

September 11, 2017

## CONFIDENTIAL TREATMENT REQUESTED

## CERTAIN PORTIONS OF THIS LETTER AS FILED VIA EDGAR HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED BY VERICEL CORPORATION PURSUANT TO 17 CFR 200.83 WITH RESPECT TO THE OMITTED PORTIONS. OMITTED INFORMATION HAS BEEN REPLACED IN THIS LETTER AS FILED VIA EDGAR WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[\*\*\*\*]." AN UNREDACTED VERSION OF THIS LETTER HAS BEEN DELIVERED TO THE DIVISION OF CORPORATE FINANCE OF THE SECURITIES AND EXCHANGE COMMISSION.

<u>VIA EDGAR SUBMISSION</u> Securities and Exchange Commission 100 F Street, N.E. Mail Stop 4720 Washington, D.C. 20549

Attention: Jacob Luxenburg, Staff Accountant

Re: Vericel Corporation Form 10-K for the Fiscal Year Ended December 31, 2016 Filed March 13, 2017 File No. 001-35280

Dear Mr. Luxenburg:

On behalf of Vericel Corporation ("Vericel" or the "Company"), this letter is in response to the comments provided to Vericel from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") in a letter dated August 11, 2017 (the "Letter"), relating to Vericel's Form 10-K for the fiscal year ended December 31, 2016 (the "Form 10-K"). Set forth below are the Staff's comments followed by the Company's responses. The responses are keyed to the numbering of the comments in the Letter and appear following the comments, which are restated below.

## Management's Discussion and Analysis of Financial Condition and Results of Operations

<u>Critical Accounting Estimates</u> <u>Recognition and Net Product Sales, page 57</u>

- 1. You disclose that you recognize revenue when persuasive evidence of an arrangement exists, the goods are shipped or delivered, depending on shipping terms, title and risk of loss pass to the customer and collectability is reasonably assured; however, you do not provide disclosure related to estimates of items that reduce gross revenue such as product returns, chargebacks, customer rebates and other discounts and allowances. Please address the following:
  - Clarify your accounting policy for your customer and end user incentives describing the factors that you consider in estimating each gross to net adjustment and any related reserves.

## **RESPONSE:**

Our products consist of implantable autologous cultured chondrocytes, which are human-derived cells obtained from the patient's own cartilage, implanted by orthopedic surgeons after obtaining a cartilage biopsy during an arthroscopic procedure for that particular patient. Because the products are patient-specific and implantable there are no product returns. Sales volumes are known because our implantable cell therapy products cannot be stored at a third party distributor or wholesaler and are prepared for the individual patient. Prior to June 30, 2016, we sold our product through a pharmacy, US Bioservices Corporation ("US Bio"), who purchased the product and assumed risks associated with reimbursement from insurance providers but never took physical possession, as the products are always shipped directly from our facility to the surgical suite. Sales incentives such as rebates or chargebacks that were offered to this distributor were known and recorded at the time of sale and not subject to significant estimation. Following June 30, 2016, after we changed to a direct distribution model involving third party service providers Dohmen Life Sciences Services, LLC ("Dohmen") and Vital Care, Inc. and its franchisees ("Vital Care"). We did not offer our customers or end users any chargebacks, rebates or other types of sales incentives that would factor into a gross to net revenue calculation or result in a liability requiring a reserve.

As stated in footnote 2 of our Form 10-K, under the direct sales model net product revenue for all products (Carticel, MACI and Epicel) is recognized when the surgery is performed and calculated based on expected insurance, hospital and/or patient payments. Prior authorization or confirmation of coverage by the patient's private insurance plan, hospital payer or government payer is a prerequisite to the shipment of product to a patient. In order to recognize revenue, evidence of coverage and medical necessity from the insurance

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provider or hospital must exist. The net revenue recorded per implant is based on several factors including the patient's type of insurance coverage, contractual rates in effect for certain payers, and the reimbursement history for certain classes of customers. Our contractual arrangements with both Dohmen and Vital Care incorporated the inclusion of Carticel and MACI into Dohmen and Vital Care's contracts with insurance companies.

All available information, including payment history, is taken into consideration when we recognize the amount of insurance reimbursement expected as revenue and therefore, neither reserves nor liabilities are initially recorded. In certain cases, insurance payment and reimbursement received can differ from the original estimate, which results in changes to the amounts ultimately recognized in net revenue. Factors that could cause differences between the original revenue recognized versus the amount reimbursed for individual implants include changes in the actual or expected levels of patient co-pay amounts and deductibles, and the insurance company questioning the in-network or out-of-network status of the product or the adequacy of documentation regarding medical necessity and authorization. As required by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 954-605 *Health Care Entities*, in each quarter we may increase or decrease the expected insurance reimbursement for previous claims based on the best information available at the time of issuance of the financial statements. Such adjustments have historically been immaterial with the exception of the Vital Care matter which is discussed in detail below.

- In your response please include a roll forward of the liability for each estimate for each period presented showing the following:
  Beginning balance,
  - · Current provision related to sales made in current period,
  - · Current provision related to sales made in prior periods,
  - · Actual returns or credits in current period related to sales made in current period,
  - · Actual returns or credits in current period related to sales made in prior periods,
  - Ending balance

# **RESPONSE:**

As noted above, there are no product returns, and we do not offer customer or end user sales incentives and therefore do not have any such liabilities recorded. As stated in footnote 4 of our quarterly filings for the period ended March 31, 2017 and June 30, 2017, there has been a change in estimate related to a contractual dispute between our third party service provider, Vital Care, and a third party payer regarding the settlement of insurance reimbursement. This was recognized as a change in estimated revenue in accordance with ASC 954-605 *Health Care Entities – Revenue Recognition*. All of the information and subsequent changes related to the reserve is included in our quarterly reports on Form 10-Q for the periods ended March 31, 2017 and June 30, 2017. This adjustment to our revenue is discussed in further detail below.

Please provide us a discussion of the amount of and reason for fluctuations for each type of reduction of gross revenue (i.e. product returns, chargebacks, customer rebates and other discounts and allowances) including the effect that changes in your estimates of these items had on your revenues and operations.

### **RESPONSE:**

As noted above, the only significant adjustment to our revenue in 2017 was limited to the contractual dispute between our third party service provider, Vital Care, and a third party payer related to the settlement of a dispute regarding insurance reimbursement. This adjustment to our revenue is discussed in further below.

 Tell us whether and how your customer and end user incentives changed pursuant to the June 30, 2016 change in the scope of your agreement with US Bioservices Corporation and due to the new agreement with Dohmen Life Science Services, LLC. Please explain your accounting for this change.

## **RESPONSE:**

Prior to June 30, 2016, US Bio was our only end customer. US Bio took title to our products and assumed counter party reimbursement risk, which included the risk associated with any settlements with insurance providers or collections from patients. We received a fixed amount per Carticel implant from US Bio when the surgery was performed. These transactions were accounted for in accordance with ASC Topic 605 Revenue Recognition and Staff Accounting Bulletin ("SAB") No. 104, Revenue Recognition, given the traditional buyer and seller relationship with US Bio. As stated in footnote 4 of our Form 10-K, effective July 1, 2016, we transitioned to a direct sales model whereby the third party payer (insurance company, hospital, government, etc.) paid on the patient's behalf, with the exception of patient co-pays. As discussed above we accounted for these multiple party transactions in accordance with ASC Topic 954-605 *Healthcare Entities*. As of July 1, 2017, we utilized a new service provider, Dohmen, to provide patient support and reimbursement services under their reimbursement contracts but this provider did not purchase or take title to Carticel. We subsequently added Vital Care as a second service provider to expand the available network of contracted third-party payers for Carticel and MACI. Pursuant to our agreements with Dohmen and Vital Care, we retained counter party risk from the sale of our products including settlements with insurance providers or collections from patients. Dohmen and Vital Care were compensated as service providers.

We note for the Staff that by the start of the third quarter in the fiscal year ended December 31, 2017, we have moved the majority of our MACI and Carticel business to Orsini Pharmaceutical Services, Inc. ("Orsini"). Orsini is a distributor and we will account for our transactions with Orsini similar to how we accounted for our arrangement with US Bio described above in accordance with

ASC 605. Orsini will take title and will pay us a fixed fee and there is no adjustment related to final reimbursement and/or patient payment. We intend to include the disclosure below regarding our transition to Orsini in our quarterly report on Form 10-Q for the quarter ended September 30, 2017.

 Explain to us how the contractual dispute between Vital Care, Inc., and the third-party payer related to certain of its insurance reimbursement claims associated with Carticel and MACI surgeries performed in 2016 and the first quarter of 2017 affects your revenue recognition analysis. Clarify whether or not the "negotiated reimbursement" represents the final settlement of the dispute. Please provide the date of the final negotiation or settlement in your response.

#### **RESPONSE:**

In April 2017, one third party payer notified Vital Care that [\*\*\*\*].

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[\*\*\*\*]. Our original reserve of \$2.8 million related to 2016 and 2017 surgeries, subject to reimbursement from this third party payer, assumed an out-of-network reimbursement rate.

[\*\*\*\*]. The change in estimate from the quarter-ended March 31, 2017 to June 30, 2017 resulted in a reversal of \$1.4 million of the previously recorded reserve. FASB ASC Topic 954-605 *Health Care Entities* is predicated on the fact that revenue recognition of health care entities is subject to inherent uncertainties and complexities and revenue for the period reflects the amount the entity expects to collect based upon management's best estimate, knowledge of and experience with past and current events and assumptions about conditions that it expects to exist and courses of action that it expects to take. We concluded in accordance with ASC 954-605 that settlements should reflect our best estimate of amounts expected to be received and the final settlement agreement in July 2017 as discussed above confirmed our best estimate as of June 30, 2017.

## [\*\*\*\*].

We highlight for the Staff that given the different nature of the two arrangements (US Bio and Dohmen/Vital Care) described above, the accounting policy and accounting guidance followed for each differs. The reimbursement received under the Dohmen and Vital Care contracts is received from third party payers on behalf of the patients receiving the Carticel and MACI implants. We have determined that these arrangements should be accounted for under ASC 954-605 *Health Care Entities – Revenue Recognition*. This arrangement differs from our other revenue arrangements in which the distributor, acting as our customer, purchases and takes title for the product and pays for the product directly without adjustments related to final reimbursement which are accounted for under ASC Topic 605 *Revenue Recognition* and SAB No. 104, *Revenue Recognition*. While we continue to believe our disclosure was acceptable, we have further refined our disclosure in footnote 4 prospectively as follows beginning in our Form 10-Q for the period-ended September 30, 2017. For ease of the Staff we have presented a track changes version to our current disclosure, which includes some disclosure from our Form 10-K for the year ended December 31, 2016:

Total revenues are comprised of product sales of Carticel, <u>The Company sells</u> Epicel, <u>MACI</u> and surgical kits.- directly to the customer based on contracted amounts. Revenue <u>is from sales to the customers are</u> recognized <u>in accordance with ASC 605</u>, <u>Revenue</u> <u>Recognition and SAB Topic 104</u>, <u>Revenue Recognition</u>, when persuasive evidence of an arrangement exists, the goods are shipped or delivered <u>and implanted</u>, depending on shipping terms, title and risk of loss pass to the

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customer and collectability is reasonably assured. Shipping and handling costs are included as a component of revenue. The Company recognizes product revenues from sales of Epicel, Carticel and MACI upon delivery to patients as long as (i) there is persuasive evidence that an arrangement exists between ourselves and the customer, (ii) collectability is reasonably assured and (iii) the price is fixed or determinable. For Carticel and MACI, prior

Prior to July 1, 2016, the Company sold Carticel to a distributor and followed ASC 605, *Revenue Recognition* and SAB Topic 104 *Revenue Recognition* to record revenue. This distributor purchased and took title to Carticel upon shipment of the product and assumed credit and collection risk related to the end customers. The distributor worked with the payers on behalf of patients and surgeons to ensure medical coverage and to obtain reimbursement for Carticel implantation procedures. The Company retained responsibility for shipment of the product to the surgical suite. Revenue was recorded for Carticel upon occurrence of the surgery, net of provisions for rebates and cash discounts which were \$0.5 million for the six month period ending June 30, 2016. These rebates and prompt payment cash discounts were established by the Company at the time of sale, based on actual experience adjusted to reflect known changes in the factors that impact such reserves. Adjustments to these reserves have historically not been significant.

On June 30, 2016, the Company reduced the scope of the agreement with its exclusive distributor by terminating their services for a significant portion of its Carticel sales. On July 1, 2016, the Company transitioned to a direct sales model for Carticel and MACI whereby the Company retains credit and collection risk from the end customer, the patient. The Company utilized a new provider, Dohmen Life Science Services, LLC (DLSS), to provide patient support services but this provider did not purchase and take title to Carticel or MACI. In addition, the Company utilized Vital Care Inc. and its franchisees as a second provider to expand the available network of contracted third-party payers for Carticel and MACI. Under this direct sales model, the patient bears the ultimate financial responsibility for the purchase of Carticel or MACI and as such the Company recognized revenue in accordance with ASC 954-605,

<u>Health Care Entities – Revenue Recognition. The third party payer (insurance company, government, etc.) pays all or some of the product</u> price on the patient's behalf.

Under the direct sales model, the Company recognized product revenues from sales of Carticel upon implantation at which time the claim is billable to patient's insurance provider on behalf of the patient and is billed by either DLSS or Vital Care. Prior authorization or confirmation of coverage level by the patient's private insurance plan, hospital or government payer is a prerequisite to the shipment of product to a patient. The Company's net product revenues are calculated by estimating expected payments for insurance, hospital or patient payments at the time it invoices and recognizes the gross revenue. The estimates are updated prospectively as new information becomes available.

The Company sells Epicel directly to hospitals and retains the credit and collection risk from the end customer. From July 1, 2016 through June 30, 2017, the Company utilized a direct sales model for Carticel and MACI whereby the Company retained the credit and collection risk from the end customer. During that period, the Company utilized Dohmen Life Science Services, LLC (DLSS) to provide patient support services and reimbursement services, but this provider did not purchase and take title to Carticel or MACI. On May 15, 2017, both parties mutually terminated the agreement effective June 30, 2017.

The Company utilizes Vital Care, Inc. (Vital Care) to provide data reporting services and to purchase, bill and collect from certain payers for Carticel and MACI.

In April 2017, the Company was notified of a contractual dispute between Vital Care and a third-party payer and as a result, during the three months ended March 31, 2017, the Company increased its estimated revenue allowances, reducing revenue by \$2.1 million related to 2016 sales

and \$0.7 million related to 2017 sales to reflect the lower reimbursement that would be obtained if the claims are ultimately required to be treated as out-of-network. <u>SubsequentlyDuring the three months ended June 30, 2017</u>, the dispute was resolved and the negotiated reimbursement resulted in the Company's ability to reduce its estimated sales allowances by \$1.4 million, which resulted in additional revenue in the second quarter related to sales which originated primarily in 2016. As a result of the continuing evaluation and assessment of these expected payments, our estimates for expected payments could change.

On May 15, 2017, the Company entered into a distribution agreement with Orsini Pharmaceutical Services, Inc. (Orsini) to appoint Orsini as a specialty pharmacy distributor of Carticel and MACI to patients' physicians and other healthcare providers. <del>Orsini will work with the Company's third party service provider for the management of patient cases related to Carticel and MACI.</del> The initial term of the distribution agreement will end on May 15, 2019 with the option of two additional two-year terms. Orsini takes title to Carticel and MACI upon shipment of the product and assumes credit and collection risk-<u>at which point the Company recognizes revenue</u>. The Company ships the product to the surgical suite. <u>There are no chargebacks</u>, <u>rebates or other types of sales incentives that would impact revenue under the agreement with Orsini</u>.

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In connection with responding to the Staff's comments, the Company acknowledges that (i) it is responsible for the adequacy and accuracy of the disclosure in the Form 10-K, (ii) Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to the Form 10-K and (iii) the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please contact me at (617) 588-5750 if you have any questions or require any additional information.

Very truly yours,

/s/ Gerard Michel

Gerard Michel Chief Financial Officer and Vice President