
**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 5, 2020**

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: **(617) 588-5555**

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 5, 2020, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended June 30, 2020, 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 Second Quarter 2020 Financial Results” August 5, 2020 |
| 104 | Cover page interactive data file (embedded within the Inline XBRL document) |

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
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| 104 | Cover page interactive data file (embedded within the Inline XBRL document) |

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 5, 2020

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Financial Officer and Vice
President Corporate Development



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Vericel Reports Second Quarter 2020 Financial Results
Product Revenues of \$20.0 Million Reported for the Second Quarter

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., August 5, 2020 (GLOBE NEWSWIRE) — Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today reported financial results and business highlights for the second quarter ended June 30, 2020.

Second Quarter 2020 Financial Highlights

- Total net product revenues of \$20.0 million, compared to \$26.2 million in the second quarter of 2019;
- MACI[®] net revenue of \$15.1 million and Epicel[®] net revenue of \$4.9 million;
- Gross margin of 57%, compared to gross margin of 66% in the second quarter of 2019;
- Net loss of \$8.3 million, or \$0.18 per share, compared to \$19.8 million, or \$0.45 per share, in the second quarter of 2019, which included the \$17.5 million upfront license payment to MediWound Ltd. for North American rights to NexoBrid[®];
- Non-GAAP adjusted EBITDA loss of \$3.5 million, compared to positive adjusted EBITDA of \$1.8 million in the second quarter of 2019; and
- As of June 30, 2020, the company had \$80.9 million in cash and investments, compared to \$79.0 million as of December 31, 2019, and no debt.

Business Highlights and Updates

- Total net product revenues, which decreased approximately 23% for the quarter, declined approximately 78% in April and 32% in May compared to the same periods in 2019, and increased approximately 29% in June compared to June 2019;
- MACI implants, which declined approximately 84% in April and 37% in May, compared to the same periods in 2019, increased approximately 21% in June, compared June 2019;
- MACI biopsies declined approximately 79% in April and 22% in May, compared to the same periods in 2019, and increased approximately 23% in June, compared June 2019;
- Epicel graft volume, which declined 70% in April, increased approximately 20% in the May through June period compared to the same period in 2019;
- Epicel biopsies increased approximately 6% in the second quarter compared to the second quarter of 2019; and

- The company announced the submission of a Biologics License Application to the FDA for NexoBrid for the treatment of severe thermal burns.

“In light of the ongoing pandemic, we are very pleased with our second quarter results as we saw a strong recovery as the quarter progressed and COVID-19 restrictions on elective surgeries were lifted across the country,” said Nick Colangelo, President and CEO of Vericel. “Looking ahead, while uncertainties remain, we are confident in the fundamental prospects of our business and for the third quarter we expect MACI revenue growth over the third quarter of 2019, Epicel revenue to increase sequentially over the second quarter of 2020 and return to recent historical levels, and to recognize revenue in connection with the first delivery of NexoBrid under the BARDA procurement contract, which is scheduled to take place later this quarter.”

Second Quarter 2020 Results

Total net product revenues for the quarter ended June 30, 2020 decreased 23% to \$20.0 million, compared to \$26.2 million in the second quarter of 2019. Total net product revenues for the quarter included \$15.1 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$4.9 million of Epicel (cultured epidermal autografts) net revenue, compared to \$20.8 million of MACI net revenue and \$5.3 million of Epicel net revenue, respectively, in the second quarter of 2019.

Gross profit for the quarter ended June 30, 2020 was \$11.4 million, or 57% of net revenues, compared to \$17.1 million, or 66% of net revenues, for the second quarter of 2019.

Total operating expenses for the quarter ended June 30, 2020 were \$19.7 million, compared to \$37.3 million for the same period in 2019, which included 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 remained essentially flat as reductions to discretionary spend and variable cost reductions offset the cost increases associated with the expanded MACI sales force.

Vericel’s net loss for the quarter ended June 30, 2020 was \$8.3 million, or \$0.18 per share, compared to \$19.8 million, or \$0.45 per share, for the second quarter of 2019, which included the \$17.5 million license payment for NexoBrid.

Non-GAAP adjusted EBITDA loss was \$3.5 million for the quarter ended June 30, 2020, compared to positive adjusted EBITDA of \$1.8 million in the second quarter of 2019. A table reconciling non-GAAP measures is included in this press release for reference.

As of June 30, 2020, the company had \$80.9 million in cash and investments, compared to \$79.0 million as of December 31, 2019, and no debt.

Conference Call Information

Today’s conference call will be available live at 8:30am Eastern 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 2020 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 4, 2021. A replay of the call will also be available until 11:00am (EDT) on August 12, 2020 by calling (855) 859-2056, or from outside the U.S. by calling (404) 537-3406. The conference ID is 5851304.

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 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 certain 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, 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 comparisons of its financial measures with other companies in Vericel's industry. However, the 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. © 2020 Vericel Corporation. All rights reserved.

Vericel cautions you that all statements other than statements of historical fact included in this press release that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Although we believe that we

have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Our actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “intends,” “estimates,” “plans,” “expects,” “continues,” “believe,” “guidance,” “outlook,” “target,” “future,” “potential,” “goals” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “could,” “may,” or similar expressions.

Among the factors that could cause actual results to differ materially from those set forth in the forward-looking statements include, but are not limited to uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic, growth in revenues for MACI and Epicel, the expected target surgeon audience, the estimate of the commercial growth potential of our products and product candidates, availability of funding from the Biomedical Research and Development Authority under its agreement with MediWound Ltd. for use in connection with NexoBrid development activities, potential fluctuations in sales and volumes and our results of operations over the course of the year, competitive developments, timing and conduct of clinical trial and product development activities, timing or likelihood of regulatory approvals, market demand for our products, changes in third party coverage and reimbursement, and our ability to supply or meet customer demand for our products.

With respect to COVID-19, we are currently unable to reasonably estimate the specific extent, or duration, of the impact of the COVID-19 outbreak on our business, financial and operating results. We are also unable to predict how the outbreak will affect the pace with which state and local governments lift restrictions on the performance of elective surgical procedures or whether additional such restrictions may be imposed by states in the future, the availability of physicians and/or their treatment prioritizations or the impact of the outbreak on the overall healthcare infrastructure. In addition, patients who have cancelled or postponed surgeries may not reschedule cases in a timely fashion, or at all. Other disruptions or potential disruptions include restrictions on the ability of Company personnel to travel and access customers for training, promotion and case support, delays in approvals by regulatory bodies, delays in product development efforts, and additional government-imposed quarantines and requirements to “shelter at home” or other incremental mitigation efforts that may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products. The total impact of these disruptions could have a material impact on the Company’s financial condition, cash flows and results of operations.

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, 2019, filed with the Securities and Exchange Commission (“SEC”) on February 25, 2020, Vericel’s Quarterly Report on Form 10-Q for the quarter ended June, 30, 2020, filed with the SEC on August 5, 2020, and in other filings with the SEC. These forward-looking statements reflect our 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.

Investor Contacts:

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VERICEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands)

| | June 30, 2020 | December 31, 2019 |
|---|------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 55,704 | \$ 26,889 |
| Short term investments | 25,086 | 42,829 |
| Accounts receivable (net of allowance for doubtful accounts of \$207 and \$306, respectively) | 23,655 | 32,168 |
| Inventory | 8,417 | 6,816 |
| Other current assets | 2,900 | 2,953 |
| Total current assets | 115,762 | 111,655 |
| Property and equipment, net | 7,040 | 7,144 |
| Restricted cash | 89 | 89 |
| Right-of-use leased assets | 23,800 | 25,103 |
| Long term investments | — | 9,247 |
| Total assets | \$ 146,691 | \$ 153,238 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,535 | \$ 6,345 |
| Accrued expenses | 7,975 | 7,948 |
| Current portion of operating lease liabilities | 5,570 | 5,461 |
| Other liabilities | 41 | 41 |
| Total current liabilities | 18,121 | 19,795 |
| Operating lease liabilities | 20,881 | 22,242 |
| Other long-term liabilities | 93 | 110 |
| Total liabilities | \$ 39,095 | \$ 42,147 |
| COMMITMENTS AND CONTINGENCIES | | |
| Shareholders' equity: | | |
| Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 45,194 and 44,864, respectively | \$ 499,103 | \$ 489,749 |
| Other comprehensive gain | 146 | 21 |
| Accumulated deficit | (391,653) | (378,679) |
| Total shareholders' equity | 107,596 | 111,091 |
| Total liabilities and shareholders' equity | \$ 146,691 | \$ 153,238 |

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, | |
|--|-----------------------------|-------------|---------------------------|-------------|
| | 2020 | 2019 | 2020 | 2019 |
| Product sales, net | \$ 20,014 | \$ 26,151 | \$ 46,692 | \$ 47,961 |
| Cost of product sales | 8,660 | 9,022 | 18,582 | 17,662 |
| Gross profit | 11,354 | 17,129 | 28,110 | 30,299 |
| Research and development | 3,226 | 21,070 | 6,989 | 24,078 |
| Selling, general and administrative | 16,486 | 16,259 | 34,555 | 29,779 |
| Total operating expenses | 19,712 | 37,329 | 41,544 | 53,857 |
| Loss from operations | (8,358) | (20,200) | (13,434) | (23,558) |
| Other income (expense): | | | | |
| Interest income | 147 | 428 | 453 | 908 |
| Interest expense | (1) | (2) | (3) | (4) |
| Other income (expense) | (57) | (18) | 10 | 18 |
| Total other income (expense) | 89 | 408 | 460 | 922 |
| Net loss | \$ (8,269) | \$ (19,792) | \$ (12,974) | \$ (22,636) |
| Net loss per share attributable to common shareholders (Basic and Diluted) | \$ (0.18) | \$ (0.45) | \$ (0.29) | \$ (0.52) |
| Weighted average number of common shares outstanding (Basic and Diluted) | 45,137 | 43,956 | 45,031 | 43,841 |

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, | |
|--|-----------------------------|-------------|---------------------------|-------------|
| | 2020 | 2019 | 2020 | 2019 |
| Net loss | \$ (8,269) | \$ (19,792) | \$ (12,974) | \$ (22,636) |
| Non-recurring license agreement purchase | — | 17,500 | — | 17,500 |
| Stock compensation expense | 4,376 | 4,182 | 8,144 | 6,810 |
| Depreciation and amortization | 546 | 376 | 1,079 | 700 |
| Net interest income | (146) | (426) | (450) | (904) |
| Adjusted EBITDA (Non-GAAP) | \$ (3,493) | \$ 1,840 | \$ (4,201) | \$ 1,470 |