
**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 9, 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 November 9, 2021, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 Third Quarter 2021 Financial Results” November 9, 2021
104	Cover page interactive data file (embedded within the Inline XBRL document)



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Vericel Reports Third Quarter 2021 Financial Results

Third Quarter Total Net Revenue of \$34.5 Million

Year-To-Date 2021 Revenue Increased 38% to \$108.6 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., November 9, 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 third quarter ended September 30, 2021.

Third Quarter 2021 Financial Highlights

- Total net revenue of \$34.5 million, compared to \$32.3 million in the third quarter of 2020
- MACI[®] net revenue of \$23.9 million, Epicel[®] net revenue of \$9.8 million, and NexoBrid[®] revenue of \$0.8 million related to the U.S. Biomedical Advanced Research and Development Authority (BARDA) procurement for emergency response preparedness
- Gross margin of 64%, compared to 70% in the third quarter of 2020
- Net loss of \$4.9 million, or \$0.11 per share, compared to net income of \$3.6 million, or \$0.08 per share, in the third quarter of 2020
- Non-GAAP adjusted EBITDA of \$4.3 million, compared to \$6.7 million in the third quarter of 2020
- Operating cash flow of \$3.6 million
- As of September 30, 2021, the Company had approximately \$119 million in cash and investments, compared to approximately \$100 million as of December 31, 2020, and no debt

Year-to-Date 2021 Financial Highlights

- Total net revenue of \$108.6 million, compared to \$79.0 million in 2020
- MACI net revenue of \$74.2 million, Epicel net revenue of \$31.8 million, and NexoBrid revenue of \$2.6 million related to BARDA procurement for emergency response preparedness
- Gross margin of 66%, compared to 64% for the same period in 2020
- Net loss of \$12.0 million, or \$0.26 per share, compared to net loss of \$9.4 million, or \$0.21 per share, for the same period in 2020
- Non-GAAP adjusted EBITDA of \$16.7 million, compared to \$2.5 million for the same period in 2020
- Operating cash flow of \$18.5 million

Business Highlights and Updates

- Growth in surgeons taking MACI biopsies in 2021 is on track to exceed 20% and growth in total MACI biopsies is expected to exceed 30%, compared to 2020
- Epicel net revenue growth of 48% compared to the third quarter of 2020 and the fourth straight quarter with Epicel revenue over \$9 million
- Growth of over 30% in Epicel biopsies and treated patients through the first nine months of 2021 compared to the same period in 2020
- Following a Type A meeting with the FDA, the Company anticipates resubmission of the NexoBrid Biologics License Application in mid-2022
- Expanded executive leadership team and appointed Patrick Fowler as Vericel's Senior Vice President of Corporate Development and Strategy

“Despite additional COVID-19 disruptions in the third quarter, the Company delivered solid commercial and operational results and continued to generate top-line revenue growth, positive adjusted EBITDA and operating cash flow for the quarter,” said Nick Colangelo, President and CEO of Vericel. “Based on the strength of the underlying growth drivers for MACI and Epicel, we are poised to deliver strong growth for both of our franchises this year with Epicel growth of approximately 50% for the year and with MACI expected to achieve the highest fourth quarter sequential revenue growth since launch and record quarterly revenue to close the year.”

Full-Year 2021 Financial Guidance Update

- Total net revenue now expected to increase 27%-30% to approximately \$158-\$161 million
- Gross margin now expected to be approximately 70%
- Adjusted EBITDA margin now expected to be approximately 22%
- Estimated operating expenses of approximately \$114 million

Third Quarter 2021 Results

Total net revenue for the quarter ended September 30, 2021 increased 7% to \$34.5 million, compared to \$32.3 million in the third quarter of 2020. Total net product revenue for the quarter included \$23.9 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$9.8 million of Epicel (cultured epidermal autografts) net revenue, compared to \$24.4 million of MACI net revenue and \$6.7 million of Epicel net revenue, respectively, in the third quarter of 2020. Total net revenue for the quarter also included \$0.8 million of revenue related to the procurement of NexoBrid (concentrate of proteolytic enzymes enriched in bromelain) by BARDA for emergency response preparedness, compared to \$1.2 million in the third quarter of 2020.

Gross profit for the quarter ended September 30, 2021 was \$22.1 million, or 64% of net revenue, compared to \$22.5 million, or 70% of net revenue, for the third quarter of 2020.

Total operating expenses for the quarter ended September 30, 2021 were \$27.1 million, compared to \$19.0 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 and lower spend in the prior year due to COVID-19-related factors.

Net loss for the quarter ended September 30, 2021 was \$4.9 million, or \$0.11 per share, compared to net income of \$3.6 million, or \$0.08 per share, for the third quarter of 2020.

Non-GAAP adjusted EBITDA for the quarter ended September 30, 2021 was \$4.3 million, or 12% of net revenue, compared to \$6.7 million, or 21% of net revenue, for the third quarter of 2020. A table reconciling non-GAAP measures is included in this press release for reference.

As of September 30, 2021, the Company had approximately \$119 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 second 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 November 9, 2022. A replay of the call will also be available until 11:30am (EDT) on November 13, 2021 by calling (855) 859-2056, or from outside the U.S. by calling (404) 537-3406. The conference ID is 2998214.

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. © 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 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 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 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 predict whether the current spread of the COVID-19 "Delta" variant 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, 2020, filed with the Securities and Exchange Commission (SEC) on February 24, 2021, Vericel’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 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.

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,553	\$ 33,620
Short-term investments	43,738	42,187
Accounts receivable (net of allowance for doubtful accounts of \$40 and \$143, respectively)	28,910	34,504
Inventory	13,059	9,356
Other current assets	4,686	3,893
Total current assets	144,946	123,560
Property and equipment, net	11,819	7,633
Restricted cash	211	211
Right-of-use assets	46,713	50,105
Long-term investments	20,235	24,099
Other long-term assets	219	—
Total assets	\$ 224,143	\$ 205,608
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,575	\$ 6,755
Accrued expenses	10,932	11,293
Current portion of operating lease liabilities	2,280	4,394
Other liabilities	41	41
Total current liabilities	18,828	22,483
Operating lease liabilities	48,493	48,789
Other long-term liabilities	42	76
Total liabilities	\$ 67,363	\$ 71,348
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding 46,767 and 45,804, respectively	544,624	510,061
Accumulated other comprehensive income (loss)	(23)	14
Accumulated deficit	(387,821)	(375,815)
Total shareholders' equity	156,780	134,260
Total liabilities and shareholders' equity	\$ 224,143	\$ 205,608

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,	
	2021	2020	2021	2020
Product sales, net	\$ 33,718	\$ 31,020	\$ 106,025	\$ 77,712
Other revenue	788	1,238	2,568	1,238
Total revenue	34,506	32,258	108,593	78,950
Cost of product sales	12,408	9,787	36,600	28,369
Gross profit	22,098	22,471	71,993	50,581
Research and development	4,284	2,913	12,363	9,902
Selling, general and administrative	22,775	16,041	71,625	50,596
Total operating expenses	27,059	18,954	83,988	60,498
Income (loss) from operations	(4,961)	3,517	(11,995)	(9,917)
Other income (expense):				
Interest income	44	121	163	574
Interest expense	(1)	(2)	(3)	(5)
Other income (expense)	(13)	(18)	45	(8)
Total other income	30	101	205	561
Income (loss) before tax expense	(4,931)	3,618	(11,790)	(9,356)
Tax expense	—	—	(215)	—
Net income (loss)	\$ (4,931)	\$ 3,618	\$ (12,006)	\$ (9,356)
Net income (loss) per common share (Basic and Diluted)	\$ (0.11)	\$ 0.08	\$ (0.26)	\$ (0.21)
Weighted average common shares outstanding (Basic)	46,669	45,272	46,355	45,112
Weighted average common shares outstanding (Diluted)	46,669	47,314	46,355	45,112

**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,	
	2021	2020	2021	2020
Net income (loss)	\$ (4,931)	\$ 3,618	\$ (12,006)	\$ (9,356)
Stock-based compensation expense	8,596	2,675	26,481	10,819
Depreciation and amortization	679	570	2,185	1,649
Net interest income	(43)	(119)	(160)	(569)
Income tax expense	—	—	215	—
Adjusted EBITDA (Non-GAAP)	<u>\$ 4,301</u>	<u>\$ 6,744</u>	<u>\$ 16,715</u>	<u>\$ 2,543</u>