



June 16, 2014

## **Aastrom Announces Strategic Plan for Recently Acquired Cell Therapy and Regenerative Medicine Business**

- Manufacturing of MACI in Denmark to be discontinued
- Sales of MACI in Europe, representing 1% of revenues in 2014, temporarily ceased
- U.S. action plan implemented to optimize R&D, manufacturing and commercial operations
- Measures expected to enable company to generate positive cash flow from the U.S. Carticel and Epicel business in 2015

*Conference call and slide presentation with Aastrom's senior management today at 8:30 a.m. Eastern Time*

ANN ARBOR, Mich., June 16, 2014 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of patient-specific expanded cellular therapies for the treatment of severe diseases and conditions, today announced its strategic plan to maximize the profitability and growth potential of the cell therapy and regenerative medicine business that it recently acquired from Sanofi.

### **Business Summary**

On May 30, 2014, Aastrom acquired the cell therapy and regenerative medicine business of Sanofi for a purchase price of \$6.5 million, with \$4 million paid in cash at closing and \$2.5 million payable in the form of a promissory note. Through the acquisition, Aastrom acquired three approved autologous cell therapy products: Carticel<sup>®</sup> (autologous cultured chondrocytes) and Epicel<sup>®</sup> (cultured epidermal autografts), which currently are marketed in the United States, and MACI<sup>™</sup> (matrix-applied characterized autologous cultured chondrocytes), which is approved in the European Union and is a Phase 3 product candidate in the United States. Aastrom also acquired a commercial organization based principally in the United States, global manufacturing and production centers located in the United States and Denmark, and approximately \$4.3 million in net working capital.

Carticel, a first-generation autologous chondrocyte implant (ACI) product for the treatment and repair of cartilage defects in the knee, is the first and only FDA-approved autologous cartilage repair product. MACI is a third-generation ACI product for the treatment of focal chondral cartilage defects in the knee. MACI has been commercially available in the European Union since 1998 and is the first and only tissue-engineered product approved under the Advanced Therapy Medicinal Product guidelines by the European Commission.

Epicel is a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area and currently is marketed in the United States. It is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was approved in the United States in 2007 as a Humanitarian Use Device (HUD) and is supplied outside the U.S. on a named-patient basis. Under its approval as a HUD, Epicel currently cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution.

The acquired products have been supported by a commercial organization based in the U.S. and Europe and manufacturing and production facilities in Cambridge, Massachusetts and Copenhagen, Denmark. The Cambridge facility has been used for U.S. manufacturing and distribution of Carticel, worldwide manufacturing and distribution of Epicel and production of MACI for clinical testing. The Cambridge facility also houses the Manufacturing and Technical Services organization, which is responsible for process development, release assay development and technology transfers between sites and departments. The Copenhagen manufacturing facility has been responsible for MACI commercial manufacturing and distribution in Europe.

### **Financial Results for Prior Periods**

As reflected in the special purpose combined financial statements in the Form 8-K/A which will be filed today with the Securities and Exchange Commission, the acquired business generated net revenues of approximately \$44 million for the year ended December 31, 2013. Net revenues were \$35.2 million for Carticel, \$7.1 million for Epicel, and \$1.6 million for MACI for the year ended December 31, 2013.

Net revenues less operating expenses were approximately (\$21.6) million for the period ending December 31, 2013, reflecting a net loss for the period of (\$33.6) million reduced by \$12.0 million in non-cash amortization charges and the write-off of

intangibles. In addition to the amortization charges, expenses for the year ended December 31, 2013 included \$12.7 million in other non-cash expenses and expenses allocated to the acquired business by Sanofi and its subsidiaries, as well as expenses for development activities which have been substantially completed. These expenses included approximately \$9.3 million in research and development expenses that were attributable to MACI development activities for the year ended December 31, 2013. Selling, general and administrative costs included \$2.2 million of costs and expenses allocated to the acquired business. Additional non-cash charges for depreciation and stock-based compensation totaled \$1.2 million for the year ended December 31, 2013. Sales of MACI in Europe were \$1.6 million, or 4% of total sales, and net losses attributable to European operations were approximately \$7.0 million for the year ended December 31, 2013.

Net revenues for the quarter ended March 31, 2014 were \$10.4 million compared to net revenues of \$10.3 million for the quarter ended March 31, 2013. Net revenues were \$7.9 million for Carticel, \$2.5 million for Epicel, and \$0.1 million for MACI for the quarter ended March 31, 2014.

Net revenues less expenses was (\$5.4) million for the quarter ended March 31, 2014 compared to (\$8.5) million for the quarter ended March 31, 2013. Expenses included \$2.3 million of costs and expenses allocated to the acquired business and non-cash charges. Research and development and selling, general and administrative expenses allocated to the acquired business were \$2.0 million for the quarter ended March 31, 2014. Additional non-cash charges for depreciation and stock-based compensation totaled \$0.3 million for the quarter ended March 31, 2014. Sales of MACI in Europe were \$0.1 million, or 1% of total revenues, and net losses attributable to European operations were approximately \$1.6 million for the quarter ended March 31, 2014.

Nick Colangelo, president and CEO of Aastrom, stated: "We believe that there is significant medical need and commercial opportunity for the acquired products and that they represent a strong platform for our future growth. However, the acquired business has been operating at a loss, the reimbursement environment for MACI in Europe has been difficult, and we believe that commercial operations for the acquired products can be more efficiently supported in the future utilizing the Cambridge manufacturing facility in the U.S. By taking immediate steps to eliminate redundancies, reduce costs and expenses, and improve operating efficiencies, we expect that the acquired U.S. Carticel and Epicel business will generate positive cash flow and be accretive to Aastrom beginning in 2015."

## **New Strategic Initiatives**

After conducting a comprehensive strategic review of the acquired business, Aastrom has initiated the following actions:

- **Discontinue manufacturing of MACI in Denmark and temporarily cease sales of MACI in Europe**
  - U.S. manufacturing facility to serve as the exclusive manufacturing facility for commercial products of the acquired business
  - Denmark manufacturing facility, licensed for commercial production in the EU, planned to be sold
  - MACI sales in Europe, representing 1% of revenues in 2014, temporarily ceased until U.S. production is available
  - Actions reduce annual operating expenses by approximately \$7 million
- **Significantly reduce R&D expenses as a result of the substantial completion of research activities required to support MACI BLA filing in the U.S.**
  - Company to clarify registration path for MACI in the U.S. with the FDA
  - R&D expenses reduced by approximately \$9 million
- **Optimize manufacturing and commercial operations in the U.S.**
  - Sales territories realigned to optimize Carticel sales potential and sales incentive plan revised to drive improved Carticel profitability
  - Epicel price increase to fully reflect allowable charges under the Humanitarian Device Exemption regulations
  - Manufacturing efficiencies being implemented based upon existing Carticel biopsy shelf-life data and anticipated improvements in biopsy-to-implant ratios
  - U.S. FTE reductions decrease annual operating expenses by approximately \$4 million
- **Immediate reduction of approximately 80 global FTE positions**

Mr. Colangelo added: "Aastrom is uniquely positioned to identify and execute these strategic initiatives to optimize the acquired business given our management team's history in developing these acquired products, building successful commercial brands in the U.S., and integrating and optimizing combined biopharmaceutical organizations. Our ultimate goal is to improve the experience of patients and physicians with our products, create a world-class cell therapy and regenerative medicine business, and create value for our shareholders."

## **Conference Call Information**

Aastrom's management will host a conference call today at 8:30 a.m. Eastern time to discuss this announcement. Interested

parties should call toll-free 877-312-5881 (from outside the U.S. call 253-237-1173) and reference the Aastrom Biosciences conference call. The call will be available live in the Investors section of Aastrom's website at <http://investors.aastrom.com/investors.cfm>. A copy of the presentation slides will be available in the Investors section of the Aastrom website at <http://investors.aastrom.com/events.cfm>. A replay of the call will be available beginning June 16, 2014 at 11:30 a.m. Eastern Time until June 21, 2014 by calling 855-859-2056 (from outside the U.S. call 404-537-3406) and referencing conference ID 61387590.

## About Aastrom Biosciences

Aastrom Biosciences is the 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, and is developing 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](http://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 profitability, growth in revenue and earnings per share, cash payments, the costs and expenses as well as expected benefits and cost savings that we anticipate will result from the strategic restructuring plan 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 risks and uncertainties associated with competitive developments, estimating profitability, cash payments, growth in revenues and earnings per share prior to us closing our books and verifying such information, our ability to successfully implement the strategic restructuring plan described herein to reduce expenses and produce cost savings, leverage synergies and optimize our resources, the impact of the strategic restructuring plan described herein on our business, regulatory and product development activities as well as potential adverse effects on revenues and other financial results, or unanticipated charges not currently contemplated that may occur as a result of the strategic restructuring plan described herein. 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.*

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