
**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): **February 23, 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 February 23, 2023, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter and year-ended December 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 Fourth Quarter and Full-Year 2022 Financial Results and Provides Full-Year 2023 Financial Guidance”
104	Cover page interactive data file (embedded within the Inline XBRL document)

EXHIBIT INDEX

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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: February 23, 2023

By: /s/ Joseph A. Mara

Name: Joseph A. Mara

Title: Chief Financial Officer (Principal
Financial Officer)



Vericel Corporation
 64 Sidney Street Cambridge, MA 02139
 T (617) 588-5555 F (617) 588-5554
www.vcel.com

Vericel Reports Fourth Quarter and Full-Year 2022 Financial Results and Provides Full-Year 2023 Financial Guidance

Record Fourth Quarter Total Revenue of \$52.7 Million and 31% Net Income Growth

Full-Year 2022 Total Revenue of \$164.4 Million, with MACI Revenue of \$132 Million

Full-Year 2023 Total Revenue Guidance of \$180 to \$188 Million, with MACI Revenue of \$152 to \$156 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., February 23, 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 fourth quarter and year ended December 31, 2022, and provided full-year 2023 financial guidance.

Fourth Quarter 2022 Financial Highlights

- Total net revenue of \$52.7 million
- MACI® net revenue of \$46.3 million, and Epicel® net revenue of \$6.3 million
- Gross margin of 73%
- Net income of \$5.9 million, or \$0.12 per diluted share
- Non-GAAP adjusted EBITDA of \$14.9 million, or adjusted EBITDA margin of 28%
- Operating cash flow of \$7.0 million
- As of December 31, 2022, the Company had approximately \$140 million in cash and investments, and no debt

Full-Year 2022 Financial Highlights

- Total net revenue of \$164.4 million
- MACI net revenue of \$132 million, Epicel net revenue of \$31.7 million, and NexoBrid® revenue of \$0.7 million
- Gross margin of 67%
- Net loss of \$16.7 million, or \$0.35 per diluted share
- Non-GAAP adjusted EBITDA of \$24.2 million, or adjusted EBITDA margin of 15%
- Operating cash flow of \$17.7 million

Business Highlights and Updates

- Record quarterly total revenue of \$52.7 million
- Fourth-quarter MACI revenue growth of 24% compared to the prior year and approximately 50% sequential growth versus the prior quarter, representing the highest quarterly revenue since the launch of MACI
- Fourth-quarter net income growth of 31% compared to the prior year
- 10th straight quarter of positive adjusted EBITDA and operating cash flow
- Announced FDA approval of NexoBrid (anacaulase-bcbd) for the removal of eschar in adults with deep partial-thickness and/or full-thickness thermal burns, with U.S. commercial availability expected in the second quarter of 2023
- Announced that the Company is planning to initiate a human factors validation study in 2023 to support expanding the MACI label to include arthroscopic administration of MACI for the treatment of cartilage defects of the knee and now anticipates an accelerated commercial launch of arthroscopic MACI in 2024
- Announced that the Company will hold a pre-IND meeting with the FDA during the first half of 2023 regarding the clinical development program for MACI for the treatment of cartilage injuries in the ankle

“The Company delivered strong financial and business results to end the year as we generated record quarterly MACI and total revenue and another quarter of profitability,” said Nick Colangelo, President and CEO of Vericel. “We also achieved significant development milestones for the Company with the approval of NexoBrid and an accelerated regulatory pathway for the MACI arthroscopic delivery program. Based on our current portfolio and anticipated new product launches, we believe that the Company is well-positioned to continue to deliver strong revenue and profit growth over the long term.”

2023 Financial Guidance

- Total net revenue for 2023 expected to be in the range of \$180 to \$188 million
 - MACI revenue expected to be in the range of \$152 to \$156 million
 - Total Burn Care revenue, which includes Epicel and NexoBrid, expected to be in the range of \$28 to \$32 million
- Gross margin expected to be in the high-60% range
- Adjusted EBITDA margin expected to be in the mid-teens % range

Fourth Quarter 2022 Results

Total net revenue for the quarter ended December 31, 2022 increased 11% to \$52.7 million, compared to \$47.6 million in the fourth quarter of 2021. Total net product revenue for the quarter included \$46.3 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$6.3 million of Epicel (cultured epidermal autografts) net revenue, compared to \$37.3 million of MACI net revenue and \$9.7 million of Epicel net revenue, respectively, in the fourth quarter of 2021.

Gross profit for the quarter ended December 31, 2022 was \$38.2 million, or 73% of net revenue, compared to \$34.0 million, or 72% of net revenue, for the fourth quarter of 2021.

Total operating expenses for the quarter ended December 31, 2022 were \$32.2 million, compared to \$29.9 million for the same period in 2021. The increase in operating expenses was primarily due to an increase in headcount and higher sales and marketing expenses.

Net income for the quarter ended December 31, 2022 was \$5.9 million, or \$0.12 per diluted share, compared to net income of \$4.5 million, or \$0.09 per diluted share, for the fourth quarter of 2021.

Non-GAAP adjusted EBITDA for the quarter ended December 31, 2022 was \$14.9 million, or 28% of net revenue, compared to \$12.8 million, or 27% of net revenue, for the fourth quarter of 2021. A table reconciling non-GAAP measures is included in this press release for reference.

As of December 31, 2022, the Company had approximately \$140 million in cash and investments, and no debt.

Full-Year 2022 Results

Total net revenue for the year ended December 31, 2022 was \$164.4 million, compared to \$156.2 million in 2021. Total net product revenue for the year included \$132.0 million of MACI net revenue and \$31.7 million of Epicel net revenue, compared to \$111.6 million of MACI net revenue and \$41.5 million of Epicel net revenue, respectively, in 2021. Total net revenue in 2022 also included \$0.7 million of revenue related to the procurement of NexoBrid by the U.S. Biomedical Advanced Research and Development Authority (BARDA) for emergency response preparedness, compared to \$3.1 million of revenue in 2021.

Gross profit for the year ended December 31, 2022 was \$109.8 million, or 67% of net revenue, compared to \$106.0 million, or 68% of net revenue, in 2021.

Total operating expenses for the year ended December 31, 2022 were \$126.8 million, compared to \$113.9 million in 2021. The increase in operating expenses was primarily due to an increase in headcount, higher sales and marketing expenses and a \$2.9 million increase in non-cash stock-based compensation expense.

Net loss for the year ended December 31, 2022 was \$16.7 million, or \$0.35 per diluted share, compared to net income of \$7.5 million, or \$0.16 per diluted share, in 2021.

Non-GAAP adjusted EBITDA for the year ended December 31, 2022 was \$24.2 million, or 15% of net revenue, compared to \$29.5 million, or 19% of net revenue, in 2021. A table reconciling non-GAAP measures is included in this press release for reference.

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 February 23, 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 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 sufficient quantities of 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, 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.

Investor Contact:

Eric Burns
ir@vcel.com
+1 (734) 418-4411

Media Contact:

Julie Downs
media@vcel.com

VERICEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts - unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Product sales, net	\$ 52,694	\$ 47,050	\$ 163,698	\$ 153,075
Other revenue	—	541	667	3,109
Total revenue	52,694	47,591	164,365	156,184
Cost of product sales	14,445	13,559	54,577	50,159
Gross profit	38,249	34,032	109,788	106,025
Research and development	5,245	3,924	19,943	16,287
Selling, general and administrative	26,919	25,967	106,903	97,592
Total operating expenses	32,164	29,891	126,846	113,879
Income (loss) from operations	6,085	4,141	(17,058)	(7,854)
Other income (expense):				
Interest income	763	61	1,341	224
Interest expense	(223)	(1)	(366)	(4)
Other income (expense)	(3)	8	95	52
Total other income	537	68	1,070	272
Income (loss) before income taxes	6,622	4,209	(15,988)	(7,582)
Income tax expense (benefit)	700	(326)	721	(111)
Net income (loss)	\$ 5,922	\$ 4,535	\$ (16,709)	\$ (7,471)
Net income (loss) per common share:				
Basic	\$ 0.13	\$ 0.10	\$ (0.35)	\$ (0.16)
Diluted	\$ 0.12	\$ 0.09	\$ (0.35)	\$ (0.16)
Weighted-average common shares outstanding:				
Basic	47,232	46,821	47,130	46,472
Diluted	49,204	49,939	47,130	46,472

RECONCILIATION OF REPORTED NET INCOME (LOSS) (GAAP) TO ADJUSTED EBITDA (NON-GAAP MEASURE) - UNAUDITED

(In thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Net income (loss)	\$ 5,922	\$ 4,535	\$ (16,709)	\$ (7,471)
Stock-based compensation expense	7,740	7,841	37,183	34,322
Depreciation and amortization	1,039	780	3,981	2,965
Net interest income	(540)	(60)	(975)	(220)
Income tax expense (benefit)	700	(326)	721	(111)
Adjusted EBITDA (Non-GAAP)	<u>\$ 14,861</u>	<u>\$ 12,770</u>	<u>\$ 24,201</u>	<u>\$ 29,485</u>

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

	December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 51,067	\$ 68,330
Short-term investments	68,471	35,068
Accounts receivable (net of allowance for doubtful accounts of \$47 and \$40, respectively)	46,539	37,437
Inventory	15,986	13,381
Other current assets	4,803	4,246
Total current assets	186,866	158,462
Property and equipment, net	15,837	13,308
Intangible assets, net	7,500	—
Restricted cash	—	211
Right-of-use assets	41,535	45,720
Long-term investments	19,962	25,687
Other long-term assets	1,303	317
Total assets	<u>\$ 273,003</u>	<u>\$ 243,705</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 16,930	\$ 9,016
Accrued expenses	16,190	14,045
Current portion of operating lease liabilities	4,302	2,950
Other current liabilities	41	41
Total current liabilities	37,463	26,052
Operating lease liabilities	43,268	47,147
Other long-term liabilities	—	44
Total liabilities	80,731	73,243
Total shareholders' equity	192,272	170,462
Total liabilities and shareholders' equity	<u>\$ 273,003</u>	<u>\$ 243,705</u>