

**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 10, 2023**

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 10, 2023, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended March 31, 2023, 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 2023 Financial Results and Raises Full-Year 2023 Financial Guidance”
104	Cover page interactive data file (embedded within the Inline XBRL document)

**Vericel Corporation**

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Vericel Reports First Quarter 2023 Financial Results and Raises Full-Year 2023 Financial Guidance

Record First Quarter Total Revenue of \$41 Million

MACI Revenue Increased 32% to \$34.2 Million

Full-Year 2023 Revenue Guidance Raised to \$184-\$192 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., May 10, 2023 (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, 2023, and provided updated full-year 2023 financial guidance.

First Quarter 2023 Financial Highlights

- Total net revenue of \$41.0 million
- MACI[®] net revenue of \$34.2 million and Epicel[®] net revenue of \$6.8 million
- Gross margin of 65%
- Net loss of \$7.5 million, or \$0.16 per diluted share
- Non-GAAP adjusted EBITDA of \$1.7 million
- Operating cash flow of \$7.9 million
- As of March 31, 2023, the Company had approximately \$139 million in cash and investments, and no debt

Business Highlights and Updates

- Record first quarter total revenue
- Highest first quarter MACI revenue since launch, representing growth of 32% compared to the prior year
- Highest number of surgeons taking MACI biopsies and second highest number of MACI biopsies in a quarter since launch
- 11th straight quarter of positive adjusted EBITDA and operating cash flow
- MACI arthroscopic delivery program remains on track for an anticipated 2024 commercial launch
- Tracking ahead of initial goals on NexoBrid[®] Pharmacy and Therapeutics (P&T) committee submissions and approvals at target burn centers

- NexoBrid selected for inclusion in the pre-conference healthcare professional educational sessions at the upcoming American Burn Association (ABA) annual meeting with hands-on lab demonstrations by leading burn surgeons

“The Company had a very strong start to the year, delivering record quarterly MACI and total revenue and another quarter of profitability and operating cash flow,” said Nick Colangelo, President and CEO of Vericel. “MACI has continued on its high-growth trajectory with first quarter revenue growth of more than 30% and, based on our positive first quarter performance and strong underlying business fundamentals, we have increased our 2023 full-year revenue guidance. We look forward to the upcoming commercial launch of NexoBrid and continue to advance the MACI arthroscopic delivery program, which we believe will drive further growth in the years ahead.”

2023 Financial Guidance

- Total net revenue for 2023 now expected to be in the range of \$184 to \$192 million compared to the previous guidance of \$180 to \$188 million
- Maintaining profitability guidance of gross margin in the high-60% range and adjusted EBITDA margin in the mid-teens % range

First Quarter 2023 Results

Total net revenue for the quarter ended March 31, 2023 increased 14% to \$41.0 million, compared to \$36.1 million in the first quarter of 2022. Total net product revenue for the quarter included \$34.2 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$6.8 million of Epicel (cultured epidermal autografts) net revenue, compared to \$26.0 million of MACI net revenue and \$9.9 million of Epicel net revenue, respectively, in the first quarter of 2022.

Gross profit for the quarter ended March 31, 2023 was \$26.5 million, or 65% of net revenue, compared to \$23.5 million, or 65% of net revenue, for the first quarter of 2022.

Total operating expenses for the quarter ended March 31, 2023 were \$34.7 million, compared to \$30.7 million for the same period in 2022. The increase in operating expenses was primarily due to an increase in employee-related expenses and higher sales and marketing expenses.

Net loss for the quarter ended March 31, 2023 was \$7.5 million, or \$0.16 per diluted share, compared to \$7.1 million, or \$0.15 per diluted share, for the first quarter of 2022.

Non-GAAP adjusted EBITDA for the quarter ended March 31, 2023 was \$1.7 million, or 4% of net revenue, compared to \$3.2 million, or 9% of net revenue, for the first quarter of 2022. A table reconciling non-GAAP measures is included in this press release for reference.

As of March 31, 2023, the Company had approximately \$139 million in 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 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 March 31, 2024.

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 and one specialty biologic product 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[®] (anacaulase-bcdb), a biological orphan product containing proteolytic enzymes, which is indicated for the removal of eschar in adults with deep partial-thickness and/or full-thickness burns. For more information, please visit 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. © 2023 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, Epicel, and NexoBrid, growth in profit, gross margins and operating margins, the ability to continue to scale our manufacturing operations to meet the demand for our cell therapy products, including the timely completion of a new headquarters and manufacturing facility in Burlington, Massachusetts, 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 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, competitive developments, changes in third-party coverage and reimbursement, the ultimate timing of the commercial launch of NexoBrid in the United States, physician and burn center adoption of NexoBrid, supply chain disruptions or other events affecting MediWound Ltd.’s ability to manufacture and supply NexoBrid to meet customer demand, 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, 2022, filed with the Securities and Exchange Commission (SEC) on February 23, 2023, Vericel's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 10, 2023, 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
(in thousands, except per share amounts - unaudited)

	Three Months Ended March 31,	
	2023	2022
Product sales, net	\$ 41,017	\$ 35,852
Other revenue	—	222
Total revenue	41,017	36,074
Cost of product sales	14,497	12,622
Gross profit	26,520	23,452
Research and development	5,212	4,860
Selling, general and administrative	29,485	25,865
Total operating expenses	34,697	30,725
Loss from operations	(8,177)	(7,273)
Other income (expense):		
Interest income	839	88
Interest expense	(145)	(18)
Other (expense) income	(12)	112
Total other income	682	182
Net loss	\$ (7,495)	\$ (7,091)
Net loss per common share:		
Basic and diluted	\$ (0.16)	\$ (0.15)
Weighted-average common shares outstanding:		
Basic and diluted	47,387	46,985

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

	Three Months Ended March 31,	
	2023	2022
Net loss	\$ (7,495)	\$ (7,091)
Stock-based compensation expense	8,731	9,531
Depreciation and amortization	1,158	873
Net interest income	(694)	(70)
Adjusted EBITDA (Non-GAAP)	<u>\$ 1,700</u>	<u>\$ 3,243</u>

VERICEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands - unaudited)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 61,834	\$ 51,067
Short-term investments	57,442	68,471
Accounts receivable (net of allowance for doubtful accounts of \$47 and \$47, respectively)	38,359	46,539
Inventory	15,370	15,986
Other current assets	4,540	4,803
Total current assets	177,545	186,866
Property and equipment, net	18,197	15,837
Intangible assets, net	7,344	7,500
Right-of-use assets	40,851	41,535
Long-term investments	19,910	19,962
Other long-term assets	1,249	1,303
Total assets	\$ 265,096	\$ 273,003
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 11,125	\$ 16,930
Accrued expenses	13,111	16,190
Current portion of operating lease liabilities	4,497	4,302
Other current liabilities	20	41
Total current liabilities	28,753	37,463
Operating lease liabilities	42,365	43,268
Total liabilities	\$ 71,118	\$ 80,731
Total shareholders' equity	193,978	192,272
Total liabilities and shareholders' equity	\$ 265,096	\$ 273,003