VERICEL CORP

FORM 8-K
(Current report filing)

Filed 11/07/17 for the Period Ending 11/07/17

Address	64 SIDNEY ST. CAMBRIDGE, MA, 02139
Telephone	7349305555
CIK	0000887359
Symbol	VCEL
SIC Code	2836 - Biological Products, (No 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): **November 7, 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 2. 02. Results of Operations and Financial Condition

On November 7, 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 of Vericel Corporation, "Vericel Reports Third-Quarter 2017 Financial Results" dated November 7, 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: November 7, 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 Third-Quarter 2017 Financial Results" dated November 7, 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 Third-Quarter 2017 Financial Results

Record Third Quarter Revenue of $14.3 Million Represents a 30% Increase Over Third Quarter 2016

Results Driven by Continued Momentum of MACI Uptake and Expanded Epicel Usage

Conference Call Today at 8:00am Eastern Time

CAMBRIDGE, Mass., November 7, 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 for the third quarter ended September 30, 2017 .

Total net revenues for the quarter ended September 30, 2017 were $14.3 million, which included $9.9 million of MACI® (autologous cultured chondrocytes on porcine collage membrane) net revenues and $4.4 million of Epicel® (cultured epidermal autografts) net revenues, compared to $8.3 million of Carticel® (autologous cultured chondrocytes) net revenues and $2.6 million of Epicel net revenues, respectively, in the third quarter of 2016. Total net revenues increased 30% compared to the third quarter of 2016, with MACI revenues increasing 19% and Epicel revenues increasing 67%, respectively, compared to the same period in 2016.

Gross profit for the quarter ended September 30, 2017 was $7.1 million, or 50% of net revenues, compared to $4.1 million, or 37% of net revenues, for the third quarter of 2016.

Research and development expenses for the quarter ended September 30, 2017 were $2.9 million compared to $3.4 million in the third quarter of 2016. The reduction in third-quarter research and development expenses is primarily due to a reduction in clinical trial expenses.

Selling, general and administrative expenses for the quarter ended September 30, 2017 were $8.2 million compared to $7.0 million for the same period in 2016. The increase in selling, general and administrative expenses is primarily due to an increase in expenses for marketing initiatives related to the launch of MACI and an increase in personnel costs primarily related to an increase in the MACI sales force.

Loss from operations for the quarter ended September 30, 2017 was $4.0 million, compared to $6.4 million for the third quarter of 2016. Material non-cash items impacting the operating loss

for the quarter included $0.8 million of stock-based compensation expense and $0.4 million in depreciation expense.

Other expense for the quarter ended September 30, 2017 was $1.4 million compared to $0.3 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 third quarter of 2017 compared to the same period in 2016 and interest expense on the company's outstanding revolving credit agreement and term loans.

Vericel's net loss for the quarter ended September 30, 2017 was $5.4 million, or $0.16 per share, compared to a net loss of $6.7 million, or $0.38 per share, for the same period in 2016.

As of September 30, 2017, the company had $15.5 million in cash compared to $23.0 million in cash at December 31, 2016.

"We had a very strong third quarter in which we achieved record third quarter revenues and the second straight quarter of 30% or higher revenue growth compared to the same quarter of the prior year," said Nick Colangelo, president and CEO of Vericel. "Our significant revenue growth and gross margin expansion were driven by both the accelerating uptake of MACI as well as substantial growth for Epicel in the quarter."

Recent Business Highlights

During and since the third quarter of 2017, the company:

- Achieved record third quarter revenues and the second straight quarter of 30% or greater revenue growth versus same quarter of the prior year;
- Achieved 19% growth in MACI net revenues for the third quarter of 2017 compared to Carticel revenues for the same period in 2016;
- Achieved 67% growth in Epicel net revenues for the third quarter of 2017 compared to the same period in 2016;
- Achieved gross margins of 50% of net revenues in the third quarter of 2017 versus 37% of net revenues in the same period in 2016;
- Trained more than 440 surgeons on the MACI surgical procedures to date, with approximately 50% of trained surgeons coming from former Carticel user and non-Carticel user segments;
- Increased MACI biopsies 44% in the third quarter of 2017 compared to the same period in 2016;
- Announced that medical benefit policies have been updated to include MACI at multiple commercial plans including UnitedHealthcare; at this time, the number of covered lives

for commercial plans providing access to MACI is approximately equivalent to the number of covered lives for commercial plans that previously covered Carticel; and

- Announced plans to expand the MACI sales force from 28 to 40 sales representatives.

“Based on the expanding surgeon customer base and the increasing volume of MACI biopsies and implants, we believe that demand for MACI will far exceed that for Carticel” added Mr. Colangelo. “Given the MACI launch momentum and expanded patient access, we have initiated another sales force expansion in order to drive continued strong revenue growth in 2018 and beyond.”

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 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 November 7, 2018. A replay of the call will also be available until 11:00am (EST) on November 11, 2017 by calling (855) 859-2056, or from outside the U.S. (404) 537-3406. The conference ID is 7097908.

About Vericel Corporation

Vericel develops, manufactures, and markets expanded autologous cell therapies for the treatment of patients with serious diseases and conditions. The company markets two 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. Vericel is also marketing Epicel ® (cultured epidermal autografts), 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. 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.

Global Media Contacts:
David Schull
Russo Partners LLC
+1 212-845-4271 (office)
+1 858-717-2310 (mobile)
David.schull@russopartnersllc.com

Karen Chase
Russo Partners LLC
+1 646-942-5627 (office)
+1 917-547-0434 (mobile)
Karen.chase@russopartnersllc.com

Investor Contacts:
Chad Rubin
The Trout Group
crubin@troutgroup.com
+1 (646) 378-2947

Lee Stern
The Trout Group
lstern@troutgroup.com
+1 (646) 378-2922

VERICEL CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, amounts in thousands)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash	$ 15,466	$ 22,978
Accounts receivable (net of allowance for doubtful accounts of $226 and $225, respectively)	15,430	17,093
Inventory	4,049	3,488
Other current assets	1,366	1,164
Total current assets	36,311	44,723
Property and equipment, net	3,967	3,875
Total assets	$ 40,278	$ 48,598
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,972	$ 6,535
Accrued expenses	4,514	4,523
Current portion of term loan credit agreement (net of deferred costs of $110)	2,557	779
Warrant liabilities	1,269	757
Other	216	259
Total current liabilities	14,528	12,853
Revolving and term loan credit agreement (net of deferred costs of $211 and $293, respectively)	7,400	9,318
Long term deferred rent	1,613	1,687
Other long term debt	—	32
Total liabilities	23,541	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 and 12, respectively	—	38,389
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 34,852 and 31,595, respectively	377,711	329,720
Warrants	190	190
Accumulated deficit	(361,164)	(343,591)
Total shareholders' equity	16,737	24,708
Total liabilities and shareholders' equity	$ 40,278	$ 48,598

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,	
	2017	2016	2017	2016
Product sales, net	$ 14,260	$ 10,929	$ 40,574	$ 37,860
Cost of product sales	7,186	6,856	21,965	20,716
Gross profit	7,074	4,073	18,609	17,144
Research and development	2,919	3,443	9,357	11,037
Selling, general and administrative	8,186	7,010	25,427	19,463
Total operating expenses	11,105	10,453	34,784	30,500
Loss from operations	(4,031)	(6,380)	(16,175)	(13,356)
Other income (expense):				
(Increase) decrease in fair value of warrants	(1,060)	(203)	(512)	99
Foreign currency translation loss	(6)	(6)	(20)	(17)
Interest income	2	—	6	7
Interest expense	(317)	(86)	(878)	(92)
Other income (expense)	5	—	6	(10)
Total other income (expense)	(1,376)	(295)	(1,398)	(13)
Net loss	$ (5,407)	$ (6,675)	$ (17,573)	$ (13,369)
Net loss per share attributable to common shareholders (Basic and Diluted)	$ (0.16)	$ (0.38)	$ (0.54)	$ (0.84)
Weighted average number of common shares outstanding (Basic and Diluted)	33,667	22,744	32,783	22,678