

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **November 13, 2014**

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan
(State or other jurisdiction
of incorporation)

000-22025
(Commission
File Number)

94-3096597
(I.R.S. Employer
Identification No.)

24 Frank Lloyd Wright Drive, Lobby K
Ann Arbor, Michigan
(Address of principal executive offices)

48105
(Zip Code)

Registrant's telephone number, including area code: **(734) 418-4400**

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition

On November 13, 2014, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1 Press release, dated November 13, 2014.

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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 hereunto duly authorized.

Date: November 13, 2014

Aastrom Biosciences, Inc.

By: /s/ Gerard Michel
Name: Gerard Michel
Title: Chief Financial Officer, and Vice President,
Corporate Development

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Aastrom Biosciences Reports Third-Quarter 2014 Financial Results

Conference Call Today at 8:30 a.m. Eastern Time

ANN ARBOR, Mich., November 13, 2014 (GLOBE NEWSWIRE) — Aastrom Biosciences, Inc. (Nasdaq: ASTM), a leading developer of patient-specific expanded cellular therapies for the treatment of severe diseases and conditions, today reported financial results for the quarter ended September 30, 2014. The results for the three months ended September 30, 2014 incorporate the first full quarter of operating results following the May 30, 2014 acquisition of Sanofi's cell therapy and regenerative medicine business (the acquired business).

Aastrom reported a net loss for the quarter ended September 30, 2014 of \$6.9 million, or \$0.82 per share, compared to a net loss of \$2.3 million, or \$1.20 per share, for the same period a year ago. The results include a one-time \$3.2 million charge to earnings in connection with a settlement agreement that eliminates all future milestone payments related to the development and commercialization of MACI™ in the United States. Excluding the \$3.2 million charge, the net loss for the quarter ended September 30, 2014 was \$3.8 million, or \$0.52 per share.

The acquired business generated \$1.0 million of positive contribution for the period, including \$0.4 million in restructuring charges and losses from operations in Denmark, which is expected to be shut down by the end of the year. Adjusting for those items, the acquired business contributed \$1.4 million in the third quarter.

Net revenues for the quarter ended September 30, 2014 were \$9.7 million and were comprised of approximately \$7.5 million of net sales of Carticel® implants and surgical kits, approximately \$1.8 million of net sales of Epicel®, \$0.2 million of sales of MACI from the Denmark subsidiary, and approximately \$0.2 million of revenue from commercial sales of bone marrow generated by Marrow Donation, LLC.

Gross profit for the quarter ended September 30, 2014 was \$4.1 million. Gross profit was reduced for this period by \$0.2 million of charges included in cost of goods sold related to the restructuring of the acquired business.

Research and development expenses for the quarter ended September 30, 2014 were \$7.8 million versus \$2.6 million for the same period a year ago. The increase in research and development expenses is due to the \$3.2 million charge related to the settlement agreement that eliminates all future milestone payments related to the development and commercialization of MACI in the United States, \$0.8 million of additional expenses from the newly acquired business, and a \$1.3 million increase in clinical trial expenses resulting from increased enrollment in the Phase 2b ixCELL-DCM clinical trial of ixmyelocel-T for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM).

Selling, general and administrative expenses for the quarter ended September 30, 2014 were \$4.3 million compared to \$1.1 million for the same period a year ago. The increase in SG&A expenses is due to approximately \$1.9 million in sales and marketing expenses from the newly acquired business, approximately \$0.8 million in increased IT, legal consulting and personnel costs related to integrating

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and managing the acquired business in the U.S. and \$0.6 million in SG&A costs related to the acquired business in Denmark, which is expected to be shut down by the end of the year.

Other income for the quarter ended September 30, 2014 was \$1.1 million compared to \$1.4 million for the same period a year ago. The decrease in other income is due primarily to the non-cash change in the fair value of warrants as well as the impact of the exercise of warrants in the third quarter of 2014.

As of September 30, 2014, the company had \$37.6 million in cash and cash equivalents compared to \$8.1 million in cash and cash equivalents at December 31, 2013.

Recent Business Highlights

During and since the third quarter of 2014, the company:

- Achieved \$1.0 million in positive contribution from the acquired business, or \$1.4 million excluding Denmark operations and restructuring charges;
- Raised gross proceeds of \$40.25 million through an underwritten public offering of common stock and the full exercise of the underwriters' option to purchase additional shares;
- Achieved enrollment and treatment of more than 80% of patients in the Phase 2b ixCELL-DCM clinical trial of ixmyelocel-T for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM);
- Announced that results from the Phase 2a clinical studies of ixmyelocel-T in DCM patients were published in the peer-reviewed journal *Circulation Research*, demonstrating that treatment with ixmyelocel-T reduced the incidence of major adverse cardiovascular events in patients with ischemic DCM;
- Announced that three-year results from the SUMMIT extension study on the clinical efficacy and safety of MACI for treating cartilage defects will be presented at the American Academy of Orthopedic Surgeons (AAOS) 2015 Annual Meeting;
- Ceased manufacturing of MACI in Denmark, consolidated manufacturing of commercial products in Cambridge, and gained EMA approval to suspend the MACI license in Europe for up to three years;
- Eliminated up to \$15.8 million in future milestone payments relating to the development and commercialization of MACI in the United States for a one-time payment of approximately \$3.2 million;
- Announced plans to change its corporate name to Vericel Corporation and move its corporate headquarters to Cambridge, Massachusetts.

"I'm very encouraged by the performance of our commercial business for the third quarter, which reflects the positive changes that we are making with our business during this transition period," said Nick Colangelo, president and chief executive officer of Aastrom. "In addition, our recent stock offering has put us in a stronger financial position to execute our clinical and commercial programs and enables new opportunities for product development and growth."

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Conference Call Information

Aastrom's management will host a conference call to discuss these results today at 8:30 a.m. Eastern time. Interested parties should call toll-free (877) 312-5881, or from outside the U.S. (253) 237-1173 and use conference ID 29268567. The call will be available live in the Investors section of Aastrom's website at <http://investors.aastrom.com/investors.cfm>. A replay of the call will be available until November 17, 2014 by calling (855) 859-2056, or from outside the U.S. at (404) 537-3406 and using conference ID 29268567.

About Aastrom Biosciences

Aastrom Biosciences is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. Aastrom markets two autologous cell therapy products in the United States for the treatment of cartilage repair and skin replacement. Aastrom is also developing MACI™, a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee, and ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy. For more information, please visit Aastrom's website at www.aastrom.com.

The Aastrom Biosciences, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=3663>

This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of our products and growth in revenues, intended product development, clinical activity timing, integration of the acquired business, and objectives and expectations regarding our company described herein, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with competitive developments, integration of the acquired business, clinical trial and product development activities, regulatory approval requirements, the availability and allocation of resources among different potential uses, estimating the commercial potential of our products and product candidates and growth in revenues, market demand for our products, and our ability to supply or meet customer demand for our products. These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission ("SEC") on March 13, 2014, Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

AASTROM BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited, amounts in thousands)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash	\$ 37,578	\$ 8,059
Accounts receivable	3,959	8
Inventory	1,711	—
Other current assets	1,468	409
Total current assets	44,716	8,476
Property and equipment, net	2,398	739
Intangible assets	3,267	—
Total assets	<u>\$ 50,381</u>	<u>\$ 9,215</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,390	\$ 2,676
Accrued employee benefits	2,176	620
Verigen payment liability	3,158	—
Restructuring reserve and asset retirement obligation	2,511	—
Current portion of long-term debt	38	6
Warrant liabilities	1,209	2,019
Total current liabilities	12,482	5,321
Long term debt:	115	—
Total liabilities	12,597	5,321
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved — 39, shares issued and outstanding — 12	38,389	38,389
Common stock, no par value; shares authorized — 75,000 and 15,000; shares issued and outstanding — 23,786 and 4,723, respectively	304,780	253,270
Other comprehensive income	(70)	—
Accumulated deficit	(305,315)	(287,765)

Total shareholders' equity	37,784	3,894
Total liabilities and shareholders' equity	<u>\$ 50,381</u>	<u>\$ 9,215</u>

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AASTROM BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, amounts in thousands except per share amounts)

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

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AASTROM BIOSCIENCES, INC.
CONDENSED STATEMENT OF OPERATIONS — LEGACY AND ACQUIRED BUSINESS
(Unaudited, amounts in thousands except per share amounts)

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

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NON-GAAP FINANCIAL MEASURES

In addition to the results reported in accordance with generally accepted accounting principles in the United States (GAAP), management is providing information regarding three non-GAAP financial measures.

Contribution from the acquired business:

The results for the three months ended September 30, 2014 incorporate the first full quarter of operating results following the May 30, 2014 acquisition of Sanofi's cell therapy and regenerative medicine business. The Company is providing this non-GAAP financial measure to help investors better understand the future impact of the acquired business on Aastrom's financial performance after certain costs, severance payments and other costs associated with the restructure activities. During the quarter ended September 30, 2014, management used this non-GAAP financial measure in making decisions related to the operations of the acquired business because, in addition to meaningful supplemental information regarding the future operating performance of the acquired business, the measure gives us a better understanding of the acquired business and the resources we should devote to successfully integrating the acquired business and ultimately achieve profitability.

Adjusted net loss:

During the quarter, the Company recorded a charge to earnings in connection with a settlement agreement that eliminates all future milestones related to the development and commercialization of MACI™ in the United States. The amount significantly increased research and development costs, and the quarter's net loss. During the quarter, management evaluated the operations excluding this amount, and believes this non-GAAP financial measure is important to understand the results of the business.

Adjusted Earnings Per Share (EPS):

The adjusted EPS is similar to Adjusted net loss as it incorporates the EPS impacts of the settlement agreement that eliminates all future milestones related to the development and commercialization of MACI™ in the United States. The amount significantly impacted EPS and management believes this non-GAAP financial measure is meaningful information.

The non-GAAP measures are intended only as a supplement to the comparable GAAP measurements and the Company compensated for the limitations inherent in the use of these non-GAAP measures by using GAAP measures in conjunction with the non-GAAP measures. As a result, investors should consider these non-GAAP measures in addition to, and not in substitution for or as superior to, the comparable measurement of financial performance prepared in accordance with GAAP.

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Non-GAAP Financial Measures: (in thousands of dollars):

Contribution from acquired business — Non-GAAP	2014
Net loss — GAAP - for the three months ended September 30, 2014	\$ (6,917)
Legacy business loss	7,901
Subtotal — Acquired business results	984
Restructure costs	77
Denmark business results	381
Contribution from acquired business — for the three months ended September 30, 2014 - Non-GAAP	<u>\$ 1,442</u>
Adjusted net loss — Non-GAAP	2014
Net loss - GAAP — for the three months ended September 30, 2014	\$ (6,917)
Impact of accrued expense for the Verigen agreement	3,158
Adjusted Net loss — for the three months ended September 30, 2014 - Non-GAAP	<u>\$ (3,759)</u>
Adjusted earnings per share (EPS) — Non-GAAP	2014
EPS - for the three months ended September 30, 2014 — GAAP	\$ (0.82)
Impact of accrued expense for the Verigen agreement	0.30
Adjusted Net loss — for the three months ended September 30, 2014 - Non-GAAP	<u>\$ (0.52)</u>

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