
**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): **August 4, 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 August 4, 2021, Vericel Corporation issued a press release announcing its financial results for the fiscal quarter ended June 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 Second Quarter 2021 Financial Results and Raises Full-Year 2021 Revenue Guidance” August 4, 2021
104	Cover page interactive data file (embedded within the Inline XBRL document)



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Vericel Reports Second Quarter 2021 Financial Results and Raises Full-Year 2021 Revenue Guidance

Second Quarter Total Net Revenue Increased 97% to \$39.5 Million

Full-Year 2021 Revenue Guidance Raised to \$168-\$171 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., August 4, 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 second quarter ended June 30, 2021.

Second Quarter 2021 Financial Highlights

- Total net revenue of \$39.5 million, an increase of 97% compared to the second quarter of 2020 and 51% compared to the second quarter of 2019
- MACI® net revenue of \$26.5 million, Epicel® net revenue of \$12.2 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 68%, compared to 57% in the second quarter of 2020
- Net loss of \$3.8 million, or \$0.08 per share, compared to \$8.3 million, or \$0.18 per share, in the second quarter of 2020
- Non-GAAP adjusted EBITDA of \$7.8 million, or 20% of net revenue, compared to adjusted EBITDA loss of \$3.5 million in the second quarter of 2020
- Operating cash flow of \$4.8 million
- As of June 30, 2021, the Company had \$116 million in cash and investments, compared to \$100 million as of December 31, 2020, and no debt

Business Highlights and Updates

- MACI net revenue growth of 76% compared to the second quarter of 2020 and 27% compared to the second quarter of 2019
- MACI biopsy growth of more than 50% in the first half of 2021 compared to the same period in 2020, with a record quarterly high in the number of biopsies and the number of surgeons taking biopsies in the second quarter
- Record quarterly Epicel revenue, with growth of 148% compared to the second quarter of 2020 and 128% compared to the second quarter of 2019
- Record quarterly high in the number of Epicel biopsies and grafting burn centers

“The Company continued to execute extremely well in the second quarter as we delivered another quarter of strong financial and commercial results,” said Nick Colangelo, President and CEO of Vericel. “Based on the strength of the underlying growth drivers for MACI and Epicel, we believe that the Company is well-positioned to continue driving sustainable penetration into the addressable markets for both products in the years ahead.”

Full-Year 2021 Financial Guidance

- Total net revenue now expected to be in the range of \$168-\$171 million, compared to previous guidance of approximately \$165-\$168 million
- Adjusted EBITDA margin now expected to be in the range of 23% to 25%, compared to previous guidance of 21.5% to 23.5%
- Maintaining gross margin guidance of 70% to 71% and estimated operating expenses of approximately \$115 million

Second Quarter 2021 Results

Total net revenue for the quarter ended June 30, 2021 increased 97% to \$39.5 million, compared to \$20.0 million in the second quarter of 2020. Total net product revenue for the quarter included \$26.5 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and \$12.2 million of Epicel (cultured epidermal autografts) net revenue, compared to \$15.1 million of MACI net revenue and \$4.9 million of Epicel net revenue, respectively, in the second 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.

Gross profit for the quarter ended June 30, 2021 was \$26.9 million, or 68% of net revenue, compared to \$11.4 million, or 57% of net revenue, for the second quarter of 2020.

Total operating expenses for the quarter ended June 30, 2021 were \$30.6 million, compared to \$19.7 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 over the past year and lower spend in the prior year due to COVID-19-related factors.

Net loss for the quarter ended June 30, 2021 was \$3.8 million, or \$0.08 per share, compared to \$8.3 million, or \$0.18 per share, for the second quarter of 2020.

Non-GAAP adjusted EBITDA for the quarter ended June 30, 2021 was \$7.8 million, or 20% of net revenue, compared to an adjusted EBITDA loss of \$3.5 million in the second quarter of 2020. A table reconciling non-GAAP measures is included in this press release for reference.

As of June 30, 2021, the Company had \$116 million in cash and investments, compared to \$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 August 4, 2022. A replay of the call will also be available until 11:30am (EDT) on August 11, 2021 by calling (855) 859-2056, or from outside the U.S. by calling (404) 537-3406. The conference ID is 2969646.

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 or likelihood of approval by the U.S. Food & Drug Administration (FDA) of a Biologics License Application (BLA) for NexoBrid for treatment of severe burns in the United States following MediWound’s receipt of a complete response for NexoBrid on June 28, 2021, 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 a resurgence of COVID-19 infections or the spread of COVID-19 variants 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, 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 June 30, 2021, filed with the SEC on August 4, 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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 51,761	\$ 33,620
Short-term investments	39,214	42,187
Accounts receivable (net of allowance for doubtful accounts of \$3 and \$143, respectively)	31,732	34,504
Inventory	12,959	9,356
Other current assets	2,854	3,893
Total current assets	138,520	123,560
Property and equipment, net	10,590	7,633
Restricted cash	211	211
Right-of-use assets	47,798	50,105
Long-term investments	24,826	24,099
Total assets	\$ 221,945	\$ 205,608
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,134	\$ 6,755
Accrued expenses	11,077	11,293
Current portion of operating lease liabilities	4,611	4,394
Other liabilities	41	41
Total current liabilities	23,863	22,483
Operating lease liabilities	46,928	48,789
Other long-term liabilities	62	76
Total liabilities	\$ 70,853	\$ 71,348
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 46,579 and 45,804, respectively	534,005	510,061
Accumulated other comprehensive income (loss)	(23)	14
Accumulated deficit	(382,890)	(375,815)
Total shareholders' equity	151,092	134,260
Total liabilities and shareholders' equity	\$ 221,945	\$ 205,608

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Product sales, net	\$ 38,680	\$ 20,014	\$ 72,307	\$ 46,692
Other revenue	839	—	1,780	—
Total revenue	39,519	20,014	74,087	46,692
Cost of product sales	12,609	8,660	24,192	18,582
Gross profit	26,910	11,354	49,895	28,110
Research and development	4,449	3,226	8,079	6,989
Selling, general and administrative	26,190	16,486	48,850	34,555
Total operating expenses	30,639	19,712	56,929	41,544
Loss from operations	(3,729)	(8,358)	(7,034)	(13,434)
Other income (expense):				
Interest income	43	147	119	453
Interest expense	(1)	(1)	(2)	(3)
Other income (expense)	(27)	(57)	57	10
Total other income	15	89	174	460
Net loss before tax provision	(3,714)	(8,269)	(6,860)	(12,974)
Tax provision	(72)	—	(215)	—
Net loss	\$ (3,786)	\$ (8,269)	\$ (7,075)	\$ (12,974)
Net loss per share attributable to common shareholders (Basic and diluted)	\$ (0.08)	\$ (0.18)	\$ (0.15)	\$ (0.29)
Weighted average number of common shares outstanding (Basic and diluted)	46,403	45,137	46,195	45,031

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	\$ (3,786)	\$ (8,269)	\$ (7,075)	\$ (12,974)
Stock compensation expense	10,866	4,376	17,885	8,144
Depreciation and amortization	695	546	1,506	1,079
Net interest income	(42)	(146)	(117)	(450)
Income tax provision	72	—	215	—
Adjusted EBITDA (Non-GAAP)	\$ 7,805	\$ (3,493)	\$ 12,414	\$ (4,201)