

**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 9, 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 November 9, 2022, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 Third Quarter 2022 Financial Results” |
| 104 | Cover page interactive data file (embedded within the Inline XBRL document) |

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | <u>Press Release of Vericel Corporation, “Vericel Reports Third Quarter 2022 Financial Results”</u> |
| 104 | <u>Cover page interactive data file (embedded within the Inline XBRL document)</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: November 9, 2022

By: /s/ Joseph A. Mara

Name: Joseph A. Mara
Chief Financial Officer
(Principal Financial Officer)



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Vericel Reports Third Quarter 2022 Financial Results

Total Net Product Revenue of \$38.6 Million

MACI Net Revenue Increased 30% to \$31.0 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., November 9, 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 third quarter ended September 30, 2022.

Third Quarter 2022 Financial Highlights

- Total net revenue of \$38.6 million
- MACI[®] net revenue of \$31.0 million, Epicel[®] net revenue of \$7.3 million, and NexoBrid[®] revenue of \$0.2 million
- Gross margin of 65%
- Net loss of \$6.6 million, or \$0.14 per share
- Non-GAAP adjusted EBITDA of \$3.3 million
- Operating cash flow of \$4.1 million
- As of September 30, 2022, approximately \$133 million in cash and investments, and no debt

Business Highlights and Updates

- Third-quarter MACI revenue growth of 30% compared to the prior year and 8% sequential growth versus the prior quarter, representing the highest quarterly revenue outside of the seasonally-high fourth quarter since the launch of MACI
- Ninth straight quarter of positive adjusted EBITDA and operating cash flow
- FDA's review of NexoBrid BLA is progressing, with inspections of manufacturing facilities in Taiwan and Israel underway
- Type C meeting with the FDA scheduled for December to discuss MACI arthroscopic delivery program

“The Company executed well in the third quarter, delivering strong MACI revenue growth, record third-quarter total revenue, and continued quarterly profitability and positive operating

cash flow,” said Nick Colangelo, President and CEO of Vericel. “We also continued to advance important pipeline programs with planned meetings with the FDA for both the MACI arthroscopic delivery and ankle development programs, as well as continued pre-launch activities for the potential launch of NexoBrid, which we believe positions the Company for continued strong growth in the years ahead.”

Full-Year 2022 Financial Guidance Update

- Total net revenue expected to be in the range of \$164 to \$166 million
- MACI revenue expected to be approximately \$130 to \$132 million
- Total burn care revenue, including Epicel and NexoBrid, expected to be approximately \$34 million
- Gross margin expected to be in the mid-60% range
- Adjusted EBITDA margin in the mid-teens % range

Third Quarter 2022 Results

Total net revenue for the quarter ended September 30, 2022 increased 12% to \$38.6 million, compared to \$34.5 million in the third quarter of 2021. Total net product revenue for the quarter included \$31.0 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$7.3 million of Epicel (cultured epidermal autografts) net revenue, compared to \$23.9 million of MACI net revenue and \$9.8 million of Epicel net revenue, respectively, in the third 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 the U.S. Biomedical Advanced Research and Development Authority (BARDA) for emergency response preparedness, compared to \$0.8 million in the third quarter of 2021.

Gross profit for the quarter ended September 30, 2022 was \$25.2 million, or 65% of net revenue, compared to \$22.1 million, or 64% of net revenue, for the third quarter of 2021.

Total operating expenses for the quarter ended September 30, 2022 were \$32.0 million, compared to \$27.1 million for the same period in 2021. The increase in operating expenses was primarily due to an increase in employee expenses, continued investment in commercialization initiatives and additional stock-based compensation expense.

Net loss for the quarter ended September 30, 2022 was \$6.6 million, or \$0.14 per share, compared to \$4.9 million, or \$0.11 per share, for the third quarter of 2021.

Non-GAAP adjusted EBITDA for the quarter ended September 30, 2022 was \$3.3 million, or 9% of net revenue, compared to \$4.3 million, or 12% of net revenue, for the third quarter of 2021. A table reconciling non-GAAP measures is included in this press release for reference.

As of September 30, 2022, the Company had approximately \$133 million in cash and investments, compared to approximately \$129 million as of December 31, 2021, 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 by telephone, please register here to receive dial-in details and your personal passcode. A replay of the webcast will be available on the Vericel website until November 9, 2023.

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, likelihood of the FDA’s potential approval of the NexoBrid BLA resubmission seeking approval for the treatment of severe burns in the United States, timing and likelihood of the FDA’s potential approval of the arthroscopic delivery of MACI to the knee or the use of MACI to treat cartilage defects in the ankle, 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, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine, global geopolitical tensions or record inflation and the ongoing or future impacts of the COVID-19 pandemic on our business or the economy generally.

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 September 30, 2022, filed with the SEC on November 9, 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 September 30, | | Nine Months Ended September 30, | |
|---|----------------------------------|------------|---------------------------------|-------------|
| | 2022 | 2021 | 2022 | 2021 |
| Product sales, net | \$ 38,326 | \$ 33,718 | \$ 111,004 | \$ 106,025 |
| Other revenue | 225 | 788 | 667 | 2,568 |
| Total revenue | 38,551 | 34,506 | 111,671 | 108,593 |
| Cost of product sales | 13,318 | 12,408 | 40,132 | 36,600 |
| Gross profit | 25,233 | 22,098 | 71,539 | 71,993 |
| Research and development | 5,046 | 4,284 | 14,698 | 12,363 |
| Selling, general and administrative | 26,975 | 22,775 | 79,984 | 71,625 |
| Total operating expenses | 32,021 | 27,059 | 94,682 | 83,988 |
| Loss from operations | (6,788) | (4,961) | (23,143) | (11,995) |
| Other income (expense): | | | | |
| Interest income | 342 | 44 | 578 | 163 |
| Interest expense | (105) | (1) | (143) | (3) |
| Other income (expense) | (5) | (13) | 98 | 44 |
| Total other income | 232 | 30 | 533 | 204 |
| Loss before income taxes | (6,556) | (4,931) | (22,610) | (11,791) |
| Income tax expense | 21 | — | 21 | 215 |
| Net loss | \$ (6,577) | \$ (4,931) | \$ (22,631) | \$ (12,006) |
| Net loss per common share: | | | | |
| Basic | \$ (0.14) | \$ (0.11) | \$ (0.48) | \$ (0.26) |
| Diluted | \$ (0.14) | \$ (0.11) | \$ (0.48) | \$ (0.26) |
| Weighted-average common shares outstanding: | | | | |
| Basic | 47,182 | 46,669 | 47,096 | 46,355 |
| Diluted | 47,182 | 46,669 | 47,096 | 46,355 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------------|----------------------------------|-----------------|---------------------------------|------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Net loss | \$ (6,577) | \$ (4,931) | \$ (22,631) | \$ (12,006) |
| Stock-based compensation expense | 9,104 | 8,596 | 29,443 | 26,481 |
| Depreciation and amortization | 1,014 | 679 | 2,942 | 2,185 |
| Net interest income | (237) | (43) | (435) | (160) |
| Income tax expense | 21 | — | 21 | 215 |
| Adjusted EBITDA (Non-GAAP) | <u>\$ 3,325</u> | <u>\$ 4,301</u> | <u>\$ 9,340</u> | <u>\$ 16,715</u> |

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

| | September 30, 2022 | December 31, 2021 |
|--|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 65,216 | \$ 68,330 |
| Short-term investments | 45,724 | 35,068 |
| Accounts receivable (net of allowance for doubtful accounts of \$115 and \$40, respectively) | 34,296 | 37,437 |
| Inventory | 16,729 | 13,381 |
| Other current assets | 4,410 | 4,246 |
| Total current assets | 166,375 | 158,462 |
| Property and equipment, net | 15,918 | 13,308 |
| Restricted cash | — | 211 |
| Right-of-use assets | 42,628 | 45,720 |
| Long-term investments | 21,739 | 25,687 |
| Other long-term assets | 1,357 | 317 |
| Total assets | \$ 248,017 | \$ 243,705 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 8,113 | \$ 9,016 |
| Accrued expenses | 13,948 | 14,045 |
| Current portion of operating lease liabilities | 4,902 | 2,950 |
| Other current liabilities | 41 | 41 |
| Total current liabilities | 27,004 | 26,052 |
| Operating lease liabilities | 43,176 | 47,147 |
| Other long-term liabilities | — | 44 |
| Total liabilities | 70,180 | 73,243 |
| Total shareholders' equity | 177,837 | 170,462 |
| Total liabilities and shareholders' equity | \$ 248,017 | \$ 243,705 |