

**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 8, 2015**

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 St.
Cambridge, Massachusetts
(Address of principal executive offices)

02139
(Zip Code)

Registrant's telephone number, including area code: **(734) 418-4400**

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:

- 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))

Item 7.01. Regulation FD Disclosure.

On December 8, 2015, Vericel Corporation issued a press release announcing its submission of a Humanitarian Device Exemption supplement to the U.S. Food and Drug Administration to revise the labeled indications for use of Epicel[®] to specifically include use in pediatric patients and add pediatric labeling. A copy of this press release is filed herewith as Exhibit 99.1.

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.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated December 8, 2015.

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 8, 2015

By: /s/ Gerard Michel

Name: Gerard Michel
Title: Chief Financial Officer and Vice President, Corporate
Development

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated December 8, 2015.

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Vericel Corporation
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 Cambridge, MA 02139
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Vericel Submits HDE Supplement to the FDA to Revise the Labeled Indications for Use and Add Pediatric Labeling for Epicel

CAMBRIDGE, Mass., December 8, 2015 (GLOBE NEWSWIRE) — Vericel Corporation (NASDAQ: VCEL), a leading developer of patient-specific expanded cellular therapies for the treatment of severe diseases and conditions, today announced that it has submitted a Humanitarian Device Exemption (HDE) supplement to the U.S. Food and Drug Administration to revise the labeled indications for use of Epicel® (cultured epidermal autografts) to specifically include use in pediatric patients and add pediatric labeling for Epicel.

Epicel is a permanent skin replacement for the treatment of patients with deep dermal or full thickness burns comprising greater than or equal to 30 percent of total body surface area. Epicel has been used in the United States and internationally to treat severely burned patients since 1988. Epicel was approved by the FDA in 2007 as Humanitarian Use Device (HUD) under the HDE regulations.

“We believe that the revised label will provide valuable information describing the safety and clinical use of Epicel for pediatric patients and will better inform physicians regarding the safety of Epicel in this patient population,” said David Recker, MD, chief medical officer of Vericel.

About Humanitarian Use Devices and the Humanitarian Device Exemption

HUDs are medical devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States per year. Devices that receive HUD designation from the Office of Orphan Products Development of the FDA may be eligible for marketing approval under an HDE application. FDA approval of an HDE application authorizes the applicant to market the device, subject to certain profit and use restrictions.

Except in certain circumstances, HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). A HUD is eligible to be sold for profit after receiving HDE approval if the device meets certain eligibility criteria, including where the device is intended for the treatment of a disease or condition that occurs in pediatric patients and such device is labeled for use in pediatric patients in which the disease or condition occurs. If the FDA determines that a HUD meets the eligibility criteria, the HUD may be sold for profit as long as the number of devices

distributed in any calendar year does not exceed the annual distribution number (ADN). The ADN is defined as the number of devices reasonably needed to treat a population of 4,000 individuals per year in the United States.

About Vericel Corporation

Vericel Corporation (formerly Aastrom Biosciences, Inc.) is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. The company markets two autologous cell therapy products in the U.S.: Carticel® (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel® (cultured epidermal autografts), a permanent skin replacement for the treatment of patients with deep-dermal or full-thickness burns comprising greater than or equal to 30% of total body surface area. Vericel is also developing MACI™, a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee, and ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy. For more information, please visit the company’s website at www.vcel.com.

The Vericel Corporation logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=29189>.

Epicel® and Carticel® are registered trademarks and MACI™ is a trademark of Vericel Corporation. © Vericel Corporation. All rights reserved.

This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of our products, and revenue trends and gross margin improvements, intended product development, clinical activity timing and regulatory pathway and timing, integration of the acquired business, and objectives and expectations regarding our company described herein, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “intends,” “estimates,” “plans,” “expects,” “we believe,” “we intend,” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “potential,” “can continue,” “could,” “may,” or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with competitive developments, integration of the acquired business, clinical trial and product development activities, regulatory approval requirements, the availability and allocation of resources among different potential uses, estimating the commercial potential of our products and product candidates and growth in revenues and improvement in costs, market demand for our products, and our ability to supply or meet customer demand for our products. 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, 2014, filed with the Securities and Exchange Commission (“SEC”) on March 25, 2015, Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements reflect

management’s current views and Vericel does not undertake 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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