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): **September 16, 2020**

Vericel Corporation
(Exact name of registrant as specified in its charter)

Michigan	**001-35280**	**94-3096597**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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: **(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 8.01. Other Events.

On September 16, 2020, Vericel issued a press release announcing the Food and Drug Administration's (FDA) acceptance for filing of its recently submitted Biologics License Application (BLA) for NexoBrid® (concentrate of proteolytic enzymes enriched in Bromelain) for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. The FDA has assigned a PDUFA (Prescription Drug User Fee Act) date of June 29, 2021 for its review of the BLA. In addition, the FDA communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.

NexoBrid is approved in the European Union and other international markets and has been designated as an orphan biologic in the United States, European Union and other international markets. Vericel holds an exclusive license for North American commercial rights to NexoBrid. Funding and technical support to MediWound Ltd. for development of NexoBrid is provided, in part, by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release of Vericel Corporation, dated September 16, 2020
104	Cover page interactive data file (embedded within the Inline XBRL document)

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: September 16, 2020

By: /s/ Sean C. Flynn
Name: Sean C. Flynn
Title: Vice President, General Counsel and Secretary

Exhibit 99.1

Vericel Corporation
64 Sidney Street
Cambridge, MA 02139
T 617 588-5555 **F** 617 588-5554
www.vcel.com

Vericel Announces FDA Acceptance of Biologics License Application for NexoBrid for the Treatment of Severe Thermal Burns

CAMBRIDGE, Mass., September 16, 2020 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ: VCEL) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the recently submitted Biologics License Application (BLA) for NexoBrid® (concentrate of proteolytic enzymes enriched in bromelain) for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021. In addition, the FDA communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.

“The FDA’s acceptance of the NexoBrid BLA for review represents another important milestone toward our goal of providing a new standard of care for eschar removal in patients with severe burns,” said Nick Colangelo, President and CEO of Vericel. “We look forward, together with MediWound, to working with the FDA during the BLA review process as we seek marketing approval for NexoBrid in the United States.”

Sharon Malka, CEO of MediWound added, “The acceptance of the NexoBrid BLA is a major milestone for MediWound and it is gratifying to know NexoBrid is one step closer to being available to help burn victims in the United States. We thank all of the investigators, their teams, our employees and all our partners, especially BARDA and Vericel, for their commitment to the program.”

Vericel will host a virtual Analyst and Investor Day on Friday, October 16, 2020, from 9:00 a.m. - 11:00 a.m. EST which will focus on NexoBrid. In addition to a general corporate update, Vericel executives will facilitate discussions with burn surgeon thought leaders on current burn debridement practices and how NexoBrid, upon approval, could change the current treatment paradigm for debridement of severe thermal burns.

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 from MediWound Ltd. for North American rights to NexoBrid®, a registration-stage biological orphan product for debridement of severe thermal burns. Funding and technical support to MediWound Ltd. for development of NexoBrid is provided by the U.S. Biomedical Advanced Research and Development Authority (BARDA). For more information, please visit the company's website at www.vcel.com.

Cautionary Note Regarding 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, all of which are difficult to predict and many of which are beyond our control. 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.

Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, objectives, expectations and commercial potential of NexoBrid. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the timing and conduct of clinical trial and product development activities; the ability to successfully develop and commercialize NexoBrid, including its commercial growth potential and the market demand for the product; the availability of funding from BARDA under its agreement with MediWound for use in connection with NexoBrid development activities; competitive developments; whether FDA will provide marketing approval for NexoBrid in the United States; the risks related to the timing and conduct of our NEXT Study; the impact of applicable laws and regulations; and the uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation
efforts also may impact our ability to source supplies for our operations or our ability to sell and support the use of NexoBrid in the future.

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 June 30, 2020, filed with the SEC on August 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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