

**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 2, 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 August 2, 2023, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended June 30, 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 Second Quarter 2023 Financial Results and Raises Full-Year 2023 Financial Guidance”
104	Cover page interactive data file (embedded within the Inline XBRL document)



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

Record Second Quarter Total Revenue of \$45.9 Million, Representing 24% Growth versus Prior Year

MACI Revenue Growth of 27% to \$36.3 Million

Epicel Revenue Growth of 17% to \$9.6 Million

Full-Year 2023 Revenue Guidance Raised to \$190-197 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., August 2, 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 second quarter ended June 30, 2023, and provided updated full-year 2023 financial guidance.

Second Quarter 2023 Financial Highlights

- Total net revenue of \$45.9 million
- MACI® net revenue of \$36.3 million and Epicel® net revenue of \$9.6 million
- Gross margin of 65%
- Net loss of \$5.0 million, or \$0.11 per diluted share
- Non-GAAP adjusted EBITDA of \$4.4 million
- Operating cash flow of \$10.2 million
- As of June 30, 2023, the Company had approximately \$147 million in cash, restricted cash and investments, and no debt

Business Highlights and Updates

- Record second quarter total revenue of \$45.9 million, representing 24% growth versus the prior year
- MACI second-quarter revenue growth of 27%, representing the fourth straight quarter of 20%+ growth compared to the prior year
- MACI revenue growth of 29% in the first half of 2023 versus the prior year
- Highest number of surgeons taking MACI biopsies in a quarter and second highest number of MACI biopsies in a quarter since launch

- Second quarter Epicel growth of 17% versus the prior year and 40% sequential growth versus the first quarter
- 12th straight quarter of positive adjusted EBITDA and operating cash flow, with adjusted EBITDA growth of 60% in the second quarter versus the prior year
- Human factors validation study for MACI arthroscopic delivery program planned for Q3 and program remains on track for an anticipated 2024 commercial launch; market research confirms significant opportunity with high level of surgeon interest
- Executed long-term extension of exclusive supply agreement with Matricel GmbH for the MACI ACI-Maix collagen membrane

“The Company continues to execute well, generating very strong revenue growth for both MACI and Epicel in the second quarter, as well as our 12th consecutive quarter of positive adjusted EBITDA and operating cash flow,” said Nick Colangelo, President and CEO of Vericel. “The underlying growth drivers of our business remain strong, as evidenced by our outstanding performance in the first half of the year and, as a result, we are increasing our total net revenue guidance for the full year. We look forward to building on this momentum as we expect a further acceleration in total company revenue growth in 2024 driven by the planned launch of arthroscopic MACI and a significant contribution from NexoBrid.”

2023 Financial Guidance

- Total net revenue for 2023 now expected to be in the range of \$190 to \$197 million compared to the previous guidance of \$184 to \$192 million
- Maintaining profitability guidance of gross margin in the high-60% range and adjusted EBITDA margin in the mid-teens % range

Second Quarter 2023 Results

Total net revenue for the quarter ended June 30, 2023 increased 24% to \$45.9 million, compared to \$37.0 million in the second quarter of 2022. Total net product revenue for the quarter included \$36.3 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$9.6 million of Epicel (cultured epidermal autografts) net revenue, compared to \$28.6 million of MACI net revenue, \$8.2 million of Epicel net revenue, and \$0.2 million of NexoBrid (anacaulase-bcdb) net revenue, respectively, in the second quarter of 2022.

Gross profit for the quarter ended June 30, 2023 was \$29.9 million, or 65% of net revenue, compared to \$22.9 million, or 62% of net revenue, for the second quarter of 2022.

Total operating expenses for the quarter ended June 30, 2023 were \$35.9 million, compared to \$31.9 million for the same period in 2022. The increase in operating expenses was primarily due to higher sales and marketing expenses and research and development program costs.

Net loss for the quarter ended June 30, 2023 was \$5.0 million, or \$0.11 per diluted share, compared to \$9.0 million, or \$0.19 per diluted share, for the second quarter of 2022.

Non-GAAP adjusted EBITDA for the quarter ended June 30, 2023 was \$4.4 million, or 10% of net revenue, compared to \$2.8 million, or 7% of net revenue, for the second quarter of 2022. A table reconciling non-GAAP measures is included in this press release for reference.

As of June 30, 2023, the Company had approximately \$147 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 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 August 2, 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.

Epichel[®] 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, Epichel, 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 potential 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 June 30, 2023, filed with the SEC on August 2, 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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Product sales, net	\$ 45,922	\$ 36,826	\$ 86,939	\$ 72,678
Other revenue	—	220	—	442
Total revenue	45,922	37,046	86,939	73,120
Cost of product sales	15,981	14,192	30,478	26,814
Gross profit	29,941	22,854	56,461	46,306
Research and development	5,253	4,792	10,465	9,652
Selling, general and administrative	30,649	27,144	60,134	53,009
Total operating expenses	35,902	31,936	70,599	62,661
Loss from operations	(5,961)	(9,082)	(14,138)	(16,355)
Other income (expense):				
Interest income	1,095	148	1,934	236
Interest expense	(149)	(20)	(294)	(38)
Other (expense) income	(5)	(9)	(17)	103
Total other income	941	119	1,623	301
Net loss	\$ (5,020)	\$ (8,963)	\$ (12,515)	\$ (16,054)
Net loss per common share:				
Basic and diluted	\$ (0.11)	\$ (0.19)	\$ (0.26)	\$ (0.34)
Weighted-average common shares outstanding:				
Basic and diluted	47,572	47,117	47,480	47,052

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

	Three Months Ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Net loss	\$ (5,020)	\$ (8,963)	\$ (12,515)	\$ (16,054)
Stock-based compensation expense	8,761	10,808	17,492	20,339
Depreciation and amortization	1,171	1,055	2,329	1,928
Net interest income	(946)	(128)	(1,640)	(198)
Pre-occupancy lease expense	475	—	475	—
Adjusted EBITDA (Non-GAAP)	<u>\$ 4,441</u>	<u>\$ 2,772</u>	<u>\$ 6,141</u>	<u>\$ 6,015</u>

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 43,023	\$ 51,067
Restricted cash	27,794	—
Short-term investments	54,808	68,471
Accounts receivable (net of allowance for doubtful accounts of \$44 and \$47, respectively)	38,319	46,539
Inventory	13,883	15,986
Other current assets	5,044	4,803
Total current assets	182,871	186,866
Property and equipment, net	23,408	15,837
Intangible assets, net	7,188	7,500
Right-of-use assets	75,063	41,535
Long-term investments	20,985	19,962
Other long-term assets	1,196	1,303
Total assets	<u>\$ 310,711</u>	<u>\$ 273,003</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 14,401	\$ 16,930
Accrued expenses	13,971	16,190
Current portion of operating lease liabilities	7,218	4,302
Other current liabilities	21	41
Total current liabilities	35,611	37,463
Operating lease liabilities	76,144	43,268
Other long-term liabilities	28	—
Total liabilities	<u>\$ 111,783</u>	<u>\$ 80,731</u>
Total shareholders' equity	198,928	192,272
Total liabilities and shareholders' equity	<u>\$ 310,711</u>	<u>\$ 273,003</u>