

**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 24, 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 February 24, 2022, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter and year-ended December 31, 2021, 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 2021 Financial Results and Provides Full-Year 2022 Financial Guidance”
104	Cover page interactive data file (embedded within the Inline XBRL document)

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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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 24, 2022

By: /s/ Joseph A. Mara

Name: Joseph A. Mara

Title: Chief Financial Officer (Principal
Financial Officer)



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Vericel Reports Fourth Quarter and Full-Year 2021 Financial Results and Provides Full-Year 2022 Financial Guidance

Full-Year 2021 Total Revenue Growth of 26%

Full-Year 2022 Total Revenue Guidance of \$178 to \$189 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., February 24, 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 fourth quarter and year ended December 31, 2021, and provided full-year 2022 financial guidance.

Fourth Quarter 2021 Financial Highlights

- Total net revenue of \$47.6 million, compared to \$45.2 million in the fourth quarter of 2020
- MACI® net revenue of \$37.3 million, Epicel® net revenue of \$9.7 million, and NexoBrid® revenue of \$0.5 million related to the U.S. Biomedical Advanced Research and Development Authority (BARDA) procurement for emergency response preparedness
- Gross margin of 72%, compared to 74% in the fourth quarter of 2020
- Net income of \$4.5 million, or \$0.09 per share, compared to \$12.2 million, or \$0.25 per share, in the fourth quarter of 2020
- Non-GAAP adjusted EBITDA of \$12.8 million, compared to \$16.0 million in the fourth quarter of 2020
- Operating cash flow of \$10.6 million

Full-Year 2021 Financial Highlights

- Total net revenue of \$156.2 million, compared to \$124.2 million in 2020
- MACI net revenue of \$111.6 million, Epicel net revenue of \$41.5 million, and NexoBrid revenue of \$3.1 million related to BARDA procurement for emergency response preparedness
- Gross margin of 68%, compared to gross margin of 68% in 2020
- Net loss of \$7.5 million, or \$0.16 per share, compared to net income of \$2.9 million, or \$0.06 per share, in 2020
- Non-GAAP adjusted EBITDA of \$29.5 million, compared to \$18.6 million in 2020
- Operating cash flow of \$29.0 million

- As of December 31, 2021, the Company had approximately \$129 million in cash and investments, compared to \$100 million as of December 31, 2020, and no debt

Business Highlights and Updates

- Total net revenue growth of 26% for 2021, in line with the Company’s compounded annual revenue growth rate since the launch of MACI in 2017
- Full-year net revenue growth of 18% for MACI, achieving record quarterly revenue in the fourth quarter
- Full-year net revenue growth of 51% for Epicel and the fifth straight quarter with revenue over \$9.5 million
- Achieved 20% growth in surgeons taking MACI biopsies and 30% growth in MACI biopsies for the year, with a record quarterly high in the number of biopsies and the number of surgeons taking biopsies in the fourth quarter
- Achieved over 30% growth in Epicel biopsies and burn centers treating patients with Epicel compared to 2020
- Announced plans for a new state-of-the-art cell therapy manufacturing facility and corporate headquarters to support long-term growth

“We delivered another strong year of revenue growth and generated record adjusted EBITDA and operating cash flow to end the year in a very strong financial position,” said Nick Colangelo, President and CEO of Vericel. “The Company continues to execute very well across all areas of the business, generating record revenue and biopsies for MACI in the fourth quarter and driving over 50% growth in Epicel revenue for the year. Looking forward, given the significant market opportunities and the continued progress across both of our franchises, we believe that we are well-positioned for continued strong revenue and profitability growth in 2022 and the years ahead.”

2022 Financial Guidance

- Total net revenue for 2022 expected to be in the range of \$178 to \$189 million
 - MACI revenue expected to be in the range of \$132 to \$141 million
 - Epicel revenue expected to be in the range of \$45.5 to \$47.5 million
- Gross margin expected to be approximately 70%
- Adjusted EBITDA margin expected to be approximately 21%

Fourth Quarter 2021 Results

Total net revenue for the quarter ended December 31, 2021 increased 5% to \$47.6 million, compared to \$45.2 million in the fourth quarter of 2020. Total net product revenue for the quarter included \$37.3 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$9.7 million of Epicel (cultured epidermal autografts) net revenue, compared to \$34.7 million of MACI net revenue and \$9.6 million of Epicel net revenue, respectively, in the fourth quarter of 2020. Total net revenue for the quarter also included \$0.5 million of revenue related to the procurement of NexoBrid (concentrate of proteolytic enzymes enriched in bromelain) by BARDA for emergency response preparedness, compared to \$1.0 million in the fourth quarter of 2020.

Gross profit for the quarter ended December 31, 2021 was \$34.0 million, or 72% of net revenue, compared to \$33.6 million, or 74% of net revenue, for the fourth quarter of 2020.

Total operating expenses for the quarter ended December 31, 2021 were \$29.9 million, compared to \$21.4 million for the same period in 2020. The increase in operating expenses was primarily due to an increase in stock-based compensation expense driven by share price appreciation.

Net income for the quarter ended December 31, 2021 was \$4.5 million, or \$0.09 per share, compared to net income of \$12.2 million, or \$0.25 per share, for the fourth quarter of 2020.

Non-GAAP adjusted EBITDA for the quarter ended December 31, 2021 was \$12.8 million, or 27% of net revenue, compared to \$16.0 million, or 35% of net revenue, for the fourth quarter of 2020. A table reconciling non-GAAP measures is included in this press release for reference.

Full-Year 2021 Results

Total net revenue for the year ended December 31, 2021 increased 26% to \$156.2 million, compared to \$124.2 million in 2020. Total net product revenue for the year included \$111.6 million of MACI net revenue and \$41.5 million of Epicel net revenue, compared to \$94.4 million of MACI net revenue and \$27.5 million of Epicel net revenue, respectively, in 2020. Total net revenue in 2021 also included \$3.1 million of revenue related to the procurement of NexoBrid by BARDA for emergency response preparedness, compared to \$2.2 million of revenue in 2020.

Gross profit for the year ended December 31, 2021 was \$106.0 million, or 68% of net revenue, compared to \$84.2 million, or 68% of net revenue, in 2020.

Total operating expenses for the year ended December 31, 2021 were \$113.9 million, compared to \$81.9 million in 2020. The increase in operating expenses was primarily due to an increase in stock-based compensation expense driven by share price appreciation and lower spend in 2020 due to COVID-19-related factors.

Net loss for the year ended December 31, 2021 was \$7.5 million, or \$0.16 per share, compared to net income of \$2.9 million, or \$0.06 per share, in 2020.

Non-GAAP adjusted EBITDA for the year ended December 31, 2021 was \$29.5 million, or 19% of net revenue, compared to \$18.6 million, or 15% of net revenue, in 2020. A table reconciling non-GAAP measures is included in this press release for reference.

As of December 31, 2021, the Company had approximately \$129 million in cash and investments, compared to approximately \$100 million as of December 31, 2020, 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 in the live call by telephone, please call (877) 312-5881 and reference Vericel Corporation's fourth quarter 2021 investor conference call. If calling from outside the U.S., please use the international phone number (253) 237-1173.

If you are unable to participate in the live call, the webcast will be available at <http://investors.vcel.com/events-presentations> until February 24, 2023. A replay of the call will also be available until 11:30am (EDT) on February 28, 2022 by calling (855) 859-2056, or from outside the U.S. by calling (404) 537-3406. The conference ID is 5795764.

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, timing of the resubmission to the Food & Drug Administration (FDA) of a Biologics License Application (BLA) for NexoBrid seeking approval for the treatment of severe burns in the United States following MediWound's receipt of a complete response letter on June 28, 2021, timing or likelihood of approval by the FDA of the NexoBrid BLA resubmission, 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, and the ongoing impacts of the COVID-19 pandemic on our business or the economy generally.

With respect to COVID-19, we are currently unable to predict whether the recent spread of the COVID-19 Delta and Omicron variants or a future resurgence of COVID-19 infections that may limit the effectiveness of approved vaccines will result in future restrictions on the performance of elective surgical procedures or affect the availability of physicians and/or their treatment prioritizations, cause healthcare facility staffing shortages, effect the willingness or ability of patients to seek treatment, or heighten the impact of the outbreak on the overall healthcare infrastructure. Other disruptions or potential disruptions include restrictions on the ability of Company personnel to travel and access customers for training, promotion and case support, delays in product development efforts, and additional government-imposed quarantines and requirements to “shelter at home” or other incremental mitigation efforts or initiatives that may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products. With respect to NexoBrid, the COVID-19 pandemic may impact the FDA’s response times to future regulatory submissions, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections of manufacturing facilities involved in the production of NexoBrid, any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of NexoBrid. The total impact of these disruptions could have a material impact on the Company’s financial condition, cash flows and results of operations.

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, 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 December 31, 2021		Twelve Months Ended December 31, 2021	
	2021	2020	2021	2020
Product sales, net	47,050	44,256	153,075	121,968
Other revenue	541	973	3,109	2,211
Total revenue	47,591	45,229	156,184	124,179
Cost of product sales	13,559	11,582	50,159	39,951
Gross profit	34,032	33,647	106,025	84,228
Research and development	3,924	3,118	16,287	13,020
Selling, general and administrative	25,967	18,240	97,592	68,836
Total operating expenses	29,891	21,358	113,879	81,856
Income (loss) from operations	4,141	12,289	(7,854)	2,372
Other income (expense):				
Interest income	61	117	224	691
Interest expense	(1)	(1)	(4)	(6)
Other income (expense)	8	(5)	52	(13)
Total other income (expense)	68	111	272	672
Income (loss) before income taxes	4,209	12,400	(7,582)	3,044
Income tax (benefit) expense	(326)	180	(111)	180
Net income (loss)	4,535	12,220	(7,471)	2,864
Net income (loss) per common share:				
Basic	0.10	0.27	(0.16)	0.06
Diluted	0.09	0.25	(0.16)	0.06
Weighted-average common shares outstanding:				
Basic	46,821	45,545	46,472	45,221
Diluted	49,939	48,101	46,472	47,282

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,	
	2021	2020	2021	2020
Net income (loss)	\$ 4,535	\$ 12,220	\$ (7,471)	\$ 2,864
Stock-based compensation expense	7,841	3,024	34,322	13,843
Depreciation and amortization	780	734	2,965	2,383
Net interest income	(60)	(116)	(220)	(685)
Income tax (benefit) expense	(326)	180	(111)	180
Adjusted EBITDA (Non-GAAP)	\$ 12,770	\$ 16,042	\$ 29,485	\$ 18,585

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

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 68,330	\$ 33,620
Short-term investments	35,068	42,187
Accounts receivable (net of allowance for doubtful accounts of \$40 and \$143, respectively)	37,437	34,504
Inventory	13,381	9,356
Other current assets	4,246	3,893
Total current assets	158,462	123,560
Property and equipment, net	13,308	7,633
Restricted cash	211	211
Right-of-use assets	45,720	50,105
Long-term investments	25,687	24,099
Other long-term assets	317	—
Total assets	\$ 243,705	\$ 205,608
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,016	\$ 6,755
Accrued expenses	14,045	11,293
Current portion of operating lease liabilities	2,950	4,394
Other current liabilities	41	41
Total current liabilities	26,052	22,483
Operating lease liabilities	47,147	48,789
Other long-term liabilities	44	76
Total liabilities	73,243	71,348
Total shareholders' equity	170,462	134,260
Total liabilities and shareholders' equity	\$ 243,705	\$ 205,608