# 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, 2015

# **Vericel Corporation**

(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction of incorporation)

001-35280

(Commission File Number)

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

**64 Sidney Street** 

Cambridge, MA

(Address of principal executive offices)

**02139** (Zip Code)

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

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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, 2015, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Item 9.01. Financial Statements and Exhibits.

Exhibit No. Description

99.1

Press Release dated November 13, 2015.

#### SIGNATURES

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.

Vericel Corporation

Date: November 13, 2015

By: /s/ Gerard Michel

Name: Gerard Michel Title: Chief Financial Officer and Vice President Corporate Development

#### Exhibit 99.1



Vericel Corporation 64 Sidney Street Cambridge, MA 02139 T (617) 252-7999 F (617) 252-7550 www.vcel.com

# Vericel Reports Third-Quarter 2015 Financial Results Total Revenues of \$11.3 Million Reported for the Third Quarter Carticel and Epicel Revenues Increase 19% Compared to Third Quarter of 2014

Conference Call Today at 8:00am Eastern Time

CAMBRIDGE, Mass., November 13, 2015 (GLOBE NEWSWIRE) - Vericel Corporation (NASDAQ: VCEL), 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, 2015. Total revenues for the third quarter were generated primarily from net sales of Carticel<sup>®</sup> (autologous cultured chondrocytes) implants and surgical kits and Epicel<sup>®</sup> (cultured epidermal autografts), which were acquired on May 30, 2014 as part of the acquisition of Sanofi's cell therapy and regenerative medicine business.

Total revenues for the quarter ended September 30, 2015 were \$11.3 million and included \$7.7 million in net sales of Carticel implants and surgical kits and \$3.3 million in net sales of Epicel. Total Carticel and Epicel net product revenues in the third quarter increased approximately 19% over third-quarter net product revenues in 2014. Epicel and Carticel net product revenues increased 83% and 4%, respectively, compared to the same period a year ago. For the nine months ended September 30, 2015, total Carticel and Epicel net product revenues were \$35.1 million and increased 18% over pro-forma Carticel and Epicel net product revenues for the same period in 2014.

Gross profit for the quarter ended September 30, 2015 was \$4.5 million, or 40% of total revenues. Gross profit for the quarter was reduced by 4% due to higher than normal inventory write-offs.

Research and development expenses for the quarter ended September 30, 2015 were \$3.7 million versus \$7.8 million for the same period a year ago. The decrease in third-quarter research and development expenses is primarily due to a reduction in expenses associated with the ongoing ixCELL-DCM clinical trial and a \$3.2 million payment to Verigen shareholders in 2014 pursuant to a settlement agreement that eliminated all future milestone payments related to the development and commercialization of MACI<sup>TM</sup> (matrix-applied characterized autologous cultured chondrocytes) in the United States, partially offset by the addition of personnel and other expenses associated with Epicel, Carticel and MACI. MACI is Vericel's investigational third-generation autologous cultured chondrocyte implant for the treatment of symptomatic full-thickness cartilage defects of the knee.

Selling, general and administrative expenses for the quarter ended September 30, 2015 were \$5.7 million compared to \$4.3 million for the same period in 2014. The increase in SG&A expenses is primarily due to an increase in sales and marketing expenses associated with Carticel and Epicel as well as strategic planning activities for MACI.

Loss from operations for the quarter ended September 30, 2015 was \$4.9 million compared to \$8.0 million for the same period a year ago. Material non-cash items impacting the operating loss for the quarter included \$0.6 million of stock-based compensation expense and \$0.5 million in depreciation and amortization expense.

Other income for the quarter ended September 30, 2015 was \$0.5 million compared to \$1.1 million for the same period a year ago. The change in other income for the quarter is primarily due to the non-cash change in the fair value of warrants.

Vericel reported a net loss for the quarter ended September 30, 2015 of \$4.4 million, or \$0.26 per share, compared to a net loss of \$6.9 million, or \$0.82 per share, for the same period in 2014.

As of September 30, 2015, the company had \$18.7 million in cash compared to \$30.3 million in cash at December 31, 2014.

## **Recent Business Highlights**

During and since the third quarter of 2015, the company:

- Increased total third-quarter Carticel and Epicel net product revenues by 19% versus net product revenues for the third quarter of 2014;
- Achieved 83% growth in Epicel net product revenues versus net product revenues for the third quarter of 2014;
- Announced plans to submit a Humanitarian Device Exemption (HDE) supplement to the FDA in the fourth quarter of 2015 to revise the labeled indications for use of Epicel to specifically include pediatric patients and to add pediatric labeling for Epicel;
- Continued to prepare a Biologics License Application (BLA) for submission by the end of 2015 for MACI for the treatment of focal chondral cartilage defects in the knee;
- Announced the execution of a long-term supply agreement with Matricel GmbH for the ACI-Maix collagen membrane used in the manufacture of MACI; and
- Continued to evaluate patients in the ongoing Phase 2b ixCELL-DCM clinical trial of ixmyelocel-T for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy.

"Vericel continued to generate strong revenue growth during the third quarter, which reflects the success of our commercial initiatives," said Nick Colangelo, Vericel's president and chief executive officer. "We also made substantial progress in advancing our upcoming regulatory submissions for MACI and Epicel. These important initiatives have the potential to significantly expand our cartilage repair and burn therapy franchises and position the company for continued strong growth in the years ahead."

### **Conference Call Information**

Today's conference call will be available live at 8:00am Eastern time in the Investors section of the Vericel website at http://investors.vcel.com/events.cfm. Please access the site at least 15 minutes prior to the scheduled start time in order to download the required audio software if

necessary. To participate in the live call by telephone, please call (877) 312-5881 and reference Vericel Corporation's third-quarter 2015 investor conference call. If calling from outside the U.S., please use the international phone number (253) 237-1173.

If you are unable to participate in the live call, the webcast will be available at http://investors.vcel.com/events.cfm until Monday, November 14, 2016. A replay of the call will also be available until 11:59 pm (EDT) on 11/17/2015 23:59, 2015 by calling (855) 859-2056, or from outside the U.S. (404) 537-3406. The conference ID is 71018424.

## **About Vericel Corporation**

Vericel Corporation (formerly Aastrom Biosciences, Inc.) is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. The company markets two autologous cell therapy products in the U.S.: Carticel<sup>®</sup> (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel<sup>®</sup> (cultured epidermal autografts), a permanent skin replacement for the treatment of patients with deep-dermal or full-thickness burns comprising greater than or equal to 30% of total body surface area. Vericel is also developing MACI<sup>™</sup>, a third-generation autologous chondrocyte implant for the treatment of cartilage defects. 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 the company's website at www.vcel.com.

The Vericel Corporation logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=29189.

This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of our products, revenue trends, intended product development, clinical activity timing and regulatory pathway and 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," "can continue," "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 and improvement in costs, 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 Vericel's Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission ("SEC") on March 25, 2015, Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements reflect management's current views and Vericel does not undertake to update any of these forwardlooking 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.

### VERICEL CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited, amounts in thousands)

	Se	ptember 30,	December 31,	
		2015	2014	
ASSETS				
Current assets:				
Cash	\$	18,724	\$	30,343
Accounts receivable (net of allowance for doubtful accounts of \$54 and \$40, respectively)		7,639		8,191
Inventory		1,639		1,920
Other current assets		514		1,036
Total current assets		28,516		41,490
Property and equipment, net		4,315		2,892
Intangible assets		2,987		3,197
Total assets	\$	35,818	\$	47,579
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	4,995	\$	5,824
Accrued expenses		3,311		4,714
Warrant liabilities		825		1,081
Other		130		210
Total current liabilities		9,261		11,829
Long term debt		81		109
Other long-term liabilities		66		_
Total liabilities		9,408		11,938
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; shares issued and outstanding — 23,789 and 23,786, respectively.		307,207		305,008
Other comprehensive loss		(71)		(71)
Accumulated deficit		(319,115)		(307,685)
Total shareholders' equity		26,410		35,641
Total liabilities and shareholders' equity	\$	35,818	\$	47,579

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

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2015		2014		2015		2014
Revenues:								
Product sales	\$	11,309	\$	9,658	\$	35,748	\$	14,090
Total revenues		11,309		9,658		35,748		14,090
Costs and expenses:								
Cost of product sales		6,772		5,532		19,241		10,541
Gross profit		4,537		4,126		16,507		3,549
Research and development		3,740		7,835		11,486		15,470
Selling, general and administrative		5,674		4,313		16,735		9,267
Total operating expenses		9,414		12,148		28,221		24,737
Loss from operations		(4,877)		(8,022)		(11,714)		(21,188)
Other income (expense):								
Decrease (increase) in fair value of warrants		461		949		256		(155)
Bargain purchase gain				—		—		3,634
Foreign currency translation gain (loss)		(5)		154		5		154
Interest income		7		3		29		9
Interest expense		(2)		(1)		(6)		(4)
Total other income (expense)		461		1,105		284		3,638
Net loss	\$	(4,416)	\$	(6,917)	\$	(11,430)	\$	(17,550)
Net loss per share attributable to common shareholders (Basic and Diluted)	\$	(0.26)	\$	(0.82)	\$	(0.69)	\$	(2.90)
Weighted average number of common shares outstanding (Basic and Diluted)		23,788		10,273		23,786		7,569

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