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# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**FOR THE QUARTERLY PERIOD ENDED March 31, 2014,**

**OR**

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

**FOR THE TRANSITION PERIOD FROM TO**

**Commission file number 0-22025**

# AASTROM BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

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

**(800) 556-0311**
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

| **COMMON STOCK, NO PAR VALUE** | **6,497,127** |
|---|---|
| (Class) | Outstanding at April 30, 2014 |

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**AASTROM BIOSCIENCES, INC.**
**QUARTERLY REPORT ON FORM 10-Q**

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## PART I - FINANCIAL INFORMATION

### Item 1. Financial Statements

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

**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(Unaudited, amounts in thousands)**

| | December 31, 2013 | March 31, 2014 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 8,059 | $ 8,836 |
| Other current assets | 417 | 400 |
| Total current assets | 8,476 | 9,236 |
| Property and equipment, net | 739 | 642 |
| Total assets | $ 9,215 | $ 9,878 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 2,676 | $ 2,475 |
| Accrued employee benefits | 620 | 406 |
| Current portion of long-term debt | 6 | 2 |
| Warrant liabilities | 2,019 | 3,226 |
| Total current liabilities | 5,321 | 6,109 |
| Shareholders' equity: | | |
| Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved — 39, shares issued and outstanding — 12 | 38,389 | 38,389 |
| Common stock, no par value; shares authorized — 15,000; shares issued and outstanding — 4,723 and 6,245, respectively shares issued and outstanding — 20,028 and 28,256, respectively | 253,270 | 259,140 |

| | | |
|---|---|---|
| Deficit accumulated during the development stage | (287,765) | (293,760) |
| Total shareholders' equity | 3,894 | 3,769 |
| Total liabilities and shareholders' equity | $ 9,215 | $ 9,878 |

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



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

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

| | Quarter Ended March 31, | | March 24, 1989 (Inception) to March 31, |
|---|---|---|---|
| | 2013 | 2014 | 2014 |
| Revenues: | | | |
| Product sales and rentals | $ 8 | $ — | $ 1,917 |
| Research and development agreements | — | — | 2,105 |
| Grants | — | — | 9,901 |
| Total revenues | 8 | — | 13,923 |
| Costs and expenses: | | | |
| Cost of product sales and rentals | 2 | — | 3,051 |
| Research and development | 5,538 | 3,271 | 235,105 |
| Selling, general and administrative | 1,633 | 1,374 | 99,847 |
| Total costs and expenses | 7,173 | 4,645 | 338,003 |
| Loss from operations | (7,165) | (4,645) | (324,080) |
| Other income (expense): | | | |
| (Increase) decrease in fair value of warrants | 1,619 | (1,352) | 20,522 |
| Other income | — | — | 1,249 |
| Interest income | 5 | 4 | 10,842 |
| Interest expense | (3) | (2) | (504) |
| Total other income (expense) | 1,621 | (1,350) | 32,109 |
| Net loss | $ (5,544) | $ (5,995) | $ (291,971) |
| Net loss per share attributable to common shareholders (Basic and Diluted) (see note 7) | $ (3.00) | $ (1.26) | |
| Weighted average number of common shares outstanding (Basic and Diluted) | 2,243 | 5,868 | |

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



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

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

| | Quarter Ended March 31, | | March 24, 1989 (Inception) to March 31, |
|---|---|---|---|
| | 2013 | 2014 | 2014 |
| Operating activities: | | | |
| Net loss | $ (5,544) | $ (5,995) | $ (291,971) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | | |
| Depreciation and amortization | 150 | 97 | 8,733 |
| Loss on property held for resale | — | — | 110 |
| Amortization of discounts and premiums on investments | — | — | (1,704) |
| Stock compensation expense | (43) | 270 | 18,691 |
| Change in fair value of warrants | (1,619) | 1,352 | (20,522) |
| Inventory write downs | — | — | 2,240 |
| Stock issued pursuant to license agreement | — | — | 3,300 |
| Provision for losses on accounts receivable | — | — | 204 |
| Changes in operating assets and liabilities: | | | |
| Inventories | — | — | (2,335) |
| Other current assets | 52 | 17 | (629) |
| Accounts payable and accrued expenses | (232) | (201) | 2,243 |
| Accrued employee benefits | 475 | (214) | 406 |

| | | | |
|---|---|---|---|
| Net cash used for operating activities | (6,761) | (4,674) | (281,234) |
| Investing activities: | | | |
| Organizational costs | — | — | (73) |
| Purchase of short-term investments | — | — | (217,041) |
| Maturities of short-term investments | — | — | 218,745 |
| Property and equipment purchases | (18) | — | (7,530) |
| Proceeds from sale of property held for resale | — | — | 400 |
| Net cash used for investing activities | (18) | — | (5,499) |
| Financing activities: | | | |
| Net proceeds from issuance of preferred stock | — | — | 89,267 |
| Net proceeds from issuance of common stock and warrants | 2,378 | 5,455 | 204,947 |
| Payments received for stock purchase rights and other, net | — | — | 3,500 |
| Proceeds from long-term debt | — | — | 751 |
| Principal payments under long-term debt obligations | (11) | (4) | (2,878) |
| Other, net | — | — | (18) |
| Net cash provided by financing activities | 2,367 | 5,451 | 295,569 |
| Net increase (decrease) in cash | (4,412) | 777 | 8,836 |
| Cash at beginning of period | 13,638 | 8,059 | — |
| Cash at end of period | $ 9,226 | $ 8,836 | $ 8,836 |
| Supplemental cash flow information (non-cash): | | | |
| Accretion of convertible preferred stock | $ 1,263 | $ — | $ 6,224 |
| Warrants exchanged for common stock | $ — | $ 145 | $ 10,527 |

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 March 31, 2014 (UNAUDITED)**

## 1. Organization and Summary of Significant Accounting Policies

Aastrom Biosciences, Inc. was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. The Company operates its business in one reportable segment — research and product development involving the development of patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic ischemic cardiovascular diseases.

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

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. As of March 31, 2014, the Company had $8,836,000 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 common shares through an At the Market Sales Agreement (ATM) or direct Lincoln Park Capital Fund, LLC (Lincoln Park) to purchase up to $15,000,000 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. 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 rate and degree of progress for 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 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 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.

## 2. Basis of Presentation

The condensed consolidated financial statements included herein have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America (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 three months ended March 31, 2014, are not necessarily

indicative of the results to be expected for the full year or for any other period. The December 31, 2013 condensed consolidated balance sheet data was derived from 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.



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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**FOR THE QUARTER ENDED March 31, 2014 (UNAUDITED) (CONTINUED)**

The consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany and Marrow Donation, LLC, located in San Diego, California (collectively, the Company). All inter-company transactions and accounts have been eliminated in consolidation. The subsidiaries are not a significant component of the consolidated financial statements as each has limited operations historically and Aastrom Biosciences GmbH has ceased operations.

### 3. 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 quarter ended March 31, 2014, the Company granted 114,025 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 Company's Option Plan during the quarter ended March 31, 2013 and 2014 was $17.00 and $2.55, respectively.

The net compensation expense recorded for the service-based stock options related to employees and directors was ($43,000) and $270,000 for the quarter ended March 31, 2013 and 2014, respectively. The March 31, 2013 compensation cost includes forfeiture adjustments, primarily due to restructuring activities announced on March 27, 2013, which reduced expense by $938,000.

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 | Quarter Ended March 31, 2013 | Quarter Ended March 31, 2014 |
|---|---|---|
| Expected dividend rate | 0% | 0% |
| Expected stock price volatility | 74.0% | 82.4 – 83.3% |
| Risk-free interest rate | 1.4% | 2.1 - 2.2% |
| Expected life (years) | 6.3 | 6.1 - 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 | 114,025 | $ 3.57 | | |
| Exercised | — | $ — | | $ — |
| Expired | — | $ — | | |
| Forfeited | (12,350) | $ 38.00 | | |
| Outstanding at March 31, 2014 | 399,535 | $ 29.31 | 8.1 | $ 92,000 |
| Exercisable at March 31, 2014 | 179,240 | $ 42.92 | 6.8 | $ — |

As of March 31, 2014 there was $1,329,000 of total unrecognized compensation cost related to non-vested service-based stock options granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 2.9 years.

The total fair value of options vested during the three months ended March 31, 2013 and 2014 was $917,000 and $693,000, respectively.



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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**FOR THE QUARTER ENDED March 31, 2014 (UNAUDITED) (CONTINUED)**

### 4. 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 March 31, 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 | $ 19.63 | $ 3.30 | $ 4.80 |
| Expiration date | July 21, 2015 | December 15, 2015 | August 16, 2018 |
| Total shares issuable on exercise | 226,299 | 15,405 | 1,089,200 |

The exercise price per share for the January 2010 warrants were adjusted for the anti-dilution provisions triggered by the issuance of common stock during the quarter ended March 31, 2014.

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

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:

| January 2010 Class A Warrants | December 31, 2013 | March 31, 2014 |
|---|---|---|
| Closing stock price | $ 3.23 | $ 4.39 |
| Expected dividend rate | 0% | 0% |
| Expected stock price volatility | 84.6% | 118.8% |
| Risk-free interest rate | 0.3% | .2% |
| Expected life (years) | 1.50 | 1.25 |

| December 2010 Warrants | December 31, 2013 | March 31, 2014 |
|---|---|---|
| Closing stock price | $ 3.23 | $ 4.39 |
| Expected dividend rate | 0% | 0% |
| Expected stock price volatility | 80.4% | 103.7% |
| Risk-free interest rate | 0.4% | 0.3% |
| Expected life (years) | 1.96 | 1.71 |

| August 2013 Warrants | December 31, 2013 | March 31, 2014 |
|---|---|---|
| Closing stock price | $ 3.23 | $ 4.39 |
| Expected dividend rate | 0% | 0% |
| Expected stock price volatility | 77.5% | 87.1% |
| Risk-free interest rate | 1.6% | 1.5% |
| Expected life (years) | 4.63 | 4.38 |



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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**FOR THE QUARTER ENDED March 31, 2014 (UNAUDITED) (CONTINUED)**

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

| Warrant Liabilities | |
|---|---|
| Balance at December 31, 2013 | $ 2,019 |
| Warrant exercise | (145) |
| Increase in fair value | 1,352 |
| Balance at March 31, 2014 | $ 3,226 |

The following table presents the Company's liabilities that are measured at fair value on a recurring basis at December 31, 2013 and March 31, 2014:

| | December 31, 2013 | | |
|---|---|---|---|
| | Level 1 | Level 2 | Level 3 |
| Warrant liabilities | — | $ 1,934,000 | $ 85,000 |

| | March 31, 2014 | | |
|---|---|---|---|
| | Level 1 | Level 2 | Level 3 |
| Warrant liabilities | — | $ 3,030,000 | $ 196,000 |

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

*Warrants (in thousands)*:

| | March 31, 2014 |
|---|---|
| Beginning balance | $ 85 |
| Increase in fair value | 111 |
| Ending balance | $ 196 |

**5. 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, into shares of common stock at a conversion price of $3.25 per share of common stock. At any time after the five year anniversary of issuance, 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 five year anniversary of issuance. As of March 31, 2014, there are approximately 164,501 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 time after the five year anniversary of issuance, 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 Deficit accumulated during the development stage using the effective interest method.



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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**FOR THE QUARTER ENDED March 31, 2014 (UNAUDITED) (CONTINUED)**

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 has been reclassified from mezzanine into shareholders' equity.

**6. Shareholders' Equity**

On January 21, 2014, the Company entered into a purchase agreement (the "Purchase Agreement"), together with a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park to sell to Lincoln Park up to $15,000,000 in shares of its common stock, subject to certain limitations, from time to time over a 30-month period commencing on the date that a registration statement (the "Initial Registration Statement"), which the Company agreed to file with the Securities and Exchange Commission ("SEC") pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed. The Company filed the Initial Registration Statement with the SEC on February 10, 2014, and it became effective on April 3, 2014. The final prospectus was filed with the SEC on April 3, 2014.

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, the Company issued to Lincoln Park 48,063 shares of common stock. As of March 31, 2014, no sales had been made under the Purchase Agreement. Subsequent to March 31, 2014, the Company raised nets proceeds of $1,042,000 under the Purchase Agreement. Additionally, during the quarter ended March 31, 2014, the Company raised net proceeds of $5,286,000 utilizing the ATM.

**7. 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:

| (Amounts in thousands except per share amounts) | Quarter Ended March 31, 2013 | 2014 |
|---|---|---|
| **Numerator:** | | |
| Net loss | $ (5,544) | $ (5,995) |
| Less: earnings attributable to convertible preferred stock | 1,263 | 1,418 |
| Numerator of basic and diluted EPS | $ (6,807) | $ (7,413) |
| | | |
| **Denominator:** | | |
| Denominator for basic and diluted EPS: | | |
| Weighted-average common shares outstanding | 2,243 | 5,868 |
| Net loss per share attributable to common shareholders (basic and diluted) | $ (3.00) | $ (1.26) |



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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**FOR THE QUARTER ENDED March 31, 2014 (UNAUDITED) (CONTINUED)**

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 March 31, 2013 and 2014 were 1,528,000 and 2,510,000, respectively.

**8. Subsequent Event**

On April 19, 2014, the Company entered into an Asset Purchase Agreement (Agreement), by and between the Company and Sanofi (Seller). Pursuant to the Agreement, the Company has agreed to acquire certain assets, including all of the outstanding equity interests of Genzyme Biosurgery ApS, a wholly-owned subsidiary of Seller, and over 250 patents and patent applications, of the Seller and certain of its Subsidiaries and assume certain liabilities of the Seller for purposes of acquiring the portions of the cell therapy and regenerative medicine business of the Seller currently operated through Genzyme Biosurgery ApS, which researches, develops, manufactures, markets and sells the Carticel®, Epicel® and MACI® products. The Company will also acquire global manufacturing and production centers located in the United States and Denmark. As consideration, the Company will, on the closing date of the Transaction pay to the Seller $6,500,000, subject to certain post-closing adjustments based upon working capital of Seller or Genzyme Biosurgery ApS on the transaction closing date, of which $4,000,000 will be paid in cash and the remaining $2,500,000 will be payable in the form of a promissory note to be held by the Seller. The promissory note will accrue interest at the short term applicable federal rate in effect on the Closing Date, be prepayable without prepayment penalty, and be due upon the earliest to occur of (i) July 12, 2014, (ii) a liquidation, dissolution or winding up of the Company, or a (iii) or closing of: (i) a merger of the Company or any other transaction or series of related transactions (other than a future equity financing of the Company) in which, in any of the foregoing cases, at least 50% of the outstanding equity securities of the Company or the surviving or resulting entity. In connection with the sale of the business, the Seller intends to transfer substantially all of the Seller's employees primarily engaged in the Business to the Company prior to or after the Closing Date. The transaction is expected to close in the second quarter of 2014.

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

**Overview**

We are a clinical-stage biotechnology company focused on developing innovative cell therapies that repair and regenerate damaged tissue for use in the treatment of severe, chronic ischemic cardiovascular diseases. We are developing patient-specific (autologous) multicellular therapies utilizing our proprietary, highly automated and scalable manufacturing system. Our manufacturing technology platform, the Aastrom Replicell System (ARS), enables the expansion of a variety of cell types, including the production of multicellular therapies expanded from an adult patient's own bone marrow, which can be delivered directly to damaged tissues using conventional syringes and cell injection catheter systems.

Our lead product, ixmyelocel-T, has demonstrated multiple biological activities that promote tissue repair and regeneration by reducing inflammation, promoting angiogenesis and remodeling ischemic tissue. Preclinical and clinical data suggest that ixmyelocel-T is safe and effective in treating patients with severe, chronic ischemic cardiovascular diseases such as advanced heart failure due to dilated cardiomyopathy (DCM), the third leading cause of heart failure, and critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD).



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Our lead ixmyelocel-T clinical development program is for the treatment of advanced heart failure due to ischemic DCM. Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of DCM, which we believe provides an efficient and cost-effective path to approval for ixmyelocel-T in this heart failure indication. 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. The study is designed to enroll 108 patients at approximately 35 sites across the United States and Canada. We also have ongoing ixmyelocel-T clinical programs for the treatment of CLI and craniofacial reconstruction, as well as preclinical research and development programs for the treatment of cardiovascular diseases.

On April 19, 2014, we entered into an Agreement to acquire certain assets, including all of the outstanding equity interests of Genzyme Biosurgery ApS, a wholly-owned subsidiary of Sanofi, and over 250 patents and patent applications and assume certain liabilities. We acquired portions of the cell therapy and regenerative medicine business of Sanofi, which includes three commercial products, Carticel®, Epicel® and MACI®, a fully formed workforce and two global manufacturing and production centers located in the United States and Denmark. As consideration, we will pay to the Sanofi $6,500,000, subject to certain post-closing adjustments on the transaction closing date, of which $4,000,000 will be paid in cash and the remaining $2,500,000 will be payable in the form of a promissory note to be held by the Sanofi. The transaction is expected to close in the second quarter of 2014.

**Our Therapy**

Ixmyelocel-T is a unique multicellular product derived from an adult patient's own bone marrow. Our proprietary cell manufacturing process significantly expands the mesenchymal stromal cells (MSCs) and M2-like anti-inflammatory macrophages in the patient's bone marrow mononuclear cells while retaining many of the hematopoietic cells. These cell types are known to regulate the immune response and play a key role in tissue repair and regeneration by resolving pathologic inflammation, promoting angiogenesis, and remodeling ischemic tissue. Ixmyelocel-T is the only multicellular product known to have expanded cell populations of both MSCs and M-2 like anti-inflammatory macrophages.

MSCs and M2-like macrophages have a wide range of biological activities that promote repair and regeneration of damaged tissues through the paracrine effects of their secreted factors, as well as their direct cell activities. These cells produce high levels of potent anti-inflammatory and angiogenic factors, as well as factors involved in extracellular matrix remodeling. These cells also have direct activities such as phagocytosis of cellular debris and apoptotic cells, which control the inflammatory response, uptake of LDL and removal of cholesterol, and remodeling of extracellular matrix. We believe that, together, these paracrine effects and direct cell activities are responsible for ixmyelocel-T's demonstrated therapeutic effects of resolving inflammation, promoting angiogenesis, and remodeling and repairing damaged tissue.

Ixmyelocel-T has several features that we believe are primarily responsible for success in treating adult patients with severe ischemic cardiovascular diseases such as DCM and critical limb ischemia:

*Patient-specific (autologous)* — we start with the patient's own cells, which are accepted by the patient's immune system, allowing the cells to integrate into existing functional tissues. We believe that this characteristic of our therapy eliminates both the risk of rejection and the need to use immunosuppressive therapy pre- or post-therapy. Our data also suggests that ixmyelocel-T provides the potential for long-term engraftment and tissue repair.

*Expanded* — we begin with a small amount of bone marrow from the patient (up to 60 ml) and significantly expand the number of certain cell types, primarily MSCs and M2-like anti-inflammatory macrophages, to a substantially greater number than are present in the patient's own bone marrow (up to 200 times the number of certain cell types compared with the starting bone marrow).

*Multicellular* — we believe the multiple cell types in ixmyelocel-T, which are normally found in bone marrow but in smaller quantities, possess the key functions required for reducing chronic inflammation and promoting angiogenesis and tissue repair. By reducing inflammation, we believe that ixmyelocel-T provides the ideal conditions to allow for the growth of new tissue and blood vessels.



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*Minimally invasive* — our procedure for collecting bone marrow can be performed in an out-patient setting and takes approximately 15 minutes. Administration of ixmyelocel-T for the treatment of DCM is performed in the cardiac catheterization laboratory using a cell injection catheter system in a one-time procedure. For diseases such as CLI, administration of ixmyelocel-T is performed with a syringe in an outpatient setting in a one-time, approximately 20 minute procedure.

*Safe* — bone marrow and bone marrow-derived therapies have been used safely and efficaciously in medicine for over three decades. Ixmyelocel-T leverages this body of scientific study and medical experience, and appears well tolerated in over 200 patients treated to date.

**Our Technology Platform**

Our patient-specific multicellular therapies are manufactured using the Company's proprietary Aastrom Repicell System (ARS) cell manufacturing system. Our manufacturing process is conducted in a highly-automated, fully-closed and rigorously controlled system. Our system is highly scalable and reproducible and located in a 5,000-square-foot centralized manufacturing facility in Ann Arbor, Michigan. Production is conducted under current Good Manufacturing Practices (cGMP) guidelines required by the FDA with current annual capacity to treat up to 3,000 patients.

**Our Strategy**

Our objective is to become the leading global biotechnology company in the development, manufacture, and commercialization of autologous multicellular therapies for the treatment of severe ischemic cardiovascular diseases. To achieve this objective, we intend to:

- Complete our Phase 2b ixCELL-DCM clinical study for the treatment of advanced heart failure due to ischemic DCM and, if successful, progress ixmyelocel-T into pivotal Phase 3 clinical studies for this orphan indication.
- Complete patient follow-up in the REVIVE-CLI study to evaluate safety and efficacy endpoints, and pursue opportunities through investigator-sponsored studies and strategic relationships to continue to develop ixmyelocel-T as a stand-alone and/or adjunct therapy for the treatment of critical limb ischemia.
- Conduct additional preclinical and clinical studies of ixmyelocel-T to pursue additional high-value indications for the treatment of severe ischemic cardiovascular diseases.
- Utilize our proprietary ARS cell-expansion manufacturing platform to expand our product portfolio of cell therapies for the treatment of immune/inflammatory, cardiovascular and fibrovascular diseases.
- Leverage our leading proprietary cell manufacturing platform and expertise to provide manufacturing services and capabilities to other development and commercial-stage biopharmaceutical companies.
- Prepare to commercialize ixmyelocel-T through continued development of our internal commercialization capabilities and/or strategic partnerships for North America, Europe and Asia.

**Clinical Development Programs**

Our clinical development programs are focused on addressing areas of high unmet medical need in severe, chronic ischemic cardiovascular diseases. We have completed our Phase 1/2 clinical trials in DCM, and 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 ongoing ixmyelocel-T clinical programs for the treatment of CLI and craniofacial reconstruction.

Results to date in our clinical trials may not be indicative of results obtained from subsequent patients enrolled in those trials or from future clinical trials. Further, our future clinical trials may not be successful or we may not be able to obtain the required Biologic License Application (BLA) approval to commercialize our products in the



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United States in a timely fashion, or at all. See “Risk Factors” included in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

***Heart Failure Due to Dilated Cardiomyopathy***

Heart failure represents a significant unmet medical need and a growing public health problem. The American Heart Association reports that there are approximately 6 million patients currently suffering from heart failure in the United States and an estimated 650,000 new cases in the U.S. each year. Current medical costs to treat these patients exceed $25 billion and this is expected to more than triple to nearly $80 billion by 2030 as a result of a growing patient population and the high cost of the limited treatment alternatives for advanced heart failure patients, as described below.

DCM is a leading cause of heart failure and of heart transplantation in the United States. DCM is a disease characterized by weakening of the heart muscle, thinning of the heart walls, enlargement of the heart chambers, and the inability to sufficiently pump blood throughout the body. Patients with DCM typically present with symptoms of congestive heart failure, including limitations in physical activity and shortness of breath. Ischemic DCM is associated with atherosclerotic cardiovascular disease and prior heart attacks and is the most common form of dilated cardiomyopathy, representing an estimated 60% of all DCM patients. Patient prognosis depends on the stage and cause of the disease, but is typically characterized by a very poor quality of life and a high mortality rate.

Current treatments for ischemic DCM patients that are refractory to further medical therapy such as prescription drugs, devices, and/or further revascularization procedures including bypass surgery and angioplasty, are limited to heart transplantation and placement of left ventricular assist devices (LVADs). There are less than 2,500 heart transplantations in the United States each year. Many refractory DCM patients are not eligible for heart transplantation and transplants are extremely expensive at an estimated cost of approximately $1 million. LVADs are also expensive at an estimated cost of over $175,000 and have a mortality rate of 50% at two years.

A majority of advanced heart failure patients that are refractory to medical therapy have DCM, and we believe that the refractory ischemic DCM market represents a substantial market opportunity for ixmyelocel-T. These refractory ischemic DCM patients are currently the target patient population for our clinical development of ixmyelocel-T, with approximately 175,000 patients in the United States alone. Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM, which we believe provides an efficient and cost-effective path to approval for ixmyelocel-T in this heart failure indication.

We have conducted two Phase 2a multicenter, randomized, open-label clinical studies in patients with ischemic DCM and nonischemic DCM investigating surgical (IMPACT-DCM) and catheter-based (Catheter-DCM) delivery of ixmyelocel-T. We reported 12-month data for the surgical IMPACT-DCM study at the Heart Failure Society of America meeting in September 2011 and final 12-month results from the Catheter-DCM study at the Society for Cardiovascular Angiography and Interventions (SCAI) 2012 Scientific Sessions. Results from these studies demonstrated that ixmyelocel-T was well-tolerated in patients with DCM. In the Catheter-DCM study and post-surgery in the IMPACT-DCM study, the incidence of adverse events was comparable between the ixmyelocel-T groups and the control groups. Cardiac failure was reported more frequently in the control group relative to ixmyelocel-T in both studies.

While these exploratory Phase 2a studies were not powered for determining differences in efficacy between treatment groups, there were consistent trends of clinically meaningful improvement in clinical endpoints observed in the ischemic DCM (IDCM) groups in both studies. In the combined IDCM groups across both studies, major adverse cardiovascular events (MACE) were experienced by a lower percentage of ixmyelocel T-treated patients compared to control patients, representing greater than 50% reduction in the number of patients having a MACE event. Likewise, patients in the combined ischemic DCM groups that were treated with ixmyelocel-T had a reduction in the average number of MACE events per patient. MACE is the recommended endpoint (mortality and cardiovascular hospitalizations) in Phase 3 heart failure studies as stated in the FDA 2009 Somatic Cell Therapy for Cardiac Diseases Draft Guidance. Consistent positive trends also were observed in several secondary efficacy measures in the IDCM groups. The majority of ixmyelocel T-treated patients with IDCM, but not control patients, had improvement in NYHA Class that was sustained over the 12 months following treatment. Improvement in NYHA Class is considered clinically meaningful. Additionally, a higher percentage of ixmyelocel T-treated IDCM



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patients showed a clinically meaningful improvement in self-reported quality of life and increased 6 minute walk distance compared to the IDCM control patients.

We are currently enrolling patients in the Phase 2b ixCELL-DCM clinical study, which is a multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of ixmyelocel-T in patients with advanced heart failure due to ischemic DCM. The study is designed to enroll 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.

***Critical Limb Ischemia***

CLI is the most serious and advanced stage of PAD resulting from chronic inflammation and lipid accumulation. PAD is a chronic atherosclerotic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other serious clinical conditions including hypertension, cardiovascular disease, dyslipidemia, diabetes, obesity and stroke. CLI is used to describe patients with chronic ischemia-

induced pain (even at rest) or tissue loss (ulcers or gangrene) in the limbs, often leading to amputation and death. Many CLI patients are considered unsuitable for revascularization as they have exhausted all other reasonable treatment options and will likely require amputation. The one-year and four-year mortality rates for CLI patients that are unsuitable for revascularization that progress to amputation are approximately 25% and 70%, respectively. Currently, there are an estimated 250,000 CLI patients that are unsuitable for revascularization in the United States.

Ixmyelocel-T has shown significant promise in the treatment of CLI patients with existing tissue loss that are unsuitable for revascularization. Our U.S. Phase 2b RESTORE-CLI program was a multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of ixmyelocel-T in the treatment of patients with CLI that are unsuitable for revascularization. It was the largest multi-center, randomized, double-blind, placebo-controlled cellular therapy study ever conducted in CLI patients. We completed enrollment of this trial in February 2010 with a total of 86 patients at 18 sites across the United States.

Final results of the Phase 2b RESTORE-CLI clinical trial were presented at the American Heart Association Scientific Sessions in November 2011 and published in the peer-reviewed journal Molecular Therapy in April 2012. Patients in the treatment arm showed a 62% reduction in risk relative to placebo in the primary efficacy endpoint of time to first occurrence of treatment failure (p=0.0032). While the study was not powered to show statistical significance in the secondary endpoint of amputation free survival, results from a subgroup of 45 patients with wounds at baseline (the approximate profile of the Phase 3 patient population) showed a 61% reduction in risk (21% ixmyelocel-T treated versus 44% control event rate; p=0.0802). The study also met the primary safety endpoint with no meaningful differences between the treated and control groups.

We initiated the Phase 3 REVIVE-CLI clinical study, a multicenter, randomized, double-blind, placebo controlled study to evaluate the efficacy and safety of ixmyelocel-T in patients with CLI, in 2012. We had previously received Fast Track Designation from the FDA for use of ixmyelocel-T for the treatment of CLI and reached agreement with the FDA on a Special Protocol Assessment. Patients were randomized 1:1 and were to be followed for 12 months for the primary efficacy endpoint of amputation-free survival. On March 27, 2013 we announced that we were stopping enrollment in the study for strategic business reasons. This study has been amended and is ongoing for the 41 patients that are enrolled in the study, and we plan to continue following these patients for 12 months to evaluate safety and certain efficacy measures. We expect to have results from this study in the second quarter of 2014.

**Results of Operations**

Research and development expenses decreased to $3,271,000 for the quarter ended March 31, 2014 from $5,538,000 for the quarter ended March 31, 2013. The decrease is primarily due to a reduction in clinical trial



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expenses due to stopping of enrollment in the Phase 3 REVIVE clinical trial and the execution of a corporate restructuring that we announced on March 27, 2013 that reduced staff and operating expenses.

Our major ongoing research and development programs are focused on the clinical development of ixmyelocel-T for treatment of severe, chronic cardiovascular diseases. The following table summarizes the approximate allocation of cost for our research and development projects (*in thousands)*:

| | Quarter Ended March 31 | |
|---|---|---|
| | 2013 | 2014 |
| Critical Limb Ischemia | $ 4,471 | $ 218 |
| Dilated Cardiomyopathy | 1,059 | 3,053 |
| Other | 8 | — |
| Total research and development expenses | $ 5,538 | $ 3,271 |

Selling, general and administrative expenses decreased to $1,374,000 for the quarter ended March 31, 2014 compared to $1,633,000 for the quarter ended March 31, 2013. The decrease is primarily due to the execution of a corporate restructuring that reduced staff and operating expenses.

The income (expense) related to the non-cash change in fair value of warrants was ($1,352,000) for the quarter ended March 31, 2014 compared to $1,619,000 for the quarter ended March 31, 2013. The increase in fair value of warrants was primarily due to the increase in our stock price and the issuance of the August 2013 warrants. Fluctuations in the fair value of warrants in future periods could result in significant non-cash adjustments to the condensed consolidated financial statements, however any income or expense recorded will not impact our cash, operating expenses or cash flows.

Our net loss was $5,995,000, or $1.26 per share, for the quarter ended March 31, 2014 compared to $5,544,000, or $3.00 per share, for the quarter ended March 31, 2013. The changes in net loss are primarily due to the non-cash change in the fair value of warrants and decreases in both research and development and selling, general and administrative expenses.

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

| | Quarter Ended March 31, | |
|---|---|---|
| | 2013 | 2014 |
| Research and development | $ (341) | $ (16) |
| Selling, general and administrative | 298 | 286 |
| Total non-cash stock-based compensation expense (income) | $ (43) | $ 270 |

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 three months ended March 31, 2013 for research and development and general, selling and administrative for this announcement were $968,000 and $157,000, respectively.

**Liquidity and Capital Resources**

We are currently focused on utilizing our technology to produce patient specific cell-based therapies for use in severe, chronic ischemic cardiovascular diseases. At such time as we satisfy, if at all, applicable regulatory approval requirements, we expect the sales of our cell-based therapies to constitute nearly all of our product sales revenues.

We do not expect to generate positive cash flows from our consolidated operations for at least the next several years and then only if we achieve significant product sales. Until that time, we expect that our revenue sources from our current activities will consist of only minor sales of our cell products and manufacturing supplies to our



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academic collaborators, grant revenue, research funding and potential licensing fees or other financial support from potential future corporate collaborators.

We expect that we will need to raise significant additional funds or pursue strategic 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. During the three months ended March 31, 2014, we raised net proceeds of $5,286,000 utilizing our ATM, which has remaining capacity to raise approximately $9,624,000 through sales of our common stock. As a development stage company, we have never been profitable and do not anticipate having net income unless significant product sales commence. With respect to our current activities, such sales are not likely to occur until we obtain additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through March 31, 2014, we had accumulated a deficit of $293,760,000. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, commence product sales or complete additional corporate partnering or acquisition transactions.

We have also, but to a lesser degree, financed our operations through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments, stock option and warrant exercises and funding under equipment leasing agreements. These financing sources, in addition to our public and private sales of our equity securities, is how we have generated cash in the past to fund operations.

Our cash totaled $8,836,000 at March 31, 2014, an increase of $777,000 from December 31, 2013. During the three months ended March 31, 2014, the primary uses of cash and cash equivalents included $4,674,000 for our operations and working capital requirements for the Phase 2 clinical program for ixmyelocel-T. As of March 31, 2014 we had $7,643,000 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 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 commercializing our product candidates. We intend to seek additional funding through research and development agreements or grants, distribution and marketing agreements and through public or private debt or equity financing transactions. Successful future operations are subject to several technical and risk factors, including our continued ability to obtain future funding, satisfactory product development, obtaining required regulatory approvals and market acceptance for our products.

As of March 31, 2014, we have $8,836,000 of cash and cash equivalents. This is not sufficient to sustain our operations for one year. In light of our financial position, recent Asset Purchase Agreement entered into, 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 $15,000,000 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 in order to 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



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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 March 31, 2014, we were not party to any off-balance sheet arrangements.

**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 on 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;
- anticipation of future losses;
- commercialization plans; and
- revenue expectations and operating results.



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**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As of March 31, 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.

Our vendors in countries outside the United States are typically paid in Euro. However, such expenditures have not been significant to date. Accordingly, we are not directly exposed to significant market risks from currency exchange rate fluctuations. We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances. We do not enter into hedging transactions and do not purchase derivative instruments.

**Item 4. Controls and Procedures**

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2014. The term "disclosure controls and procedures" is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on their evaluation, our management, including our Chief Executive Office and Chief Accounting Officer, concluded that our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 2014, there were no changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



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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, you should carefully consider the information regarding risk factors of the Company is 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 factor below, which could materially adversely affect our business, financial condition and/or results of operations. 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 Form 10-K.

***Our pending acquisition of the Sanofi Cell Therapy and Regenerative business is subject to closing conditions that may not be satisfied.***

On April 19, 2014, we entered into an Asset Purchase Agreement with Sanofi to acquire certain assets, including all of the outstanding equity interests of Genzyme Biosurgery ApS, a wholly-owned subsidiary of Sanofi, and inventory and assume certain liabilities for purposes of purchasing Sanofi's cell therapy and regenerative medicine business, which is currently operated through Genzyme Biosurgery ApS. The transaction is subject to a number of conditions that must be satisfied before it can be completed, and if those conditions are not met, the acquisition may not close.

**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 March 31, 2014. All information regarding the unregistered sales of securities during the quarter ended March 31, 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: May 15, 2014

AASTROM BIOSCIENCES, INC.

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



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**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 31.1 | Certification by Chief Executive Officer and 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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith). |
| 10.1 | Purchase Agreement, dated as of January 21, 2014, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 27, 2014). |
| 10.2 | Registration Rights Agreement, dated as of January 21, 2014, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 27, 2014). |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |

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## GLOSSARY

| TERM | DEFINITION |
|---|---|
| Adverse Event | Any adverse change in health or “side-effect” that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed. |
| Autologous (Patient Specific) | Originating from the patient receiving treatment. (Aastrom uses only autologous cells). |
| BLA — Biologics License Application | An application containing product safety, efficacy and manufacturing information required by the FDA to market biologics products in the U.S. |
| CLI — Critical Limb Ischemia | An atherosclerotic vascular disease characterized by insufficient blood flow in the lower extremities that causes severe pain, tissue loss or both. |
| Controlled Clinical Trial | A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment. |
| DCM — Dilated Cardiomyopathy | A chronic cardiac disease where expansion of the patient’s heart reduces the pumping function to a point that the normal circulation of blood cannot be maintained. |
| Double-Blind Clinical Trial | Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo. |
| FDA — Food & Drug Administration | The U.S. FDA ensures that medicines, medical devices, and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of $1 trillion worth of goods annually. |
| GMP — Good Manufacturing Practice | GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. |
| Hematopoietic Cells | All of the cells in the blood system including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells). |
| Ischemia | A shortage or inadequate flow of blood to a body part (commonly an organ or tissue) caused by a constriction or obstruction of the blood vessels supplying it. |
| LVEF — Left Ventricular Ejection Fraction | The fraction of blood pumped out of the left |



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| | 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. |

**EXHIBIT 31.1**

**CERTIFICATION**

I, Dominick C. Colangelo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aastrom Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2014

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo
*President and Chief Executive Officer*
*(Principal Executive Officer)*
*Chief Accounting Officer and Treasurer*
*(Principal Financial and Accounting Officer)*

**EXHIBIT 32.1**

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

In connection with the Quarterly Report of Aastrom Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), 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: May 15, 2014

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

A signed original of this written statement required by Section 906 has been provided to Aastrom Biosciences, Inc. and will be retained by Aastrom Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.