
**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, 2021**

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, 2021, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter and year-ended December 31, 2020, 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 2020 Financial Results and Provides Full Year 2021 Financial Guidance”
104	Cover page interactive data file (embedded within the Inline XBRL document)

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Vericel Corporation, "Vericel Reports Fourth Quarter and Full-Year 2020 Financial Results and Provides Full Year 2021 Financial Guidance" February 24, 2021
104	Cover page interactive data file (embedded within the Inline XBRL document)

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, 2021

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 2020 Financial Results and Provides Full-Year 2021 Financial Guidance

Record Fourth Quarter Total Revenue, Gross Margin, Net Income and Operating Cash Flow

Full-Year 2021 Total Revenue Expected to Grow 30%-32% to Approximately \$161 to \$164 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., February 24, 2021 (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, 2020, and provided full-year 2021 financial guidance.

Fourth Quarter 2020 Financial Highlights

- Total net revenue increased 15% to \$45.2 million, compared to \$39.4 million in the fourth quarter of 2019
- MACI[®] net revenue of \$34.7 million, Epicel[®] net revenue of \$9.6 million and NexoBrid[®] revenue of \$1.0 million related to the U.S. Biomedical Advanced Research and Development Authority (BARDA) procurement for national response preparedness
- Gross margin of 74%, compared to gross margin of 73% in the fourth quarter of 2019
- Net income of \$12.2 million, or \$0.25 per share, compared to \$9.5 million, or \$0.20 per share, in the fourth quarter of 2019
- Non-GAAP adjusted EBITDA of \$16.0 million, or 35% of net revenue, compared to \$12.8 million, or 33% of net revenue, in the fourth quarter of 2019
- Operating cash flow of \$11.3 million

Full-Year 2020 Financial Highlights

- Total net revenue increased 5% to \$124.2 million, compared to \$117.9 million in 2019
- MACI net revenue of \$94.4 million, Epicel net revenue of \$27.5 million and NexoBrid revenue of \$2.2 million related to the BARDA procurement for national response preparedness
- Gross margin of 68%, compared to gross margin of 68% in 2019

- Net income of \$2.9 million, or \$0.06 per share, compared to a net loss of \$9.7 million, or \$0.22 per share, in 2019
- Non-GAAP adjusted EBITDA of \$18.6 million, or 15% of net revenue, compared to \$21.2 million, or 18% of net revenue, in 2019
- Operating cash flow of \$17.6 million
- As of December 31, 2020, the company had \$100 million in cash and investments, compared to \$79 million as of December 31, 2019, and no debt

Business Highlights and Updates

- Record fourth-quarter and full-year total net revenue
- Record quarterly gross margin, net income and operating cash flow
- Record quarterly and full-year MACI implants and net revenue
- Record fourth-quarter and full-year Epicel grafts and net revenue, and the second highest quarterly Epicel grafts and revenue in history
- Received MACI biopsies from approximately 1,500 surgeons in 2020, an increase from approximately 1,400 surgeons in 2019
- Record quarterly high in the number of surgeons taking MACI biopsies in the fourth quarter
- Double-digit growth in MACI biopsies in the fourth quarter, achieving a record quarterly high and a record monthly high in December
- Announced expansion of MACI coverage by UnitedHealthcare to include patella and multiple cartilage defects in the knee
- Appointed Joe Mara as Chief Financial Officer

“We delivered a record fourth quarter across multiple financial and operational metrics and ended the year in a very strong financial position,” said Nick Colangelo, President and CEO of Vericel. “With revenue growth for both products in 2020, we demonstrated the resiliency of the Company’s growth profile and are on track for significant growth in the years ahead. Our guidance for 2021 reflects a return to MACI’s pre-COVID growth trajectory, continued momentum for Epicel, and significant adjusted EBITDA growth.”

2021 Financial Guidance

- Total net revenue for 2021 expected to grow 30%-32% to approximately \$161 million to \$164 million
- Gross margin expected to be 70% to 71%
- Adjusted EBITDA margin expected to be 21% to 23%

Fourth Quarter 2020 Results

Total net revenue for the quarter ended December 31, 2020 increased 15% to \$45.2 million, compared to \$39.4 million in the fourth quarter of 2019. Total net product revenue for the quarter included \$34.7 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 \$33.6 million of MACI net revenue and \$5.8 million of Epicel net revenue, respectively, in the fourth quarter of 2019. Total net revenue for the quarter also included \$1.0 million of revenue related to the procurement of NexoBrid (concentrate of proteolytic enzymes enriched in bromelain) by BARDA for emergency response preparedness.

Gross profit for the quarter ended December 31, 2020 was \$33.6 million, or 74% of net revenue, compared to \$28.8 million, or 73% of net revenue, for the fourth quarter of 2019.

Total operating expenses for the quarter ended December 31, 2020 were \$21.4 million, compared to \$19.6 million for the same period in 2019. The increase in operating expenses was primarily due to incremental employee expenses related to the MACI sales force expansion.

Net income for the quarter ended December 31, 2020 was \$12.2 million, or \$0.25 per share, compared to \$9.5 million, or \$0.20 per share, for the fourth quarter of 2019.

Non-GAAP adjusted EBITDA for the quarter ended December 31, 2020 was \$16.0 million, or 35% of net revenue, compared to \$12.8 million, or 33% of net revenue, in the fourth quarter of 2019. A table reconciling non-GAAP measures is included in this press release for reference.

Full-Year 2020 Results

Total net revenue for the year ended December 31, 2020 increased 5% to \$124.2 million, compared to \$117.9 million in 2019. Total net product revenue for the year included \$94.4 million of MACI net revenue and \$27.5 million of Epicel net revenue compared to \$91.6 million of MACI net revenue and \$26.2 million of Epicel net revenue, respectively, in 2019. Total net revenue in 2020 also included \$2.2 million of revenue related to the procurement of NexoBrid by BARDA for emergency response preparedness.

Gross profit for the year ended December 31, 2020 was \$84.2 million, or 68% of net revenue, compared to \$80.3 million, or 68% of net revenue, in 2019.

Total operating expenses for the year ended December 31, 2020 were \$81.9 million, compared to \$91.5 million for the same period in 2019. Operating expenses in 2019 included the \$17.5 million upfront license payment to MediWound Ltd. for North American rights to NexoBrid.

Net income for the year ended December 31, 2020 was \$2.9 million, or \$0.06 per share, compared to a net loss of \$9.7 million, or \$0.22 per share, in 2019.

Non-GAAP adjusted EBITDA for the year ended December 31, 2020 was \$18.6 million, or 15% of net revenue, compared to \$21.2 million, or 18% of net revenue, in 2019. A table reconciling non-GAAP measures is included in this press release for reference.

As of December 31, 2020, the company had \$100 million in cash and investments, compared to \$79 million as of December 31, 2019, 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 third-quarter 2020 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, 2022. A replay of the call will also be available until 11:30am (EDT) on March 3, 2021 by calling (855) 859-2056, or from outside the U.S. by calling (404) 537-3406. The conference ID is 4364298.

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.

Epigel[®] and MACI[®] are registered trademarks of Vericel Corporation. NexoBrid[®] is a registered trademark of MediWound Ltd. and is used under license to Vericel Corporation. © 2021 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 Epigel, 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 or likelihood of approval by the U.S. Food & Drug Administration of the NexoBrid Biologics License Application (BLA) for treatment of severe burns in the United States or other North American markets, the estimate of the commercial growth potential of our products and product candidates, availability of funding from BARDA under its agreement with MediWound Ltd. 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 wide-ranging impacts of the COVID-19 pandemic on our business or the economy generally.

With respect to COVID-19, we are currently unable to reasonably estimate the specific extent, or duration, of the impact of the COVID-19 outbreak on our business, financial and operating results. We are also unable to predict how the outbreak will affect the pace with which state and local governments lift restrictions on the performance of elective surgical procedures or whether additional such restrictions may be imposed by states in the future, the availability of physicians and/or their treatment prioritizations, the willingness or ability of patients to seek treatment or 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 FDA’s review of the pending NexoBrid BLA, the COVID-19 pandemic may impact the FDA’s response times to 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, 2020, filed with the Securities and Exchange Commission (SEC) on February 24, 2021, 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 Contacts:

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

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 33,620	\$ 26,889
Short-term investments	42,187	42,829
Accounts receivable (net of allowance for doubtful accounts of \$143 and \$306, respectively)	34,504	32,168
Inventory	9,356	6,816
Other current assets	3,893	2,953
Total current assets	123,560	111,655
Property and equipment, net	7,633	7,144
Restricted cash	211	89
Right-of-use assets	50,105	25,103
Long-term investments	24,099	9,247
Total assets	\$ 205,608	\$ 153,238
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,755	\$ 6,345
Accrued expenses	11,293	7,948
Current portion of operating lease liabilities	4,394	5,461
Other liabilities	41	41
Total current liabilities	22,483	19,795
Operating lease liabilities	48,789	22,242
Other long-term liabilities	76	110
Total liabilities	71,348	42,147
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 45,804 and 44,864, respectively	510,061	489,749
Accumulated other comprehensive income	14	21
Accumulated deficit	(375,815)	(378,679)
Total shareholders' equity	134,260	111,091
Total liabilities and shareholders' equity	\$ 205,608	\$ 153,238

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Product sales, net	\$ 44,256	\$ 39,390	\$ 121,968	\$ 117,850
Other revenue	973	—	2,211	—
Total revenue	45,229	39,390	124,179	117,850
Cost of product sales	11,582	10,585	39,951	37,571
Gross profit	33,647	28,805	84,228	80,279
Research and development	3,118	3,217	13,020	30,391
Selling, general and administrative	18,240	16,378	68,836	61,139
Total operating expenses	21,358	19,595	81,856	91,530
Income (loss) from operations	12,289	9,210	2,372	(11,251)
Other income (expense):				
Interest income	117	321	691	1,614
Interest expense	(1)	(2)	(6)	(8)
Other expense	(5)	(28)	(13)	(20)
Total other income	111	291	672	1,586
Net income (loss) before tax provision	\$ 12,400	\$ 9,501	\$ 3,044	\$ (9,665)
Tax provision	180	—	180	—
Net income (loss)	\$ 12,220	\$ 9,501	\$ 2,864	\$ (9,665)
Net income (loss) per share attributable to common shareholders (Basic)	\$ 0.27	\$ 0.21	\$ 0.06	\$ (0.22)
Net income (loss) per share attributable to common shareholders (Diluted)	\$ 0.25	\$ 0.20	\$ 0.06	\$ (0.22)
Weighted average number of common shares outstanding (Basic)	45,545	44,775	45,221	44,180
Weighted average number of common shares outstanding (Diluted)	48,101	46,803	47,282	44,180

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,	
	2020	2019	2020	2019
Net income (loss)	\$ 12,220	\$ 9,501	\$ 2,864	\$ (9,665)
Upfront license agreement payment	—	—	—	17,500
Stock compensation expense	3,024	3,083	13,843	13,179
Depreciation and amortization	734	573	2,383	1,744
Net interest income	(116)	(319)	(685)	(1,606)
Income tax expense	180	—	180	—
Adjusted EBITDA (Non-GAAP)	\$ 16,042	\$ 12,838	\$ 18,585	\$ 21,152