VERICEL CORP

FORM 8-K
(Current report filing)

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Address	64 SIDNEY ST. CAMBRIDGE, MA 02139
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Industry	Pharmaceuticals
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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): **May 10, 2017**

Vericel Corporation
(Exact name of registrant as specified in its charter)

Michigan	**001-35280**	**94-3096597**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

64 Sidney Street **Cambridge, MA**	**02139**
(Address of principal executive offices)	(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))

Indicate by a checkmark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§240.12b-2 of this chapter). Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On May 9, 2017, Vericel Corporation (the "Company"), a Michigan corporation, entered into a Second Loan Modification Agreement (the "Loan Modification Agreement") between the Company, as borrower, and Silicon Valley Bank, in its capacity as Administrative Agent ("Agent"), and Silicon Valley Bank, MidCap Funding IV Trust, MidCap Funding III Trust, and ELM 2016-1 Trust as lenders ("Lenders"). The Loan Modification Agreement modifies certain sections of the Loan and Security Agreement dated as of September 9, 2016, by and between the Company, Agent and Silicon Valley Bank, MidCap Financial Trust, MidCap Funding III Trust and other lenders listed therein as lenders, as amended by that certain First Loan Modification Agreement, dated as of December 30, 2016.

The Loan Modification Agreement modifies (i) certain financial covenants; (ii) the terms of the final payment of the Term Loan Advances (as defined in the Loan Modification Agreement) to an amount equal to the aggregate original principal amount of the Term Loan Advances, multiplied by seven percent (7%); and (iii) the terms of the Availability Amount (as defined in the Loan Modification Agreement) to exclude from the Revolving Line or the Borrowing Base (each as defined in the Loan Modification Agreement) a specified amount until the Company has complied with the minimum financial covenants for two consecutive quarters.

The foregoing description of the Loan Modification Agreement is qualified in its entirety by reference to the full text of the Loan Modification Agreement.

Item 2. 02. Results of Operations and Financial Condition

On May 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 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth in response to Item 1.01 of Form 8-K above regarding the Loan Modification Agreement is incorporated by reference in response to this Item 2.03 of Form 8-K.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Vericel Corporation, "Vericel Reports First-Quarter 2017 Financial Results" dated May 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: May 10, 2017

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Financial Officer and Vice President Corporate Development

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Vericel Corporation, "Vericel Reports First-Quarter 2017 Financial Results" dated May 10, 2017.

Exhibit 99.1

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

Vericel Reports First-Quarter 2017 Financial Results

Conference Call Today at 8:00am Eastern Time

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

Total net revenues for the quarter ended March 31, 2017 were approximately $9.4 million, net of a $2.8 million revenue reserve related to an unresolved contractual dispute between one of the Company's pharmacy providers and a payer. Net revenue included approximately $5.0 million of Carticel® (autologous cultured chondrocytes) and MACI® (autologous cultured chondrocytes on porcine collage membrane) net revenues and approximately $4.4 million of Epicel® (cultured epidermal autografts) net revenues, compared to $8.8 million of Carticel revenues and $5.3 million of Epicel revenues, respectively, in the first quarter of 2016.

Carticel and MACI net revenues reflect a change in estimate for revenue reserves of $2.1 million related to 2016 sales and $0.7 million related to 2017 sales. The company engages pharmacies to contract with insurance providers and recently received notification of a dispute between one contracted pharmacy and a payer. Since the company retains credit and collection risk from the end customer, we revised our estimate by assuming cases processed by that pharmacy will be paid at a lower out-of-network rate. The earlier estimates were based on claims being paid on an in-network basis consistent with the actual payment history and the pharmacy's interpretation of its contract with the payer.

Gross profit for the quarter ended March 31, 2017 was $2.3 million, or 24% of net revenues, compared to $7.5 million, or 54% of net product revenues, for the first quarter of 2016.

Research and development expenses for the quarters ended March 31, 2017 and March 31, 2016 were $3.5 million. Clinical trial expenses for the ixCELL-DCM clinical trial and research and development expenses related to Epicel were consistent for both periods. Research and development expenses related to Carticel decreased, offset by an increase in research and development expenses related to MACI.

Selling, general and administrative expenses for the quarter ended March 31, 2017 were $8.4 million compared to $6.0 million for the same period in 2016. The increase in SG&A expenses is primarily due to an increase in consulting expenses of $0.8 million for marketing initiatives related to the launch of MACI, an increase in personnel costs of $0.8 million primarily related to an increase in the MACI sales force, costs associated with reimbursement and patient support services for Carticel and MACI of $0.5 million, and an increase in professional fees of $0.3 million.

Loss from operations for the quarter ended March 31, 2017 was $9.6 million, compared to $2.0 million for the first quarter of 2016. Material non-cash items impacting the operating loss for the quarter included $0.5 million of stock-based compensation expense and $0.4 million in depreciation expense.

Other expense for the quarter ended March 31, 2017 was $0.2 million compared to $1.7 million for the same period in 2016. The change in other expense for the quarter is primarily due to the change in the fair value of warrants in the first quarter of 2017 compared to the same period in 2016.

Vericel's net loss for the quarter ended March 31, 2017 was $9.8 million, or $0.31 per share, compared to a net loss of $3.7 million, or $0.24 per share, for the same period in 2016.

As of March 31, 2017, the company had $19.8 million in cash compared to $23.0 million in cash at December 31, 2016.

Recent Business Highlights
During and since the first quarter of 2017, the company:

- Commenced MACI launch activities and 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;
- Trained more than 200 surgeons on MACI, with nearly half of trained surgeons coming from former Carticel user and non-Carticel user segments;
- Increased MACI biopsies 17% in Q1 2017 compared to Q1 2016;
- Medical benefit policies updated to include MACI at several commercial plans, including four of the top ten commercial plans for MACI/Carticel;
- Announced the presentation of outcomes data from over 950 severe burn patients treated with Epicel demonstrating a probable survival benefit at the 49th annual meeting of the American Burn Association;
- 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;
- Received the FDA Regenerative Medicine Advanced Therapy (RMAT) designation for ixmyelocel-T for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy; and

- Completed treatment of eligible patients in the open-label crossover extension portion of the ixCELL-DCM study.

“The first quarter of 2017 was challenging due to a number of factors, but we are very pleased with the customer response to MACI,” said Nick Colangelo, president and CEO of Vericel. “Moreover, while our focus remains on our core commercial business, we are very pleased with to have received the RMAT designation for ixmyelocel-T and to have signed the license agreement with ICT, which we believe have the potential to create shareholder value moving forward.”

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 first-quarter 2017 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 May 14, 2018. A replay of the call will also be available until 11:00 am (EST) on May 14, 2017 by calling (855) 859-2056, or from outside the U.S. (404) 537-3406. The conference ID is 11385924.

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.

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, our ability to secure consistent reimbursement 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, 2016, filed with the Securities and Exchange Commission ("SEC") on March 13, 2017, 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.

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VERICEL CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, amounts in thousands)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash	$ 19,847	$ 22,978
Accounts receivable (net of allowance for doubtful accounts of $249 and $225, respectively)	12,127	17,093
Inventory	3,958	3,488
Other current assets	1,018	1,164
Total current assets	36,950	44,723
Property and equipment, net	3,638	3,875
Total assets	$ 40,588	$ 48,598
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,335	$ 6,535
Accrued expenses	6,030	4,523
Current portion of term loan credit agreement, net of deferred costs of $110	1,446	779
Warrant liabilities	650	757
Other	291	259
Total current liabilities	14,752	12,853
Revolving and term loan credit agreement, net of deferred costs of $265 and $293, respectively	8,679	9,318
Long term deferred rent	1,632	1,687
Other long term debt	21	32
Total liabilities	25,084	23,890
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved — 39, shares issued and outstanding — 0 and12, respectively	—	38,389
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 32,724 and 31,595, respectively	368,683	329,720
Warrants	190	190
Accumulated deficit	(353,369)	(343,591)
Total shareholders' equity	15,504	24,708
Total liabilities and shareholders' equity	$ 40,588	$ 48,598

VERICEL CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, amounts in thousands except per share amounts)

	Three Months Ended March 31,	
	2017	**2016**
Product sales, net	$ 9,361	$ 14,108
Cost of product sales	7,109	6,560
Gross profit	2,252	7,548
Research and development	3,467	3,536
Selling, general and administrative	8,408	6,004
Total operating expenses	11,875	9,540
Loss from operations	(9,623)	(1,992)
Other income (expense):		
Decrease (increase) in fair value of warrants	107	(1,640)
Foreign currency translation loss	(1)	(10)
Interest income	1	5
Interest expense	(262)	(3)
Other expense	—	(10)
Total other income (expense)	(155)	(1,658)
Net loss	$ (9,778)	$ (3,650)
Net loss per share attributable to common shareholders (Basic and Diluted)	$ (0.31)	$ (0.24)
Weighted average number of common shares outstanding (Basic and Diluted)	31,896	22,604