
**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 7, 2016

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:

- 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 7, 2016, 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 7, 2016. |

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 7, 2016

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Financial Officer and Vice President Corporate
Development



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

Vericel Reports Third-Quarter 2016 Financial Results

Total Revenues of \$10.9 Million Reported for the Quarter

Conference Call Today at 4:30pm Eastern Time

CAMBRIDGE, Mass., November 7, 2016 (GLOBE NEWSWIRE) - Vericel Corporation (NASDAQ: VCEL), a leading developer of autologous expanded cell therapies for the treatment of severe diseases and conditions, today reported financial results for the third quarter ended September 30, 2016.

Total net revenues for the quarter ended September 30, 2016 were approximately \$10.9 million and included approximately \$8.3 million of Carticel[®] (autologous cultured chondrocytes) net revenues and approximately \$2.6 million of Epicel[®] (cultured epidermal autografts) net revenues. Total Carticel and Epicel net revenues for the quarter ended September 30, 2016 were approximately flat compared to total net product revenues in the third quarter of 2015, with Carticel net revenues increasing \$0.6 million and Epicel net revenues decreasing \$0.6 million compared to the same period in 2015. While Epicel orders for the quarter ended September 30, 2016 were equal to the number of orders in the third quarter of 2015, the average number of grafts per order was lower in this quarter. For the nine months ended September 30, 2016, total Carticel and Epicel net revenues were \$37.9 million and included over \$26.1 million of Carticel net revenues and over \$11.7 million of Epicel net revenues. Total Carticel and Epicel net revenues increased approximately 8% compared to the first nine months of 2015, with Carticel revenue increasing 9% and Epicel revenues increasing 5%, respectively, compared to the same period in 2015.

Gross profit for the quarter ended September 30, 2016 was \$4.1 million, or 37% of net revenues, compared to \$4.5 million, or 40% of net product revenues, for the third quarter of 2015. Gross profit for the first nine months of 2016 was \$17.1 million, or 45% of net revenues, compared to \$16.5 million, or 46% of net product revenues, for the first nine months of 2015.

Research and development expenses for the quarter ended September 30, 2016 were \$3.4 million compared to \$3.7 million in the third quarter of 2015. The decrease in third quarter research and development expenses is primarily due to a decrease in research, development, and regulatory consulting expenses for MACI[®] (autologous cultured chondrocytes on porcine

collagen membrane). MACI is Vericel's investigational third-generation autologous cultured chondrocyte product intended for the treatment of symptomatic full-thickness cartilage defects of the knee. Development expenses for the ixmylocel-T program were \$1.9 million for the third quarter of 2016, which were primarily due to ongoing clinical development activities related to the double-blind portion of the ixCELL-DCM study and preparations for the open-label crossover extension portion of the study.

Selling, general and administrative expenses for the quarter ended September 30, 2016 were \$7.0 million compared to \$5.7 million for the same period in 2015. The increase in selling, general and administrative expenses in 2016 is primarily due to the costs associated with Vericel's new provider of patient support and reimbursement services for Carticel and MACI, if approved, and professional services related to preparing for the potential launch of MACI.

Loss from operations for the quarter ended September 30, 2016 was \$6.4 million, compared to \$4.9 million for the third quarter of 2015. Material non-cash items impacting the operating loss for the quarter included \$0.7 million of stock-based compensation expense and \$0.5 million in depreciation and amortization expense.

Other expense for the quarter ended September 30, 2016 was \$0.3 million compared to other income of \$0.5 million for the same period in 2015. The change in other expense for the quarter is primarily due to the change in the fair value of warrants in the third quarter of 2016 compared to the same period in 2015.

Vericel's GAAP net loss for the quarter ended September 30, 2016 was \$6.7 million, or \$0.38 per share, compared to a net loss of \$4.4 million, or \$0.26 per share, for the same period in 2015. Vericel reported an adjusted net loss for the quarter ended September 30, 2016 of \$6.5 million dollars, or \$0.27 per share, compared to an adjusted net loss of \$4.9 million, or \$0.21 per share, for the same period in 2015. The adjusted net loss excludes the non-cash change in the fair value of warrants and the non-cash accumulated dividend on the Series B convertible preferred stock. The adjusted net loss per share includes common shares reserved as treasury shares received in exchange for the Series A non-voting convertible preferred stock.

As of September 30, 2016, the company had \$8.9 million in cash compared to \$14.6 million in cash at December 31, 2015.

Recent Business Highlights

During and since the third quarter of 2016, the company:

- Increased total Carticel and Epicel net revenues approximately 8% compared to the first nine months of 2015, with Carticel revenue increasing 9% and Epicel revenues increasing 5%, respectively, compared to the same period in 2015;
- Implemented the new agreement with Dohmen Life Science Services, LLC for patient support services, as well as payer contracting and product reimbursement services, for Carticel and MACI, if approved;

- Increased preparations for the potential launch of MACI in anticipation of the January 3, 2017 PDUFA goal date;
- Received FDA approval for in-house production of 3T3 cells used in the Epicel manufacturing process, which is expected to yield more than \$1 million in annual savings in cost of product sales once the current inventory of purchased 3T3 cells is exhausted;
- Entered into an expanded \$20 million credit facility and term loan with Silicon Valley Bank and MidCap Financial Services and a \$25 million common stock at the market offering program with Cowen and Company, LLC;
- Announced the acceptance of an abstract for presentation on November 14, 2016 at the American Heart Association's Scientific Sections 2016 entitled: "Reduction in Ventricular Arrhythmias with Ixmyelocel-T: Results from the ixCELL-DCM Trial"; and
- Initiated the open-label crossover portion of the ixCELL-DCM study with the first patient treated in October 2016.

"This is an exciting time for Vericel as we head into our historically strongest quarter of the year, prepare for the potential launch of MACI and expand our promotional efforts for Epicel," said Nick Colangelo, president and CEO of Vericel. "We believe that the investments we are making to expand our commercial organization and implement new programs to support our patients and other key stakeholders will drive a period of significant growth for the company in 2017 and beyond. "

Conference Call Information

Today's conference call will be available live at 4:30pm 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 2016 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 November 7, 2016. A replay of the call will also be available until 7:29 pm (EDT) on November 11, 2016 by calling (855) 859-2056, or from outside the U.S. (404) 537-3406. The conference ID is 765207.

About Vericel Corporation

Vericel develops, manufactures, and markets autologous expanded cell therapies for the treatment of patients with serious diseases and conditions. The company markets two cell therapy products in the United States. Carticel[®] (autologous cultured chondrocytes) is an autologous chondrocyte implant for the treatment of cartilage defects in the knee in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. Epicel[®] (cultured epidermal autografts) is a permanent skin replacement for the treatment of

patients with deep dermal or full thickness burns greater than or equal to 30% of total body surface area. Vericel is also developing two additional cell products. MACI[®] (**autologous cultured chondrocytes on porcine collagen membrane**) is a third generation autologous chondrocyte implant intended to treat cartilage defects in the knee. Ixmyelocel-T is an autologous multicellular therapy intended to treat advanced heart failure due to ischemic dilated cardiomyopathy (DCM). For more information, please visit the company's website at www.vcel.com.

Epicel[®], Carticel[®], and MACI[®] are registered trademarks of Vericel Corporation. © Vericel Corporation. All rights reserved.

Non-GAAP Financial Measures

Vericel has provided in this release financial information that has not been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. Vericel believes that the use of these non-GAAP financial measures provides supplementary information for investors to use in evaluating operating performance and in comparing its financial measures with other companies in Vericel's industry. The adjusted net loss excludes the non-cash change in the fair value of warrants and the non-cash accumulated dividend on the Series B convertible preferred stock. The adjusted earnings per share includes common shares reserved as treasury shares received in exchange for the Series A non-voting convertible preferred stock. Non-GAAP financial measures that Vericel uses may differ from measures that other companies may use. In addition, non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation or as substitutes for results prepared in accordance with GAAP.

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, regulatory progress, including the potential clearance of MACI, 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, clinical trial and product development activities, regulatory approval requirements, estimating the commercial growth 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, 2015, filed with the Securities and Exchange Commission ("SEC") on March 14, 2016, 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 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.

CONTACT:

Chad Rubin
The Trout Group
crubin@troutgroup.com
(646) 378-2947

or

Lee Stern
The Trout Group
lstern@troutgroup.com
(646) 378-2922

VERICEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

| | September 30, 2016 | December 31, 2015 |
|--|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash | \$ 8,880 | \$ 14,581 |
| Accounts receivable (net of allowance for doubtful accounts of \$97 and \$68, respectively) | 7,871 | 10,919 |
| Inventory | 3,607 | 1,379 |
| Other current assets | 741 | 464 |
| Total current assets | 21,099 | 27,343 |
| Property and equipment, net | 4,215 | 4,049 |
| Intangible assets, net | 2,708 | 2,917 |
| Total assets | <u>\$ 28,022</u> | <u>\$ 34,309</u> |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,467 | \$ 7,588 |
| Accrued expenses | 3,398 | 3,603 |
| Revolving and term loan credit agreement, net of deferred costs of \$433 | 5,566 | — |
| Warrant liabilities | 658 | 757 |
| Short-term deferred rent | 232 | 118 |
| Other | 39 | 42 |
| Total current liabilities | 15,360 | 12,108 |
| Long-term deferred rent | 1,227 | — |
| Long term debt | 42 | 71 |
| Total liabilities | 16,629 | 12,179 |
| COMMITMENTS AND CONTINGENCIES | | |
| Shareholders' equity: | | |
| Series A non-voting convertible preferred stock, no par value: shares authorized and reserved — 1; shares issued and outstanding — 1 | 3,150 | 3,150 |
| 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 — 22,745 and 23,789, respectively | 310,208 | 307,766 |
| Treasury stock — 1,250 shares | (3,150) | (3,150) |
| Warrants | 190 | |
| Accumulated deficit | (337,394) | (324,025) |
| Total shareholders' equity | 11,393 | 22,130 |
| Total liabilities and shareholders' equity | <u>\$ 28,022</u> | <u>\$ 34,309</u> |

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, | |
|---|----------------------------------|------------|---------------------------------|-------------|
| | 2016 | 2015 | 2016 | 2015 |
| Revenues: | | | | |
| Product sales | \$ 10,929 | \$ 11,309 | \$ 37,860 | \$ 35,748 |
| Total revenues | 10,929 | 11,309 | 37,860 | 35,748 |
| Costs and expenses: | | | | |
| Cost of product sales | 6,856 | 6,772 | 20,716 | 19,241 |
| Gross profit | 4,073 | 4,537 | 17,144 | 16,507 |
| Research and development | 3,443 | 3,740 | 11,037 | 11,486 |
| Selling, general and administrative | 7,010 | 5,674 | 19,463 | 16,735 |
| Total operating expenses | 10,453 | 9,414 | 30,500 | 28,221 |
| Loss from operations | (6,380) | (4,877) | (13,356) | (11,714) |
| Other income (expense): | | | | |
| Decrease (increase) in fair value of warrants | (203) | 461 | 99 | 256 |
| Foreign currency translation (loss) gain | (6) | (5) | (17) | 5 |
| Interest income | — | 7 | 7 | 29 |
| Interest expense | (86) | (2) | (92) | (6) |
| Other (income) expense | — | — | (10) | — |
| Total other income (expense) | (295) | 461 | (13) | 284 |
| Net loss | \$ (6,675) | \$ (4,416) | \$ (13,369) | \$ (11,430) |
| Net loss per share attributable to common shareholders (Basic and Diluted) (see note 11) | | | | |
| | \$ (0.38) | \$ (0.26) | \$ (0.84) | \$ (0.69) |
| Weighted average number of common shares outstanding (Basic and Diluted) | | | | |
| | 22,744 | 23,788 | 22,678 | 23,786 |

**RECONCILIATION OF REPORTED NUMERATOR AND DENOMINATOR IN NET LOSS PER SHARE (GAAP) TO ADJUSTED NET LOSS
PER SHARE (NON-GAAP MEASURE) - UNAUDITED**

| (Amounts in thousands except per share amounts) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|------------|---------------------------------|-------------|
| | 2016 | 2015 | 2016 | 2015 |
| Numerator: | | | | |
| Numerator of basic and diluted EPS | \$ (8,606) | \$ (6,070) | \$ (18,960) | \$ (16,395) |
| Add: (Decrease) increase in fair value of warrants | 203 | (461) | (99) | (256) |
| Add: Dividends accumulated on convertible preferred stock | 1,931 | 1,654 | 5,591 | 4,965 |
| Adjusted net loss - Non-GAAP | \$ (6,472) | \$ (4,877) | \$ (13,468) | \$ (11,686) |
| Denominator: | | | | |
| Denominator for basic and diluted EPS: | | | | |
| Weighted-average common shares outstanding | 22,744 | 23,788 | 22,678 | 23,786 |
| Add: Treasury stock | 1,250 | — | 1,250 | — |
| Adjusted denominator for basic and diluted EPS - Non-GAAP | 23,994 | 23,788 | 23,928 | 23,786 |
| Adjusted net loss per share (basic and diluted) - Non-GAAP | \$ (0.27) | \$ (0.21) | \$ (0.56) | \$ (0.49) |