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): **December 29, 2022**

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: **(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 8.01 Other Events

On December 29, 2022, Vericel Corporation issued a press release titled "Vericel Announces FDA Approval of NexoBrid for the Treatment of Severe Thermal Burns in Adults." A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1**	Press Release, dated December 29, 2022, titled "Vericel Announces FDA Approval of NexoBrid for the Treatment of Severe Thermal Burns in Adults."
104	Cover Page Interactive Data File (embedded within the Inline XBRL)

** Filed herewith

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: December 29, 2022

By: /s/ Sean C. Flynn
Name: Sean C. Flynn
Title: Senior 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 Approval of NexoBrid for the Treatment of Severe Thermal Burns in Adults

Potential to become the new standard of care for eschar removal in patients with deep partial- and/or full- thickness thermal burns

Label supported by robust clinical data demonstrating significantly higher incidence of complete eschar removal in patients treated with NexoBrid compared to placebo

CAMBRIDGE, Mass., December 29, 2022 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced that the U.S. Food and Drug Administration (FDA) has approved NexoBrid® (anacaulase-bcdb) for the removal of eschar in adults with deep partial-thickness and/or full-thickness thermal burns.

“There is a considerable unmet need for non-surgical eschar removal for patients with severe thermal burns, and the FDA’s approval of NexoBrid marks an important advancement in the treatment paradigm for these patients,” said Nick Colangelo, President and CEO of Vericel. “The addition of NexoBrid to our commercial portfolio significantly expands our target addressable market, and we look forward to executing on our NexoBrid commercial launch plans and establishing NexoBrid as the new standard of care for eschar removal.”

The FDA approval of NexoBrid is based on multiple preclinical and clinical studies, including the pivotal Phase 3 U.S. clinical study (DETECT) which evaluated NexoBrid in adult patients with deep partial-thickness and full-thickness thermal burns of 3%-30% of total body surface area (TBSA). The study met its primary endpoint of complete eschar removal as well as all secondary endpoints, including shorter time to eschar removal and a lower incidence of surgical eschar removal compared to standard of care (SOC), including both surgical and non-surgical eschar removal methods. A key safety endpoint, non-inferiority in time to >95% wound closure compared with patients treated with SOC, was also achieved.

NexoBrid can be applied in up to two applications of four hours each. A first application of NexoBrid may be applied to an area of up to 15% body surface area. A second application of NexoBrid may be applied 24 hours later, with a total treated area for both applications of up to 20% TBSA.

“When treating partial- and full-thickness burns, a critical first step is the rapid removal of eschar and I believe the approval of NexoBrid provides us with an important non-surgical option to quickly and effectively treat severe thermal burns,” said Jeremy Goverman, MD, Massachusetts General Hospital. “As a principal investigator in the Phase 3 DETECT clinical trial, I look forward to further incorporating NexoBrid into my practice, as I believe it will lead to improved outcomes for my patients.”

NexoBrid is anticipated to be commercially available in the U.S. in the second quarter of 2023. To learn more about NexoBrid, please visit www.NexoBrid-US.com.

About NexoBrid

NexoBrid (anacaulase-bcdb) is a botanical drug product containing proteolytic enzymes indicated for the removal of eschar in adults with deep partial- and/or full-thickness thermal burns.

Indications for Use: NexoBrid (anacaulase-bcdb) is indicated for eschar removal in adults with deep partial-thickness and/or full-thickness thermal burns.

Limitations of Use

The safety and effectiveness of NexoBrid have not been established for treatment of:

- Chemical or electrical burns
- Burns on the face, perineum, or genitalia
- Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease
- Circumferential burns
- Burns in patients with significant cardiopulmonary disease, including inhalation injury

NexoBrid is not recommended for wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance.

Important Safety Information

- **Contraindications**: NexoBrid is contraindicated in patients with: known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any other components; known hypersensitivity to papayas or papain because of the risk of cross-sensitivity.
- **Warnings and Precautions:**
  - **Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarketing use of anacaulase-bcdb.
  - **Pain Management:** Manage pain as appropriate for an extensive dressing change of burn wounds. At least 15 minutes prior to NexoBrid-related procedures ensure adequate pain control measures are in place.
  - **Proteolytic Injury to Non-Target Tissues:** NexoBrid is not recommended for treatment of burn wounds where medical devices or vital structures could become exposed during eschar removal.
  - **Coagulopathy:** Avoid use of NexoBrid in patients with uncontrolled disorders of coagulation. Use with caution in patients on anticoagulant therapy or other drugs affecting coagulation, and in patients with low platelet counts and increased risk of bleeding from other causes. Monitor patients for possible signs of coagulation abnormalities and signs of bleeding.
- **Adverse Reactions:** The most common adverse reactions (>10%) were pruritus and pyrexia.

- **Geriatric:** Clinical studies of NexoBrid did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

- To report negative side-effects, contact the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

- For complete risk information, please see the **Full Prescribing Information**.

About Vericel Corporation

Vericel is a leader in advanced therapies for sports medicine and severe burn care. The Company develops, manufactures and 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. Vericel also holds an exclusive license for North American rights to NexoBrid, a biological orphan product containing proteolytic enzymes, which is approved for eschar removal in adults with deep partial-thickness and/or full-thickness burns. For more information, please visit www.vcel.com.

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, the ultimate timing of the commercial launch of NexoBrid in the United States, physician and burn center adoption and market penetration for NexoBrid, the estimate of the future commercial growth potential of NexoBrid, competitive developments, changes in third-party coverage and reimbursement, supply chain disruptions or other events affecting MediWound’s ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine, global geopolitical tensions or record inflation and the ongoing or future impacts of the COVID-19 pandemic on our business or the economy generally.

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, 2021, filed with the Securities and Exchange Commission (SEC) on February 24, 2022, Vericel's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the SEC on November 9, 2022, 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 Contact:
Eric Burns
ir@vcel.com
+1 (734) 418-4411

Media Contact:
Julie Downs
media@vcel.com