

**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): **May 6, 2019**

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
(Address of
principal executive
offices)

02139
(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))

Indicate by a checkmark 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Common Stock

Trading Symbol(s)
VCEL

Name of each exchange on which registered
NASDAQ

Item 1.01 Entry into a Material Definitive Agreement.

On May 6, 2019, Vericel Corporation (“Vericel”) entered into exclusive license and supply agreements with MediWound Ltd. (“MediWound”) to commercialize NexoBrid® in all countries of North America (the “Territory”). NexoBrid is a topically-administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns.

NexoBrid is currently in clinical development in the Territory, and pursuant to the terms of the License Agreement described below, MediWound will continue to conduct all clinical activities described in the development plan to support the filing of a biologics license application (“BLA”) with the United States Food and Drug Administration under the supervision of a Central Steering Committee comprised of members of each party.

License Agreement.

Vericel entered into a license agreement (the “License Agreement”) with MediWound pursuant to which MediWound granted Vericel an exclusive license, with the right to grant sublicenses, to develop and commercialize NexoBrid and any improvements of NexoBrid (the “Licensed Product”) in the Territory.

Pursuant to the terms of the License Agreement, Vericel will have exclusive control regarding the commercialization of Licensed Products in the Territory and must use commercially reasonable efforts to commercialize Licensed Products within the Territory. Vericel and MediWound have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

Within ten days from May 6, 2019, Vericel is obligated to pay MediWound \$17,500,000 (the “Upfront Payment”). Vericel is also obligated to pay MediWound \$7.5 million upon U.S. regulatory approval of the BLA for NexoBrid and up to \$125 million contingent upon meeting certain sales milestones. The first sales milestone of \$7.5 million would be triggered when annual net sales of the Licensed Products in the Territory exceed \$75 million. Vericel is also obligated to pay MediWound tiered royalties on net sales of Licensed Products ranging from high single-digit to low double-digit percentages, subject to certain customary reductions, and a split of gross profits on committed Biomedical Advanced Research and Development Authority (BARDA) procurement orders and a double-digit royalty on any additional future BARDA purchases of NexoBrid. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (i) twelve years following the first commercial sale of such Licensed Product in such country, (ii) the earliest date on which there are no valid claims of MediWound patent rights covering such Licensed Product in such country, and (iii) the expiration of the regulatory exclusivity period for such Licensed Product in such country (the “Royalty Term”). Such royalties are subject to reduction in the event that (a) Vericel must license additional third-party intellectual property in order to develop, manufacture or commercialize a Licensed Product, or (b) biosimilar competition occurs with respect to the Licensed Product in any country within the Territory. After the expiration of the applicable royalties for the Licensed Product in any country within the Territory, the license for such Licensed Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license.

The License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with its terms. Either party may terminate the Agreement upon the failure of the other party to comply with its material obligations under the Agreement if such failure is not remedied within certain specified cure periods or in the event of a party’s insolvency. In addition, Vericel may terminate the Agreement upon one hundred fifty (150) days written notice to MediWound.

Supply Agreement.

On May 6, 2019, concurrent with the License Agreement, Vericel entered into a supply agreement (the “Supply Agreement”) with MediWound pursuant to which MediWound is obligated to supply Vericel with NexoBrid for sale in the Territory on an exclusive basis for the first five years of the term of the Supply Agreement. The Supply Agreement requires MediWound to take steps to ensure that its manufacturing capacity meets Vericel’s demand for NexoBrid. In addition, after the exclusivity period or upon supply failure, Vericel will be permitted to establish an alternate source of supply.

Pursuant to the Supply Agreement, MediWound will supply NexoBrid to Vericel based on Vericel's fixed orders on a unit price basis. After a specified period, the unit price, on an annual basis, may be increased based on the United States Producer Price Index for Chemical Manufacturing published by the Bureau of Labor Statistics.

The Supply Agreement's initial term is five years (the "Initial Term") with Vericel required to provide MediWound with notice regarding whether it plans to extend the Initial Term for an additional two years by the third anniversary of the Supply Agreement. After the Initial Term and optional two-year extension, Vericel, at its sole discretion, may choose to extend the Supply Agreement's term for additional one-year periods for a potential total term of fifteen years.

The Supply Agreement will automatically terminate upon the expiration or termination of the License Agreement. Either party may terminate the Supply Agreement upon the failure of the other party to comply with its material obligations under the Supply Agreement if such failure is not remedied within certain specified cure periods. After the Initial Term, Vericel may terminate the Supply Agreement upon twelve (12) months prior written notice to MediWound, and MediWound may terminate the Supply Agreement upon thirty-six (36) months prior written notice to Vericel.

Vericel and MediWound have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

The foregoing descriptions of the material terms of the License Agreement and the Supply Agreement do not purport to be complete and are subject to, and are qualified in their entirety by, reference to the License Agreement and the Supply Agreement, which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.

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: May 7, 2019

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Financial Officer and Vice President Corporate
Development