
**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 5, 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. o

Item 2.02. Results of Operations and Financial Condition

On November 5, 2019, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended September 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 | Press Release of Vericel Corporation, "Vericel Reports Record Third Quarter Revenues, Net Income and Operating Cash Flow" November 5, 2019 |

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release of Vericel Corporation, "Vericel Reports Record Third Quarter Revenues, Net Income and Operating Cash Flow" November 5, 2019 |

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 5, 2019

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Financial Officer and Vice
President Corporate Development



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Vericel Reports Record Third Quarter Revenues, Net Income and Operating Cash Flow

Product Revenues of \$30.5 Million Increase 36% Over Third Quarter 2018

Full Year 2019 Revenue Guidance Raised to \$116 to \$118 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., November 5, 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 third quarter ended September 30, 2019, and recent business highlights.

Third Quarter 2019 Financial Highlights

- Total net product revenues increased 36% to \$30.5 million compared to \$22.5 million in the third quarter of 2018, marking the tenth consecutive quarter with record revenues for the reported quarter;
- MACI[®] net revenue of \$20.6 million and Epicel[®] net product revenue of \$9.9 million, the highest quarterly Epicel revenue in history;
- Gross margin of 69% compared to gross margin of 64% in the third quarter of 2018;
- Net income of \$3.5 million, or \$0.07 per share, compared to a net loss of \$1.1 million, or \$0.02 per share, in the third quarter of 2018;
- Non-GAAP adjusted EBITDA of \$6.8 million compared to \$0.9 million in the third quarter of 2018;
- Operating cash flow of \$7.9 million;
- As of September 30, 2019, the company had \$74.7 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 \$116 to \$118 million compared to previous full year revenue guidance of \$112 to \$116 million.

Recent Business Highlights

- During and since the third quarter of 2019, the company:
- Announced plans to expand the MACI sales force from 49 to 76 sales representatives and from six to nine sales regions by the second quarter of 2020;
- Completed an initial expansion of the burn care sales team from six to nine sales representatives and burn clinical specialists; and
- Announced initiation of the NexoBrid[®] Expanded Access Treatment Protocol (NEXT) to treat patients with deep partial- and full-thickness burns in the United

States during the preparation and review of the NexoBrid Biologics License Application.

“We are very pleased with the growth of our business and expect to maintain strong double-digit revenue growth for the foreseeable future as we continue to make targeted investments in our sports medicine and burn care commercial franchises,” said Nick Colangelo, president and CEO of Vericel. “Given the consistent improvement in our gross profit and operating margin, we believe that we are also well-positioned to generate strong profit and cash flow growth in the years ahead.”

Third Quarter 2019 Results

Total net product revenues for the quarter ended September 30, 2019 increased 36% to \$30.5 million compared to \$22.5 million in the third quarter of 2018. Total net product revenues for the quarter included \$20.6 million of MACI[®] (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$9.9 million of Epicel[®] (cultured epidermal autografts) net revenue, compared to \$16.4 million of MACI net revenue and \$6.0 million of Epicel net revenue, respectively, in the third quarter of 2018.

Gross profit for the quarter ended September 30, 2019 was \$21.2 million, or 69% of net revenues, compared to \$14.3 million, or 64% of net revenues, for the third quarter of 2018.

Total operating expenses for the quarter ended September 30, 2019 were \$18.1 million, compared to \$15.7 million for the same period in 2018. The increase in operating expenses was primarily due to a \$1.1 million increase in stock-based compensation expenses, a \$0.8 million increase in marketing expenses and a \$0.7 million increase in MACI sales force expenses driven by the sales force expansion in the second quarter of 2019.

Vericel’s net income for the quarter ended September 30, 2019 was \$3.5 million, or \$0.07 per share, compared to a net loss of \$1.1 million, or \$0.02 per share, for the third quarter of 2018.

Non-GAAP adjusted EBITDA was \$6.8 million for the quarter ended September 30, 2019 compared to \$0.9 million in the third quarter of 2018. A table reconciling non-GAAP measures is included in this press release for reference.

As of September 30, 2019, the company had \$74.7 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 \$116 to \$118 million, compared to the previous full year revenue guidance of \$112 to \$116 million.

Conference Call Information

Today’s conference call will be available live at 8:30am Eastern Standard Time and can be accessed through the Investor Relations section of the Vericel website at <http://>

investors.vcel.com/events-presentations. A slide presentation with highlights from 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 November 5, 2020. A replay of the call will also be available until 11:00am (EDT) on November 10, 2019 by calling (855) 859-2056, or from outside the U.S. at (404) 537-3406. The conference ID is 1685887.

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 EBITDA described in the release, which includes 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.

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, profit, and cash flow, and objectives and expectations regarding our company as 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, the expected target surgeon audience, improvements in gross margins, 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 the Biomedical Advanced Research and Development Authority ("BARDA") under its agreement with MediWound Ltd. for use in connection with NexoBrid development activities, 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 views as of the date hereof and Vericel does not assume and specifically disclaims any obligation 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)

| | September 30, 2019 | December 31, 2018 |
|---|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 36,905 | \$ 18,286 |
| Short-term investments | 37,760 | 64,638 |
| Accounts receivable (net of allowance for doubtful accounts of \$643 and \$514, respectively) | 19,958 | 23,454 |
| Inventory | 6,823 | 3,558 |
| Other current assets | 3,272 | 2,847 |
| Total current assets | 104,718 | 112,783 |
| Property and equipment, net | 7,190 | 5,906 |
| Right-of-use assets | 25,619 | — |
| Total assets | \$ 137,527 | \$ 118,689 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,281 | \$ 7,108 |
| Accrued expenses | 6,960 | 6,930 |
| Current portion of operating lease liabilities | 2,836 | — |
| Other liabilities | 35 | 754 |
| Total current liabilities | 15,112 | 14,792 |
| Operating lease liabilities | 25,311 | — |
| Other long-term liabilities | 114 | 1,666 |
| Total liabilities | 40,537 | 16,458 |
| COMMITMENTS AND CONTINGENCIES | | |
| Shareholders' equity: | | |
| Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 44,520 and 43,578, respectively | 485,141 | 471,180 |
| Other comprehensive gain (loss) | 29 | (39) |
| Warrants | — | 104 |
| Accumulated deficit | (388,180) | (369,014) |
| Total shareholders' equity | 96,990 | 102,231 |
| Total liabilities and shareholders' equity | \$ 137,527 | \$ 118,689 |

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, | |
|--|----------------------------------|------------|---------------------------------|-------------|
| | 2019 | 2018 | 2019 | 2018 |
| Product sales, net | \$ 30,499 | \$ 22,484 | \$ 78,460 | \$ 59,522 |
| Cost of product sales | 9,324 | 8,138 | 26,986 | 23,531 |
| Gross profit | 21,175 | 14,346 | 51,474 | 35,991 |
| Research and development | 3,096 | 3,113 | 27,174 | 10,581 |
| Selling, general and administrative | 14,982 | 12,569 | 44,761 | 35,314 |
| Total operating expenses | 18,078 | 15,682 | 71,935 | 45,895 |
| Income (loss) from operations | 3,097 | (1,336) | (20,461) | (9,904) |
| Other income (expense): | | | | |
| Increase (decrease) in fair value of warrants | — | 420 | — | (2,524) |
| Interest income | 385 | 307 | 1,293 | 390 |
| Interest expense | (2) | (460) | (6) | (1,340) |
| Other income (expense) | (10) | — | 8 | (1) |
| Total other income (expense) | 373 | 267 | 1,295 | (3,475) |
| Net income (loss) | \$ 3,470 | \$ (1,069) | \$ (19,166) | \$ (13,379) |
| Net income (loss) per share (Basic) | \$ 0.08 | \$ (0.02) | \$ (0.44) | \$ (0.34) |
| Weighted average number of common shares outstanding (Basic) | 44,251 | 42,925 | 43,979 | 39,163 |
| Net income (loss) per share (Diluted) | \$ 0.07 | \$ (0.02) | \$ (0.44) | \$ (0.34) |
| Weighted average number of common shares outstanding (Diluted) | 46,667 | 42,925 | 43,979 | 39,163 |

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

| (In thousands) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-----------------------------------|----------------------------------|------------|---------------------------------|-------------|
| | 2019 | 2018 | 2019 | 2018 |
| Net income (loss) (GAAP) | \$ 3,470 | \$ (1,069) | \$ (19,166) | \$ (13,379) |
| Upfront license agreement payment | — | — | 17,500 | — |
| Change in fair value of warrants | — | (420) | — | 2,524 |
| Stock compensation expense | 3,285 | 1,932 | 10,095 | 5,739 |
| Depreciation and amortization | 475 | 320 | 1,174 | 1,133 |
| Net interest expense | (383) | 153 | (1,287) | 950 |
| Adjusted EBITDA (Non-GAAP) | \$ 6,847 | \$ 916 | \$ 8,316 | \$ (3,033) |