

**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 1, 2024**

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 1, 2024, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended June 30, 2024, 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 2024 Financial Results”
104	Cover page interactive data file (embedded within the Inline XBRL document)



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Vericel Reports Second Quarter 2024 Financial Results

Total Revenue of \$52.7 Million, with MACI Revenue Growth of 21% to \$44.1 Million

NexoBrid Revenue Growth of 76% Over Prior Quarter

Gross Margin of 70% and Adjusted EBITDA Growth of 42%

Full-Year Profitability Guidance Raised to 71% Gross Margin and 21% Adjusted EBITDA Margin

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., August 1, 2024 (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, 2024.

Second Quarter 2024 Financial Highlights

- Total net revenue of \$52.7 million
- MACI[®] net revenue growth of 21% to \$44.1 million
- Burn Care net revenue of \$8.5 million, consisting of \$7.8 million of Epicel[®] revenue and \$0.8 million of NexoBrid[®] revenue
- Gross margin of 70%, an increase of 430 basis points versus the prior year
- Net loss of \$4.7 million, or \$0.10 per diluted share
- Non-GAAP adjusted EBITDA increased 42% to \$6.3 million, representing adjusted EBITDA margin of 12%, an increase of approximately 230 basis points versus the prior year
- Operating cash flow of approximately \$18.5 million
- As of June 30, 2024, the Company had approximately \$154 million in cash, restricted cash and investments, and no debt

First Half 2024 Financial Highlights

- Total net revenue increased 20% to \$103.9 million
- MACI net revenue growth of 20% to \$84.3 million
- Burn Care net revenue growth of 20% to \$19.6 million
- Gross margin of 69%, an increase of approximately 430 basis points versus the prior year
- Net loss of \$8.5 million, or \$0.18 per diluted share

- Non-GAAP adjusted EBITDA increased 120% to \$13.5 million, representing adjusted EBITDA margin of 13%, an increase of approximately 600 basis points versus the prior year
- Operating cash flow of approximately \$26 million

Business Highlights and Updates

- Record second quarter total revenue and MACI revenue
- Second highest number of MACI biopsies and surgeons taking biopsies in a quarter since launch, including the highest number of biopsies in any month since launch
- Commercial plans progressing for MACI Arthro™ in advance of anticipated launch later this quarter
- NexoBrid launch progressing with approximately 70 Pharmacy and Therapeutics (P&T) committee submissions, more than 40 burn centers obtaining approval and approximately 40 centers placing initial orders
- FDA approval of pediatric indication for NexoBrid expected in the third quarter of 2024

“The Company had another strong quarter as we generated record second quarter revenue, highlighted by continued high growth for MACI and solid progression in NexoBrid demand, and delivered another quarter of significant margin expansion as our growth in profitability continues to outpace our high revenue growth,” said Nick Colangelo, President and CEO of Vericel. “In light of the strong performance of our core portfolio in the first half of the year, with both MACI and the Burn Care franchise delivering 20% growth, and with the expected contributions from new product launches, we believe that the Company is very well-positioned for continued high revenue and profit growth in 2024 and beyond.”

2024 Financial Guidance

- Reaffirmed total net revenue guidance of \$238 to \$242 million, or 20% to 23% growth
- Profitability guidance raised to 71% gross margin and 21% adjusted EBITDA margin, compared to the previous guidance of 70% and 20%, respectively

Second Quarter 2024 Results

Total net revenue for the quarter ended June 30, 2024 increased 15% to \$52.7 million, compared to \$45.9 million in the second quarter of 2023. Total net product revenue for the quarter included \$44.1 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue, \$7.8 million of Epicel (cultured epidermal autografts) net revenue, and \$0.8 million of NexoBrid (anacaulase-bcdb) net revenue, compared to \$36.3 million of MACI net revenue and \$9.6 million of Epicel net revenue, respectively, in the second quarter of 2023.

Gross profit for the quarter ended June 30, 2024 was \$36.6 million, or 70% of net revenue, compared to \$29.9 million, or 65% of net revenue, for the second quarter of 2023.

Total operating expenses for the quarter ended June 30, 2024 were \$42.6 million, compared to \$35.9 million for the same period in 2023. The increase in operating expenses was primarily due

to development and pre-launch activities for MACI Arthro, increased headcount and related employee expenses, and lease expense associated with the Company's new facility that is under construction.

Net loss for the quarter ended June 30, 2024 was \$4.7 million, or \$0.10 per diluted share, compared to \$5.0 million, or \$0.11 per diluted share, for the second quarter of 2023.

Non-GAAP adjusted EBITDA for the quarter ended June 30, 2024 was \$6.3 million, or 12% of net revenue, compared to \$4.4 million, or 10% of net revenue, for the second quarter of 2023. A table reconciling non-GAAP measures is included in this press release for reference.

As of June 30, 2024, the Company had approximately \$154 million in cash, restricted cash and investments, and no debt.

Conference Call Information

Today's conference call will be available live at 8:30 a.m. 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 1, 2025.

About Vericel Corporation

Vericel is a leading provider of advanced therapies for the sports medicine and severe burn care markets. The Company combines innovations in biology with medical technologies, resulting in a highly differentiated portfolio of innovative cell therapies and specialty biologics that repair injuries and restore lives. Vericel markets three 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. Vericel 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 this 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. © 2024 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, physician and burn center adoption of NexoBrid, supply chain disruptions or other events or factors affecting MediWound's ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, including but not limited to the ongoing Israel-Hamas war or other military

conflicts in the Middle East, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine and the Israel-Hamas war, adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, global geopolitical tensions or record inflation and potential future impacts on our business or the economy generally stemming from a resurgence of COVID-19 or another similar public health emergency.

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, 2023, filed with the Securities and Exchange Commission (SEC) on February 29, 2024, Vericel's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 1, 2024, 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,	
	2024	2023	2024	2023
Product sales, net	\$ 52,662	\$ 45,922	\$ 103,943	\$ 86,939
Total revenue	52,662	45,922	103,943	86,939
Cost of product sales	16,061	15,981	31,988	30,478
Gross profit	36,601	29,941	71,955	56,461
Research and development	7,363	5,253	13,781	10,465
Selling, general and administrative	35,269	30,649	69,669	60,134
Total operating expenses	42,632	35,902	83,450	70,599
Loss from operations	(6,031)	(5,961)	(11,495)	(14,138)
Other income (expense):				
Interest income	1,510	1,095	3,272	1,934
Interest expense	(153)	(149)	(306)	(294)
Other expense	(8)	(5)	(15)	(17)
Total other income	1,349	941	2,951	1,623
Net loss	\$ (4,682)	\$ (5,020)	\$ (8,544)	\$ (12,515)
Net loss per common share:				
Basic and diluted	\$ (0.10)	\$ (0.11)	\$ (0.18)	\$ (0.26)
Weighted-average common shares outstanding:				
Basic and diluted	48,686	47,572	48,413	47,480

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,	
	2024	2023	2024	2023
Net loss	\$ (4,682)	\$ (5,020)	\$ (8,544)	\$ (12,515)
Stock-based compensation expense	9,520	8,761	19,354	17,492
Depreciation and amortization	1,323	1,171	2,701	2,329
Net interest income	(1,357)	(946)	(2,966)	(1,640)
Pre-occupancy lease expense	1,509	475	2,986	475
Adjusted EBITDA (Non-GAAP)	<u>\$ 6,313</u>	<u>\$ 4,441</u>	<u>\$ 13,531</u>	<u>\$ 6,141</u>

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

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 50,291	\$ 69,088
Restricted cash	25,563	17,778
Short-term investments	52,217	40,469
Accounts receivable (net of allowance for doubtful accounts of \$10 and \$43, respectively)	47,996	58,356
Inventory	14,887	13,087
Other current assets	6,432	6,853
Total current assets	197,386	205,631
Property and equipment, net	73,086	41,635
Intangible assets, net	6,563	6,875
Right-of-use assets	73,020	73,462
Long-term investments	26,120	25,283
Other long-term assets	664	771
Total assets	\$ 376,839	\$ 353,657
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 25,216	\$ 22,347
Accrued expenses	12,856	17,215
Current portion of operating lease liabilities	5,791	6,187
Total current liabilities	43,863	45,749
Operating lease liabilities	89,801	81,856
Other long-term liabilities	198	100
Total liabilities	\$ 133,862	\$ 127,705
Total shareholders' equity	242,977	225,952
Total liabilities and shareholders' equity	\$ 376,839	\$ 353,657