

**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 4, 2022**

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 May 4, 2022, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended March 31, 2022, 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 First Quarter 2022 Financial Results” |
| 104 | Cover page interactive data file (embedded within the Inline XBRL document) |



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Vericel Reports First Quarter 2022 Financial Results

First Quarter Total Net Revenue of \$36.1 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., May 4, 2022 (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 first quarter ended March 31, 2022.

First Quarter 2022 Financial Highlights

- Total net revenue of \$36.1 million, compared to \$34.6 million in the first quarter of 2021
- MACI[®] net revenue of \$26.0 million, Epicel[®] net revenue of \$9.9 million, and NexoBrid[®] revenue of \$0.2 million related to the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) procurement for emergency response preparedness
- Gross margin of 65%, compared to 66% in the first quarter of 2021
- Net loss of \$7.1 million, or \$0.15 per share, compared to \$3.3 million, or \$0.07 per share, in the first quarter of 2021
- Non-GAAP adjusted EBITDA of \$3.2 million, compared to \$4.6 million in the first quarter of 2021
- Operating cash flow of \$3.5 million
- As of March 31, 2022, the Company had approximately \$130 million in cash, restricted cash and investments, and no debt

Business Highlights and Updates

- Double-digit growth in surgeons taking MACI biopsies compared to the first quarter of 2021, with the second highest monthly biopsies in March 2022 since the launch of MACI
- Growth of more than 20% in burn centers treating patients and taking Epicel biopsies compared to the first quarter of 2021, with a record monthly high in Epicel biopsies in March 2022
- Remain on track for a planned mid-year 2022 resubmission of the NexoBrid Biologics License Application to the FDA, and

- Expanded the Company's commercial leadership team with the appointment of Mike Gilligan as Vice President, MACI National Sales

“The Company executed well in the first quarter and we remain on track to deliver another year of significant revenue growth, margin expansion, and operating cash flow driven by continued strong results for both MACI and Epicel,” said Nick Colangelo, President and CEO of Vericel. “We also continue to advance important regulatory and clinical programs across both our sports medicine and burn care franchises as we remain on track for a mid-year resubmission of the NexoBrid BLA and for planned discussions with the FDA to review both the MACI arthroscopic and ankle development programs, initiatives that we believe will support continued strong growth in the years ahead.”

2022 Financial Guidance

The Company reaffirmed financial guidance for full-year 2022

- Total net revenue for 2022 expected to be in the range of \$178 to \$189 million
 - MACI revenue expected to be in the range of \$132 to \$141 million
 - Epicel revenue expected to be in the range of \$45.5 to \$47.5 million
- Gross margin expected to be approximately 70%
- Adjusted EBITDA margin expected to be approximately 21%

First Quarter 2022 Results

Total net revenue for the quarter ended March 31, 2022 increased 4% to \$36.1 million, compared to \$34.6 million in the first quarter of 2021. Total net product revenue for the quarter increased 7% and included \$26.0 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 \$23.8 million of MACI net revenue and \$9.8 million of Epicel net revenue, respectively, in the first quarter of 2021. Total net revenue for the quarter also included \$0.2 million of revenue related to the procurement of NexoBrid (concentrate of proteolytic enzymes enriched in bromelain) by BARDA for emergency response preparedness, compared to \$0.9 million in the first quarter of 2021.

Gross profit for the quarter ended March 31, 2022 was \$23.5 million, or 65% of net revenue, compared to \$23.0 million, or 66% of net revenue, for the first quarter of 2021.

Total operating expenses for the quarter ended March 31, 2022 were \$30.7 million, compared to \$26.3 million for the same period in 2021. The increase in operating expenses was primarily due to higher stock-based compensation expense.

Net loss for the quarter ended March 31, 2022 was \$7.1 million, or \$0.15 per share, compared to a net loss of \$3.3 million, or \$0.07 per share, for the first quarter of 2021.

Non-GAAP adjusted EBITDA for the quarter ended March 31, 2022 was \$3.2 million, or 9% of net revenue, compared to \$4.6 million, or 13% of net revenue, for the first quarter of 2021. A table reconciling non-GAAP measures is included in this press release for reference.

As of March 31, 2022, the Company had approximately \$130 million in cash, restricted cash and investments, 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 first quarter 2022 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 May 4, 2023. The conference ID is 7195435.

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. (MediWound) and is used under license to Vericel Corporation. © 2022 Vericel Corporation. All rights reserved.

Forward-Looking Statements

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 our expectations regarding future revenue, growth in revenue, market penetration for MACI and Epicel, growth in profit, gross margins and operating margins, the ability to achieve or sustain profitability, contributions to adjusted EBITDA, the expected target surgeon audience, potential fluctuations in sales and volumes and our results of operations over the course of the year; timing and conduct of clinical trial and product development activities, timing of the resubmission to the Food & Drug Administration (FDA) of a Biologics License Application (BLA) for NexoBrid seeking approval for the treatment of severe burns in the United States following MediWound’s receipt of a complete response letter on June 28, 2021, timing or likelihood of approval by the FDA of the NexoBrid BLA resubmission, the estimate of the commercial growth potential of our products and product candidates, availability of funding from BARDA under its agreement with MediWound for use in connection with NexoBrid development activities, competitive developments, changes in third-party coverage and reimbursement, our ability to supply or meet customer demand for our products, and the ongoing impacts of the COVID-19 pandemic on our business or the economy generally.

With respect to COVID-19, we are currently unable to predict whether a future resurgence of COVID-19 infections will result in future restrictions on the performance of elective surgical procedures or affect the availability of physicians and/or their treatment prioritizations, cause healthcare facility staffing shortages, effect the willingness or ability of patients to seek treatment, or heighten the impact of the pandemic on the overall healthcare infrastructure.

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 product development efforts, and additional government-imposed quarantines or other incremental mitigation efforts or initiatives 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. With respect to NexoBrid, the COVID-19 pandemic may impact the FDA's response times to future regulatory submissions, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections of manufacturing facilities involved in the production of NexoBrid, any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of NexoBrid. 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, 2021, filed with the Securities and Exchange Commission (SEC) on February 24, 2022, Vericel's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 4, 2022, 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.

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VERICEL CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, amounts in thousands, except per share amounts)

| | Three Months Ended March 31, | |
|---|------------------------------|------------|
| | 2022 | 2021 |
| Product sales, net | \$ 35,852 | \$ 33,627 |
| Other revenue | 222 | 941 |
| Total revenue | 36,074 | 34,568 |
| Cost of product sales | 12,622 | 11,583 |
| Gross profit | 23,452 | 22,985 |
| Research and development | 4,860 | 3,630 |
| Selling, general and administrative | 25,865 | 22,660 |
| Total operating expenses | 30,725 | 26,290 |
| Loss from operations | (7,273) | (3,305) |
| Other income (expense): | | |
| Interest income | 88 | 76 |
| Interest expense | (18) | (1) |
| Other income | 112 | 84 |
| Total other income | 182 | 159 |
| Loss before income taxes | (7,091) | (3,146) |
| Income tax expense | — | 143 |
| Net loss | \$ (7,091) | \$ (3,289) |
| Net loss per common share: | | |
| Basic | \$ (0.15) | \$ (0.07) |
| Diluted | \$ (0.15) | \$ (0.07) |
| Weighted-average common shares outstanding: | | |
| Basic | 46,985 | 45,984 |
| Diluted | 46,985 | 45,984 |

VERICEL CORPORATION
RECONCILIATION OF REPORTED NET LOSS (GAAP)
TO ADJUSTED EBITDA (NON-GAAP MEASURE)
(Unaudited, amounts in thousands)

| | Three Months Ended March 31, | |
|----------------------------------|------------------------------|-----------------|
| | 2022 | 2021 |
| Net loss | \$ (7,091) | \$ (3,289) |
| Stock-based compensation expense | 9,531 | 7,019 |
| Depreciation and amortization | 873 | 811 |
| Net interest income | (70) | (75) |
| Income tax expense | — | 143 |
| Adjusted EBITDA (Non-GAAP) | <u>\$ 3,243</u> | <u>\$ 4,609</u> |

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

| | March 31, 2022 | December 31, 2021 |
|---|-------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 55,659 | \$ 68,330 |
| Short-term investments | 44,888 | 35,068 |
| Accounts receivable (net of allowance for doubtful accounts of \$40 and \$40, respectively) | 31,855 | 37,437 |
| Inventory | 14,385 | 13,381 |
| Other current assets | 5,093 | 4,246 |
| Total current assets | 151,880 | 158,462 |
| Property and equipment, net | 14,451 | 13,308 |
| Restricted cash | 6,184 | 211 |
| Right-of-use assets | 44,653 | 45,720 |
| Long-term investments | 22,803 | 25,687 |
| Other long-term assets | 317 | 317 |
| Total assets | \$ 240,288 | \$ 243,705 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 7,750 | \$ 9,016 |
| Accrued expenses | 10,793 | 14,045 |
| Current portion of operating lease liabilities | 3,147 | 2,950 |
| Other current liabilities | 41 | 41 |
| Total current liabilities | 21,731 | 26,052 |
| Operating lease liabilities | 46,053 | 47,147 |
| Other long-term liabilities | 19 | 44 |
| Total liabilities | \$ 67,803 | \$ 73,243 |
| Total shareholders' equity | 172,485 | 170,462 |
| Total liabilities and shareholders' equity | \$ 240,288 | \$ 243,705 |