10	\$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	123.4%	80.4%
Risk-free interest rate	0.3%	0.4%
Expected life (years)	1.46	1.96

<b>August 2013 Warrants</b>	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Closing stock price	4.10	\$ 3.23
Expected dividend rate	0%	0%
Expected stock price volatility	89.9%	77.5%
Risk-free interest rate	1.4%	1.6%
Expected life (years)	4.13	4.63

**NOTE 11—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. 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 June 30, 2014, there are approximately 187,181 accumulated but undeclared Series B-1 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

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

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 \$38,389,000 Series B preferred stock was reclassified from mezzanine into shareholders' equity.

**NOTE 12—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.

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:

<b>(Amounts in 000's except per share amounts)</b>	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b>Numerator:</b>				
Net loss	\$ 4,638	\$ 4,889	\$ 10,633	\$ 10,433
Less: dividends accumulated on convertible preferred stock	1,474	1,314	2,892	2,577
Numerator of basic and diluted EPS	<u>\$ 6,112</u>	<u>\$ 6,203</u>	<u>\$ 13,525</u>	<u>\$ 13,010</u>
<b>Denominator:</b>				
Denominator for basic and diluted EPS:				
Weighted-average common shares outstanding	6,518	2,283	6,195	2,263

Net loss per share attributable to common shareholders (basic and diluted)	\$	(0.94)	\$	(2.72)	\$	(2.18)	\$	(5.75)
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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 June 30, 2014 and 2013 were 2,639,000 and 1,320,000, respectively.

#### NOTE 13—BORROWINGS:

##### Promissory note

The Company has a short term promissory note associated with the purchase of the CTRM Business. The interest rate for the principle amount is at the short term applicable federal rate in effect on May 30, 2014. The promissory note is prepayable without prepayment penalty and due upon the earliest to occur of (i) July 30, 2014, (ii) a liquidation, dissolution or winding up of the Company, or a (iii) sale of the Company. The balance outstanding on the promissory note as of June 30, 2014 was \$2.5 million. The promissory note approximates the fair value of the obligation.

On July 30, 2014, the Company repaid the promissory note due to Sanofi in connection with the acquisition of the CTRM Business in the amount of \$2.5 million plus interest of \$1.4 thousand.

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

#### NOTE 14—SHAREHOLDERS' EQUITY:

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 (with a remaining balance of \$11.8 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 six months ended June 30, 2014, the Company issued to Lincoln Park 772,361 shares of common stock and raised \$3.2 million. Additionally, during the six months ended June 30, 2014, the Company raised net proceeds of \$5.3 million utilizing the ATM. At June 30, 2014 there was approximately \$9.3 million of net capacity remaining on the ATM.

#### NOTE 15—CONCENTRATION OF CREDIT RISK

Revenue from one third party customer in the U.S. represented 76% of total revenue during the three and six month period ended June 30, 2014. Reported revenue reflects sales related to the acquisition of the CTRM Business from Sanofi since May 30, 2014. No other customer represented more than 10% of net sales.

#### NOTE 16 — 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 June 30, 2014, future minimum payments related to operating leases are as follows:

(in 000's)	2014	2015	2016	2017	2018	More than 5	Total
Leased office space	\$ 1,784	\$ 4,088	\$ 4,056	\$ 1,196	\$ 333	—	\$ 11,457
Sales force leased auto fleet	97	194	166	57	5	—	519
Total	\$ 1,881	\$ 4,282	\$ 4,222	\$ 1,253	\$ 338	\$ —	\$ 11,976

Rent expense for the three and six months ended June 30, 2014 was approximately \$0.6 million and \$0.8 million, respectively, compared to \$0.3 million and \$0.5 million for those same periods in 2013.

As part of its the 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. If the Company further develops MACI in the U.S., it will be obligated to pay Verigen up to \$15.8 million in developmental milestones relating to regulatory and commercialization of MACI

in the United States. No amounts have been accrued for payments of these potential milestone payments, any amounts to be paid cannot be reasonably estimated and are not probable.

## **NOTE 17—SUBSEQUENT EVENT**

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. As a result of this transaction, there are now 724,950 of the 2013 Warrants outstanding and the warrant liability has been reduced by approximately 33%.

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### **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 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 \$3.0 million and expect to incur additional costs in the second half of 2014. See Note 6, "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 will be 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<sup>2</sup>). 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 23-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 an 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. 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. 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. 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." A manufacturer may not distribute more than the annual distribution number assigned by the FDA at the time the exemption is granted. We are currently investigating the potential impact of this change on our ability to sell Epicel for a profit.

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 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 will be 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 of Verigen AG in 2005. As part of the acquisition of Verigen AG, Genzyme Corporation agreed to make cash payments upon the achievement of developmental milestones relating to regulatory and commercialization of MACI in the United States. If we further develop MACI in the U.S., we will be obligated to pay certain developmental milestones relating to regulatory and commercialization of MACI in the United States. No amounts have been accrued for payments of these potential milestone payments, any amounts to be paid cannot be reasonably estimated and are not probable.

## **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

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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 six months ended June 30, 2014 totaled (\$4.6 million) or (\$0.94) per share and (\$10.6 million) or (\$2.18) per share. The results for the three and six months ended June 30, 2014 include one month of operating results of the acquired CTRM Business including restructuring charges of \$3.0 million, expenses for the exited Denmark business of \$0.2 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 six months ended June 30, 2014 (in thousands):

	For the Three Months Ended June 30, 2014			For the Six Months Ended June 30, 2014		
	Legacy Business	Acquired Business	Consolidated Business	Legacy Business	Acquired Business	Consolidated Business
<b>Total revenues</b>	\$ 59	\$ 4,373	\$ 4,432	\$ 59	\$ 4,373	\$ 4,432
Cost of product sales	87	4,922	5,009	87	4,922	5,009
<b>Gross profit (loss)</b>	<b>(28)</b>	<b>(549)</b>	<b>(577)</b>	<b>(28)</b>	<b>(549)</b>	<b>(577)</b>
Total operating expenses	5,851	2,094	7,945	10,495	2,094	12,589
<b>Loss from operations</b>	<b>(5,879)</b>	<b>(2,643)</b>	<b>(8,522)</b>	<b>(10,523)</b>	<b>(2,643)</b>	<b>(13,166)</b>
Other income (expense)	250	—	250	(1,101)	—	(1,101)
Bargain purchase gain	3,634	—	3,634	3,634	—	3,634
Total other income loss	3,884	—	3,884	2,533	—	2,533
<b>Net loss</b>	<b>\$ (1,995)</b>	<b>\$ (2,643)</b>	<b>\$ (4,638)</b>	<b>\$ (7,990)</b>	<b>\$ (2,643)</b>	<b>\$ (10,633)</b>

## REVENUES

(in 000's)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
<b>Segment:</b>				
Aastrom Cell Therapy	\$ 4,432	\$ 3	\$ 4,432	\$ 11
<b>Geographic Region</b>				
United States of America	\$ 4,432	\$ 3	\$ 4,432	\$ 11

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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.

Net revenues for the three and six months ended June 30, 2014 were \$4.4 million and reflect one month of results from commercial operations of the CTRM Business in the U.S. Revenues were comprised of approximately \$3.4 million of net sales of Carticel implants and surgical kits, approximately \$0.9 million of net sales of Epicel grafts and biopsy kits, and approximately \$0.1 million of revenue from commercial sales of bone marrow generated by Marrow Donation.

## GROSS PROFIT AND GROSS PROFIT RATIO

(in 000's)	Three Months Ended June 30		Six Months Ended June 30,	
	2014	2013	2014	2013
Gross profit	\$ (577)	\$ 2	\$ (577)	\$ 8
Gross profit %	(13)%	67%	(13)%	73%

Period comparisons for gross profit are not meaningful due to the May 30, 2014 acquisition of the CTRM Business. Gross Profit for both the three and six month periods ending June 30, 2014 included \$2.4 million of restructuring expenses which reduced the gross profit by 54 percentage points.

## RESEARCH AND DEVELOPMENT COSTS

(in 000's)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development costs	\$ 4,364	\$ 3,676	\$ 7,635	\$ 9,214

The \$0.7 million increase in Research and development (R&D) costs for the three months ended June 30, 2014 is due to additional costs of \$1.0 million resulting from increased enrollment in the DCM trial and approximately \$0.5 million in R&D costs from the CTRM Business offset by a decrease of approximately \$0.8 million due to the completion of the CLI trial and a 2013 restructuring of \$0.4 million. The \$1.6 million decrease in R&D costs in the six months ended June 30, 2014 is due to an increase of \$3.0 million as the DCM trial increased enrollment and approximately \$0.5 million in R&D costs from the CTRM Business offset by a decrease of approximately \$5.1 million due to the completion of the CLI trial and a 2013 restructuring of \$0.4 million.

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:

(In 000's)	2014	2013	2014	2013
Critical Limb Ischemia	\$ 326	\$ 1,167	\$ 544	\$ 5,637
Dilated Cardiomyopathy	3,545	2,509	6,598	3,568
Other	493	—	493	9
Total research and development expenses	\$ 4,364	\$ 3,676	\$ 7,635	\$ 9,214

## SELLING, GENERAL AND ADMINISTRATIVE COSTS

(in 000's)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Selling, general and administrative costs	\$ 3,581	\$ 1,560	\$ 4,954	\$ 3,193

The increase in Selling, general and administrative (SG&A) costs for the three months ended June 30, 2014 of \$2.0 million is due to an increase of approximately \$0.4 million in legal and other expenses related to the acquisition of the CTRM Business, approximately \$0.6 million in restructuring expenses, approximately \$0.8 million in additional SG&A costs from the CTRM Business in the US and \$0.2 million in SG&A costs from the CTRM Business in Denmark partially offset by the reduced staffing and operating expenses due to the 2013 restructuring plan of \$0.1 million.

The increase in SG&A costs for the six months ended June 30, 2014 of \$1.8 million is due to an increase of approximately \$0.4 million in legal and other expenses related to the CTRM Business, approximately \$0.6 million in restructuring expenses, approximately \$0.8 million in additional SG&A costs from the CTRM Business in the U.S. and \$0.2 million in SG&A costs from the CTRM Business in Denmark partially offset by the reduced staffing and operating expenses due to the 2013 restructuring plan of \$0.1 million.

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### OTHER INCOME (EXPENSE)

(in 000's)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
(Increase) decrease in fair value of warrants	\$ 248	\$ 345	\$ (1,104)	\$ 1,964
Other income	3,634	—	3,634	—
Net interest income	2	—	3	2
TOTAL	\$ 3,884	\$ 345	\$ 2,533	\$ 1,966

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. 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 and cash equivalents, operating expenses, or cash flow.

The other income of approximately \$3.6 million for the three months ended and six months ended June 30, 2014 represents the bargain purchase gain associated with the acquisition of the CTRM Business on May 30, 2014.

### 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:

(000's)	Six Months Ended June 30,	
	2014	2013
Research and development	\$ 65	\$ (158)
Selling, general and administrative	386	541
Total non-cash stock-based compensation expense (income)	\$ 451	\$ 383

The increase in stock-based compensation expense 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. The forfeiture adjustments for the six months ended June 30, 2013 for research and development and selling, general and administrative for this announcement were \$968 thousand and \$157 thousand, respectively.

### 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 recently acquired CTRM business.

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

We expect that we will need to raise significant additional funds or pursue strategic transactions or other strategic alternatives in order to complete our product development programs, 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, and we expect to continue to seek to obtain the required capital in a similar manner. In connection with a purchase agreement with Lincoln Park, in the six months ended June 30, 2014, we issued to Lincoln Park 772,361 shares of common stock and raised \$3.2 million and have \$11.8 million of remaining capacity under the agreement. Additionally, during the six months ended June 30, 2014, the Company raised net proceeds of \$5.3 million utilizing our at the market sales agreement (ATM) with MLV & Co., LLC. which has approximately \$9.3 million of remaining net capacity.



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Our cash totaled \$7.3 million at June 30, 2014, a decrease of (\$796 thousand) from December 31, 2013. During the six months ended June 30, 2014, the primary uses of cash and cash equivalents included \$10.7 million for our operations and working capital requirements. As of June 30, 2014 we had \$795 thousand 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 the next several years due to the expected spending for research and development programs and the cost of marketing and commercializing our products and product candidates. We intend to seek additional funding through research and development agreements or grants, distribution and marketing agreements and through public or private debt or equity financing transactions. Successful future operations are subject to several technical and risk factors, including our continued ability to obtain future funding, satisfactory product development, obtaining required regulatory approvals and market acceptance for our products.

As of June 30, 2014, we have \$7.3 million of cash and cash equivalents. This is not sufficient to sustain our operations for one year. In light of our financial position, we are evaluating strategic and financial opportunities in the short-term in order to maintain adequate liquidity through December 31, 2014 and beyond. We could sell shares through our ATM or direct Lincoln Park to purchase up to an additional \$11.8 million worth of shares of common shares under the purchase agreement between the Company and Lincoln Park in order to raise additional capital, though there are certain factors, such as volume of trading in our stock, our stock price and the ability to terminate the agreement with notice, which could limit the amount we could raise in a short period of time. On a longer term basis, we will need to raise additional funds to successfully integrate the CTRM Business, complete product development programs and complete clinical trials needed to market and commercialize 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: the rate and degree of progress for our product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the United States and other countries, the liquidity and market volatility of our equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If we cannot raise such funds, we will not be able to develop 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 need to raise additional capital, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Off-Balance Sheet Arrangements**

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

### *Significant Accounting Policies and Newly Issued Accounting Standards*

During the six months ended June 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 as of and for the year ended December 31, 2013, and the notes thereto, which are included in our Annual Report on Form 10-K filed with the SEC on March 13, 2014.

### *Inventories*

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 asset has been impaired.

### *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.

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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 at each reporting date. 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 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*

Revenue arising from the sale of products is presented in these financial statements in Total Revenues. Total Revenues were comprised of revenue from sales of Carticel, Epicel, bone marrow, and surgical kits. Revenue is recognized from product sales 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, chargebacks 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.

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### *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 its consolidated financial statements.

### **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 June 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 June 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.

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 begun to take steps to remediate the material weakness noted above. On a temporary basis we have hired experienced 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. Additionally, during the current quarter, we hired a Chief Financial Officer, who has extensive finance experience. 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 June 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.

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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.*

### Risks Related to our Business

***Our past losses and expected future losses cast doubt on our ability to continue as a going concern and operate profitably.***

As of June 30, 2014, we had \$7.3 million of cash and cash equivalents. This is not sufficient to sustain our operations for one year. In light of our financial position, we are evaluating strategic and financial opportunities in the short-term in order to maintain adequate liquidity through the coming year and beyond. While we have access to certain amounts of financing through an agreement with Lincoln Park Capital Fund, LLC (Lincoln Park), 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. Also, the integration of the recently acquired CTRM business with our existing business will require additional financing. 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 as of the date of this registration statement. 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 will 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 distribution network of third party distributors and independent sales professionals for the distribution 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, technological developments by competitors, and other factors. 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 need to raise additional capital, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. 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 June 30, 2014, we had accumulated a deficit of \$298 million and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development (including clinical trials) of our cell culture technologies and our cell manufacturing system, general and administrative expenses, 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

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components, acquisition and development of complementary activities and raising sufficient cash to fund our operating activities. Therefore, we may not be able to achieve or sustain profitability.

***The 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 190 full-time employees as of June 30, 2014. 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 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.***

We will require substantial additional capital resources in order to complete our product development programs, 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 will need to raise a significant amount of additional funds. We will also need significant additional funds or a collaborative partner, or both, to finance the research and development activities of our cell 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;

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- 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 June 30, 2014, we had sold \$3.2 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 through the Lincoln Park Equity Line. 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 will 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 will still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences would have a material adverse effect on our business, operating results, financial condition and prospects.

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;
- 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 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. Each of these cell therapy products is, under current regulations, regulated as a biologic, which requires a BLA.

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***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 efficacy, 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 affected and we may experience difficulties in raising the substantial additional capital required to fund our business.

***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.

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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 efficacy 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, 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 agents used 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.

***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 (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

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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.

***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 (recently increased by an additional \$4.0 million in the U.S. as a result of the Transaction), 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 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. Recently, our manufacturing facility in Cambridge, Massachusetts was inspected by the FDA, resulting in the issuance of an FDA 483 List of Inspectional Observations. 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. 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 would be complex, time-consuming and expensive. 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. In addition, before we can apply for a BLA for MACI in the U.S., we will be obligated to pay certain developmental milestones relating to regulatory and commercialization of MACI in the United States. We have the option to extinguish these obligations for a one-time payment of €2.5 million.

***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.

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 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

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If HUD approval is suspended or revoked, Epicel would require an approved 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 one or more 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 offer 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 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.

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***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 IND applications, or supplements to our BLA or 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;
- 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 FDCA 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

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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 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.

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

The markets for our products are 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

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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 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.

***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 Patient Protection and Affordable Care Act (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, 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.

***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.

***Unintended consequences of recently adopted healthcare reform legislation in the U.S. may adversely affect our business.***

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals, resulting from political and economic influences, to change the healthcare system in ways that could affect our ability to sell our products. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

In March 2010, President Obama signed into law the PPACA which substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the biotechnology and medical industries. The PPACA includes, among other things, the following measures:

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- a 2.3% excise tax on the sale price of medical devices to be paid by any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions;
- a new Patient-Centered Outcomes Research Institute to oversee, identify research priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on biological product and device manufacturers, also known as the Sunshine Act, for any payment or other “transfer of value” made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests with data collection requirements beginning in 2013 and the first reports due in 2014;
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models;
- an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biological products that are demonstrated to be biosimilar or interchangeable with a licensed biological product.

These provisions could meaningfully change the way healthcare is delivered and financed. If the legislation causes certain unintended consequences or has an indirect impact on us, it could have a material adverse effect on our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (ATRA) 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.

In the future there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the price that we are able to charge for our products, or the amount of reimbursement available for our products, and could limit the acceptance and availability of our products for various indications. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations and financial condition.

***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.

***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.

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## **Risks Related to Intellectual Property**

***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.

Furthermore, with respect to ixmyelocel-T, we rely on exclusive, world-wide licenses relating to the production of human cells granted to us by the University of Michigan. If we materially breach such agreements or otherwise fail to materially comply with such agreements, or if such agreements expire or are otherwise terminated by us, we may lose our rights under the patents held by the University of Michigan. At the latest, each of these licenses will terminate when the patent underlying the license expires, with the last to expire during the third quarter of 2014. Once the patents expire, third parties may be able to practice the inventions covered by those patents and thus compete with us.

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, 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 U.S. Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics, or 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 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, or 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 for further consideration in light of their decision in the Prometheus case. The Federal Circuit heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit 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’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.

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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.

***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

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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.

***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 will 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.

***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 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.

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**Risks Related to an Investment in our Common Stock**

***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.***

Aastrom's business in recent history differs from that of the acquired business, and the business of the combined company will differ from that of ours, 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.

***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 six months ended June 30, 2014, we have sold (i) an aggregate gross amount of approximately \$5,450,000 of shares of common stock pursuant to our At-the-Market Sales Agreement (ATM) with MLV & Co. LLC (MLV) (formerly McNicoll, Lewis & Vlæk) through June 30, 2014, and (ii) an aggregate of approximately \$3,195,000 of shares of our common stock to Lincoln Park pursuant to the Lincoln Park Equity Line. During 2013, we sold (i) an aggregate of approximately \$4,900,000 of shares of common stock pursuant to our ATM through December 31, 2013, and (ii) in August 2013, we sold 1,500,000 shares of common stock and warrants to purchase up to 1,500,000 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 June 30, 2014 had remaining capacity of approximately \$9,300,000, 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 \$100,000,000 of our securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014, and we intend to file a new registration statement on Form S-3 to continue the ATM program in the coming months. Additionally, pursuant to the Lincoln Park Equity Line we may direct Lincoln Park to purchase up to \$15,000,000 worth of shares of our common stock over a 30-month period generally in amounts up to 50,000 shares of our common stock. As of June 30, 2014, we had remaining capacity of approximately \$11,800,000 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 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 the Company's 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.

## 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 June 30, 2014. All information regarding the unregistered sales of securities during the quarter ended June 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: August 14, 2014

AASTROM BIOSCIENCES, INC.

/s/ DOMINICK C. COLANGELO

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Dominick C. Colangelo  
President and Chief Executive Officer  
(Principal Executive Officer)

/s/ GERARD MICHEL

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Gerard Michel  
Chief Financial Officer and Vice President, Corporate Development  
(Principal Financial Officer)

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### EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
10.1	Asset Purchase Agreement, dated as of April 19, 2014, by and between the Company and Sanofi (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on June 2, 2014).
10.2	Employment Agreement, dated May 13, 2014, by and between the Company and Gerard Michel (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 4, 2014).
10.3	Transition Services Agreement, dated as of May 30, 2014, by and between the Company and Genzyme Corporation (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 2, 2014).
10.4	Transition Supply Agreement, dated as of May 30, 2014, by and between the Company and Genzyme Corporation (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 2, 2014).
10.5	Form of Warrant Exercise Agreement, dated July 9, 2014 (incorporated herein by reference to Exhibit 10 to the Company's Report on

10.6	Employment Agreement, dated as of March 27, 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 April 1, 2014).
10.7	Employment Agreement, dated as of March 27, 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 April 1, 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**

<u>TERM</u>	<u>DEFINITION</u>
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 heart beat.
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.

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## 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: August 14, 2014

/s/ DOMINICK C. COLANGELO

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Dominick C. Colangelo  
President and Chief Executive Officer  
(Principal Executive Officer)

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## 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: August 14, 2014

/s/ GERARD MICHEL

Gerard Michel

*Chief Financial Officer and Vice President, Corporate Development  
(Principal Financial Officer)*

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**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 June 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: August 14, 2014

/s/ DOMINICK C. COLANGELO

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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.

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**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 June 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: August 14, 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.

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