
**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): **August 6, 2019**

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 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 (see General Instruction A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	VCEL	NASDAQ

Indicate by a check mark 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 August 6, 2019, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended June 30, 2019, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Vericel Corporation, “Vericel Reports Second Quarter 2019 Financial Results and Raises Full Year 2019 Revenue Guidance” dated August 6, 2019</u>

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Vericel Corporation, "Vericel Reports Second Quarter 2019 Financial Results and Raises Full Year 2019 Revenue Guidance" dated August 6, 2019</u>

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: August 6, 2019

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Financial Officer and Vice
President Corporate Development



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Vericel Reports Second Quarter 2019 Financial Results and Raises Full Year 2019 Revenue Guidance

**Record Second Quarter Product Revenues of \$26.2 Million Represent a 38% Increase Over Second Quarter 2018
 Full Year 2019 Revenue Guidance Raised to \$112 to \$116 Million**

Conference Call Today at 8:00am Eastern Time

CAMBRIDGE, Mass., August 6, 2019 (GLOBE NEWSWIRE) - Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today reported financial results for the second quarter ended June 30, 2019, and recent business highlights.

Second Quarter 2019 Financial Highlights

- Total net product revenues increased 38% to \$26.2 million compared to \$19.0 million in the second quarter of 2018;
- Gross margin of 66% compared to gross margin of 59% in the second quarter of 2018;
- Net loss of \$19.8 million, or \$0.45 per share, which includes the \$17.5 million upfront license payment to MediWound for North American rights to NexoBrid®;
- Non-GAAP adjusted net loss, excluding the \$17.5 million upfront license payment to MediWound, of \$2.3 million, or \$0.05 per share, compared to a net loss of \$4.7 million, or \$0.12 per share, in the second quarter of 2018;
- Non-GAAP adjusted EBITDA of \$1.8 million compared to a loss of \$1.4 million in the second quarter of 2018;
- As of June 30, 2019, the company had \$66.0 million in cash and short-term investments compared to \$82.9 million as of December 31, 2018; and
- Full year 2019 revenue guidance for MACI® and Epicel® raised to \$112 to \$116 million compared to previous full year revenue guidance of \$110 million to \$114 million.

Recent Business Highlights

During and since the second quarter of 2019, the company:

- Reported record second quarter revenues, marking the ninth consecutive quarter with record revenues for the reported quarter and the highest Epicel revenue for a second quarter in history;
- Deployed the expanded MACI sales force, which increased from 40 to 48 sales representatives and initiated a MACI sales force sizing assessment based on an expanded target audience of approximately 5,000 surgeons who perform a high volume of cartilage repair procedures;
- Announced an exclusive license agreement with MediWound for North American rights to NexoBrid, a registration-stage biological orphan product for debridement of severe thermal burns;
- Announced that the U.S. Biomedical Advanced Research and Development Authority (BARDA) has agreed to fund the NexoBrid expanded access treatment (NEXT) protocol; and
- Confirmed plans after meeting with the U.S. Food and Drug Administration (FDA) to submit a Biologics License Application (BLA) for NexoBrid to the FDA in the second quarter of 2020.

“The continued strength in MACI revenue growth reflects the increasing number of surgeons who view MACI as the standard of care for certain large, full thickness cartilage defects,” said Nick Colangelo, president and CEO of Vericel. “Given the significant growth in new surgeons and biopsy volume, as well as the strength in Epicel demand, we have increased our revenue guidance for 2019. Looking forward, we anticipate submitting the NexoBrid BLA in the second quarter of 2020 which, upon FDA approval, would create a third growth driver for the company in 2021 and beyond.”

Second Quarter 2019 Results

Total net product revenues for the quarter ended June 30, 2019 increased 38% to \$26.2 million compared to \$19.0 million in the second quarter of 2018. Total net product revenues for the quarter included \$20.8 million of MACI® (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$5.3 million of Epicel® (cultured epidermal autografts) net revenue, compared to \$14.1 million of MACI net revenue and \$4.9 million of Epicel net revenue, respectively, in the second quarter of 2018.

Gross profit for the quarter ended June 30, 2019 was \$17.1 million, or 66% of net revenues, compared to \$11.3 million, or 59% of net revenues, for the second quarter of 2018.

Total operating expenses for the quarter ended June 30, 2019 were \$37.3 million, including the \$17.5 million upfront license payment to MediWound Ltd. for North American Rights to NexoBrid. Excluding the \$17.5 million license payment, operating expenses were \$19.8 million, compared to \$15.5 million for the same period in 2018. The increase in operating expenses was primarily due to a \$1.4 million increase in stock-based compensation, an incremental \$0.7 millio

n in MACI sales force expenses as a result of the sales force expansion in 2019, and a \$0.9 million increase in selling expenses and patient reimbursement support services.

Vericel's net loss for the quarter ended June 30, 2019, which includes the \$17.5 million upfront license payment for NexoBrid, was \$19.8 million, or \$0.45 per share. Non-GAAP adjusted net loss, excluding the \$17.5 million upfront license payment for NexoBrid, was \$2.3 million, or \$0.05 per share, compared to a net loss of \$4.7 million, or \$0.12 per share, for the second quarter of 2018. See table reconciling non-GAAP measures for more details. Non-GAAP adjusted EBITDA was \$1.8 million for the quarter ended June 30, 2019 compared to a loss of \$1.4 million in the second quarter of 2018. See table reconciling non-GAAP measures for more details. As of June 30, 2019, the company had \$66.0 million in cash and short-term investments compared to \$82.9 million as of December 31, 2018.

Full Year 2019 Financial Guidance

The company now expects total MACI and Epicel net product revenues for the full year 2019 to be in the range of \$112 to \$116 million, compared to the previous full year revenue guidance of \$110 to \$114 million.

Conference Call Information

Today's conference call will be available live at 8:00am Eastern time in the Investor Relations section of the Vericel website at <http://investors.vcel.com/events-presentations>. A presentation supporting today's conference call will be available on the webcast and in the Investor Relations section of the Vericel website. 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 second-quarter 2019 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-presentations> until August 6, 2020. A replay of the call will also be available until 11:00am (EDT) on August 11, 2019 by calling (855) 859-2056, or from outside the U.S. (404) 537-3406. The conference ID is 6576007.

About Vericel Corporation

Vericel is a leader in advanced therapies for the sports medicine and severe burn care markets. The company markets two cell therapy products in the United States. MACI[®] (autologous cultured chondrocytes on porcine collagen membrane) is 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. 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. The company also holds an exclusive license for North American commercial rights to NexoBrid[®], a registration-stage biological orphan product for debridement of severe thermal burns. For more information, please visit the company's website at www.vcel.com.

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 the non-GAAP adjusted net loss, non-GAAP adjusted net loss per share, and non-GAAP adjusted EBITDA described in the release, which include adjustments for specific items that are generally not indicative of our core operations, provide additional information that is useful to investors in understanding Vericel's underlying performance, business and performance trends, and help facilitate period to period comparisons and comparisons of 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.

About BARDA

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies. Funding and support for development of NexoBrid has been provided by BARDA, under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C and HHSO100201800023C.

Epicel® and MACI® are registered trademarks of Vericel Corporation. NexoBrid® is a registered trademark of MediWound Ltd. and is used under license to Vericel Corporation. © 2019 Vericel Corporation. All rights reserved.

This document contains forward-looking statements, including, without limitation, statements regarding full-year 2019 revenue and financial guidance, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of our products and growth in revenues, 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," "guidance," "outlook," "future," 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 our expectations regarding 2019 revenues, growth in revenues for MACI and Epicel, gross profit and target surgeon audience, improvements in gross margins, ability to achieve standard of care for MACI, our need to generate significant sales to become profitable, potential fluctuations in sales volumes and our results of operations over the course of the year, competitive developments, estimating the commercial growth potential of our products and product candidates, timing and conduct of clinical trial and product development activities, timing or likelihood of regulatory submissions or approvals, availability of funding

from BARDA, market demand for our products, changes in third party coverage and reimbursement, our ability to maintain and expand our network of direct sales employees, 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, 2018, filed with the Securities and Exchange Commission ("SEC") on February 26, 2019, 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)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 13,962	\$ 18,286
Short-term investments	52,047	64,638
Accounts receivable (net of allowance for doubtful accounts of \$748 and \$514, respectively)	21,084	23,454
Inventory	4,788	3,558
Other current assets	2,167	2,847
Total current assets	94,048	112,783
Property and equipment, net	6,963	5,906
Right-of-use assets	24,815	—
Total assets	\$ 125,826	\$ 118,689
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,250	\$ 7,108
Accrued expenses	4,701	6,930
Current portion of operating lease liabilities	2,558	—
Other liabilities	34	754
Total current liabilities	12,543	14,792
Operating lease liabilities	24,607	—
Other long-term liabilities	134	1,666
Total liabilities	37,284	16,458
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 44,066 and 43,578, respectively	480,050	471,180
Other comprehensive gain (loss)	38	(39)
Warrants	104	104
Accumulated deficit	(391,650)	(369,014)
Total shareholders' equity	88,542	102,231
Total liabilities and shareholders' equity	\$ 125,826	\$ 118,689

VERICEL CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, amounts in thousands except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Product sales, net	\$ 26,151	\$ 19,011	\$ 47,961	\$ 37,038
Cost of product sales	9,022	7,727	17,662	15,393
Gross profit	17,129	11,284	30,299	21,645
Research and development	21,070	3,739	24,078	7,468
Selling, general and administrative	16,259	11,791	29,779	22,745
Total operating expenses	37,329	15,530	53,857	30,213
Loss from operations	(20,200)	(4,246)	(23,558)	(8,568)
Other income (expense):				
Increase in fair value of warrants	—	(37)	—	(2,944)
Interest income	428	83	908	83
Interest expense	(2)	(448)	(4)	(880)
Other income (expense)	(18)	(3)	18	(1)
Total other income (expense)	408	(405)	922	(3,742)
Net loss	\$ (19,792)	\$ (4,651)	\$ (22,636)	\$ (12,310)
Net loss per share (Basic and Diluted)	\$ (0.45)	\$ (0.12)	\$ (0.52)	\$ (0.33)
Weighted average number of common shares outstanding (Basic and Diluted)	43,956	38,349	43,841	37,251

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

(In thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss (GAAP)	\$ (19,792)	\$ (4,651)	\$ (22,636)	\$ (12,310)
Upfront license agreement payment	17,500	—	17,500	—
Adjusted Net Loss (Non-GAAP)	\$ (2,292)	\$ (4,651)	\$ (5,136)	\$ (12,310)
Adjusted Net Loss per Share (Non-GAAP) (Basic and Diluted)	\$ (0.05)	\$ (0.12)	\$ (0.12)	\$ (0.33)

RECONCILIATION OF REPORTED NET LOSS (GAAP) TO ADJUSTED EBITDA (NON-GAAP MEASURE) - UNAUDITED

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss (GAAP)	\$ (19,792)	\$ (4,651)	\$ (22,636)	\$ (12,310)
Upfront license agreement payment	17,500	—	17,500	—
Change in fair value of warrants	—	37	—	2,944
Stock compensation expense	4,182	2,465	6,810	3,807
Depreciation and amortization	376	386	700	813
Net interest expense	(426)	365	(904)	797
Adjusted EBITDA (Non-GAAP)	\$ 1,840	\$ (1,398)	\$ 1,470	\$ (3,949)