

**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): **November 5, 2020**

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 November 5, 2020, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 Third Quarter 2020 Financial Results” November 5, 2020
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 Third Quarter 2020 Financial Results" November 5, 2020
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: November 5, 2020

By: /s/ Sandra L. Pennell

Name: Sandra L. Pennell

Title: Vice President and Corporate Controller
(Principal Financial and Accounting Officer)



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Vericel Reports Record Third Quarter Revenues and Net Income

Total Net Revenues of \$32.3 Million and Net Income of \$3.6 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., November 5, 2020 (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 third quarter ended September 30, 2020.

Third Quarter 2020 Financial Highlights

- Total net revenues of \$32.3 million, compared to \$30.5 million in the third quarter of 2019;
- MACI® net revenue of \$24.4 million, Epicel® net revenue of \$6.7 million and NexoBrid® revenue of \$1.2 million related to the U.S. Biomedical Advanced Research and Development Authority (BARDA) procurement for national response preparedness;
- Gross margin of 70%, compared to gross margin of 69% in the third quarter of 2019;
- Net income of \$3.6 million, or \$0.08 per share, compared to \$3.5 million, or \$0.07 per share, in the third quarter of 2019;
- Non-GAAP adjusted EBITDA of \$6.7 million, compared to \$6.8 million in the third quarter of 2019;
- Operating cash flow of \$4.6 million; and
- Cash and investments of \$85.5 million as of September 30, 2020, compared to \$79.0 million as of December 31, 2019, and no debt.

Business Highlights and Updates

- Reported record third quarter MACI revenue and total revenues, and the second highest quarterly Epicel revenue in history;
- Achieved double-digit growth in MACI revenue, implants and biopsies in the third quarter, including a record monthly high for biopsies in September;
- Announced the first delivery of NexoBrid to BARDA for emergency response preparedness; and
- Announced that the FDA accepted for review the Biologics License Application for NexoBrid for the treatment of severe thermal burns, with a PDUFA goal date of June 29, 2021.

“Our company executed exceedingly well during the third quarter as we generated stronger than expected financial results, drove strong commercial performance for MACI and Epicel, and achieved important milestones towards our goal of obtaining marketing approval of NexoBrid in the United States,” said Nick Colangelo, President and CEO of Vericel. “Our third quarter results demonstrated the strength of our business across several measures and, while uncertainties related to COVID-19 remain, we are highly confident in the underlying fundamentals of our business and we remain on track to deliver strong revenue and profit growth in the years ahead.”

Third Quarter 2020 Results

Total net revenues for the quarter ended September 30, 2020 increased 6% to \$32.3 million, compared to \$30.5 million in the third quarter of 2019. Total net product revenues for the quarter included \$24.4 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$6.7 million of Epicel (cultured epidermal autografts) net revenue compared to \$20.6 million of MACI net revenue and \$9.9 million of Epicel net revenue, respectively, in the third quarter of 2019, and \$1.2 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 September 30, 2020 was \$22.5 million, or 70% of net revenues, compared to \$21.2 million, or 69% of net revenues, for the third quarter of 2019.

Total operating expenses for the quarter ended September 30, 2020 were \$19.0 million, compared to \$18.1 million for the same period in 2019. The increase was primarily driven by incremental employee expenses related to the MACI sales force expansion.

Vericel’s net income for the quarter ended September 30, 2020 was \$3.6 million, or \$0.08 per share, compared to \$3.5 million, or \$0.07 per share, for the third quarter of 2019.

Non-GAAP adjusted EBITDA was \$6.7 million for the quarter ended September 30, 2020, compared to \$6.8 million in the third quarter of 2019. A table reconciling non-GAAP measures is included in this press release for reference.

As of September 30, 2020, the company had \$85.5 million in cash and investments, compared to \$79.0 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 November 5, 2021. A replay of the call will also be

available until 11:00am (EDT) on November 12, 2020 by calling (855) 859-2056, or from outside the U.S. by calling (404) 537-3406. The conference ID is 5426489.

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. and is used under license to Vericel Corporation. © 2020 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 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, timing and conduct of clinical trial and product development activities, timing or likelihood of regulatory approvals, the estimate of the commercial growth potential of our products and product candidates, availability of funding from the U.S. Biomedical Research and Development Authority 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 whether the outbreak will cause state and local governments to impose future restrictions on the performance of elective surgical procedures or the pace with which such restrictions may be lifted should they be imposed, the willingness or ability of patients to seek treatment, 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 times 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.

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 43,507	\$ 26,889
Short-term investments	42,035	42,829
Accounts receivable (net of allowance for doubtful accounts of \$187 and \$306, respectively)	26,174	32,168
Inventory	10,080	6,816
Other current assets	3,586	2,953
Total current assets	125,382	111,655
Property and equipment, net	7,115	7,144
Restricted cash	211	89
Right-of-use leased assets	24,796	25,103
Long-term investments	—	9,247
Total assets	\$ 157,504	\$ 153,238
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,475	\$ 6,345
Accrued expenses	8,695	7,948
Current portion of operating lease liabilities	6,102	5,461
Other liabilities	41	41
Total current liabilities	21,313	19,795
Operating lease liabilities	21,487	22,242
Other long-term liabilities	74	110
Total liabilities	\$ 42,874	\$ 42,147
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 45,315 and 44,864, respectively	\$ 502,587	\$ 489,749
Other comprehensive gain	78	21
Accumulated deficit	(388,035)	(378,679)
Total shareholders' equity	114,630	111,091
Total liabilities and shareholders' equity	\$ 157,504	\$ 153,238

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Product sales, net	\$ 31,020	\$ 30,499	\$ 77,712	\$ 78,460
Other revenue	1,238	—	1,238	—
Total revenue	32,258	30,499	78,950	78,460
Cost of product sales	9,787	9,324	28,369	26,986
Gross profit	22,471	21,175	50,581	51,474
Research and development	2,913	3,096	9,902	27,174
Selling, general and administrative	16,041	14,982	50,596	44,761
Total operating expenses	18,954	18,078	60,498	71,935
Income (loss) from operations	3,517	3,097	(9,917)	(20,461)
Other income (expense):				
Interest income	121	385	574	1,293
Interest expense	(2)	(2)	(5)	(6)
Other income (expense)	(18)	(10)	(8)	8
Total other income	101	373	561	1,295
Net income (loss)	\$ 3,618	\$ 3,470	\$ (9,356)	\$ (19,166)
Net income (loss) per share attributable to common shareholders (Basic)	\$ 0.08	\$ 0.08	\$ (0.21)	\$ (0.44)
Weighted average number of common shares outstanding (Basic)	45,272	44,251	45,112	43,979
Net income (loss) per share attributable to common shareholders (Diluted)	\$ 0.08	\$ 0.07	\$ (0.21)	\$ (0.44)
Weighted average number of common shares outstanding (Diluted)	47,314	46,667	45,112	43,979

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	\$ 3,618	\$ 3,470	\$ (9,356)	\$ (19,166)
Non-recurring license agreement purchase	—	—	—	17,500
Stock compensation expense	2,675	3,285	10,819	10,095
Depreciation and amortization	570	475	1,649	1,174
Net interest income	(119)	(383)	(569)	(1,287)
Adjusted EBITDA (Non-GAAP)	\$ 6,744	\$ 6,847	\$ 2,543	\$ 8,316