

**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): **January 11, 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

(Address of principal executive offices)

02139

(Zip Code)

Registrant's telephone number, including area code: **(800) 556-0311**

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 January 11, 2021, Vericel Corporation (the “Company”) issued a press release providing select business updates including preliminary unaudited fourth quarter and full-year ended 2020 product revenues and the Company’s preliminary unaudited cash and investments balance as of December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended (the “Securities Act”), except as shall be expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure.

The information included in the press release referred to under Item 2.02 above is also incorporated herein. The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Exchange Act or the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Vericel Corporation, dated January 11, 2021
104 *	Cover Page Interactive Data File (embedded within the Inline XBRL)

* Furnished herewith

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: January 11, 2021

By: /s/ Sean C. Flynn

Name: Sean C. Flynn

Title: Vice President, General Counsel and Secretary



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Vericel Announces Preliminary Fourth-Quarter and Full-Year 2020 Financial Results and Provides Business Updates

Record Quarterly and Full-Year Total Revenues

Fourth Quarter Revenue Growth of Approximately 15%

CAMBRIDGE, Mass., January 11, 2021 (GLOBE NEWSWIRE) — Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced preliminary unaudited financial results for the fourth quarter and year ended December 31, 2020, and provided business updates.

Preliminary Unaudited Fourth-Quarter and Full-Year 2020 Financial Results

Preliminary total net revenues for the fourth-quarter 2020 are expected to be in the range of \$44.9-\$45.4 million, with MACI[®] (autologous cultured chondrocytes on porcine collagen membrane) net revenue in the range of \$34.4-\$34.9 million, Epicel[®] (cultured epidermal autografts) net revenue of approximately \$9.6 million, and NexoBrid[®] (concentrate of proteolytic enzymes enriched in bromelain) revenue of approximately \$1 million related to the U.S. Biomedical Advanced Research and Development Authority's (BARDA) procurement of NexoBrid for emergency response preparedness.

Preliminary total net product revenues for the full-year 2020 are expected to be in the range of \$123.9-\$124.4 million, with MACI net revenue in the range of \$94.1-\$94.6 million, Epicel net revenue of approximately \$27.5 million, and NexoBrid revenue of approximately \$2.2 million related to the BARDA procurement.

Cash and investments increased by approximately \$14.5 million in the fourth quarter. As of December 31, 2020, the company had approximately \$100 million in cash and investments and no debt, compared to \$79.0 million as of December 31, 2019.

Business Highlights and Updates

- Record fourth-quarter and full-year total net revenues;
 - 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;
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- Received MACI biopsies from approximately 1,500 surgeons in 2020, up from approximately 1,400 surgeons in 2019;
- Record quarterly high in the number of surgeons taking MACI biopsies in the fourth quarter; and
- Double-digit growth in MACI biopsies in the fourth quarter, achieving a record quarterly high and a record monthly high in December.

“We delivered strong financial and operational results in the fourth quarter and for the full year, including record product volumes and revenue for both MACI and Epicel for the year,” said Nick Colangelo, President and CEO of Vericel. “Epicel performance was very strong in the fourth quarter, with revenue growing over 60% for the quarter. MACI performance was in line with our expectations through mid-December. However, due to the recent surge in COVID-19 cases in the United States, the scheduling of MACI pipeline cases for the last two weeks of December slowed compared to historical trends and there was an increase in case cancellations during that period. We expect, based on our experience earlier this year, that the majority of those MACI cases, which represent approximately \$2 million in revenue, will move forward in 2021. Moreover, the underlying growth drivers for MACI were in line with our expectations, which we believe will drive strong revenue and profitability growth in 2021.”

The company will host a webcast and conference call to discuss its fourth quarter 2020 financial results and business highlights on February 24, 2020, at 8:30am Eastern Time. Webcast information can be found on the events and presentation section of the Investor Relations website at <https://investors.vcel.com/events-presentations>.

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 commercial 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.

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. © 2021 Vericel Corporation. All rights reserved.

Preliminary and Unaudited Nature of Reported Results

Our revenue expectations for the fourth quarter and full year ended 2020, as well as our estimates concerning cash and investments are preliminary, unaudited and are subject to adjustment based on the completion of our ongoing internal control, review, and audit procedures.

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 may result in differences are the inherent uncertainties associated with our expectations concerning expected revenue results for the fourth quarter and full year ended 2020 and estimates of our cash and investments as of December 31, 2020. Vericel’s revenue expectations for the fourth quarter and full year ended 2020, as well as its estimates concerning cash and investments are preliminary, unaudited and are subject to adjustment during our ongoing internal review. Additional 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 revenues, growth in revenues, 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, 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 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 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 Biologics License Application, the COVID-19 pandemic may impact the FDA’s response time to regulatory submissions, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections, 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, 2019, filed with the Securities and Exchange Commission (“SEC”) on February 25, 2020, Vericel’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020, 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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