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): **April 2, 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 2.02. Results of Operations and Financial Condition.

On April 2, 2020, Vericel Corporation issued a press release providing an update on its response to the COVID-19 pandemic, preliminary unaudited first quarter revenue growth and the Company's cash and investments balance. The press release also announced the Company's withdrawal of financial guidance for 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), except as shall be expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure.

The information included in the press release referred to under Item 2.02 above is also incorporated herein. The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Exchange Act or the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

The spread of SARS-CoV-2, which causes coronavirus disease 2019, or COVID-19, creates a number of risks and uncertainties to the Company's business, which could have a material adverse effect on its current and future business, operations and financial results. As a result, the Company is supplementing the risk factors previously included in Item 1A of its Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 25, 2020, to add the following new risk factor under the section entitled "Risk Factors — Risks Related to our Business."

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely impact our business, our operations and our financial results.

The recent outbreak of COVID-19, which surfaced in Wuhan, China, in December 2019, has since been declared a pandemic and has spread to multiple global regions, including the United States and Europe. To date, multiple state and national governments – including those in Massachusetts and Michigan, where our operations are located – have issued orders requiring businesses that do not conduct essential services to temporarily close their physical workplaces to employees and customers. Vericel is currently deemed an essential business and, as a result, is exempt from these state orders, in their current form. In March 2020, we put in place a number of protective measures in response to the COVID-19 outbreak. These measures include the canceling of all commercial international travel, requesting that employees limit non-essential personal travel, enhancing our facilities' janitorial and sanitary procedures, encouraging employees to work from home to the extent their job function enables them to do so, limiting third-party access to our facilities, encouraging the use of virtual employee meetings, and providing guidance to our field-based commercial teams concerning their communications and contact with customers and healthcare professionals. We are reviewing these measures on a daily basis as the situation evolves, and we are likely to take additional actions as we learn more and as instruction is provided by national, state and local governmental agencies. Both these existing measures and any future actions we take may result in continued disruption to our business.

The continued outbreak of COVID-19, or another infectious disease, may lead to the implementation of additional responses, including additional travel restrictions, government-imposed quarantines and other public health safety measures, which may result in further disruptions to our business and operations. For example, further executive orders, travel restrictions, and limitations on gatherings could continue to impact our sales force's ability to promote our products with healthcare professionals. In addition, healthcare facilities and hospitals may continue to limit the access of non-patients, including our sales professionals, as we have seen in connection with COVID-19, which could negatively impact our access to healthcare professionals. Further, in response to COVID-19, many hospitals and surgical centers have cancelled or postponed elective medical procedures and may continue to do so. As a result of COVID-19, or another infectious disease outbreak, our customers may continue to postpone or cancel previously scheduled surgeries and may also decline to schedule surgeries utilizing our products, which would negatively impact our operations and financial results. Additionally, our customers may not reschedule such postponed or cancelled surgeries on a timely basis, or at all.

The spread of COVID-19 or similar infectious diseases in the United States may also lead to further government-imposed quarantines and restrictions, which may result in the closure of our administrative offices, with our employees working outside of our offices for an extended period of time. These actions may result in the disruption of our manufacturing operations, which are currently accomplished within our administrative offices. Additionally, such quarantines and restrictions may adversely affect our ability to conduct certain product enhancement and business development activities. Further, continued delays and disruptions related to COVID-19 or another outbreak either within the United States or in an area outside the United States, but within the Company's supply chain, may impact the Company's ability to produce our products to meet customer demand, which would negatively impact our operations and financial results.

Regulatory oversight and actions regarding our products may be disrupted or delayed in regions impacted by COVID-19, including the United States and Europe, which may impact review and approval timelines for products in development and/or changes to existing products that need regulatory review and approval.

Although it is premature to draw any conclusions at this time, given the reduction of elective surgical procedures as a result of COVID-19, the Company anticipates a decreased rate of patient enrollment to its PEAK (A Study of MACI in Patients Aged 10 to 17 Years With Symptomatic Chondral or Osteochondral Defects of the Knee) Study, which is currently being conducted at ten (10) sites throughout the United States. COVID-19 or a similar infectious disease may further and negatively impact our clinical trial operations in the United States and in other countries by limiting our ability to recruit and retain patients, principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or a similar infectious disease if an outbreak occurs in their geography. Additionally, patients who are already recruited into our clinical trials may be unable or unwilling to attend follow-up visits within the timelines specified in our trial protocols, potentially impacting our ability to meet our clinical trial endpoints. An outbreak may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out our clinical trials.

We cannot presently predict the scope and severity of potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The extent to which the current pandemic, or a future pandemic, impacts our business and operations will depend on future developments, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and governmental actions to contain the outbreak or treat its impact, which are highly uncertain and cannot be predicted with confidence.

Please also refer to the complete Item 1A of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2020 for additional risks and uncertainties facing the Company that may have a material adverse effect on the Company's business, operations and financial results.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1+	Press Release of Vericel Corporation, dated April 2, 2020

+ Furnished herewith

EXHIBIT INDEX

Exhibit No.	Description
99.1+	Press Release of Vericel Corporation, dated April 2, 2020

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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: April 2, 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 Provides Business and Financial Updates

First Quarter Preliminary Unaudited Product Revenues Increased Approximately 21% Over First Quarter 2019

Full Year 2020 Financial Guidance Withdrawn Due to Uncertainty Regarding Impact of COVID-19

CAMBRIDGE, Mass., April 2, 2020 (GLOBE NEWSWIRE) — Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced preliminary unaudited product revenue growth for the quarter ended March 31, 2020, and provided business and financial updates related to the COVID-19 pandemic.

Over the past several weeks, Vericel has implemented several measures to safeguard the health and well-being of its employees, their families, and healthcare providers, while continuing to supply its autologous cell therapy products MACI® (autologous cultured chondrocytes on porcine collagen membrane) and Epicel® (cultured epidermal autografts) to patients with knee cartilage and severe burn injuries. At this time, all Vericel employees not directly involved in the production and delivery of MACI or Epicel are working from home. For production-related teams, the Company has implemented additional measures to protect the health and safety of its workforce. Vericel representatives will also continue to provide field-based support for surgical cases, as needed, in compliance with applicable government mandated business activity restrictions and facility access rules.

“First and foremost, our thoughts are with those affected by the virus and we are especially thankful to all healthcare workers for their critical efforts to support patients during this challenging time,” said Nick Colangelo, President and Chief Executive Officer of Vericel. “While our MACI business has been impacted by the restrictions on elective surgical procedures, the fundamentals of our business remain strong. Prior to cancellations that occurred in the last two weeks of the quarter, MACI was on track to exceed revenue growth guidance and we believe that most patients will reschedule cases to the extent possible following this crisis. In addition, we believe that Epicel may be less directly impacted by the pandemic given the critical nature of severe burn injuries. We are implementing a number of initiatives to maintain our near-term and future growth opportunities while supporting patients and reducing non-essential discretionary spending. Given the strength of our financial position and the underlying fundamentals of our business, we believe that the Company is well-positioned to maintain its leadership position in the sports medicine and severe burn care markets.”

Preliminary Unaudited First Quarter Results and 2020 Financial Guidance

Preliminary unaudited total revenues for the quarter ended March 31, 2020 increased approximately 21% compared to the first quarter of 2019, with MACI revenue increasing approximately 21% and Epicel revenue increasing approximately 22%. As a result of various national, state and local restrictions on elective surgical procedures related to the COVID-19 pandemic, beginning in the middle of March there was a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders. The number of MACI procedures scheduled to occur in the first quarter that were cancelled between March 15, 2020 and the end of the quarter reduced the volume of MACI implants for the quarter by approximately 9%.

Due to the significant uncertainty regarding the duration and impact of restrictions on elective procedures related to the COVID-19 pandemic, and the fact that the U.S. Biomedical Advanced Research and Development Authority (BARDA) may adjust the emergency stockpile delivery plan for NexoBrid® due to shifting priorities related to the pandemic, the Company is withdrawing its previously announced 2020 financial guidance, which was issued on February 25, 2020. At this time, the Company cannot predict the extent or duration of the impact of the COVID-19 outbreak on its financial and operating results. The Company plans to provide additional information, to the extent practicable, during its first quarter earnings call in May.

Financial Position and Business Continuity

The Company started the year in a strong position across multiple dimensions and is taking prudent measures to ensure a rapid return to normal operations when conditions allow. As of March 31, 2020, the Company had approximately $83 million in cash and investments and carries no debt. Moreover, appropriate expense reduction measures have been implemented.

The Company continues to manufacture MACI and Epicel and maintains a significant safety stock of all key raw materials. At this time there is no indication that supply chain interruptions will impact the Company’s ongoing manufacturing operations. The Company also continues to plan for a mid-2020 submission of the NexoBrid Biologics License Application to the FDA. To drive current and future demand, the Company’s 71 MACI and 10 Epicel sales representatives and clinical support specialists are adapting their practices to support physician education initiatives using virtual tools in regions where executive orders or hospital restrictions preclude their physical presence.

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 commercial 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.

Preliminary and Unaudited Nature of Reported Results

Our revenue expectations for the first quarter, as well as our estimates concerning cash and investments are preliminary, unaudited and are subject to adjustment in the course of our ongoing internal control and review procedures.

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, we caution you that 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 may result in differences are the inherent uncertainties associated with our expectations concerning expected revenue results for the first quarter of 2020 and estimates of our cash and investments as of March 31, 2020. Vericel's revenue expectations for the first quarter, as well as its estimates concerning cash and investments are preliminary, unaudited and are subject to adjustment in the course of our ongoing internal review. Our internal control procedures over financial reporting have not yet been completed and therefore, the growth in revenue and cash and investments as described herein have not been evaluated under our internal control framework. Additional 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 growth in revenues for MACI and Epicel, the expected target surgeon audience, the estimate of the commercial growth potential of our products and product candidates, availability of funding from the Biomedical Research and Development Authority ("BARDA") under its agreement with MediWound Ltd. for use in connection with NexoBrid development activities, potential fluctuations in sales and volumes and our results of operations over the course of the year, competitive developments, timing and conduct of clinical trial and product development activities, timing or likelihood of regulatory submissions or approvals, market demand for our products, changes in third party coverage and reimbursement, our ability to maintain and expand our network of direct sales employees, our ability to supply or meet customer demand for our products, and the impact of the COVID-19 pandemic on our business or the economy generally.

With respect to COVID-19, we are currently unable to reasonably estimate the specific extent, or duration, of the impact of the COVID-19 outbreak on our business, financial and operating results. We are also unable to predict how the outbreak will affect the availability of physicians and/or their treatment prioritizations or the impact of the outbreak on the overall healthcare infrastructure. In addition to impacts on procedure and surgery volumes, we are experiencing and may experience other disruptions as a result of the COVID-19 outbreak. For example, enrollment in our clinical trials may be adversely affected. In addition, patients who have cancelled or postponed surgeries may not reschedule cases in a timely fashion, or at all. 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 approvals by regulatory bodies, delays in product development efforts, and additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts 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. 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, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, and in other filings with the SEC, including the Report on Form 8-K filed by the Company on April 2, 2020. These forward-looking statements reflect management's 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.

Global Media Contacts:
David Schull
Russo Partners LLC
David.schull@russopartnersllc.com
+1 212-845-4271 (office)
+1 858-717-2310 (mobile)

Investor Contacts:
Lee Stern
Solebury Trout
lstern@troutgroup.com
+1 (646) 378-2922