

VERICEL CORP

FORM 8-K/A (Amended Current report filing)

Filed 06/02/17 for the Period Ending 05/15/17

Address	64 SIDNEY ST. CAMBRIDGE, MA 02139
Telephone	7349305555
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Industry	Pharmaceuticals
Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K/A

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 15, 2017**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§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.

Explanatory Note:

Vericel Corporation (the “Company”), a Michigan corporation, is filing this amendment to the Current Report on Form 8-K filed by the Company on May 19, 2017 (the “Original Report”) for the purpose of filing as exhibits (i) the Distribution Agreement between the Company and Orsini Pharmaceutical Services, Inc., dated May 15, 2017 (the “Distribution Agreement”) and (ii) the Fifth Amendment, dated May 15, 2017, to the Services Agreement by and between the Company and Dohmen Life Science Services, LLC, dated April 5, 2016, as amended (the “Fifth Amendment”).

Item 1.01. Entry into a Material Definitive Agreement.

As disclosed in the Original Report, on May 15, 2017, the Company entered into the Distribution Agreement. The description of the Distribution Agreement included in the Original Report is hereby incorporated by reference into this Form 8-K/A. The Distribution Agreement is attached to this Form 8-K/A as Exhibit 10.1.

Item 1.02. Termination of a Material Definitive Agreement.

As disclosed in the Original Report, on May 15, 2017, the Company entered into the Fifth Amendment. The information set forth in Item 1.02 of the Original Report, including the description of the Fifth Amendment, is incorporated by reference as if fully set forth herein. The Fifth Amendment is attached to this Form 8-K/A as Exhibit 10.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1 *†	Distribution Agreement by and between Orsini Pharmaceutical Services, Inc. and the Company, dated May 15, 2017.
10.2 *†	Fifth Amendment, dated May 15, 2017, to the Services Agreement by and between the Company and Dohmen Life Science Services, LLC, dated April 5, 2016, as amended.

* Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the exhibit to this Current Report on Form 8-K/A and submitted separately to the Securities and Exchange Commission.

† 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: June 2, 2017

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Financial Officer and Vice President, Corporate Development

Exhibit Index

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† Filed herewith.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[***]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

DISTRIBUTION AGREEMENT

This Distribution Agreement (“Agreement”) is made as May 15, 2017 (“Effective Date”) between Vericel Corporation (“Vericel”) and Orsini Pharmaceutical Services, Inc., 1111 Nicholas Boulevard, Elk Grove Village, Illinois 60007 (“Orsini”).

Whereas, Vericel is a manufacturer of autologous cell chondrocyte products, including Carticel[®] (autologous cultured chondrocytes) and MACI[®] (Matrix-induced Autologous Chondrocyte Implantation);

Whereas, Orsini provides specialty provider and other services that focus on delivery, reimbursement support, billing collections and management of sophisticated pharmaceutical and biological therapies; and

Whereas, Vericel wants to appoint Orsini and Orsini wants to be appointed by Vericel to be a distributor of Carticel and MACI (collectively referred to herein as the “Product” or “Products”) in the United States and Puerto Rico (“Territory”) pursuant to this Agreement.

Therefore, the Parties agree as follows.

1. OBLIGATIONS OF ORSINI.

1.1. Distribution. Vericel hereby appoints Orsini as a specialty pharmacy distributor of the Products to patient’s physicians, and other healthcare providers (“Healthcare Providers”) and to a patient’s hospital, physician’s clinic or other similarly licensed facility performing surgical procedures (“Healthcare Facilities”) that require the use of Product in the Territory.

Vericel’s contractor shall conduct [***] services including [***] (collectively “Case Materials”). Vericel or a contractor or agent of Vericel shall submit Case Materials to Orsini for its review and Orsini shall review the Case Materials within [***] hours of receipt (“Review Period”). For any Case Materials covered by [***], Orsini shall use best efforts to review the Case Materials within [***] hours. In the event Orsini determines that the Case Materials are incomplete or otherwise deficient, Orsini shall, prior to the end of the Review Period, request the additional or missing Case Materials required to enable Orsini to submit a claim for the Product to Healthcare Providers, Healthcare Facilities, or insurers (collectively “Payors”).

Upon the receipt of complete Case Materials, Orsini shall purchase and take title to Product for all cases regardless of the Payor. However, in the event, Orsini determines that the case involves a patient with no covered benefits for the Product, Orsini shall immediately notify Vericel and shall not be obligated to purchase Product for such a case.

Orsini acknowledges and agrees that PRO-Spectus, Inc. will use certain Orsini identifiers for [***] including, but not limited to, provider name, address, National Provider Identifier (NPI) as well as other Orsini identifiers [***]. In that regard, Orsini acknowledges and agrees that PRO-Spectus may use the following: Name: Orsini Pharmaceutical Services Inc.; Address: 1107 Nicholas Blvd, Elk Grove, IL 60007-2516; NPI 1073608998 and any other required identifiers. The Parties acknowledge and agree that the use of such identifiers is compliant with applicable state and federal laws and does not result in a business relationship that violates federal or state laws including, without limitation, those related to [***].

1.2 Ordering. Orsini will transmit purchase orders for Product to Vericel by mutually agreeable electronic means. All orders submitted to Vericel by Orsini will identify all relevant shipping information, including requested delivery date and any other information as may be necessary to enable Vericel to fulfill the order. All orders for Product are subject to acceptance by Vericel in its sole discretion.

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Vericel will, within a reasonable time after receipt of an order from Orsini, inform Orsini whether such order has been accepted on the terms contained therein. Subject to the “Cancellation” provision set forth in Exhibit A, Orsini may not cancel an order once it is accepted by Vericel.

1.3 Shipment of Product. Vericel will ship Product purchased by Orsini to Orsini’s customer (“Customer”) on a drop-shipment basis directly from Vericel’s finished goods distribution location. Shipment of Product will be [***] so that it reaches its destination on or prior to the delivery dates requested in the purchase order accepted by Vericel. Risk of loss and title to Product purchased by Orsini will pass upon [***] identified in the order.

1.4 Payment by Orsini. Orsini will pay in full for all orders of Product pursuant to payment terms set forth in Exhibit A.

1.5 Data. Orsini agrees to utilize Vericel’s web-based data hosting portal and to cooperate with Vericel and its vendors to ensure the complete, orderly, and secure transfer of data between Vericel (including Vericel’s vendors) and Orsini. At a frequency, format, and detail level agreed upon by the Parties, Orsini shall either provide reports to Vericel or input information into Vericel’s web-based platform. Consistent with Attachment A, Vericel shall pay Orsini a data service fee on a monthly basis.

1.6 Standard of Care. Orsini shall maintain all applicable licenses or certifications, including DEA numbers, and will provide Services in accordance with applicable professional standards at the time provided and applicable federal, state and local laws, rules, regulations and guidelines (collectively, “Standards and Legal Requirements”). Orsini shall maintain internal controls to facilitate compliance with its obligations under this Agreement. In the event Orsini receives a notice from any governmental authority regarding its obligations pertaining to Standards and Legal Requirements that have a material adverse effect on its ability to comply with this Agreement, Orsini shall notify Vericel and provide Vericel with any non-confidential documentation reasonably related to such inquiry.

2 OBLIGATIONS OF VERICEL.

2.1 Purchase of Product. Vericel will sell to Orsini the Product indicated on any purchase order provided by Orsini and accepted by Vericel at the price and on terms in Exhibit A. There are no minimum or maximum order requirements. Vericel will confirm receipt of purchase orders for Product within [***] business [***] of purchase order receipt. Vericel will use commercially reasonable efforts to fill 100% of all orders from Orsini and will bear any additional expenses, including premium freight charges, differential cost of substitutions, and special delivery charges associated with fulfilling such obligation.

2.2 Invoices. Vericel will invoice Orsini for Product on the date such Product is shipped. Delivery of all quantities of Product referred to in Vericel’s invoice will be deemed to have been made in full unless Orsini notifies Vericel in writing within one business day that the Customer has not received the ordered quantities of Product.

3 OBLIGATION OF PARTIES.

3.1 Financial and Credit Position. Each Party will maintain a financial condition reasonably satisfactory to the other. If, during the Term, the financial condition of a Party is impaired or unsatisfactory, the other Party may require such Party to perform its obligations in advance or provide other reasonable adequate assurances of performance.

3.2 Compliance with Laws. Each Party shall maintain all federal, state and local registrations necessary to comply with this Agreement and will immediately notify the other Party of any denial,

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revocation or suspension of any such registration. Each Party will comply with all Standards and Legal Requirements applicable to performance of its obligations under this Agreement, including without limitation, (i) Drug Quality and Security Act, (ii) federal and state Food, Drug and Cosmetics Acts; (iii) federal and state Anti-kickback laws; (iv) any federal, state or local statutes, regulations, rules, guidelines or manuals relating to dispensing pharmaceutical products, including any requirements specific to patients covered by Medicaid; (v) guidelines of the Joint Commission on Accreditation of Healthcare Organizations; (vi) federal, state or local laws relating to billing or sales practices; (vii) applicable provisions of Executive Order 11246, Section 503 of the Rehabilitation Act of 1973, and the Vietnam Era Veteran’s Readjustment Assistance Act, and applicable regulations; and (viii) Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and applicable regulations. Additionally, each Party will take all necessary precautions to prevent Product from being possessed, used, handled, distributed or sold by those who may not lawfully possess, use, handle, distribute or sell Product. In the event there is any change in law, regulation or interpretation thereof that has the effect of prohibiting any right or obligation of a Party under the Agreement that is material to the Party’s rights and obligations under this Agreement or materially and adversely affects such right or obligation, then the Parties shall meet in good faith to mutually agree on an appropriate amendment to this Agreement to reflect the changed circumstances and, if the Parties cannot agree on such amendment, either Party may upon thirty (30) days’ prior written notice to the other Party may terminate this Agreement.

In addition, each Party will comply with all laws, including reporting or reflecting discounts, rebates and other price reductions pursuant to 42 USC Sec. 1320a-7b(b)(3)(A) on cost reports, invoices or claims submitted to federal or state healthcare programs, retaining invoices and related pricing documentation and making them available on request as required.

3.3 Debarment/Exclusion. Orsini represents and certifies that it and any person or entity employed or engaged by it including, without limitation, Orsini’s employees, contractors, or agents who will provide Services in connection with this Agreement (collectively, “Personnel”) are not currently:

- (i) excluded, debarred, suspended or otherwise ineligible to participate in federal health care programs as defined in 42 U.S.C. § 1320a-7b or in federal procurement or non-procurement activities as defined in Executive Order 12689 (collectively, “Ineligible”);
- (ii) debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), as amended, *or* any similar state law or regulation (“Debarred”);
- (iii) excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7, *et seq.* or any state agency from participation in any federal or state health care program as defined in 42 U.S.C. § 1320a-7 and 42 U.S.C. § 1320a-7b (“Excluded”); and/or
- (iv) otherwise disqualified or restricted by the FDA pursuant to 21 CFR 312.70 or any other regulatory authority (“Disqualified”).

Orsini represents and certifies that it will not utilize any Ineligible, Debarred, Excluded or Disqualified Personnel to provide any Services hereunder. During the Term, if Orsini or any Personnel becomes Ineligible, Debarred, Excluded or otherwise Disqualified, Orsini shall immediately notify Vericel in writing within five (5) business days. Upon receipt of such notice, or if Vericel becomes aware of any Ineligibility, Debarment, Exclusion or Disqualification, Vericel shall have the right to terminate this Agreement immediately and shall retain all claims, causes of action, defenses, and other rights that Vericel may have at law or inequity. Orsini represents and warrants that it has no actual knowledge of any conduct for which Orsini or Personnel could be Ineligible, Debarred, Excluded or Disqualified.

3.4. Proper Handling and Storage. Vericel will handle and, store Product in a clean and orderly location, in a manner, which will assure that the quality of Product is maintained.

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3.5. Adverse Event and Product Complaint Reporting. Orsini will, within one (1) business day of a customer complaint or receipt of information regarding an Adverse Event (as defined below) notify Vericel of the same by email: [***] with a copy to [***], as may be amended by Vericel from time to time upon notice to Orsini. Information reported shall include, to the extent available and legally permissible: patient identifiers, reporter (including reporter name and contact information), Product information (dose, route, date of administration), and details regarding the adverse event. “Adverse Event” means any adverse reaction associated with the use of Product in humans (as defined below), whether or not considered product related and whether or not confirmed by a health professional. “Associated with the use of a product in humans” is not limited to a causal relationship of the reported event to Product, and may include (i) an Adverse Event occurring in the course of the use of Product in professional practice, (ii) an Adverse Event occurring from abuse of Product, (iii) an Adverse Event occur ring from the withdrawal of Product, or (iv) any significant failure of expected action. “Product Complaint” means a claim or expression of displeasure, dissatisfaction or annoyance with Product, Product-related materials or Product-related info l mation. A Product Complaint may or may not involve a formal charge or accusation. A Product Complaint may be related to, among other things, identity, purity, potency, safety or quality of Product. Notwithstanding the definition of Product Complaint, if the complaint involves a medical event in a patient, it is regarded as an Adverse Event.

3.6. Product Informational Materials. If requested by Orsini, Vericel shall provide Orsini, at no cost, reasonable amounts of applicable supplies of materials describing the Product as prepared by Vericel in the ordinary course of Vericel’s marketing of the Product, including for example, Product FAQs and fact sheets. Orsini shall not make any changes or provide supplemental information to any descriptive, educational, promotional or other Product-related materials supplied by Vericel without the prior written authorization of Vericel. Moreover, Orsini shall not distribute any descriptive, educational, promotional or other Product-related materials created or developed by Orsini or any third Party without the prior written authorization of Vericel.

3.7 Records Retention and Audit. The Parties shall maintain complete and accurate records of all transactions related to the conduct of business under this Agreement. During the Term of this Agreement and for a period of [***] years thereafter both Parties shall retain records pertaining to transactions undertaken pursuant to this Agreement and permit inspection of these records by a mutually acceptable third Party auditor subject to a mutually agreeable nondisclosure agreement. Any audit shall be upon reasonable prior written notice, at the expense of the initiating Party and shall be conducted during regular business hours in a manner so as not to unduly interfere with the other Party’s normal business operations. Such audit and inspection must be reasonable in time and in scope, and shall be conducted no more than once annually (unless for reasonable cause). If based on any such inspection or audit it is determined that a Party has: (i) received excess credits; (ii) taken any unearned discounts; or (iii) been underpaid, the Party against whom such finding has been made shall immediately pay any such sums, subject to the other Party’s right to offer evidence to dispute such inspection or audit finding.

In addition to the Audit provision above, the Parties agree that, in the event of a dispute between the Parties or in the event the Parties encounter difficulty with any Payer, the Parties will cooperate to share with one another or the Party’s contractor, subject to the Confidentiality provisions of this Agreement, any relevant documents.

4. RECALLS. Vericel, in consultation with Orsini, will prepare and maintain a written Standard Operating Procedure (“SOP”) in compliance with FDA requirements that sets forth the Parties’ respective responsibilities in handling any recalls of any Product in the Territory. In the event that (i) any governmental agency or authority issues a request or directive or orders that the Product be recalled or retrieved, (ii) a court of competent jurisdiction orders that the Product be recalled or retrieved, or (iii) Vericel reasonably determines that the Product should be recalled, retrieved or a “dear doctor” letter is required relating to restrictions on use of Product, Orsini will provide Vericel with any reasonable

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assistance requested by Vericel, and the Parties will take all appropriate corrective actions and will execute the steps detailed in the SOP. Vericel will be responsible for all of the expenses of such activities, except to the extent the event causing the recall results from a breach of any of Orsini’s obligations under this Agreement or Orsini’s negligence or willful misconduct. For purposes of this Agreement, the expenses may include, but are not limited to, the expenses of notification and return or destruction (if authorized by Vericel) of the Product, the cost of replacement of the Product, and any costs directly associated with the distribution of replacement Product. Orsini and Vericel will cooperate fully with one another in conducting any activity contemplated by this provision. Orsini will arrange for the destruction of Product lawfully recalled only upon Vericel’s (or any regulatory authority’s) written instruction to arrange for the destruction of such Product.

5. WARRANTY; INDEMNITY.

5.1 Warranty. Vericel warrants and represents to Orsini that: (i) Vericel will convey to Orsini good title to the Product, free and clear of all security interest, liens or other encumbrances; (ii) Vericel has manufactured, packaged and is selling the Product in compliance with all Standards and Legal Requirements; and (iii) as of the date of delivery, the Product will be free from material defects in materials and workmanship and will conform to Vericel’s specifications. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT OR THE CONTINUING GUARANTY (AS DEFINED BELOW), THE WARRANTIES SET OUT IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

5.2 Indemnification by Vericel. Vericel agrees to indemnify and hold harmless Orsini, its Affiliates and the officers, directors and employees of each of them, from and against all damages, expenses, claims, judgments and liabilities including, reasonable attorneys’ fees (“Claims”), incurred by Orsini arising from or in connection with (1) Vericel’s manufacturing, processing, labeling, marketing, storage, handling or sale of Product; (2) third Party Claims that the Product [***] or any other standards and legal requirements; (3) label, promotional literature, or other information concerning the Product provided by Vericel; or (4) any negligent, grossly negligent, or willful act or omission by Vericel.

5.3 Indemnification by Orsini . Orsini agrees to indemnify and hold harmless Vericel, its Affiliates and the officers, directors and employees of any of them, from and against all Claims incurred by Vericel arising from or in connection with (1) any negligent, grossly negligent, or willful act or omission by Orsini in the performance of its obligations under this Agreement; (2) any third Party claim arising from Orsini’s negligent actions related to the Products; or (3) Orsini’s breach of this Agreement.

5.4 Limitation of Liability. Except for any third Party claims of indemnification, in no event will either Party be liable to the other for any incidental, indirect or consequential damages, including damages for lost profits or lost opportunity costs as a result of any Claim asserted by the other Party, whether in contract or in tort, arising out of or related to this Agreement.

5.5 Insurance. Orsini shall maintain primary, noncontributory medical professional insurance and Commercial General Liability insurance of not less than [***] per occurrence for claims relating to Services. If the required insurance is underwritten on a “claims made” basis, the insurance must include a provision for an extended reporting period (“ERP”) of not less than twenty-four months; Orsini further agrees to purchase the ERP if continuous claims made insurance, with a retroactive date not later than the date of this Agreement, is not continually maintained or is otherwise unavailable. Self-insured retentions and/or deductibles shall be at Orsini’s sole discretion and responsibility. Orsini warrants that it has sufficient assets to cover any self-insurance or retained risk. Upon request, Orsini will promptly provide satisfactory evidence of the required insurance.

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6. TAXES. Vericel may add to the price paid by Orsini for Product any federal, state or local taxes, including excise, sales, use or other taxes on Product (“Taxes”). Vericel will have no obligation to pay or collect Taxes on sales of Product to or by Orsini (other than Taxes on Vericel’s income). Collection and payment of Taxes on sales of Product to or by Orsini are Orsini’s responsibility (other than Taxes on Vericel’s income). Orsini will provide to Vericel a copy of exemption certificates for Taxes for any jurisdiction in which Orsini does business. Orsini will reimburse Vericel in full for any Taxes paid by Vericel for which Orsini is responsible.

7. TERM/TERMINATION.

7.1 Term. The term of this Agreement will commence on the Effective Date and continue for a period of two (2) years thereafter (the “Term”). The Parties may renew the agreement for two (2) additional two (2) year terms, upon mutual agreement. During the Term Orsini shall be the exclusive pharmacy supplying the products.

7.2 Termination. This Agreement may be terminated by the Parties as follows:

a. Either Party may terminate this Agreement for any reason upon 90 days’ written notice to the other Party.

b. In addition to other available remedies, either Party may immediately terminate this Agreement for cause upon written notice to the other Party upon the other Party’s:

1. (i) filing an application for or consenting to appointment of a trustee, receiver or custodian of its assets; (ii) having an order for relief entered in Bankruptcy Code proceedings; (iii) making a general assignment for the benefit of creditors; (iv) having a trustee, receiver, or custodian of its assets appointed unless proceedings and the person appointed are dismissed within 30 days; (v) insolvency within the meaning of Uniform Commercial Code Section 1-201 or failing generally to pay its debts as they become due within the meaning of Bankruptcy Code Section 303(h)(1), as amended; or, (vi) certification in writing of its inability to pay its debts as they become due (and either Party may periodically require the other to certify its ability to pay its debts as they become due) (collectively, “Bankruptcy”); or
2. failure to perform any material obligation and such failure continues for sixty (60) days after it receives notice of such breach from the non-breaching Party; provided, however, if the other Party has commenced to cure such breach within such sixty (60) days, but such cure is not completed within such sixty (60) days, it will have a reasonable time to complete its cure if it diligently pursues the cure until completion.

7.3 Effect of Termination. Upon expiration or earlier termination of this Agreement:

a. Each Party will immediately pay the other Party all amounts due under any invoice or

credit memo;

b. Sections 3.7, 4, 5, 7.3, 8(b), 8(d), 8(e), 8(g) and 8(h) and any provision the context of which shows the parties intended it to survive, will remain in effect after the Term until the Parties’ obligations have been fully performed; and

c. The Parties agree to cooperate with one another and use commercially reasonable efforts to ensure a smooth transition.

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8. GENERAL PROVISIONS

a. Neither Vericel nor Orsini will be liable to the other for failing or delaying the performance of any obligations under this Agreement where such failure or delay arises out of any cause beyond the reasonable control of the Party claiming relief, including, without limitation, storms, floods, other acts of nature, fires, explosions, shortage of raw materials, riots, war or civil disturbance, national strikes or other industry wide labor unrest, embargoes and other governmental actions or regulations that would prohibit the supply or distribution of Product or from performing any other aspects of a Party’s obligations hereunder, delays in transportation, inability to obtain necessary labor, supplies, or manufacturing facilities (“Force Majeure”). The Party claiming to be delayed by reason of an event of Force Majeure shall promptly notify the other Party in writing of any actual or anticipated delays and take all necessary steps to avoid, overcome or end delays without additional cost to the other Party. The notice shall contain particulars as to the nature of the claimed event of Force Majeure, the date of commencement of the event and the anticipated date on which the event is anticipated to cease. The Party claiming to be delayed by reason of an event of Force Majeure shall take all reasonable steps to mitigate the effect of delays. Such steps shall include advanced planning and contingency planning.

b. During the Term, each Party may find it necessary to disclose confidential and proprietary information to the other (“Information”). Information may include but is not limited to [***] for Product by Orsini or Vericel, delivery schedules, manufacturing schedules, [***] amounts and [***]. During the Term and for three years after, regardless of any termination earlier than the expiration of the Term, each Party will maintain Information in confidentiality and may not reveal the Information to third Parties without the written consent of the disclosing Party, except as required by law. Each Party will use Information only for the purposes of this Agreement. These restrictions do not apply to Information that:

- (1) is in the public domain at the time of disclosure or afterward, other than by breach of this Agreement by the Party receiving the Information;
- (2) the receiving Party can establish by documentary evidence was in its lawful possession at the time of disclosure by the other Party;
- (3) is in the possession of the receiving Party from third Parties not under an obligation to maintain its confidentiality;
- (4) is independently developed by employees of the receiving Party where such employees had no access to Information as shown by documentary evidence; or
- (5) is required to be disclosed by law, by a judicial or administrative order, or by a regulatory agency with appropriate jurisdiction, provided that the receiving Party gives the disclosing Party reasonable prior written notice of its intention to disclose Information under this Subsection (5) and uses reasonable means to obtain confidential treatment for such Information prior to disclosure.

c. This Agreement is the entire and only understanding between the Parties as to its subject matter and supersedes all prior promises, agreements or understandings between the Parties. This Agreement may be executed in counterparts. All attachments to this Agreement are incorporated by this reference. This Agreement may be amended only in a writing signed by duly authorized representatives of Vericel and Orsini. Any waiver or delay by any Party in enforcing this Agreement will not deprive that Party of the right to take appropriate action at a later time or due to another breach. All provisions of this Agreement will be deemed to be severable.

d. This Agreement may not be assigned by either Party without the written consent of the other Party, whose consent shall not be unreasonably withheld.

e. All notices, claims, certificates, requests, demands and other communications under this Agreement must be in writing and delivered personally or sent by facsimile transmission, nationally-

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recognized express courier, or United States registered or certified mail, return receipt requested, addressed as follows. Items delivered personally will be deemed delivered on the date of actual delivery. Items sent by facsimile will be deemed delivered on the day sent if sent during normal business hours of the receiving Party (or, otherwise, on the first business day after the date of transmission). Items sent by certified or registered mail will be deemed delivered three (3) business days after mailing. Either Party may change its contact information by a written notice delivered pursuant to this Section.

If to Vericel:

Vericel Corporation
64 Sidney Street
Cambridge, MA 02139
Attn: Chief Operating Officer

With a Copy to:

Vericel Corporation
64 Sidney Street
Cambridge, MA 02139
Attn: General Counsel

If to Orsini:

Orsini Healthcare, Inc.
1111 Nicholas Boulevard
Elk Grove, IL 60007
Attn: President

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f. Captions in this Agreement are intended for convenience of reference only. Words, regardless of the number and gender specifically used, will be construed to include any other number, singular or plural, and any gender, masculine, feminine, or neuter, as the context requires. “And” includes “or.” “Or” is disjunctive but not necessarily exclusive. “Including” means “including but not limited to.” This Agreement will be interpreted as if written jointly by the Parties. This Agreement will benefit, and be binding upon, the successors and assigns of the parties. The relationship between the Parties is that of independent contractors and not partners, joint ventures, principal and agent or employer and employee. Time is of the essence in the performance of all obligations under this Agreement.

g. Neither party shall issue or release any announcement, statement, press release or other publicity or marketing materials relating to this Agreement without the prior consent of the other party (which consent shall not unreasonably be withheld or delayed); provided, however that either Vericel or Orsini may identify the other as a provider or customer of services hereunder without obtaining the consent of the other party. Furthermore, if Vericel files a copy of this Agreement with any regulatory authority or any stock exchange, Vericel shall notify Orsini in advance and cooperate, to the extent permitted by law or the rules of any applicable stock exchange, with Orsini’s efforts to redact or otherwise obtain confidential treatment of any of the pricing or other confidential terms set forth in this Agreement.

h. Neither Party’s failure to insist on performance of any term, condition, or instruction nor failure to exercise any right or privilege or its waiver of any breach, shall thereafter be construed to constitute a waiver of such term, condition, instruction, right or privilege. No consent or waiver, expressed or implied, by a Party to the performance by the other Party or of any breach or default by the other Party of its obligations hereunder shall be deemed or construed to be a consent or waiver to or of any other breach or default in the performance by such other Party of the same or any other obligations of such other Party hereunder. The giving of consent by a Party in any one instance shall not limit or waive the necessity to obtain such Party’s consent in any future instance. No waiver of any rights under this Agreement shall be binding unless it is in writing and signed by the Party waiving such rights.

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IN WITNESS WHEREOF, the Parties executed this Agreement as of its Effective Date.

VERICEL CORPORATION

By: /s/ Daniel Orlando
Name: Daniel Orlando
Title: Chief Operating Officer

Date: 05/15/2017

ORSINI HEALTHCARE, INC.

By: /s/ Michael Fieri
Name: Michael Fieri
Title: President and CEO

Date: 05/15/2017

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EXHIBIT A — PAYMENT TERMS AND PRICING

Payment Terms.

For all Product, Orsini will pay Vericel in full, including payment of applicable Taxes, at the [***] for Product ordered by Orsini. Such payments shall be made within [***] days from the date of invoice from Vericel.

The Parties agree to periodically, no less than [***], discuss the [***] to determine whether, given the Parties’ experience regarding the Products, [***].

PRODUCTS AND PRICES

Product	NDC Number	List Price*
Carticel®	63861-1025-01	[***]
MACI	69866-1030-01	[***]

* The List Price is subject to revision, from time to time, by Vericel in its sole discretion; provided, however, Vericel must provide Orsini with a written notice of its intent to make a price change (a “Price Change Notice”) at [***] days prior to the effective date of such price change. Vericel will then inform Orsini of the new price [***] prior to the effective date of such price change. The new price will be effective for all orders placed by Orsini as of the effective date of such price change. Vericel list prices do not include applicable sales taxes. Vericel acknowledges and agrees that it will notify the applicable pricing agencies of any price changes in a timely manner.

Data Service Fee. Consistent with Section 1.5 of the Agreement, in consideration of Orsini providing requested data and information, Vericel shall pay Orsini a service fee of \$[***] per month. The Parties agree that such service fee represents fair market value for the bona fide services.

Cancellations. In the event that a Orsini Customer cancels surgery or a Product order after Vericel has begun the cell culturing process for such Product for reasons unrelated to the payment or coverage of the Product or in the event a patient or surgeon does not show up on the date of surgery for implantation of the Product, Orsini and Vericel shall notify the other Party thereof, and, if Orsini has paid Vericel for such Product, Vericel shall reimburse Orsini in an amount equal to the amount paid by Orsini for such Product, within [***] days of the cancellation or no-show. If Orsini has not yet paid for the product, the order will be canceled at no charge to Orsini.

Unanticipated Payment Denial. For Cases in which, despite Orsini using commercially reasonable efforts consistent with industry standards, a Payer denies payment for a Product purchased by Orsini, based on incorrect information provided by Vericel or Vericel’s contractor within the Case Materials submitted to Orsini, which Orsini could not independently confirm, Vericel shall reimburse Orsini an amount equal to Orsini’s purchase price.

Non-Conforming Product. Vericel will reimburse Orsini for all Products which are delivered not in conformity with Section 5.1 of the Agreement within [***] days of notification by Orsini.

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**FIFTH AMENDMENT TO
SERVICES AGREEMENT**

This Fifth Amendment to Services Agreement (this “Amendment”) is made and entered into as of May 15, 2017, by and between Vericel Corporation (“Client”) and Dohmen Life Science Services, LLC (“DLSS”).

Client and DLSS are parties to that certain Services Agreement dated April 5, 2016 (the “Original Agreement”), as amended by (i) that certain First Amendment to Services Agreement dated as of May 31, 2016, (ii) that certain Second Amendment to Services Agreement dated as of July 1, 2016, (iii) that certain Third Amendment to Services Agreement dated as of October 12, 2016 (the “Third Amendment”), and (iv) that certain Fourth Amendment to Services Agreement dated as of November 19, 2016 (each amendment, collectively with the Original Agreement, the “Agreement”). The parties now wish to amend the Agreement as follows:

1. Defined Terms. Capitalized terms in this Amendment that are not defined in this Amendment have the meanings given to them in the Agreement. If there is any conflict between the Agreement and any provision of this Amendment, this Amendment will control.
2. Mutual Termination of Agreement. Client and DLSS mutually agree to terminate the Agreement effective as of June 30, 2017 (the “Date of Termination”). The parties agree that the exclusivity provision set forth in Section 2(a) of the Agreement shall be of no further force and effect.
3. Survival of Provisions. The parties agree to delete and replace Section 13(e)(iii) of the Agreement with “obligations of each of the parties contained in each of the following provisions shall survive the termination of the Agreement: (A) Sections 3(a)(iv), 3(a)(vi), 3(a)(vii), 3(a)(xiii), 4(b), 5(b), 6(a)(iv), 6(a)(v), 6(a)(vi), 7(a), 7(b), 8, 9, 10(b), 10(c), 10(d), 11, 12, 13(e), 13(g) (solely with respect to any failure by Client to make a timely payment of any amount due to DLSS under this Amendment), 13(i), 15, 16 and 17 of the Original Agreement, and (B) all provisions contained in this Amendment.”
4. Transition of Services. The parties mutually agree to perform and comply with the post-termination transition plan set forth in Exhibit A attached hereto with any subsequent modifications as mutually agreed by the parties. DLSS shall use commercially reasonable efforts to perform such transition services and shall have no further obligations to perform any transition services other than as set forth in this Amendment and in the Agreement or as so mutually agreed to in writing. Client will prioritize the transition of pending, active and historical biopsies and implants. DLSS will cooperate and provide information, materials and data reasonably requested by Client or Client’s agent regarding the transition of all Customers to Client’s new specialty pharmacy(ies) in order to ensure an orderly transfer of such Customer relationships from DLSS to such new specialty pharmacy(ies).

After June 30, 2017, DLSS will promptly deliver or forward to Client and Client’s specialty pharmacy(ies) any orders, inquiries or other communications from all Customers. DLSS will not terminate without cause any Payer contract for Carticel or MACI until such time as DLSS is no longer obligated to pursue collection on claims as set forth in Section 6 hereof.

5. Stay Bonuses. DLSS has [***] FTEs who provide services under the Agreement (the

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“Employees”). To ensure a smooth transition of services, DLSS has agreed to pay a stay bonus (the “Stay Bonus”) to an Employee if the Employee remains in active service as an employee in good standing of DLSS through the Date of Termination, as follows:

[***];

[***];

[***]; and

[***].

For clarity, “in active service” means continuously 100% dedicated to work on services for the Client from the date of this Amendment to the Date of Termination and includes work attendance and consistent performance of services promptly and adequately to Patients and Customers through June 30, 2017 at the same level of performance experienced in the beginning of the second quarter of 2017 prior to the date hereof, in each case as reasonably determined by mutual agreement of the parties.

Promptly after the date of this Amendment, DLSS will notify the Employees regarding the existence and conditions of the relevant Stay Bonus. DLSS will calculate [***] the Stay Bonuses on June 15, 2017, [***].

6. Reimbursement Support. Commencing on the Date of Termination and continuing until the earlier of (i) such time as accounts receivable from outstanding claims from Payers for Product amount to [***] or less or (ii) [***] months from the Date of Termination (the “Final Date of Reimbursement Support”), DLSS hereby agrees to continue to use commercially reasonable efforts to pursue collection on those claims previously submitted to Payers by DLSS prior to the Date of Termination, but excluding all claims that were transferred to Vital Care, Inc. prior to the Date of Termination, and to promptly remit all such collections to Client. Denied and incomplete claims shall be resubmitted or appealed by DLSS (if eligible for resubmission or appeal as determined by the policies and procedures of the applicable Payer) within a reasonable time following DLSS’s receipt of such notice of denial or incompleteness. At Client’s cost, Client or Client’s agent will be permitted to review, on a weekly basis, the status of [***]; provided, however, that under no circumstance shall (i) Client have direct access to any systems of DLSS or (ii) Client or Client’s agent (including, without limitation, Prospectus) be permitted to communicate, orally or in writing, with any Payer for which DLSS has a contract and submitted a claim for Product prior to the Date of Termination regarding such a claim for which DLSS is pursuing collection pursuant to this Section 6. Client hereby acknowledges that DLSS under no circumstance is making any guarantee on the collection of these claims. As of the Date of Termination, DLSS shall no longer contract with any Payers or submit any new claims to Payers for reimbursement. Any obligations of DLSS under this Section 6 shall cease and be of no further force or effect upon the Final Date of Reimbursement Support, other than the obligation to promptly remit to Client any collections received by DLSS after the Final Date of Reimbursement Support (subject to any right of offset set forth in Section 10 hereof).

For purposes of this Section 6, “commercially reasonable efforts” to pursue collection of claims shall

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mean that DLSS shall perform the following: (i) with respect to any claim for which there has been no payment and has been outstanding for more than [***] days, DLSS shall perform one of the following actions at least [***]: phone call to Payer, claim re-submission or update of electronic claim status, (ii) with respect to any claim for which there has been a payment but a balance remains unpaid, DLSS shall perform one of the following actions at least [***]: phone call to Payer, claim re-submission or update of electronic claim status, and (iii) with respect to any appeal of a claim, DLSS will contact the Payer to understand the denial or takeback within [***] days of formal Payer communication.

7. Guarantee .

- (a) Client acknowledges and agrees that the amount due under the “Guarantee” contained in the Third Amendment is [***] (the “Guarantee Amount”), which such amount is net of recoupments and payments to date, and that any obligation of DLSS in connection with such Guarantee is hereby satisfied in full as an offset to the unpaid invoices and unbilled services fee due to DLSS pursuant to Section 8 below.
- (b) Client hereby agrees to promptly give DLSS written notice of any amounts collected by Client or any third party on behalf of Client (including Vital Care, Inc.) at any time on or subsequent to the date of this Amendment as payment for an implant of the Product performed during the Guarantee Period, which includes any amount paid by the Patient or reimbursement paid by the Guaranteed Payer (each collection being a “Post-Guarantee Collection”). Client further agrees to promptly pay to DLSS any Post-Guarantee Collection collected by Client or any third party; provided, however, that once the aggregate amount collected after the date of this Amendment in connection with the Guaranteed Implants equals the Guarantee Amount, any further collections from either DLSS or any third party will be remitted to or retained by Client (the “Post-Guarantee Limitation”).
- (c) Within thirty (30) days following the first anniversary of the Date of Termination, Client shall represent and warrant to DLSS, in a written certification signed by the CEO or CFO of Client, the aggregate amount of the Post-Guarantee Collections as of such date and that the full amount of such Post-Guarantee Collections has been paid to DLSS, subject to the Post-Guarantee Limitation.

8. Payment to DLSS . Within three days of the date of this Amendment, Client shall pay to DLSS, by wire transfer to the account specified in writing by DLSS, an amount equal to [***] (the “Net Payment Amount”), which such amount represents the sum of the following:

An estimated fee for services performed by DLSS during April and May 2017 in the amount of [***] (the “Estimated April-May Fee”);

Less, the excess of (i) the Guarantee Amount, over (ii) the sum of all unpaid invoices for services performed by DLSS through March 31, 2017 in the amount of [***] (which shall be deemed paid upon the payment by Client of the Net Payment Amount).

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Within [***] days following the Date of Termination, DLSS shall reasonably estimate the fee for services performed by DLSS during June 2017 and give written notice thereof to Client (the “Estimated June Fee”). Client shall pay to DLSS the Estimated June Fee within [***] days of receipt of such written notice.

Within thirty (30) days following the Date of Termination, DLSS shall invoice Client for the actual fee for services performed by DLSS during the period from April 1, 2017 through June 30, 2017 (the “Invoice Fee”) and reconcile such amount against the sum of the Estimated April-May Fee and Estimated June Fee. Client represents and warrants to DLSS that it shall promptly pay DLSS the excess, if any unless disputed in good faith, of (i) the Invoice Fee, over (ii) the sum of the Estimated April-May Fee and the Estimated June Fee, within thirty (30) days of receipt of the invoice. Likewise, DLSS represents and warrants to Client that it shall promptly pay Client the excess, if any unless disputed in good faith, of (i) the sum of the Estimated April-May Fee and Estimated June Fee, over (ii) the Invoice Fee, within thirty (30) days of the date of the invoice.

9. Public Disclosure. Client and DLSS mutually agree not to make any statements, comments, or communications that constitute disparagement of the other party. Client and DLSS further agree that any public statements regarding the termination of the business relationship shall indicate that the termination of the Agreement was mutual.
10. Recoupment. In the event of any recoupment by a Payer that occurs subsequent to the Termination Date arising from any adjustment, audit or other procedure by a Payer related to a claim for a Product submitted by DLSS in accordance with the Agreement, DLSS shall use commercially reasonable efforts to appeal such recoupment in accordance with industry standards. Following the resolution of such appeal process, Client shall reimburse DLSS for the full amount of such recoupment promptly following written notice thereof from DLSS, which notice shall include all information reasonably necessary for Client to assess the appropriateness of the amount and any documentation from the Payer concerning the recoupment, or alternatively, DLSS shall have the right to offset any such recoupment from and against any future collections received by DLSS from Payers for claims submitted by DLSS that are to otherwise be remitted to Client. Notwithstanding the foregoing, if the recoupment is due to any breach of the Agreement by DLSS related to [***] the Services, Client shall have all legal remedies available as set forth in the Agreement. DLSS also represents and warrants to Client that it has not received any written notice from any Payer that such Payer intends to make a recoupment, or has an ongoing dispute that is reasonably expected to result in a recoupment, of any claim submitted to a Payer for Product.
11. No Other Changes. This Amendment, together with the Agreement, constitutes the entire agreement between the parties and supersedes all prior or contemporaneous discussions, negotiations, representations, warranties, or agreements relating to the subject matter hereof. All other terms and conditions contained in the Agreement will remain in full force and effect. In the event of any conflict between the Agreement and this Amendment, the terms of this Amendment shall prevail, and the Agreement shall be deemed amended to incorporate the provisions contained herein.

* * * * *

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IN WITNESS WHEREOF, the parties hereto have executed this Amendment by their duly authorized representatives as of the first date set forth above.

DOHMEN LIFE SCIENCE SERVICES, LLC

By: /s/ Cynthia A. LaConte
Name: Cynthia A. LaConte
Title: CEO

VERICEL CORPORATION

By: /s/ Dominick Colangelo
Name: Dominick Colangelo
Title: President & CEO



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EXHIBIT A

[***]

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[***]

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[***]
