

VERICEL CORP

FORM 8-K (Current report filing)

Filed 03/10/17 for the Period Ending 03/10/17

Address	64 SIDNEY ST. CAMBRIDGE, MA 02139
Telephone	7349305555
CIK	0000887359
Symbol	VCEL
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

**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): March 10, 2017

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))
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Item 2. 02. Results of Operations and Financial Condition

On March 10, 2017, 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 March 10, 2017.

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: March 10, 2017

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 Fourth-Quarter and Year-End 2016 Financial Results

Record Revenues of \$16.5 Million Reported for the Fourth Quarter

Conference Call Today at 8:00am Eastern Time

CAMBRIDGE, Mass., March 10, 2017 (GLOBE NEWSWIRE) - Vericel Corporation (NASDAQ: VCEL), a leading developer of expanded autologous cell therapies for the treatment of patients with serious diseases and conditions, today reported financial results and business highlights for the fourth quarter and year ended December 31, 2016.

Total net revenues for the quarter ended December 31, 2016 were approximately \$16.5 million and included approximately \$12.7 million of Carticel[®] (autologous cultured chondrocytes) net revenues and approximately \$3.8 million of Epicel[®] (cultured epidermal autografts) net revenues. Total Carticel and Epicel net revenues in the fourth quarter increased approximately 8% over the same period in 2015.

Total net revenues for the year ended December 31, 2016 were approximately \$54.4 million, including approximately \$38.9 million of Carticel net revenues and approximately \$15.5 million of Epicel net revenues. Total Carticel and Epicel net revenues for 2016 increased approximately 8% compared to total Carticel and Epicel net revenues for 2015.

Gross profit for the quarter and year ended December 31, 2016 was \$8.9 million, or 54% of net revenues, and \$26.1 million, or 48% of net revenues, respectively, compared to \$8.2 million, or 53% of net product revenues, and \$24.7 million, or 48% of net product revenues, for the quarter and year ended December 31, 2015, respectively.

Research and development expenses for the quarter and year ended December 31, 2016 were \$4.3 million and \$15.3 million, respectively, versus \$7.4 million and \$18.9 million for the same periods in 2015. The decrease in fourth-quarter and full-year research and development expenses is primarily due to higher research, development and regulatory expenses incurred in the fourth quarter of 2015 associated with the MACI[®] (autologous cultured chondrocytes on porcine collagen membrane) Biologics License Application (BLA) and the Humanitarian Device Exemption (HDE) supplement submitted in December 2015 to revise the labeled indications for use of Epicel, offset in part by additional clinical trial expenses associated with the open-label crossover extension portion of the ixCELL-DCM study.

Selling, general and administrative expenses for the quarter and year ended December 31, 2016 were \$7.9 million and \$27.4 million, respectively, compared to \$5.7 million and \$22.5 million for the same periods 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 and additional facility fees, technology

infrastructure, personnel costs and professional services related to preparing for the commercial launch of MACI.

Loss from operations for the quarter and year ended December 31, 2016 was \$5.9 million and \$19.2 million, respectively, compared to \$5.0 million and \$16.7 million for the same periods in 2015. Material non-cash items impacting the operating loss for the quarter and year ended December 31, 2016 included \$0.5 million and \$2.5 million, respectively, of stock-based compensation expense and \$0.5 million and \$1.9 million, respectively, in depreciation and amortization expense. Loss from operations for the quarter and year ended December 31, 2016 also included \$2.6 million from the write-off of the commercial use rights primarily related to Carticel. Given the approval of MACI in December 2016 and the planned replacement of Carticel with MACI, it was determined that the Carticel-related intangible asset was fully impaired as of December 31, 2016. Excluding this charge, loss from operations for the quarter and year ended December 31, 2016 would have been \$3.3 million and \$16.6 million, respectively.

Other income (expense) for the quarter and year ended December 31, 2016 was (\$0.3) million for both periods, compared to less than \$0.1 million and \$0.3 million, respectively, for the same periods in 2015. The change for the quarter and year ended December 31, 2016 is primarily due to the interest expense related to the outstanding revolver and credit term loans incurred in 2016.

Vericel reported a net loss for the quarter and year ended December 31, 2016 of \$6.2 million, or \$0.34 per share, and \$19.6 million, or \$1.18 per share, respectively, compared to a net loss of \$4.9 million, or \$0.28 per share, and \$16.3 million, or \$0.97 per share, for the same periods in 2015. Vericel reported an adjusted net loss, a non-GAAP financial measure, for the quarter and year ended December 31, 2016 of \$3.5 million, or \$0.14 per share, and \$16.9 million, or \$0.73 per share, respectively, compared to an adjusted net loss of \$5.0 million, or \$0.20 per share, and \$16.7 million, or \$0.67 per share, for the same periods in 2015. The adjusted net loss excludes the non-cash loss on impairment of the Carticel-related intangible asset, 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 in 2015. The Series A non-voting convertible preferred stock was exchanged for common shares in 2016. On March 9, 2017 all outstanding shares of Series B Convertible Preferred Stock were converted into common stock. As of March 10, 2017, the company had 32,723,646 shares of common stock outstanding.

As of December 31, 2016, the company had \$23.0 million in cash and cash equivalents compared to \$14.6 million in cash and cash equivalents at December 31, 2015.

Recent Business Highlights

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

- Received FDA approval of MACI on December 13, 2016 for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults;
- Announced treatment of the first patient with MACI on February 1, 2017;
- Increased the number of sales representatives and expanded the marketing, market access and medical affairs teams to support the MACI launch;

- Received FDA Fast Track designation for the investigation of ixmyelocel-T for the reduction in the risk of death and cardiovascular hospitalization in patients with chronic advanced heart failure due to ischemic dilated cardiomyopathy;
- Presented additional pre-specified secondary results from the Phase 2b ixCELL-DCM clinical trial of ixmyelocel-T at the American Heart Association (AHA) Annual Meeting Scientific Sessions demonstrating a reduction of ventricular arrhythmias in patients treated with ixmyelocel-T;
- Completed treatment of eligible patients in the open-label crossover extension portion of the ixCELL-DCM study;
- Achieved 8% growth in total Carticel and Epicel net revenues for the fourth quarter and year ended 2016 compared to the same periods in 2015;
- Achieved 13% and 10% growth in Carticel net revenues for the fourth quarter and year ended 2016, respectively, versus the same periods in 2015; and
- Closed an underwritten public offering of 7,130,000 shares of common stock for gross proceeds of approximately \$20 million.

“In 2016 we created the drivers for long-term growth of the company by achieving two important regulatory milestones with the approval of a pediatric indication for Epicel and the approval of MACI,” said Nick Colangelo, president and CEO of Vericel. “These significant approvals, combined with our expanded sales and marketing infrastructure and a strong balance sheet, have positioned the company for strong revenue 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 fourth-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 at <http://investors.vcel.com/events.cfm> until March 14, 2018. A replay of the call will also be available until 12:00 pm (EST) on March 14, 2017 by calling (855) 859-2056, or from outside the U.S. (404) 537-3406. The conference ID is 61247055.

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 three cell therapy products in the United States. Vericel is marketing MACI[®] (autologous cultured chondrocytes on porcine collagen membrane), an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. 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 ixmyelocel-T, 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.

Epichel[®], Carticel[®], and MACI[®] are registered trademarks of Vericel Corporation. © 2017 Vericel Corporation. All rights reserved.

GAAP v. Non-GAAP Measures

Vericel's reported earnings are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent earnings as reported to the Securities and Exchange Commission. Vericel has provided in this release financial information that has not been prepared in accordance with GAAP. Vericel's management believes that adjusted operating loss or profit described in the release, or operating profit adjusted for specific items that are generally not indicative of our core operations, provides additional information that is useful to investors in understanding Vericel's underlying performance, business and performance trends, and helps facilitate period to period comparisons and compare its financial measures with other companies in Vericel's industry. However, non-GAAP financial measures that Vericel uses may differ from measures that other companies may use. 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, 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
CONSOLIDATED BALANCE SHEETS

(Unaudited, amounts in thousands)

	December 31,	
	2016	2015
ASSETS		
Current assets:		
Cash	\$ 22,978	\$ 14,581
Accounts receivable (net of allowance for doubtful accounts of \$225 and \$68, respectively)	17,093	10,919
Inventory	3,488	1,379
Other current assets	1,164	464
Total current assets	44,723	27,343
Property and equipment, net	3,875	4,049
Intangible assets	—	2,917
Total assets	\$ 48,598	\$ 34,309
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,534	\$ 7,588
Accrued expenses	4,523	3,603
Warrant liabilities	757	757
Current portion of term loan credit agreement, net of deferred costs of \$110	779	—
Other	259	160
Total current liabilities	12,852	12,108
Revolving and term loan credit agreement, net of deferred costs of \$293	9,318	—
Long term deferred rent	1,687	—
Other long term debt	32	71
Total liabilities	23,889	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 — 0 and 1, respectively	—	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 — 31,595 and 23,789, respectively	329,721	307,766
Treasury stock — 0 and 1,250 shares, respectively	—	(3,150)
Warrants	190	—
Accumulated deficit	(343,591)	(324,025)
Total shareholders' equity	24,709	22,130
Total liabilities and shareholders' equity	\$ 48,598	\$ 34,309

VERICEL CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, amounts in thousands except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Product sales	\$ 16,523	\$ 15,420	\$ 54,383	\$ 51,168
Cost of product sales	7,591	7,229	28,307	26,470
Gross profit	8,932	8,191	26,076	24,698
Research and development	4,258	7,404	15,295	18,890
Selling, general and administrative	7,925	5,744	27,388	22,479
Loss on impairment of intangible asset	2,638	—	2,638	—
Total operating expenses	14,821	13,148	45,321	41,369
Loss from operations	(5,889)	(4,957)	(19,245)	(16,671)
Other income (expense):				
Decrease (increase) in fair value of warrants	(99)	68	—	324
Foreign currency translation gain (loss)	12	(72)	(5)	(67)
Interest income	1	7	8	36
Other income (expense)	—	47	(10)	47
Interest expense	(222)	(3)	(314)	(9)
Total other income (expense)	(308)	47	(321)	331
Net loss	\$ (6,197)	\$ (4,910)	\$ (19,566)	\$ (16,340)
Net loss per share attributable to common shareholders (Basic and Diluted)	\$ (0.34)	\$ (0.28)	\$ (1.18)	\$ (0.97)
Weighted average number of common shares outstanding (Basic and Diluted)	24,329	23,681	23,093	23,760

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 December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Numerator:				
Numerator of basic and diluted EPS	\$ (8,185)	\$ (6,681)	\$ (27,145)	(23,076)
Add: (Decrease) Increase in fair value of warrants	99	(68)	—	(324)
Add: Dividends accumulated on convertible preferred stock	1,988	1,771	7,579	6,736
Add: Loss on impairment on intangible asset	2,638	—	2,638	—
Adjusted net loss - Non-GAAP	\$ (3,460)	\$ (4,978)	\$ (16,928)	\$ (16,664)
Denominator:				
Denominator for basic and diluted EPS:				
Weighted-average common shares outstanding	24,329	23,681	23,093	23,760
Add: Treasury stock	—	1,250	—	1,250
Adjusted denominator for basic and diluted EPS	24,329	24,931	23,093	25,010
Adjusted net loss per share (basic and diluted) - Non-GAAP	\$ (0.14)	\$ (0.20)	\$ (0.73)	\$ (0.67)