
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED: March 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-35280

VERICEL CORPORATION

(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction of
incorporation or organization)

94-3096597

(I.R.S. employer
identification no.)

64 Sidney Street

Cambridge, MA 02139

(Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code) (800) 556-0311

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes - No -

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes - No -

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer -

Non-accelerated filer -

(Do not check if a smaller reporting company)

Accelerated filer -

Smaller reporting company -

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes - No -

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date.

COMMON STOCK, NO PAR VALUE

(Class)

36,681,333

Outstanding at May 4, 2018

VERICEL CORPORATION
QUARTERLY REPORT ON FORM 10-Q
TABLE OF CONTENTS

PART I — FINANCIAL INFORMATION

Item 1.	<u>Financial Statements (Unaudited):</u>	<u>3</u>
	<u>Condensed Consolidated Balance Sheets as of March 31, 2018 and December 31, 2017</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2018 and 2017</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and 2017</u>	<u>5</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>6</u>
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>16</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>21</u>
Item 4.	<u>Controls and Procedures</u>	<u>21</u>

PART II — OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	<u>22</u>
Item 1A.	<u>Risk Factors</u>	<u>22</u>
Item 1B.	<u>Unresolved Staff Comments</u>	<u>22</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>22</u>
Item 6.	<u>Exhibits</u>	<u>23</u>
	<u>Exhibit Index</u>	<u>24</u>
	<u>Signature</u>	<u>25</u>

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

VERICEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands)

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	\$ 29,777	\$ 26,862
Accounts receivable (net of allowance for doubtful accounts of \$315 and \$249, respectively)	13,162	18,270
Inventory	3,905	3,793
Other current assets	1,358	1,581
Total current assets	48,202	50,506
Property and equipment, net	4,207	4,071
Total assets	\$ 52,409	\$ 54,577
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,768	\$ 5,552
Accrued expenses	4,007	5,573
Short term deferred rent	426	420
Current portion of term loan credit agreement (net of deferred costs of \$69 and \$67, respectively)	1,597	350
Warrant liabilities	1,921	1,014
Other	159	181
Total current liabilities	13,878	13,090
Revolving and term loan credit agreement (net of deferred costs of \$185 and \$196, respectively)	15,649	16,888
Long term deferred rent	1,947	2,059
Total liabilities	31,474	32,037
COMMITMENTS AND CONTINGENCIES (Note 12)		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 36,502 and 35,861, respectively	389,074	383,020
Warrants	397	397
Accumulated deficit	(368,536)	(360,877)
Total shareholders' equity	20,935	22,540
Total liabilities and shareholders' equity	\$ 52,409	\$ 54,577

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

VERICEL CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, amounts in thousands except per share amounts)

	Three Months Ended March 31,	
	2018	2017
Product sales, net	\$ 18,027	\$ 9,361
Cost of product sales	7,666	7,109
Gross profit	10,361	2,252
Research and development	3,729	3,467
Selling, general and administrative	10,954	8,408
Total operating expenses	14,683	11,875
Loss from operations	(4,322)	(9,623)
Other income (expense):		
(Increase) decrease in fair value of warrants	(2,907)	107
Foreign currency translation (loss)	(44)	(1)
Interest income	—	1
Interest expense	(432)	(262)
Other income	46	—
Total other income (expense)	(3,337)	(155)
Net loss	\$ (7,659)	\$ (9,778)
Net loss per share attributable to common shareholders (Basic and Diluted)	\$ (0.21)	\$ (0.31)
Weighted average number of common shares outstanding (Basic and Diluted)	36,140	31,896

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

VERICEL CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, amounts in thousands)

	Three Months Ended March 31,	
	2018	2017
Operating activities:		
Net loss	\$ (7,659)	(9,778)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	427	409
Stock compensation expense	1,342	502
Change in fair value of warrants	2,907	(107)
Inventory provision	(94)	93
Loss on sales of fixed assets	22	—
Foreign currency translation loss	44	1
Deferred rent	(106)	102
Changes in operating assets and liabilities:		
Inventory	(18)	(563)
Accounts receivable	5,108	4,966
Other current assets	223	146
Accounts payable	(229)	(300)
Accrued expenses	(1,566)	1,507
Other assets and liabilities, net	4	(100)
Net cash provided by (used for) operating activities	405	(3,122)
Investing activities:		
Expenditures for property, plant and equipment	(184)	(70)
Net cash used in investing activities	(184)	(70)
Financing activities:		
Net proceeds from issuance of common stock	985	71
Deferred financing costs	(8)	—
Proceeds from exercise of warrants	1,727	—
Repayments of short-term debt	(10)	—
Other	—	(10)
Net cash provided by financing activities	2,694	61
Net increase (decrease) in cash	2,915	(3,131)
Cash at beginning of period	26,862	22,978
Cash at end of period	\$ 29,777	\$ 19,847

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE QUARTER ENDED MARCH 31, 2018 (UNAUDITED)**

1. Organization

Vericel Corporation, a Michigan corporation (the Company, Vericel, we, us or our), was incorporated in March 1989 and began employee-based operations in 1991. On May 30, 2014, Vericel completed the acquisition of certain assets and assumed certain liabilities of Sanofi, a French *société anonyme* (Sanofi), including all of the outstanding equity interests of Genzyme Biosurgery ApS (Genzyme Denmark or the Danish subsidiary) (now known as Vericel Denmark ApS), a wholly-owned subsidiary of Sanofi, and a portfolio of patents and patent applications of Sanofi and certain of its subsidiaries for purposes of acquiring the portion of the cell therapy and regenerative medicine business (the CTRM Business), which researches, develops, manufactures, markets and sells the MAC[®] and Epicel[®] products. The Company is a fully integrated, commercial-stage biopharmaceutical company and currently markets MAC[®] and Epicel[®] in the U.S. The Company is a leader in advanced cell therapies for the sports medicine and severe burn care markets and a developer of patient-specific expanded cell therapies for use in the treatment of patients with severe diseases and conditions.

The Company operates its business primarily in the U.S. in one reportable segment — the research, product development, manufacture and distribution of patient-specific, expanded cellular therapies for use in the treatment of specific diseases.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of March 31, 2018, the Company has an accumulated deficit of \$368.5 million and had a net loss of \$7.7 million during the quarter ended March 31, 2018. The Company had cash of \$29.8 million as of March 31, 2018. The Company expects that existing cash together with its term loan and revolving line of credit agreement with Silicon Valley Bank (SVB) and MidCap Financial Services (MidCap) (the SVB-MidCap facility), will be sufficient to support the Company's current operations through at least May 2019. In connection with the SVB-MidCap facility, the Company must remain in compliance with minimum monthly net revenue covenants (determined in accordance with U.S. GAAP), measured on a trailing twelve month basis. SVB and MidCap also have the ability to call debt based on material adverse change clauses which are subjectively determinable and result in a subjective acceleration clause. If the Company's cash requirements exceed its current expectations, or if it is not in compliance with the monthly net revenue covenants or the subjective acceleration clauses are triggered under the SVB-MidCap facility, then SVB may call the debt resulting in the Company immediately needing additional funds. As of March 31, 2018, the Company was in compliance with the minimum revenue covenant set forth in the Third Loan Modification Agreement between the Company, SVB and MidCap. The Company may seek additional funding through debt or equity financings including the at-the-market sales agreement in place with Cowen and Company, LLC. However, the Company may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company needs additional funds and is unable to obtain funding on a timely basis, the Company may need to significantly curtail its operations including its research and development programs in an effort to provide sufficient funds to continue its operations, which could adversely affect its business prospects.

2. Basis of Presentation

The condensed consolidated financial statements included herein have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). The preparation of condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States of America (U.S. GAAP) requires management to make estimates, judgments, and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the three months ended March 31, 2018, are not necessarily indicative of the results to be expected for the full year or for any other period. The March 31, 2018 condensed consolidated balance sheet data was derived from the Company's audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 5, 2018 (Annual Report).

Consolidated Statement of Cash Flows

The following table presents certain supplementary cash flows information for three months ended March 31, 2018 and 2017:

(In thousands)	Three Months Ended March 31,	
	2018	2017
Supplementary Cash Flows information:		
Warrants exchanged for common stock	\$ 2,000	\$ —
Interest paid (net of interest capitalized)	357	226
Additions to equipment in process included in accounts payable	401	102

3. Recent Accounting Pronouncements

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued authoritative guidance requiring entities to apply a new model for recognizing revenue from contracts with customers and the reporting of principal versus agent considerations. The guidance supersedes the current revenue recognition guidance and requires entities to evaluate their revenue recognition arrangements using a five step model to determine when a customer obtains control of a transferred good or service. The guidance became effective for the Company beginning January 1, 2018. See note 4 for further discussion.

Accounting for Leases

The FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. In accordance with the updated guidance, lessees are required to recognize the assets and liabilities arising from operating leases on the balance sheet. The guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within 2019. The Company is currently reviewing the potential impact of adopting the new guidance.

4. Revenue

Revenue Recognition and Net Product Sales

The new revenue standard became effective for the Company on January 1, 2018, and was adopted using the modified retrospective method. Based on the Company's evaluation of all of its product revenue contracts under the new revenue standard there was no cumulative adjustment recorded in the financial statements upon adoption of Accounting Standards Codification 606, *Revenue Recognition*, (ASC 606) on January 1, 2018. In addition, there is no difference in the accounting for revenue under ASC 606 versus ASC 605 (applicable revenue guidance effective until December 31, 2017) for the three months ended March 31, 2018.

The Company recognized product revenue from sales to a customer (distributor or hospital) following the five step model in ASC 606: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) the Company satisfies the performance obligation. Under the new revenue standard, the Company recognizes revenue when its customer obtains control of the promised goods, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods. There are no contractual rights of returns, refunds or similar obligations related to MACI, kits, or Epicel as of March 31, 2018; however, in certain limited cases the Company does not bill the customer for the product if a surgery is canceled and there is no impact to revenue recognized.

Currently, for MACI, kits and Epicel there are no variable pricing arrangements, warranties or rebates offered to customers. Primarily all orders are due within 60 days of delivery. Shipping and handling costs are included as a component of revenue. The Company recognizes any commission fees as an expense when incurred due to the short-term nature (less than 1 year) of the time period from order of a product to delivery. These fees are included in selling, general, and administrative expenses. There are no returns, refunds or similar obligations related to MACI, kits, or Epicel as of March 31, 2018.

MACI Kits and Implants

MACI (and previously Carticel) kits are sold directly to hospitals based on contracted rates in the approved contract or sales order. The Company recognizes MACI (or Carticel) kit revenue upon delivery of the biopsy kit at which time the customer (the doctor) is in control of the kit. The kit provides the doctor the ability to biopsy a sampling of cells to provide to the Company that can be used later to manufacture the implant. The ordering of the kit does not obligate the Company to manufacture an implant nor does the receipt of the cell tissue. The customer's order of an implant is separate from the process of ordering the kit. Therefore, the sale of the kit and any subsequent sale of an implant are distinct contracts and are accounted for separately.

The Company recognizes product revenues from sales of MACI (and previously Carticel) implants upon delivery at which time the customer is in control of the implant and the claim is billable. 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 from hospitals are based on contracted rates stated in the approved contract or purchase order. The Company's net product revenues from the third party distributor are primarily based on a contracted rate stated in the approved contract. In certain cases, the Company sells through the distributor but retains the credit and collection risk as well as the risk that a third party payer rejected a claim or reduced the allowed amount payable for an implant. The net revenue for these certain cases are based on expected payments from the insurance provider, hospital or patient. The estimates are based on publicly available rates and past payer precedents. Changes in estimates are recorded through revenue in the period such change occurs. Net product revenues from sales to distributors may include a prompt pay discount.

Epicel

The Company sells Epicel directly to hospitals based on contracted rates stated in the approved contract or purchase order. Similar to MACI, there is no obligation to manufacture skin grafts upon receipt of a skin biopsy and Vericel has no contractual right to receive payment until the product is delivered to the hospital. The Company recognizes product revenues from sales of Epicel upon delivery to the hospital at which time the customer is in control of the skin grafts and the claim is billable to the hospital.

Revenue by Product and Customer

The following table and description below shows the products from which the Company generated its revenue:

Revenue by product (in thousands)	Three Months Ended March 31,	
	2018	2017
MACI and Carticel implants and kits		
Implants - based on contracted rate	\$ 10,749	\$ 297
Implants - subject to third party reimbursement	1,008	6,385
Biopsy kits - direct bill	436	439
Change in estimates related to prior periods	(138)	(2,114)
Epicel		
Direct bill (hospital)	5,972	4,354
Total revenue	<u>\$ 18,027</u>	<u>\$ 9,361</u>

Revenue Recognition for License Grants, Milestone and Royalty Payments

The Company recognizes other revenue from contracts with customers related to license grants, milestone related payments and royalty based payments by also following the five step model described above.

Upon adoption of ASC 606, the Company reassessed the accounting for its license agreement with Innovative Cellular Therapeutics CO., LTD. (ICT) discussed in note 15. The Company identified its performance obligations under the agreement which include the license, a training obligation, and supply of certain raw materials for technology transfer. Based on its assessment of this agreement under the new revenue standard the Company determined that the license is distinct and provides ICT with the right to use the Company's technology and accordingly revenue should be recognized at the point in time at which the Company delivered the license (December 2017). This evaluation was based on 1) the rights provided to ICT under the license, including the ability to sublicense 2) the nature of the technology (primarily rights to technology already commercially approved in the US) and 3) ICT's ability to benefit from the license on its own including using its own existing resources as a manufacturer of autologous cell therapies. The transaction price was determined to be \$1.2 million. No milestones or royalties are included in the transaction price as the criteria for including these variable payments have not yet been met. The Company assessed the allocation of arrangement consideration noting no differences in allocation from that determined under ASC 605. The license was delivered in

December 2017 and revenue of \$1.2 million was recorded in 2017 under the then applicable revenue accounting standard ASC 605. Based upon the Company's evaluation under ASC 606 there was no change in amount or timing of revenue recognized for the agreement and therefore no cumulative change adjustment was recorded upon adoption of the new revenue standard on January 1, 2018. The Company's remaining performance obligations under the ICT license agreement consist of a training obligation related to technology transfer, and supply of certain raw materials for technology transfer.

The ICT license agreement provides for future milestone payments due to the Company upon the achievement of certain developmental and commercial events. The Company evaluates these milestones under the new revenue recognition standard at contract inception and at each reporting period date. Based on the Company's evaluations to date, the Company has not included any of the future milestones in its determination of the transaction price as it is not yet probable that a significant reversal of revenue would not occur if the milestones were to be recognized. This evaluation was based on 1) the pace and eventual achievement of the milestones are largely dependent on ICT's performance of its contractual obligations and the Company has no prior experience to determine the likelihood of ICT performing those obligations, and 2) the transfer of the funds for each of the milestone payments by ICT to the Company, if achieved, is subject to approval by the State Administration of Foreign Exchange of the People's Republic of China. The Company does not anticipate receiving any milestone payments in 2018 or in the near-term. Furthermore, there can be no assurance that the Company will receive any such milestone or receive any such transfer of funds from ICT ever.

The ICT license agreement contains future sales-based royalties to the Company in the low-to-mid double digits. These royalties meet the exception for sales-based or usage-based royalties because they predominantly relate to the license and will be recognized when and if the subsequent sales occur. However, there can be no assurance that the Company will receive any such royalties or receive any such transfer of funds from ICT ever.

Concentration of Credit Risk

From July 2016 through June 2017, the Company utilized a direct sales model and contracted with Dohmen Life Science Services, LLC (DLSS) to provide administrative services associated with case management and reimbursement support and to provide billing and collection services for MACI. The Company also utilized Vital Care, Inc. (Vital Care) to provide similar billing and collection services for a subset of insurance payers and patients. In the second quarter of 2017, the Company and Dohmen Life Sciences Services, LLC (DLSS) mutually terminated their agreement effective June 30, 2017. On May 15, 2017, the Company entered into a distribution agreement with Orsini Pharmaceutical Services, Inc. as a specialty pharmacy distributor of MACI and has engaged a third party services provider to provide the patient support program previously provided by DLSS and to manage patient cases for MACI. The Company's receivables risk is now more concentrated, and the concentration of credit risk also shifted for the Company. The Company sells Epicel directly to hospitals and not through a distributor. The Company's receivables are less concentrated than those for MACI.

The Company's total revenue and accounts receivable balances were comprised of the following concentrations greater than 10% from its largest customers of Carticel, MACI and Epicel, as follows:

	Revenue Concentration		Accounts Receivable Concentration	
	Three months ended March 31,		March 31,	December 31,
	2018	2017	2018	2017
MACI and Carticel ¹	43%	—%	41%	46%
Epicel	14%	16%	—%	—%

¹ Removed from market at the end of the second quarter of 2017

5. Selected Balance Sheet Components

Inventory as of March 31, 2018 and December 31, 2017:

(In thousands)	March 31, 2018	December 31, 2017
Raw materials	\$ 3,537	\$ 3,532
Work-in-process	342	226
Finished goods	26	35
Inventory	<u>\$ 3,905</u>	<u>\$ 3,793</u>

Property and equipment, net as of March 31, 2018 and December 31, 2017:

(In thousands)	March 31, 2018	December 31, 2017
Machinery and equipment	\$ 1,249	\$ 1,249
Furniture, fixtures and office equipment	872	872
Computer equipment and software	3,584	3,536
Leasehold improvements	4,255	4,213
Construction in process	1,295	822
Total property and equipment, gross	11,255	10,692
Less: Accumulated depreciation	(7,048)	(6,621)
	<u>\$ 4,207</u>	<u>\$ 4,071</u>

Depreciation expense for both the three months ended March 31, 2018 and 2017 was \$0.4 million.

Accrued expenses as of March 31, 2018 and December 31, 2017:

(In thousands)	March 31, 2018	December 31, 2017
Bonus related compensation	\$ 752	\$ 2,693
Employee related accruals	2,577	2,389
Clinical trial related accruals	678	491
	<u>\$ 4,007</u>	<u>\$ 5,573</u>

6. Stock Purchase Warrants

The Company has historically issued warrants to purchase shares of the Company's common stock in connection with certain of its common stock offerings and in September 2016 and December 2017 the Company issued warrants in connection with the amended debt agreement discussed in note 7 (collectively the Debt Warrants). The warrants issued in August 2013 (August 2013 Warrants) include anti-dilution price protection provisions that require cash settlement of the warrants and accordingly require the warrants to be recorded as liabilities of the Company at the estimated fair value at the balance sheet date, with changes in estimated fair value recorded as income or expense (non-cash) in the Company's statement of operations in each subsequent period. The following table describes the outstanding warrants as of March 31, 2018:

	August 2013 Warrants	September 2016 Warrants	December 2017 Warrants
Exercise price	\$4.80	\$2.25	\$4.27
Expiration date	August 16, 2018	September 9, 2022	December 6, 2023
Total shares issuable on exercise	365,150	117,074	53,902

During the three months ended March 31, 2018, the Company issued 359,800 shares of common stock upon the exercise of August 2013 Warrants with an exercise price of \$4.80 per share for proceeds of \$1.7 million.

On December 7, 2017, the Company issued 53,902 warrants to two holders in conjunction with the amended debt agreement described in note 7 (December 2017 Warrants). The initial valuation of the December 2017 Warrants was partially recorded as debt issuance costs and is being amortized over the remaining life of the loan agreement to interest expense and a portion was expensed as a loss on extinguishment of debt. The December 2017 Warrants are treated as equity instruments recorded at fair

value with no subsequent remeasurement. Pursuant to the December 2017 Warrants, the holders may exercise their warrants for an aggregate of 53,902 shares of the Company's common stock.

The fair value of the warrants described in the table above is measured using the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero. See further detail in note 8 of the condensed consolidated financial statements.

The assumptions used by the Company are summarized in the following tables:

August 2013 Warrants	March 31, 2018	December 31, 2017
Closing stock price	\$ 9.95	\$ 5.45
Expected dividend rate	—%	—%
Expected stock price volatility	75.4%	63.7%
Risk-free interest rate	1.95%	1.65%
Expected life (years)	0.38	0.62

September 2016 Warrants	September 9, 2016
Closing stock price	\$ 2.20
Expected dividend rate	—%
Expected stock price volatility	89.8%
Risk-free interest rate	1.4%
Expected life (years)	6.00

December 2017 Warrants	December 6, 2017
Closing stock price	5.10
Expected dividend rate	—%
Expected stock price volatility	86.4%
Risk-free interest rate	2.2%
Expected life (years)	6.00

7. Debt

On December 6, 2017, the Company replaced its existing term loan and revolving line of credit agreement with the SVB-MidCap facility which provides access to up to \$25.0 million. The updated debt financing consists of a \$15.0 million term loan which was drawn at the closing and up to \$10.0 million of a revolving line of credit. The term loans are interest only (indexed to Wall Street Journal (WSJ) Prime plus 4.25%) until December 1, 2018 followed by 36 equal monthly payments of principal plus interest maturing December 6, 2021. Under the terms of the agreement, the revolving line of credit is limited to a borrowing base calculated using eligible accounts receivable and maturing December 6, 2021 with an interest rate indexed to WSJ Prime plus 1.25%. The Company is subject to various financial and nonfinancial covenants including but not limited to a monthly minimum net revenue covenant (determined in accordance with GAAP), measured on a trailing twelve month basis. SVB and MidCap have the ability to call debt based on material adverse change clauses which are subjectively determinable and result in a subjective acceleration clause. SVB and MidCap have a shared first priority perfected security interest in all assets of the Company other than intellectual property

As of March 31, 2018, there was an outstanding balance of \$15.0 million under the term loan and \$2.5 million under the revolving line of credit (net of total deferred costs of \$0.3 million). The weighted average interest rate on the outstanding term and revolving credit loans as of March 31, 2018 was 8.6% in addition to a final payment of 3.6% of the term loan due upon maturity. The available capacity under the revolving line of credit as of as of March 31, 2018 was \$3.8 million. The Company was, and continues to be, in compliance with its financial and non-financial debt covenants.

Annual principal payments on debt at March 31, 2018, are as follows:

(In thousands)		Amount
Years Ending December 31,		
2018	\$	417
2019		5,000
2020		5,000
2021		7,083
2022		—
Thereafter		—
	\$	17,500

8. Stock-based Compensation

Stock Option and Equity Incentive Plans

The Company has historically had various stock incentive plans and agreements that provide for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants. Options granted under these plans expire no later than ten years from the date of grant, and other than those granted to non-employee directors, generally become exercisable over a four year period, under a graded-vesting methodology, following the date of grant. The Company generally issues new shares upon the exercise of stock options.

The 2017 Omnibus Incentive Plan (2017 Plan) was approved by the Company's shareholders on May 3, 2017 at the annual meeting of shareholders. The 2017 Plan provides incentives through the grant of stock options, stock appreciation rights, restricted stock awards and restricted stock units. The exercise price of stock options granted under the 2017 Plan shall not be less than the fair market value of the Company's common stock on the date of grant. The 2017 Plan replaced the 1992 Stock Option Plan, the 2001 Stock Option Plan, the Amended and Restated 2004 Equity Incentive Plan and the 2009 Second Amended and Restated Omnibus Incentive Plan (Prior Plans), and no new awards have been granted under the Prior Plans. However, the expiration or forfeiture of options previously granted under the Prior Plans will increase the number of shares available for issuance under the 2017 Plan.

As of March 31, 2018, there were 3,081,651 shares available for future grant under the 2017 Plan.

Employee Stock Purchase Plan

Employees are able to purchase stock under the Vericel Corporation Employee Stock Purchase Plan (ESPP). The ESPP allows for the issuance of an aggregate of 1,000,000 shares of common stock of which 461,434 have been granted since the inception of the plan in 2015. Participation in this plan is available to substantially all employees. The ESPP is a compensatory plan accounted for under the expense recognition provisions of the share-based payment accounting standards. Compensation expense is recorded based on the fair market value of the purchase options at the grant date, which corresponds to the first day of each purchase period and is amortized over the purchase period. On April 3, 2018, employees purchased 31,923 shares resulting in proceeds from the sale of common stock of \$0.1 million under the ESPP.

Service-Based Stock Options

During the three months ended March 31, 2018, the Company granted 1,363,310 service-based options to purchase common stock. The options have an exercise price equal to the fair market value per share of common stock on the grant date, generally vest over four years (other than non-employee options which vest over one year), and have a term of ten years. The Company issues new shares upon the exercise of stock options. The weighted average grant-date fair value of service-based options granted under the Option Plan during the three month periods ended March 31, 2018 and 2017 was \$6.63 and \$2.00, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors (including the impact of forfeitures) for the three month periods ended March 31, 2018 and 2017 were \$1.3 million and \$0.5 million, respectively.

Stock Compensation Expense

Non-cash stock-based compensation expense (employee stock purchase plan and service-based stock options) is summarized in the following table:

(In thousands)	Three Months Ended March 31,	
	2018	2017
Cost of goods sold	\$ 142	\$ 91
Research and development	475	58
Selling, general and administrative	725	353
Total non-cash stock-based compensation expense	\$ 1,342	\$ 502

The fair value of each service-based stock option grant for the reported periods is estimated on the date of the grant using the Black-Scholes option-pricing model using the weighted average assumptions noted in the following table.

Service-Based Stock Options	Three Months Ended March 31,	
	2018	2017
Expected dividend rate	—%	—%
Expected stock price volatility	82.3 – 84.4%	81.3 – 88.2%
Risk-free interest rate	2.4 – 2.8%	2 – 2.3%
Expected life (years)	6.1 – 6.3	6.1 – 6.3

9. Fair Value Measurements

The Company's fair value measurements are classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

There was no movement between level 1 to level 2 or between level 2 to level 3. The following table summarizes the valuation of the Company's financial instruments that are measured at fair value on a recurring basis:

(In thousands)	March 31, 2018				December 31, 2017			
	Total	Fair value measurement category			Total	Fair value measurement category		
		Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
Liabilities:								
Warrant liabilities	\$ 1,921	\$ —	\$ 1,921	\$ —	\$ 1,014	\$ —	\$ 1,014	\$ —

The following table summarizes the change in the estimated fair value of the Company's outstanding warrant liabilities as of March 31, 2018:

Warrant Liabilities (In thousands)	
Balance at December 31, 2017	\$ 1,014
Increase in fair value	2,907
Warrant exercise	(2,000)
Balance at March 31, 2018	\$ 1,921

The increase in fair value of warrants is due to the increase in stock price which has a direct impact to the Black-Scholes valuation model discussed in note 6.

Revolving and Term Loan Credit Agreements

At each of March 31, 2018 and December 31, 2017, the Company had a total of \$17.2 million net debt outstanding under our revolving and term loan credit agreements, which are variable rate loans. The fair value of these loans approximates book value based on the borrowing rates currently available for variable rate loans obtained from third party lending institutions. These fair values represent Level 2 under the three-tier hierarchy described above.

10. Shareholders' Equity

At-the-Market Sales Agreement

On October 10, 2016, the Company entered into its at-the-market sales agreement with Cowen (ATM Agreement), pursuant to which the Company may sell shares of its common stock through Cowen, as sales agent, in registered transactions from the Company's shelf registration statement filed in June 2015, for aggregate proceeds of up to \$25.0 million. Shares of common stock sold under the ATM are to be sold at market prices. The Company will pay up to 3% of the gross proceeds to Cowen as a commission. A total of 2,340,879 shares of common stock have been sold under the ATM Agreement of which 1,983,023 were sold in 2017 for proceeds of \$7.2 million (net of \$0.3 million in commission and issuance costs) and as of March 31, 2018 had remaining capacity of approximately \$16.7 million. There were no shares sold under the ATM Agreement during the three months ended March 31, 2018.

11. Net Loss Per Common Share

The following reflects the net loss attributable to common shareholders and share data used in the basic and diluted earnings per share computations using the two class method:

(Amounts in thousands except per share amounts)	Three months ended March 31,	
	2018	2017
Numerator:		
Net loss	\$ (7,659)	\$ (9,778)
Denominator for basic and diluted EPS:		
Weighted-average common shares outstanding	36,140	31,896
Net loss per share attributable to common shareholders (basic and diluted)	\$ (0.21)	\$ (0.31)

Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares (related to options, warrants and preferred stock) that have been excluded from the computations of diluted net loss per common share at March 31, 2018 and 2017 were \$6.2 million and \$5.0 million, respectively.

12. Commitments and Contingencies

The Company leases facilities in Ann Arbor, Michigan and Cambridge, Massachusetts. In March 2016, the Company amended its current lease in Cambridge to, among other provisions, extend the term until February 2022. Under the amendment, the landlord will contribute approximately \$2.0 million toward the cost of tenant improvements. The contribution toward the cost of tenant improvements is recorded as deferred rent on the Company's condensed consolidated balance sheet and is amortized to our condensed consolidated statement of operations as reductions to rent expense over the lease term. As of March 31, 2018, the Company has recorded \$1.7 million of leasehold improvements funded by the tenant improvement allowance.

In addition to the property leases, the Company also leases an offsite warehouse, various vehicles and computer equipment. The Company's purchase commitments consist of minimum purchase amounts of materials used in the Company's cell manufacturing process to manufacture its marketed cell therapy products.

As of March 31, 2018, future minimum payments related to leases and other contractual obligations are as follows:

(In thousands)	Total	2018	2019	2020	2021	2022	More than 5 years
Operating leases	\$ 18,444	\$ 3,679	\$ 4,710	\$ 4,699	\$ 4,595	\$ 761	—
Purchase commitments	3,244	462	718	688	688	688	—
Capital leases	101	63	14	10	10	4	—
Debt and Interest Related Payments	18,413	1,431	6,068	5,620	5,294	\$ —	\$ —
Total	\$ 40,202	\$ 5,635	\$ 11,510	\$ 11,017	\$ 10,587	\$ 1,453	\$ —

Rent expense for the three months ended March 31, 2018 and 2017 was \$1.5 million and \$1.3 million, respectively.

License Agreement

On May 10, 2017, the Company announced that it has entered into a License Agreement (License Agreement) with Innovative Cellular Therapeutics CO., LTD. (ICT), a leading cell therapy company and developer of CAR-T cell therapy for cancer treatment, for the development and distribution of the Company's product portfolio in Greater China, South Korea, Singapore, and other countries in Asia. ICT acquired an exclusive license to certain patent rights, know-how and intellectual property relating to Carticel, MACI, ixmyelocel-T, and Epicel. The remaining variable consideration, which is related to the development and commercialization milestones and royalty based payments are monitored for completion and related revenue recognition as discussed in note 4.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Vericel Corporation is a leader in advanced cell therapies for the sports medicine and severe burn care markets, and a developer of patient-specific expanded cell therapies for use in the treatment of patients with severe diseases and conditions. We currently market two FDA approved autologous 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 that was approved by the FDA on December 13, 2016. The first shipment and implantation of MACI occurred on January 31, 2017. At the end of the second quarter of 2017, we removed MACI's predecessor, Carticel[®] (autologous cultured chondrocytes), from the market. Carticel is an autologous chondrocyte implant indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea), caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft). We also market Epicel[®] (cultured epidermal autografts), a permanent skin replacement Humanitarian Use Device (HUD) for the treatment of patients with deep-dermal or full-thickness burns comprising greater than or equal to 30 percent of total body surface area (TBSA).

Manufacturing

We have a cell-manufacturing facility in Cambridge, Massachusetts which is used for U.S. manufacturing and distribution of MACI and Epicel, and also was used for manufacturing of MACI for the SUMMIT study conducted for approval in Europe and the U.S. Throughout 2016 and early 2017, we also operated a centralized cell manufacturing facility in Ann Arbor, Michigan. The Ann Arbor facility previously supported the open label extension portion of the ixCELL-DCM clinical trial conducted in the United States and Canada.

Product Portfolio

Our approved and marketed products include two approved autologous cell therapy products: MACI, a third generation autologous implant for the repair of symptomatic, full-thickness cartilage defects of the knee in adult patients and Epicel, a permanent skin replacement for full thickness burns in adults and pediatrics with greater than or equal to 30% of TBSA, both of which are currently marketed in the U.S. We also own Carticel, a first-generation product for autologous chondrocyte implantation, or ACI, which is no longer marketed in the U.S. Our product candidate portfolio includes ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to DCM.

Carticel and MACI

Carticel, a first-generation ACI product for the treatment and repair of cartilage defects in the knee, was the first FDA-approved autologous cartilage repair product. Carticel was replaced at the end of the second quarter of 2017 by MACI, which was approved on December 13, 2016 by the FDA. MACI is a third generation autologous implant for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. The first shipment and implantation of MACI occurred on January 31, 2017, and we stopped manufacturing and marketing Carticel at the end of the second quarter in 2017.

In the U.S., the physician target audience which repairs cartilage defects is very concentrated and is comprised of a group of physicians who self-identify as or have the formal specialty of sports medicine physicians. We believe this target audience is approximately 3,000 physicians. During 2017 we announced the expansion of our field force from 28 to 40 representatives, the vast majority of whom we have employed and were in the field by the beginning of the second quarter of 2018. Most private payers have a medical policy that allows treatment with MACI. All of the top 30 largest commercial payers for Carticel have a formal medical policy for MACI or ACI in general. For those private payers which have not yet approved a medical policy for MACI, for medically appropriate cases, we can often obtain approval on a case by case basis. For the three months ended March 31, 2018, net revenues were \$12.1 million for MACI.

Epicel

Epicel is a permanent skin replacement for full thickness burns greater than or equal to 30% of TBSA. Epicel is regulated by the Center for Biologics Evaluation and Research, or CBER of the Federal Drug Administration, or FDA under medical device authorities, and is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was designated as a HUD in 1998 and an HDE application for the product was submitted in 1999. HUDs are devices that are intended for diseases or conditions that affect fewer than 8,000 individuals annually in the United States. Under an HDE approval, a HUD cannot be sold for an amount that exceeds the cost of research and development, fabrication and distribution unless certain conditions are met. For the three months ended March 31, 2018, net revenues were \$6.0 million for Epicel.

A HUD is eligible to be sold for profit after receiving HDE approval if the device meets certain eligibility criteria, including where the device is intended for the treatment of a disease or condition that occurs in pediatric patients and such device is labeled for use in pediatric patients. If the FDA determines that a HUD meets the eligibility criteria, the HUD is permitted to be sold for profit as long as the number of devices distributed in any calendar year does not exceed the ADN. The ADN is defined as the number of devices reasonably needed to treat a population of 8,000 individuals per year in the United States.

On February 18, 2016, the FDA approved our HDE supplement to revise the labeled indications of use to specifically include pediatric patients and to add pediatric labeling. The revised product label also now specifies that the probable benefit of Epicel, mainly related to survival, was demonstrated in two Epicel clinical experience databases and a physician-sponsored study comparing outcomes in patients with massive burns treated with Epicel relative to standard care. Due to the change in the label to specifically include use in pediatric patients, Epicel is no longer subject to the HDE profit restrictions. In conjunction with adding the pediatric labeling and meeting the pediatric eligibility criteria, the FDA has determined the ADN number for Epicel is 360,400 which is approximately 50 times larger than the volume of grafts sold in 2017. We currently have a 5-person field force.

Ixmyelocel-T

Our preapproval stage portfolio includes ixmyelocel-T, a unique patient-specific multicellular therapy derived from an adult patient's own bone marrow which utilizes our proprietary, highly automated and scalable manufacturing system. The patient-specific multicellular therapy was developed for the treatment of advanced heart failure due to DCM.

Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM. We completed enrolling and treating patients in our completed Phase 2b ixCELL-DCM study in February, 2015. Patients were followed for 12 months for the primary efficacy endpoint of major cardiac adverse events, or MACE. On March 10, 2016, we announced the trial had met its primary endpoint of reduction in clinical cardiac events and that the incidence of adverse events, including serious adverse events, in patients treated with ixmyelocel-T was comparable to patients in the placebo group. Patients were then followed for an additional 12 months for safety. Because the trial met the primary endpoint, patients who received placebo or were randomized to ixmyelocel-T in the double-blind portion of the trial but did not receive ixmyelocel-T have been offered the option to receive ixmyelocel-T. We successfully treated the last patients in February, 2017, and the last follow-up visit will occur approximately one year later. In addition, we have conducted clinical studies for the treatment of critical limb ischemia, and an ixmyelocel-T investigator-initiated clinical study was conducted for the treatment of craniofacial reconstruction.

On September 29, 2017, the FDA indicated we would be required to conduct at least one additional Phase 3 clinical study to support a BLA for ixmyelocel-T. Given the expense required to conduct further development and our focus on growing our existing commercial products and becoming profitable, at this time we have no current plans to initiate or fund a Phase 3 trial on our own but instead are seeking a partner to fund further development.

Results of Operations

Net Loss

Our net loss for the three months ended March 31, 2018 and 2017 totaled \$7.7 million and \$9.8 million, respectively.

(In thousands)	Three Months Ended March 31,	
	2018	2017
Total revenues	\$ 18,027	\$ 9,361
Cost of product sales	7,666	7,109
Gross profit	10,361	2,252
Total operating expenses	14,683	11,875
Loss from operations	(4,322)	(9,623)
Other income (expense)	(3,337)	(155)
Net loss	\$ (7,659)	\$ (9,778)

Net Revenues

Net revenues increased for the three months ended March 31, 2018 compared to the same period the previous year due primarily to significant increases in both MACI and Epicel volume. During the three months ended March 31, 2017, we recorded a change in estimate for revenue reserves of \$2.8 million to reflect the lower reimbursement that would be obtained if certain claims are ultimately required to be treated as out-of-network.

Revenue by product (in thousands)	Three Months Ended March 31,	
	2018	2017
Carticel and MACI	\$ 12,055	\$ 5,007
Epicel	5,972	4,354
Total Revenue	\$ 18,027	\$ 9,361

Seasonality. Over the last four years the percentage of total product revenue has on average been 21%, 25%, 21% and 33% from the first to the fourth quarters and is driven by the seasonality of both MACI and Epicel sales. MACI revenue is stronger in the second quarter and fourth quarter due to a number of factors including insurance copay limits and the time of year patients prefer to start rehabilitation. Epicel revenue is also subject to seasonal fluctuations mostly associated with the use of heating elements during the colder months, with stronger sales occurring in the winter months of the first and fourth quarters, and weaker sales occurring in the hot summer months of the third quarter. However, in any single year, this trend can be absent due to the extreme variability inherent with Epicel's patient volume. The variability between the same quarters in consecutive years has been as high as 11% of the annual volume for Epicel.

Gross Profit and Gross Profit Ratio

(In thousands)	Three Months Ended March 31,	
	2018	2017
Gross profit	\$ 10,361	\$ 2,252
Gross profit %	57%	24%

Gross profit ratio increased for the three months ended March 31, 2018 compared to the same period in 2017 due primarily to an increase in MACI and Epicel sales combined with our highly fixed manufacturing cost structure.

Research and Development Costs

(In thousands)	Three Months Ended March 31,	
	2018	2017
Research and development costs	\$ 3,729	\$ 3,467

The following table summarizes the approximate allocation of cost for our research and development projects:

(In thousands)	Three Months Ended March 31,	
	2018	2017
Dilated Cardiomyopathy	\$ 556	\$ 1,948
MACI	2,421	861
Carticel	35	110
Epicel	717	548
Total research and development costs	\$ 3,729	\$ 3,467

Research and development costs for the three months ended March 31, 2018 were \$3.7 million versus \$3.5 million for the same period a year ago, primarily due to the continued increase in MACI research and development costs related to preparations for a pediatric clinical study in the U.S., which offset the ixCELL-DCM trial expenses that were incurred in 2017, as well as increased expenses related to expanding the MACI regulatory team.

Selling, General and Administrative Costs

(In thousands)	Three Months Ended March 31,	
	2018	2017
Selling, general and administrative costs	\$ 10,954	\$ 8,408

Selling, general and administrative costs for the three months ended March 31, 2018 were \$11.0 million compared to \$8.4 million for the same period a year ago. The increase in selling, general and administrative costs for the three months ended March 31, 2018 is due primarily to higher MACI sales force employee expenses of \$1.1 million from the increased MACI sales force during 2018 versus 2017 and \$0.6 million additional spend on the reimbursement and case management services. There was also an additional \$0.4 million in stock compensation expense for the three months ended March 31, 2018 compared the same period a year ago.

Other Income (Expense)

(In thousands)	Three Months Ended March 31,	
	2018	2017
Decrease (increase) in fair value of warrants	\$ (2,907)	\$ 107
Foreign currency translation loss	(44)	(1)
Other income	46	—
Net interest expense	(432)	(261)
Total other expense	\$ (3,337)	\$ (155)

The change in other income and expense for the three months ended March 31, 2018 compared to 2017 is due primarily to the change in warrant value as a result of the fluctuations in our stock price and the reduction in the time to maturity. Fluctuations in the fair value of the warrants in future periods could result in significant non-cash adjustments to the condensed consolidated financial statements; however, any income or expense recorded will not impact our cash, operating expenses or cash flow.

Stock Compensation

Non-cash stock-based compensation expense included in cost of goods sold, research and development expenses and selling, general and administrative expenses is summarized in the following table:

(In thousands)	Three Months Ended March 31,	
	2018	2017
Cost of goods sold	\$ 142	\$ 91
Research and development	475	58
Selling, general and administrative	725	353
Total non-cash stock-based compensation expense	\$ 1,342	\$ 502

The changes in stock-based compensation expense are due primarily to fluctuations in the fair value of the options granted in 2018 compared to 2017.

Liquidity and Capital Resources

We are currently focused on investing in our existing commercial business with the goal of growing revenue. Since the acquisition in 2014 of the CTRM Business of Sanofi, the sales of Carticel and Epicel therapies have constituted nearly all of our revenues. With the approval of MACI and replacement of Carticel with MACI, we expect the sales of MACI and Epicel therapies will constitute nearly all of our revenues.

We have raised significant funds in order to complete our product development programs, and complete clinical trials needed to market and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities, funds from the SVB-Mid-Cap facility and funds from our at-the-market sales agreement (ATM Agreement) with Cowen. We are obliged to pay 3% of the gross proceeds to Cowen as commission.

In 2016 we entered into an ATM Agreement with Cowen as sales agent to sell, from time to time, our common stock, no par value per share (ATM Shares), having an aggregate sale price of up to \$25.0 million, through an “at the market offering” program. The ATM Shares are issued pursuant to our shelf registration statement on Form S-3 (File No. 333-205336). We filed a prospectus supplement, dated October 10, 2016, with the Securities and Exchange Commission in connection with the offer and sale of the ATM Shares sold under the ATM Agreement. As of March 31, 2018, approximately \$16.7 million of net capacity remained under the ATM Agreement. There were no shares sold under the ATM Agreement during the three months ended March 31, 2018.

Our cash totaled \$29.8 million as of March 31, 2018. During the three months ended March 31, 2018, the cash provided by operations was \$0.4 million. The cash provided by operations was fueled largely by collections on prior quarter sales and noncash charges including \$1.3 million of stock compensation expense, \$2.9 million due to the change in fair value of warrants and \$0.4 million of depreciation expense offset by our net loss of \$7.7 million.

The change in cash used for investing activities is the result of property plant and equipment purchases of \$0.2 million for manufacturing upgrades through March 31, 2018.

The change in cash provided from financing activities is the result of proceeds from exercise of warrants of \$1.7 million and the exercise of stock options of \$1.0 million during the three months ended March 31, 2018.

We have a term loan and revolving line of credit agreement with SVB and MidCap Financial Services, or MidCap, which provide access to up to \$25.0 million. The debt financing consists of a \$15.0 million term loan which was drawn at the closing and up to \$10.0 million of a revolving line of credit. The term loans are interest only (indexed to Wall Street Journal (WSJ) Prime plus 4.25%) until December 1, 2018 followed by 36 equal monthly payments of principal plus interest maturing December 6, 2021. Per the initial terms of the agreement, the revolving credit is limited to a borrowing base calculated using eligible accounts receivable maturing December 6, 2021 with an interest rate indexed to WSJ Prime plus 1.25%. In connection with the SVB-MidCap facility, we must remain in compliance with minimum monthly net revenue covenants (determined in accordance with U.S. GAAP), measured on a trailing twelve month basis. SVB and MidCap also have the ability to call debt based on material adverse change clauses which are subjectively determinable and result in a subjective acceleration clause. We do not believe any material adverse changes have occurred. While we believe the acceleration of the due date may be reasonably possible, it is not probable and therefore, the debt is classified in current and non-current liabilities. SVB and MidCap have a shared first priority perfected security interest in all of our assets other than intellectual property. As of March 31, 2018, there was an outstanding balance of \$15.0 million under the term loan and \$2.5 million under the revolving line of credit.

While we believe that, based on our current cash on hand, we are in a position to sustain operations through at least May 2019, if actual results differ from our projections or we pursue other strategic opportunities, we may need to access additional capital. In addition, if our revenues do not meet the existing threshold set forth in the debt covenants, and we are unable to renegotiate those thresholds, SVB could call the debt immediately. Such events could result in the need for additional funds. However, we may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of our shareholders. If we need additional funds and we are unable to obtain funding on a timely basis, we may need to significantly curtail our operations including our research and development programs in an effort to provide sufficient funds to continue our operations, which could adversely affect our business prospects. Actual cash requirements may differ from projections and will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of possible acquisition or

development of complementary business activities, the cost of product launch and market acceptance of those products and commercialization of newly approved products.

Off-Balance Sheet Arrangements

At March 31, 2018, we were not party to any off-balance sheet arrangements.

Critical Accounting Policies

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The preparation of these condensed consolidated financial statements requires the application of appropriate technical accounting rules and guidance, as well as the use of estimates. The application of these policies necessarily involves judgments regarding future events. These estimates and judgments, in and of themselves, could materially impact the condensed consolidated financial statements and disclosures based on varying assumptions. The accounting policies discussed in our Form 10-K for the fiscal year ended December 31, 2017 are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. With the exception of the new revenue standard which has been discussed in note 4 to these financial statements, there have been no material changes to that information disclosed in our Annual Report during the three months ended March 31, 2018.

Forward-Looking Statements

This report, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “trends,” “opportunity,” “comfortable,” “current,” “intention,” “position,” “assume,” “potential,” “outlook,” “remain,” “continue,” “maintain,” “sustain,” “seek,” “achieve,” “continuing,” “ongoing,” “expects,” “management believes,” “we believe,” “we intend” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “could,” “may,” or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. The factors described in our Annual Report, among others, could have a material adverse effect upon our business, results of operations and financial conditions.

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These forward-looking statements include statements regarding:

- potential strategic collaborations with others;
- future capital needs and financing sources;
- adequacy of existing capital to support operations for a specified time;
- product development and marketing plans;
- regulatory filing plans;
- features and successes of our cellular therapies;
- manufacturing and facility capabilities;
- clinical trial plans, including publication thereof;
- anticipation of future losses;
- replacement of manufacturing sources;
- commercialization plans; or
- revenue expectations and operating results.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of March 31, 2018, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio. For additional information regarding our market risk, refer to Item 7A. Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company has established disclosure controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer (its “Certifying Officers”), as appropriate, to allow timely decisions regarding required disclosure.

Management of the Company, with the participation of its Certifying Officers, evaluated the effectiveness of the Company’s disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation as of March 31, 2018, our Certifying Officers concluded that the Company’s disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes in internal control over financial reporting during the quarter ended March 31, 2018 that have materially affected, or are

reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we receive threats or may be subject to litigation matters incidental to our business. However, we are not currently a party to any material pending legal proceedings.

Item 1A. Risk Factors

Certain risks described below update the risk factors discussed in Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which could materially affect our business, financial condition, results of operations, or cash flows. The risks described below and in the Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known or currently deemed to be immaterial also may materially and adversely affect our business, financial condition, results of operations or cash flows.

Because of the complexity with our manufacturing processes, we may not be able to transfer successfully such processes to ICT. If we cannot complete the transfer of our manufacturing technology, we will not be able to achieve development or commercial milestones pursuant to our License Agreement with ICT.

If we are unable to transfer our manufacturing technology for all or some of our products to ICT, we will not achieve the manufacturing technology transfer milestones set forth in our License Agreement with ICT, and consequently, we will not receive any milestone payments from ICT as contemplated by the License Agreement. If the manufacturing technology transfer is not completed, we also will not achieve the commercial milestones or receive any commercial milestone payments associated with regulatory filings or commercial sale of the products as set forth in the License Agreement. Therefore, there can be no assurance that we will receive any milestone payments from ICT ever.

Even if the manufacturing technology transfer for any or all of our products is completed with ICT, if ICT cannot complete clinical trials for a product or such clinical trials fail to demonstrate such product's safety and efficacy, we will not receive milestone payments associated with the filing of an application for regulatory approval.

In order to file for regulatory approval in an applicable territory for a product pursuant to the License Agreement, ICT will likely be required to conduct clinical trials in humans. Clinical testing is expensive, time consuming, difficult to design and conduct, and its outcomes are uncertain. If ICT cannot complete clinical testing for a product, it will not be able to file for regulatory approval. Even if ICT completes required clinical testing for a product, there is no guarantee that the clinical testing will demonstrate the product's safety and efficacy. The results of many clinical trials are subject to varying interpretations and analyses, thus a regulatory authority could reach a different conclusion than ICT regarding the results of a clinical trial and may not give its approval. If ICT cannot receive regulatory authority for a product, we will not receive the commercial milestone payments contemplated by the License Agreement.

Even if the manufacturing technology transfer is completed and ICT submits a regulatory application for product approval, ICT may not receive regulatory approval of such application and therefore ICT may not be able to commercialize a product in accordance with the License Agreement. If ICT is unable to commercialize a product, we will not receive the commercial milestone payments triggered by the first commercial sale of a product.

In the event that the manufacturing process for a product is successfully transferred to ICT and ICT is able to conduct clinical trials of the product which ICT believes demonstrates the safety and efficacy of the product, there is no guarantee that the applicable regulatory authority in the territory will approve the product, which is a pre-requisite to the product's commercialization. A regulatory authority may refuse to grant approval for a product based on many factors, which include, but are not limited to, the results of clinical trials, but also may be based on inspections of manufacturing facilities or other interpretations of applicable law. If ICT does not receive the necessary regulatory approval to commercialize the product, we will not receive the commercial milestone payments contemplated by the License Agreement to be triggered by the first commercial sale of the product.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The Company did not repurchase any of its equity securities during the quarter ended March 31, 2018.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On May 2, 2018, the Company entered into an Amended and Restated Quality Service Agreement (the “Amended Quality Agreement”) between the Company and Matricel GmbH (“Matricel”), which amends and restates in its entirety the Quality Service Agreement, dated October 20, 2015 (the “Original Quality Agreement”), between the Company and Matricel, which was previously incorporated into that certain Amended and Restated ACI-Maix Supply Agreement between the Company and Matricel, dated March 17, 2018. The Amended Quality Agreement replaces the Original Quality Agreement as Annex 1 to the Supply Agreement and sets forth the technical requirements for the final packaged products manufactured by Matricel pursuant to the Supply Agreement. The Amended Quality Agreement remains in effect for the term of the Supply Agreement.

The foregoing description of the Amended Quality Agreement is qualified in its entirety by reference to the full text of the Amended Quality Agreement a copy of which is attached as Annex 1 to the Supply Agreement, which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Item 6. Exhibits

The Exhibits listed in the Exhibit Index are filed as a part of this Quarterly Report on Form 10-Q.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
10.1†**	<u>Amended and Restated ACI-Maix Supply Agreement, dated March 17, 2018, as amended, by and between the Company and Matricel GMBH, incorporated herein by reference.</u>
31.1**	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2**	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1**	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**	<u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS**	<u>XBRL Instance Document</u>
101.SCH**	<u>XBRL Taxonomy Extension Schema Document</u>
101.CAL**	<u>XBRL Taxonomy Extension Calculation Linkbase Document</u>
101.LAB**	<u>XBRL Taxonomy Extension Label Linkbase Document</u>
101.PRE**	<u>XBRL Taxonomy Extension Presentation Linkbase Document</u>
101.DEF**	<u>XBRL Taxonomy Extension Definition Linkbase Document</u>

** Filed herewith.

† Confidential treatment has been requested as to certain portions thereto, which portions are omitted and will be filed separately with the Securities and Exchange Commission.

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, thereunto duly authorized.

Date: May 8, 2018

VERICEL CORPORATION

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

/s/ GERARD MICHEL

Gerard Michel
Chief Financial Officer and Vice President, Corporate Development
(Principal Financial Officer)

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.

EXHIBIT 10.1

Amended and Restated ACI-Maix Supply Agreement

between

Matricel GmbH, a company duly incorporated in Germany (registered under HR B 8628 in the Commercial Register of the Lower Court of Aachen) having its registered office located at Kaiserstrasse 100, 52134 Herzogenrath, Germany ("**Matricel**")

and

Vericel Corporation, a company incorporated under the laws of Michigan, having its registered office located at 64 Sidney Street, Cambridge, MA 02139, U.S.A. ("**Vericel**").

Recitals

Whereas, Matricel and Vericel entered into an ACI-Maix Supply Agreement ("**Agreement**"), in order to define the terms of their business relationship for the term of this agreement dated October 15, 2015; and

Whereas, Matricel and Vericel have agreed to amend the Agreement and wish to amend and restate the Agreement.

Now, therefore, Vericel and Matricel, intending to be legally bound, agree as follows:

1. Definitions

For the purposes of this Agreement, the following terms shall have the following meanings:

ACI-Maix-Membrane Product shall mean the sterile ACI-Maix-Membrane, a bilayered collagen membrane product derived from an animal source, as described more closely in the Quality Service Agreement (**Annex 1** to this Agreement).

Effective Date shall mean the date of the last signature of this agreement.

Final Product shall mean Vericel's autologous chondrocyte implant incorporating the ACI-Maix-Membrane Product.

Forecast shall have the meaning as defined in Section 3.3 of this Agreement.

Quality Service Agreement shall be the Agreement which forms **Annex 1** to this Agreement.

Party shall mean Vericel or Matricel, and **Parties** shall mean Vericel and Matricel.

Specifications shall have the meaning as defined in Section 2.1 of this Agreement.

Unit Price shall have the meaning as defined in Section 3.6 of the Agreement.

KEY: M = Matricel, V = Vericel

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.

2. Supply & Release Process

2.1 Specifications

During the term of this Agreement, Matricel shall supply to Vericel ACI-Maix-Membrane Products that conform to the specifications set forth in the Quality Service Agreement attached as **Annex 1 (“Specifications”)** and incorporated herein by reference according to the terms as defined herein. All ACI-Maix-Membrane Products sold hereunder shall meet the Specifications and no changes to the Specifications shall be made by Matricel without prior written approval of Vericel.

2.2 Change in Specifications

In the event that a regulatory authority requires any changes in the Specifications as a condition to authorizing the marketing of the Final Product, or any other product that incorporates the ACI-Maix-Membrane Product, the Parties shall negotiate in good faith to amend **Annex 1** as appropriate.

2.3 Shrinkage

The Parties hereby agree to the minimum acceptable surface area of ACI-Maix-Membrane Products after hydration and before cell seeding and to jointly develop a work plan related thereto as further described in **Annex 2** (incorporated herein by this reference).

2.4 [***].

- (a) [***].
- (b) [***].
- (c) [***].
- (d) [***].
- (e) [***].

3. Terms of Sale

- 3.1 Matricel shall make the ACI-Maix-Membrane Products for the exclusive use and benefit of Vericel. Matricel shall supply to Vericel the ACI-Maix-Membrane Products on an exclusive basis and in such quantities as may be ordered by Vericel by way of binding purchase orders as set forth in Section 3.3.
- 3.2 Title to, and risk of damage or loss of, the ACI-Maix-Membrane Products shall pass to Vericel upon delivery to Vericel. Matricel shall be responsible for freight, transportation, transport insurance, shipping, storage, handling, customs duty, demurrage, taxes and other similar charges using carriers, warehouses and handlers as expressly directed by Vericel, subject to reimbursement by Vericel upon being invoiced by Matricel.
- 3.3 Upon execution of the Agreement Vericel will submit an initial non-binding forecast substantially in the form of **Annex 4 (“Initial Forecast”)**. Every [***] starting with [***], Vericel shall provide Matricel with an updated non-binding realistic forecast of its supply

KEY: M = Matricel, V = Vericel

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.

requirements for ACI-Maix-Membrane Products in the [***] following the submission of the respective forecast (“**Forecast**”), which shall be substantially in the form of **Annex 4**. Generally, the Forecasts shall not constitute an obligation of the Parties of any nature. All purchases shall be made by way of binding purchase orders only. For the first calendar year following the Effective Date, the minimum purchase volume shall be [***] units of ACI-Maix-Membrane Product. For any calendar year periods subsequent to the BLA approval of the Final Product, the minimum purchase volumes shall be [***] units of ACI-Maix-Membrane Product per [***]. The purchase volumes for the first calendar year following the BLA approval of the Final Product shall be pro-rated based on the timing of the BLA approval of the Final Product. In the event that the Final Product is approved and then is not commercially available in the U.S. for reasons of product recall [***], regulatory action, or facility closure by the FDA, any minimum purchase commitments shall be suspended until Vericel is authorized again to market the Final Product in the U.S.

Vericel will accept full lots and it is anticipated that the actual number of units in a lot will vary. For planning purposes, it is anticipated that an average lot will contain [***] units. Matricel shall inform Vericel in writing of the actual number of units of ACI-Maix Membrane Product contained in each lot and shall generally ship full ACI-Maix Membrane Product lots to Vericel. Credits can be taken by Vericel for a full lot against the minimum purchase volume of ACI-Maix Membrane Products based on the number of units in each lot [***]. Subject to Section 9.5, if greater quantities of ACI-Maix-Membrane Products are requested than the amount in the Forecast for the applicable period, Matricel shall use commercially reasonable efforts to meet the increased order.

- 3.4 All full ACI-Maix-Membrane Product lots delivered to Vericel shall have a minimum of [***] of shelf life remaining prior to expiration. Smaller ACI-Maix-Membrane Product deliveries to Vericel [***] due to reasons described in Section 3.3 shall have a minimum of [***] of shelf life remaining prior to expiration. The Parties will cooperate with each other to use diligent efforts to extend the shelf life of the ACI-Maix-Membrane Product.
- 3.5 Matricel shall ship the ordered full ACI-Maix-Membrane Product lot to the following address: 64 Sidney Street, Cambridge, MA 02139, USA within [***] days of receipt of each binding purchase order. If more than one full ACI-Maix-Membrane Product lot is ordered in the binding purchase order, then each additional lot will be delivered [***] days after shipment of the previous ACI-Maix-Membrane Product lot to the address listed above. Matricel shall package the ACI-Maix-Membrane Product in a manner suitable for shipment and sufficient to withstand the effects of shipping, and consistent with Vericel’s shipping requirements and instructions, including handling during loading and unloading. Matricel shall include the following with each shipment: (i) the Vericel purchase order number, and (ii) Matricel’s lot and batch numbers.
- 3.6 All sales of the ACI-Maix-Membrane Product shall be at a net price per ACI-Maix-Membrane Product (the “**Unit Price**”) plus Value Added Tax (if applicable) according to the staggered table below:

Volume threshold per calendar year	Unit Price
[***]	[***]
[***]	[***]
[***]	[***]

KEY: M = Matricel, V = Vericel

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.

In the event that Vericel extends the term pursuant to Section 9.1, Matricel may adjust the prices on an annual basis for calendar years [***] and beyond. Upon the first extension of this Agreement, the Unit Prices as set out in this Section 3.6 will be adjusted according to the following principle: [***].

3.7 Vericel shall pay the ordered ACI-Maix-Membrane Products within [***] days from the date of respective shipment to a bank account designated by Matricel. No cash discounts are allowed and the bank transfer costs shall be paid by Vericel.

3.8 The Parties agree that Matricel shall provide to Vericel demonstration membranes, which are not subject to the Product Specifications and may only be used by Vericel for demonstration purposes and be labeled as “Not For Human Use” in accordance with the following:

Demo Membrane	Size	Membranes per package	Price (Euros)
ACI-D4050-1	4 x 5 cm	1	[***]
ACI-D2530-10	2,5 x 3 cm	10	[***]

Demo Membranes are subject to normal lead times.

3.9 In order to fulfill the FDA requirements for ACI-Maix-Membrane Product batch release relating to [***], Vericel agrees to perform the [***] and will cover the costs for this testing. In exchange, Matricel:

- (1) agrees to perform the [***] testing and will cover the costs for this testing; and
- (2) [***].

4. Regulatory Approval & Support, Audits, Consultancy

4.1 All costs (internal & external) for maintaining regulatory approval of the medical device ACI-Maix-Membrane Product in Europe (CE mark) shall be paid for by Vericel, as a pass through cost, without markup. All costs (internal & external) for achieving or maintaining regulatory approval of Matricel’s quality system for the supply of the ACI-Maix-Membrane Product to countries designated by Vericel [***] shall be paid by Vericel (internal costs: [***]). Vericel will also reimburse Matricel for additional insurance costs for the supply of the ACI-Maix-Membrane Product to countries that are not covered by Matricel’s current insurance policy. If additional service providers are needed (e.g. regulatory consultants, publishers for FDA) or if additional internal or external studies are required for the registration or approval of the Product outside the EU, for instance to demonstrate compliance with national regulations, the Parties will agree on the performance of such studies and the costs for the studies will be covered by Vericel. [***] For any costs exceeding [***], an estimate of the costs shall be first provided to Vericel by Matricel prior to the initiation of work or payment of fees.

KEY: M = Matricel, V = Vericel

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.

- 4.2 Matricel shall support the filing and approval of Vericel’s BLA for the Final Product with the United States Food and Drug Administration (“**FDA**”). Vericel may request that Matricel disclose certain Confidential Information directly to the FDA that Vericel believes will be required or that is required by FDA to be provided in the Device Master File (“**MAF**”) or by direct correspondence with the FDA. Vericel confirms that Matricel will not be obligated to make available directly to Vericel any manufacturing process information for the ACI-Maix-Membrane Product that is considered Confidential Information by Matricel. In order to support the BLA filing and approval, the Parties have agreed [***].
- 4.3 Regulatory and compliance support by Matricel personnel, shall be provided [***] in case that it is related to either the ACI-Maix-Membrane Product in Europe or the submissions to the FDA as it relates to the ACI-Maix-Membrane Product information in the BLA and/or open and closed sections of the MAF. [***] If additional regulatory and compliance support is requested for other countries designated by Vericel or for other purposes [***] then Matricel shall [***] for consulting services. No consulting services will be performed by Matricel without a prior written request from Vericel detailing the nature and scope of the services to be provided and approval by Vericel of the approximate costs of the consulting services.
- 4.4 Matricel shall keep current with FDA medical device guidelines and standards, [***].
- 4.5 Matricel will keep complete and accurate records related to the ACI-Maix-Membrane Product (“**Records**”). All original Records on the development and manufacture of ACI-Maix-Membrane Product will be retained and archived by Matricel in accordance with 21 CFR 820 medical device regulations and applicable law, but in no case for less than a period of [***] (the “**Retention Period**”). Following the Retention Period, Matricel will not destroy the Records without first giving Vericel written notice and the opportunity to further store the Records at Vericel's expense. Matricel agrees to quality audits by Vericel [***] (as described in the Quality Service Agreement) in order to ascertain the quality of ACI-Maix-Membrane Products and compliance with all applicable rules, regulations and Specifications (and related Records) during the term of this Agreement. [***].
- 4.6 [***].
- 4.7 Matricel shall provide Vericel with a current (as and when executed by the product’s manufacturer) Certificate of Analysis, Certificate of Compliance and Letter of Origin relating to the ACI-Maix-Membrane Product within [***] after Vericel's request. Such Certificate of Compliance shall be a certified statement that [***]. Matricel shall notify Vericel in writing of any changes to the Certificate of Analysis, Certificate of Compliance and Letter of Origin relating to the ACI-Maix-Membrane Product [***] upon becoming aware of any such changes from the manufacturer and shall provide an updated copy of the Certificate of Analysis, Certificate of Compliance and Letter of Origin relating to the ACI-Maix-Membrane Product [***]. Matricel shall provide Vericel with a Certificate of Analysis [***].
- 4.8 In the performance of its obligations under this Agreement, Matricel and its employees and agents (i) shall not offer to make, make, promise, authorize or accept any payment or giving anything of value, including, without limitation, bribes, either directly or indirectly to any public official, regulatory authority or anyone else for the purpose of influencing, inducing or rewarding any act, omission or decision in order to secure an improper advantage, or obtain or retain business and (ii) shall comply with all applicable anti-corruption and anti-bribery laws and regulations. Matricel and its employees and agents shall not make any payment or provide any gift to a third party in connection with Matricel's performance of this Agreement

KEY: M = Matricel, V = Vericel

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.

except as may be expressly permitted in this Agreement or a purchase order without first identifying the intended third party recipient to Vericel and obtaining Vericel's prior written approval. Matricel shall notify Vericel immediately upon becoming aware of any breach of Matricel's obligations under this Section 4.8.

5. Representations, Warranties and Non-Conforming Products

5.1 Representations and Warranties

Matricel hereby represents and warrants (selbständiges Garantieverprechen) to Vericel that

- (a) it has obtained and shall, for the term of this Agreement, maintain a CE Marking for the ACI-Maix-Membrane Product in the European Union;
- (b) any submission to Vericel or to any regulatory body in connection with the ACI-Maix-Membrane Product was made or will be made in good faith and to the best of Matricel's knowledge contained or will contain accurate and complete data and information as required by applicable laws, rules and regulations at the registered offices of the Parties;
- (c) Matricel shall transfer good title to all ACI-Maix-Membrane Product sold to Vericel, and that the ACI-Maix-Membrane Product supplied to Vericel shall (i) have been manufactured in accordance with all applicable laws, rules and regulations, including, without limitation, 21 CFR 820 medical device regulations as well as the Quality Service Agreement, and the Specifications, (ii) be of satisfactory quality and free from defects in material and workmanship, (iii) not be adulterated or misbranded under the United States Federal Food, Drug, and Cosmetic Act or other law; and
- (d) as of the date hereof, Matricel has not been debarred or is subject to debarment and will not use in any capacity in connection with the manufacture of ACI-Maix-Membrane Product, any person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or who is the subject of a conviction described in such section. Matricel agrees to inform Vericel in writing immediately if it or any person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Matricel's knowledge, is threatened, relating to the debarment or conviction of Matricel or any person used in any capacity by Matricel in connection with the manufacture of the ACI-Maix-Membrane Product.

5.2 Non-Conforming Products

- (a) Vericel may reject any ACI-Maix-Membrane Product that is not in compliance with cGMP or fails to conform to the Specifications (“**Rejected Products**”) (i) for “apparent defects,” meaning those non-conformities that are capable of detection upon a reasonable visual inspection, within [***] days after receipt of the ACI-Maix-Membrane Products; or (ii) for “latent defects,” meaning those that are not capable of detection upon a reasonable visual inspection, within [***] days from the date of discovery of such non-conformity. Vericel shall inform Matricel of such rejection by providing notice in writing (including via email)

KEY: M = Matricel, V = Vericel

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.

and shall return the Rejected Product to Matricel in accordance with Matricel's instructions. In case of a supply by Matricel of any ACI-Maix-Membrane Products that is not in compliance with cGMP or fails to conform to the Specifications, then Vericel may choose that [***]. Matricel shall not be liable for (I) any incorrect use of the ACI-Maix-Membrane Product or (II) any use of the ACI-Maix-Membrane Product without the legally required approval of the Final Product by Vericel, or a Vericel customer. ACI-Maix-Membrane Products that comply with the Specifications but do not comply with the Minimum Acceptable Surface Area After Hydration shall not be regarded as a material defect.

- (b) Section 377 of the German Commercial Code (Handelsgesetzbuch) is expressly excluded and replaced by the provisions of this Agreement and the Quality Service Agreement.

6. Risk Management

- 6.1 In the event Vericel receives information indicative of a risk relating to the use of one of its products which incorporates the ACI-Maix-Membrane Product, or of any injury or impairment of health or death of a patient, coincidental with or relating to the use of one of its products which incorporates the ACI-Maix-Membrane Product, and to the extent such risk, injury, impairment or death may be attributable to the ACI-Maix-Membrane Product, Vericel shall report within [***] days of receipt of that information by Vericel first by telephone and followed by facsimile to Matricel, any such report of risk, injury, impairment, or death. Matricel shall have a reciprocal obligation to inform Vericel upon its receipt of any information indicative of risk, injury, impairment of health or death associated with use of the ACI-Maix-Membrane Product or similar products of Matricel.
- 6.2 The Parties agree to [***] notify each other in the event either Party is the subject of any governmental or regulatory action, investigation, or sanction, or in the event any litigation is threatened or instituted against either Party [***].

7. Indemnification and Insurance

- 7.1 Vericel shall indemnify and hold Matricel harmless against all claims injuries, disabilities, losses, fines, penalties, costs, expenses (including reasonable attorneys' fees), damages or liabilities (“**Claims**”) arising out of (i) any breach by Vericel or any of its representatives of any obligation, representation, or warranty of Vericel under this Agreement, or (ii) any negligence, error, or omission by Vericel or any of its representatives with respect to its or their obligations under or by reason of this Agreement.
- 7.2 Matricel shall indemnify and hold Vericel harmless against any and all Claims arising out of (i) any breach by Matricel or any of its representatives of any obligation, representation, or warranty of Matricel under this Agreement, (ii) any negligence, error, or omission by Matricel or any of its representatives with respect to its or their obligations under or by reason of this Agreement.
- 7.3 Vericel and Matricel shall each procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with their respective obligations in the supply of the ACI-Maix-Membrane Product under this Agreement. Such insurances shall each have a coverage of at least [***] in case of damage to property and

KEY: M = Matricel, V = Vericel

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.

[***] in case of damage to a person arising out of or relating to the ACI-Maix-Membrane Product and use thereof in Vericel's products. Upon request, the Parties shall provide to each other a certificate of coverage or other written evidence reasonably satisfactory to demonstrate the continuing existence of such insurance coverage. Each Party's maximum liability to the other under this Agreement shall be limited to the amount of insurance coverage such indemnifying Party is obliged to maintain.

7.4 The Parties shall, within [***] days from the date of receipt of notice of any claims, furnish to the other Party a copy of such notice and inform the other Party of all known facts relating to such claims. The indemnifying Party shall, at its cost and expense, to defend, negotiate, and otherwise resolve any claim [***]. Each Party shall provide all information in its possession and all reasonable assistance to the other Party as necessary to enable the other Party to defend any claims.

8. Confidentiality, Non-Disclosure

8.1 Definition

During the term of this Agreement and subject to the terms and conditions of this Agreement, a Party (“**Disclosing Party**”) may communicate to the other Party (“**Receiving Party**”) information in connection with this Agreement or the performance of its obligations under this Agreement [***] (collectively, “**Confidential Information**”). The Parties acknowledge that Vericel has certain Confidential Information of Matricel in its possession that was provided to Vericel in connection with Vericel's purchase of the cartilage repair and regenerative medicine business (including, without limitation, the Final Product) from Genzyme Corporation, and that Vericel agrees to treat such information as Confidential Information under this Agreement. Matricel permits Vericel to disclose such Confidential Information to FDA or other regulatory authorities for purposes of the BLA and other regulatory submissions, audits and related interactions with regulatory authorities.

8.2 Exclusions

Notwithstanding the foregoing, any information of a Party will not be deemed Confidential Information with respect to the Receiving Party for purposes of this Agreement if, and from such point in time, where, such information:

- (a) [sic] is already known or available to the Receiving Party or any of its affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to the Receiving Party;
- (b) is generally available or known to a third party reasonably skilled in the field to which such information pertains, or is otherwise part of the public domain, at the time of its disclosure to the Receiving Party;
- (c) becomes generally available or known to a third party reasonably skilled in the field to which such information pertains, or otherwise becomes part of the public domain, after its disclosure to the Receiving Party through no fault of or breach of its obligations under this Section 8 by the Receiving Party;

KEY: M = Matricel, V = Vericel

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.

- (d) is disclosed to the Receiving Party, other than under an obligation of confidentiality or non-use, by a third party who has no obligation not to disclose such information to others; or
- (e) is independently discovered or developed by the Receiving Party, its affiliates or permitted sublicensees, as evidenced by their written records, without the use of, Confidential Information.

8.3 Disclosure and Use Restriction

Except as expressly provided herein, the Parties agree that, during the term and for [***] thereafter, each Party and any of its affiliates and sublicensees will keep completely confidential and will not publish or otherwise disclose any Confidential Information of the other Party, its affiliates or sublicensees. Neither Party will use any Confidential Information of the other Party without such other Party's consent, except in connection with performance of this Agreement.

8.4 Authorized Disclosure

Each Party may use and disclose Confidential Information of the other Party to the extent that such use and disclosure is:

- (a) made in response to a valid order of a court of competent jurisdiction or other governmental or regulatory body of competent jurisdiction; *provided, however*, that such Party will first have given notice to such other Party and given such other Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information that is the subject of such order be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued; and *provided, further, however*, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;
- (b) otherwise required by applicable law; *provided, however*, that the Disclosing Party will provide such other Party with written notice of such disclosure in advance thereof to the extent practicable;
- (c) made by such Party, in connection with the performance of this Agreement, to affiliates, permitted sublicensees, employees or consultants, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 8.

9. Term and Termination

- 9.1 The Agreement shall have effect as of the Effective Date and, unless terminated earlier pursuant to any provisions of this Agreement, will end on December 31, 2022. So long as Matricel has not delivered written notice of its decision not to renew this Agreement to Vericel by June 30, 2021, Vericel has the option to extend the term of the Agreement by five (5) additional calendar years under the same terms defined in this Agreement by sending a written confirmation of the extension to Matricel before June 30, 2022. Following such initial term and term extension by Vericel, this Agreement shall automatically renew for one

KEY: M = Matricel, V = Vericel

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.

additional five-year period unless otherwise terminated by Matricel or by Vericel in accordance with Section 9.2.

- 9.2 At any time on or after the fifth anniversary of the Effective Date, Vericel shall have the right to terminate this Agreement, for any reason, upon nine months’ prior written notice to Matricel. At any time on or after July 1, 2021, Matricel shall have the right to terminate this Agreement for any reason upon eighteen (18) months’ prior written notice to Vericel.
- 9.3 Either Party may, at its option, terminate this Agreement in the event the other Party breaches any material obligation under this Agreement and fails to remedy or otherwise cure such breach within [***] days from the date of receipt of notice of such breach given by the non-breaching Party; *provided, however*, that if the other Party cures such breach within such [***] day period, then there shall be no termination of this Agreement for such breach pursuant to this Section 9.3.
- 9.4 Either Party shall have the right to terminate this Agreement immediately by written notice to the other Party in the event the other Party presents, or has presented, a petition for its voluntary winding up or dissolution, makes an assignment for the benefit of creditors, becomes subject to an attachment of, execution upon, or other judicial seizure of all or substantially all of its assets, or becomes subject to involuntary proceedings under any bankruptcy or insolvency law which proceedings are not dismissed within sixty (60) days.
- 9.5 Upon expiration or termination of this Agreement pursuant to Section 9.1 or 9.2, Vericel shall have the option [***].
- 9.6 Upon termination of this Agreement Vericel shall have the right to use any inventory of the ACI-Maix-Membrane Product which it then has, in accordance with its normal course of business.
- 9.7 Notwithstanding the termination of this Agreement for any reason, each Party shall be entitled to recover any and all damages that such Party shall have sustained by reason of the breach by the other Party hereto of any of the terms of this Agreement.
- 9.8 Any rights and obligations of the Parties that by their terms survive termination or expiration of this Agreement or of any purchase order will survive termination or expiration, including, without limitation, Sections 2.4 (including Annex 3, if applicable), 3.2, 3.4, 4.5, 5, 6, 7, 8, 9.5, 9.6, 9.7, 9.8, and 10.

10. General Provisions

10.1 Force Majeure

Neither Party shall be liable for any delay or failure of performance of any obligation hereunder by reason of any act or circumstance beyond the control of such Party, including, without limitation, an act of God, fire, flood, war, terrorist act, public disaster, strike or labour dispute, or governmental enactment, rule or regulation; *provided, however*, that a Party asserting any excuse for delay or failure of performance shall immediately notify the other Party, be excused from such performance only to the extent of such delay or failure, take good-faith efforts to resume performance hereunder and do all things commercially reasonably possible to remove the cause of such delay or failure and mitigate its effect, and continues performance hereunder with the utmost dispatch as soon as the cause for such

KEY: M = Matricel, V = Vericel

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.

delay or failure is removed. In the event a force majeure event exists for more than [***] days, the Parties shall meet to negotiate in good faith a mutually satisfactory solution.

10.2 Non-Waiver

Neither a Party's ongoing performance of this Agreement, nor a Party's failure to exercise or enforce, or delay in exercising or enforcing, any right conferred upon it hereunder, shall be deemed to be a waiver of any such right or any other right or operate to bar the exercise or performance thereof at any time or times thereafter. A Party's waiver of any right hereunder at any time, including right to any payment, shall not be deemed a waiver thereof for any other time.

10.3 Governing Law, Jurisdiction; Arbitration

- (a) This Agreement and all issues arising under or relating to this Agreement, including, without limitation, its construction, interpretation, breach, and damages for breach, shall be governed by and construed in accordance with the laws of Germany, excluding any conflicts or choice of law rule or principles and further excluding the UN Convention for the International Sale of Goods. The Parties agree to attempt to resolve amicably any dispute, claim or controversy arising out of or relating to this Agreement or the breach, termination, enforcement, interpretation or validity thereof.
- (b) Unless specifically reserved for the competent courts of Cologne, Germany under German law, all disputes, controversies or claims arising out of or relating to the operation or interpretation of this Agreement, the Parties shall seek arbitration under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators. Each Party appoints one arbitrator and the Chamber appoints a third arbitrator who is to be the chairman of the arbitration tribunal. If a Party fails to appoint an arbitrator within thirty (30) days of having filed or received a request for arbitration, the Chamber shall appoint such arbitrator. The award rendered shall be final and binding upon both Parties. Such arbitration shall be held in Geneva, Switzerland, and be conducted in the English language. This arbitration agreement set forth herein shall be without prejudice to the right of a Party to seek any interim or conservatory measure as it deems appropriate to enforce Section 8. Each Party shall pay for the arbitrator it selects with the cost of the third arbitrator being split equally between the Parties. All other costs shall also be split equally between the Parties.

10.4 Assignment

Neither this Agreement nor any of the rights and obligations of a Party under this Agreement shall be assigned, delegated, sold, transferred, sub-contracted, sublicensed (except as otherwise provided in this Agreement), or otherwise disposed of, by operation of law or otherwise, to any Person, without the prior written consent of the other Party, and any attempted assignment, delegation, sale, transfer, sub-contract, sublicense, or other disposition, by operation of law or otherwise, of this Agreement or of any rights or obligations under this Agreement contrary to this Section 10.4 shall be deemed a material breach of this Agreement by the attempting Party, and shall be void and without force or effect. Notwithstanding the foregoing, either party may assign this Agreement in whole to a third party who acquires all or substantially all of the assets of the business to which this Agreement relates.

KEY: M = Matricel, V = Vericel

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.

10.5 Amendment

Neither this Agreement nor any provision hereof may be amended, supplemented, waived, or modified, except by a specific writing, entitled as an amendment and specifically referring to this Agreement and this Section. This Agreement may not be amended or waived by any course of conduct.

10.6 Severability

If any provision of this Agreement shall be finally determined by a court of competent jurisdiction to be illegal, invalid or unenforceable in whole or in part, then such provision shall not invalidate or render unenforceable any other provision of this Agreement. The Parties shall negotiate in good faith to replace such provision with an appropriate, legal provision and, to the extent permitted by law, hereby waive any provision of law that renders any provision of this Agreement invalid or unenforceable in any respect.

10.7 Notices

All notices required or permitted under this Agreement shall be in writing and shall be deemed to have been duly given when delivered by hand, courier, or express mail service (with written confirmation of receipt), or mailed by registered or special delivery mail, return receipt requested, at the address set forth below (or to such other person or address as a Party may, from time to time, designate by written notice):

(a) if to Vericel:

Vericel Corporation
64 Sidney Street
Cambridge, MA 02139, U.S.A.
[***]

With a copy to:
Attn: Vice President, Legal Affairs

(b) if to Matricel:

Matricel GmbH
Kaiserstrasse 100
52134 Herzogenrath
[***]

10.8 Further Assurances

Each of the Parties shall perform such acts, execute and deliver such instruments and documents, and do all such other things as may be reasonably necessary to accomplish the transactions contemplated under this Agreement.

10.9 Independent Contractor

Nothing contained in this Agreement shall be construed to constitute either Party as a partner or agent of the other Party or to create any other form of legal association that would impose liability upon a Party for any act or omission of the other Party or provide a Party with the

KEY: M = Matricel, V = Vericel

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.

right, power, or authority to create or impose any duty or obligation on the other Party, it being intended that each Party shall remain an independent contractor acting in its own name and for its own account.

10.10 Entire Agreement

This Agreement (including its Exhibits and Annexes) represents and contains the full and complete understanding and agreement of the Parties with respect to the subject matter hereof and supersedes and replaces all prior and contemporaneous agreements, understandings, statements, clauses, and conditions (both oral and written) with respect to the transactions contemplated by this Agreement or which may be contained in any other form or document.

10.11 Language

This Agreement is executed in the English language and shall be deemed to comprise the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

* * * * *

IN WITNESS THEREOF, the Parties have caused this Agreement to be duly executed as of the date first above written.

Signed for and on behalf of **Vericel Corporation**

By: /s/ Daniel Orlando
Name: Daniel Orlando
Title: COO

Date: 07 March 2018

Signed for and on behalf of **Matricel GmbH**

By: /s/ Ingo Heschel
Name: Ingo Heschel
Title: Managing Director, Matricel GmbH

Date: 17 March 2018

Annex 1: Quality Service Agreement

Annex 2: Shrinkage

Annex 3: [***]

Annex 4: Initial Forecast

KEY: M = Matricel, V = Vericel

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.

Annex 1: Quality Service Agreement

Quality Service Agreement

between

Vericel Corporation

64 Sidney Street, Cambridge, MA 02139, USA

and

Matricel GmbH

Kaiserstrasse 100, 52134 Herzogenrath, Germany

KEY: M = Matricel, V = Vericel

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.

1.0 Quality Service Agreement Signatures

Contract Giver

Vericel Corporation (“Vericel”)
64 Sidney Street
Cambridge, MA 02139
USA

Name: Cynthia Entstrasser Date: 05/02/18

/s/ Cynthia Entstrasser

Title: Senior Director

Contract Acceptor

Matricel GmbH (“Matricel”)
Kaiserstrasse 100
D-52134 Herzogenrath, Germany

Name: Leon Olde Damink Date: 18 Apr 18

/s/ Leon Olde Damink

Title: Head of Regulatory Affairs and Quality Management

Name: Ingo Heschel Date: 18 Apr 18

/s/Ingo Heschel

Title: Managing Director

2.0 Date of Issue

2.1 This Quality Service Agreement (“Quality Agreement”) is Annex 1 to the ACI-Maix Supply Agreement between Vericel and Matricel, dated October 20, 2015, as amended and restated on March 12, 2018 (“ACI-Maix Supply Agreement”), and is valid as long as this ACI-Maix Supply Agreement is in place.

Date of issue: May 2, 2018

Version: 02

Name: /s/ Ingo Heschel

Date: 18 Apr 18

3.0 Scope

3.1 This Quality Agreement constitutes the technical agreement required under European Good Manufacturing Practice (GMP) legislation 2003/94/EC Article 12, and FDA Good Manufacturing Practices 21CFR210, 211 to cover the final packaged ACI-Maix-Membrane Product manufactured by Matricel.

KEY: M = Matricel, V = Vericel

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.

3.2 This Quality Agreement fulfills the requirements of 21 CFR 820.50 Purchasing Controls.

3.3 This Quality Agreement defines the individual responsibilities of Vericel and Matricel.

4.0 Procedures for Revision

4.1 Updates and changes will be addressed in collaboration with Vericel and Matricel.

5.0 Document Revision History

Original Version
(Issue 1)

6.0 Definitions

6.1	ACI-Maix-Membrane Product	[***]
6.2	Final Product	Vericel’s autologous chondrocyte implant incorporating the ACI-Maix-Membrane Product
6.3	For Cause Audit	An audit that is initiated for a particular reason [***]
6.4	ISO 11137, Parts 1,2,3 [in the current version(s)]	Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization for Medical Devices
6.5	ISO 13485 [in the current version(s)]	Medical Devices -Quality Management Systems - Requirements for Regulatory Purposes
6.6	ISO 14644 Parts 1-5 [in the current version(s)]	Cleanrooms and associated controlled environments
6.7	Product Recall	[***]
6.8	Product Withdrawal	[***]

KEY: M = Matricel, V = Vericel

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.

7.0 QUALITY REQUIREMENTS

- 7.1 The obligations set out in this Quality Agreement shall apply to Matricel with respect to the ACI-Maix-Membrane Products manufactured by Matricel or any of its affiliates.

[***], Matricel shall supply the ACI-Maix-Membrane Product, [***] accordance with the Specifications set forth in the applicable approved applications and such other Specifications as may from time to time be established by the applicable regulatory authorities [***].

7.2 Manufacture

- 7.2.1 Premises. All ACI-Maix-Membrane Products supplied to Vericel shall be manufactured at [***].

The premises and equipment used for manufacture must be in compliance with current device GMPs as described in Section 7.2.2, current regulatory requirements, and in accordance with the documentation approved by FDA (including without limitation calibration and maintenance in a controlled state).

- 7.2.2 GMP Regulations. The current device GMP regulations to be applied are the United States cGMPs listed in Title 21 Code of Federal Regulations (“CFR”) Part 820 and associated Compliance Guidances.

- 7.2.3 Materials. Matricel is responsible for ensuring that all materials procured for use in the ACI-Maix-Membrane Products are in full compliance with the registered Specifications.

- 7.2.4 Manufacturing Documentation. Matricel will maintain original manufacturing documentation according to record retention procedure consistent with FDA requirements.

- 7.2.5 Methods. The ACI-Maix-Membrane Products shall be manufactured and tested in accordance current device GMP regulations and the information contained in the FDA Device Master File (MAF).

- 7.2.6 Batch Numbering. Matricel’s batch numbering system will be used for numbering each batch of the ACI-Maix-Membrane Products made for sale. This identification will appear on all documents relating to the particular batch of the ACI-Maix-Membrane Products. The code for batch numbering identification will be supplied to Vericel.

KEY: M = Matricel, V = Vericel

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.

7.2.7 Expiration Dating. The expiration date shall be established from [***].

7.2.8 Particulates and Size. The ACI-Maix Membrane Product must be [***].

7.3 Quality Assurance

7.3.1 Testing. Matricel is responsible for ensuring that all required in-process testing is carried out and documented. Vericel shall, on Matricel’s behalf, conduct testing of the Product for conformance with the [***] specification.

7.3.2 Certificate of Analysis (COA) and Certificate of Compliance (COC). Matricel will issue a Certificate of Analysis (COA) substantially in the form of Attachment 2, confirming that the ACI-Maix-Membrane Product has been tested, and meets the Specifications. Test specifications and test results must be included for each test. Matricel will provide a Certificate of Compliance (COC) substantially in the form of Attachment 3, stating that the finished ACI-Maix-Membrane Product has been manufactured in accordance with the approved MAF. The COA and COC shall accompany each batch of finished ACI-Maix-Membrane Product shipped from Matricel. The COA and COC may be combined into a single document provided all required information is combined therein.

7.3.3 Products Refusal. All regulations regarding handling of product refusals of the ACI-Maix-Membrane Product are covered in the ACI-Maix Supply Agreement. Written notification will be supplied to Matricel detailing the reason(s) for the refusal of the ACI-Maix-Membrane Product.

7.3.4 Documentation/Validation Batches. Matricel is responsible for generating a validation package that includes: (1) the validation protocol, (2) full batch document packages, (3) all validation data, and (4) validation report for all validation batches of the ACI-Maix-Membrane Product manufactured.

7.3.5 Retained Samples. Matricel will retain sufficient samples of the product to carry out [***] full specification test of the ACI-Maix-Membrane Product.

7.3.6 Inspections. In the event that Matricel’s Facilities used in the manufacturing of ACI-Maix-Membrane Product hereunder are inspected [***], for the specific purpose of inspecting Matricel’s manufacture of the ACI-Maix-Membrane Product for Vericel, Matricel shall notify Vericel [***], upon learning of such inspection, and shall inform Vericel [***]. In the event that any such inspection relates to other products manufactured in Matricel’s Facilities, Matricel shall inform Vericel [***]. Matricel may ask for Vericel’s regulatory and QA support during an FDA inspection related to the ACI-Maix-Membrane Product in

KEY: M = Matricel, V = Vericel

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.

connection with the BLA review in order to assist in responding to FDA questions related to the open sections of the MAF. [***]. Matricel will notify Vericel, within [***] days, of any request made by a regulatory authority for ACI-Maix-Membrane Product samples or batches.

7.3.7 Audits

Matricel agrees to quality audits by Vericel [***].

After the conclusion of any audit Matricel will be informed in writing of the specific audit results, and will develop and execute a corrective action plan within [***] in response to any audit finding. This plan and follow-up corrective actions are subject to mutual agreement of the parties.

7.3.8 Corrective Actions from Audits

Critical defects (Substantial cGMP deficiency). In the event “Critical” defects are discovered during audits by either Vericel or a regulatory authority [***].

Other defects. In the case of other defects (minor cGMP issues) arising during audits by Vericel or regulatory authorities [***].

7.3.9 Recalls/Complaints/Adverse Events

Recalls. [***] shall initiate and implement a recall of the Final Product, whether such recall is voluntarily or requested by the regulatory authorities in accordance with the approved SOP. [***].

Complaints. Vericel will forward all the complaints related to the ACI-Maix-Membrane Product to Matricel within [***] days from the date received by Vericel’s Quality Assurance Department. Matricel will initiate an investigation according to its standard operating procedure. A written report of the investigation shall be sent to Vericel within [***] days of the forwarded complaint. Vericel shall respond directly to all complaints.

Adverse Events. All adverse events will be handled in accordance with Attachment 1 of the Quality Agreement.

7.3.10 Change Control and Deviations

Change Control. Matricel shall comply with GMP regulations in its change control procedures. Matricel shall provide prior written notice to Vericel of proposed changes to the ACI-Maix-Membrane Product [***].

Deviations.

KEY: M = Matricel, V = Vericel

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.

Matricel shall notify Vericel [***] of any planned deviations from the manufacturing process. In such a case the provisions of Attachment 1, Section 5.4 shall apply.

Matricel will record any unplanned deviations from the manufacturing process and/or testing of the ACI-Maix-Membrane Product in the batch/testing records. Matricel shall notify Vericel [***] of any confirmed quality-relevant deviations from the manufacturing process. [***]. In such a case the provisions of Attachment 1, Section 5.2 shall apply.

7.3.11 Failures Investigation. Matricel shall investigate any test result or in-process test which fails to meet specification and use [***] to determine the root cause. In case the failure results in a quality-relevant deviation [***].

The investigation must determine [***]. Additional, sampling, testing and checks may be performed in accordance with Matricel procedures and FDA guidance.

7.3.12 Annual Management Reviews. Matricel is responsible for [***] preparing the management review of the ACI-Maix-Membrane Product manufactured at Matricel. A copy shall be provided to Vericel.

7.4 Validation

7.4.1 Process. Matricel is responsible for ensuring that the manufacturing process is validated before any routine production can start. The validation should ensure that the process is capable of consistently meeting the ACI-Maix-Membrane Product Specifications. Validation protocols and reports shall be available for Vericel’s review upon request. Prior to a request for document inspection by Vericel, Matricel may redact any sensitive confidential information contained in the relevant document.

7.4.2 Equipment Cleaning. Matricel is responsible for ensuring that adequate cleaning is carried out for each manufactured ACI-Maix-Membrane Product. The cleaning process will be validated before the first ACI-Maix-Membrane Product batches are made for Vericel. All analytical methods for testing of the cleaning samples, including recovery studies shall be validated per documented protocols and reports which comply with ICH and USP guidelines, as applicable. Validation protocols and reports shall be available for Vericel’s review upon request. Prior to a request for document inspection by Vericel, Matricel may redact any sensitive confidential information contained in the relevant document.

KEY: M = Matricel, V = Vericel

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.

7.4.3 Computer System. Any electronic records will be stored in such a manner as to maintain their traceability, reliability and integrity throughout the required record keeping timeframes established in the applicable regulations.

7.5 Storage and Shipping

Matricel will ensure that during packaging, storage and shipment of the Product that there is [***]. Matricel will also notify Vericel [***] months prior to bringing additional products into the same area of Matricel’s Facilities where the ACI-Maix-Membrane is produced [***]. Matricel will only ship goods to facilities designated by Vericel.

7.6 Termination

The term of this Quality Agreement shall be for the period beginning with the Effective Date and shall remain in effect for the term of the ACI-Maix Supply Agreement between the parties. At any time on or after the fifth anniversary of the Effective Date, Vericel shall have the right to terminate the ACI-Maix Supply Agreement, for any reason, upon nine months’ prior written notice to Matricel. At any time on or after July 1, 2021, Matricel shall have the right to terminate the ACI-Maix Supply Agreement for any reason upon eighteen months’ prior written notice to Vericel. Upon such termination or expiration of the ACI-Maix Supply Agreement, this Quality Agreement will terminate automatically.

7.7 Miscellaneous

7.7.1 Amendment. This Quality Agreement may only be amended or modified by a written instrument executed by both parties hereto.

7.7.2 Assignment. This Quality Agreement shall inure to the benefit of, and shall be binding upon each of, the parties hereto and their respective successors and permitted assigns; provided, and only in accordance with the provisions and restrictions on assignment contained therein which are hereby incorporated by reference.

7.7.3 Severability. In the event that any one or more of the Quality Agreement’s provisions or terms contained herein shall be declared invalid, illegal or unenforceable in any respect, the validity of the remaining provisions herein shall in no way be affected, prejudiced or invalidated thereby.

7.7.4 Entire Agreement. This Quality Agreement, together with the Appendix hereto contains the entire agreement between the parties hereto and supersedes any agreements between them with respect to the subject matter hereof.

KEY: M = Matricel, V = Vericel

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.

7.7.5 Section Headings. The section headings contained in this Quality Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Quality Agreement.

7.7.6 Counterparts. This Quality Agreement may be executed in any number of separate counterparts, each of which shall be deemed to be an original, but which together shall constitute one and the same instrument.

7.7.7 Governing Law, Jurisdiction. This Quality Agreement and all issues arising under or relating to this Quality Agreement, including, without limitation, its construction, interpretation, breach, and damages for breach, shall be governed by and construed in accordance with the laws of Germany, excluding any conflicts or choice of law rule or principles and further excluding the UN Convention for the International Sale of Goods. The parties agree to attempt to resolve amicably any dispute, claim or controversy arising out of or relating to this Quality Agreement or the breach, termination, enforcement, interpretation or validity thereof.

7.7.8 Arbitration. Unless specifically reserved for the competent courts of Cologne, Germany under German law, all disputes, controversies or claims arising out of or relating to the operation or interpretation of this Quality Agreement, the parties shall seek arbitration under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators. Each party appoints one arbitrator and the Chamber appoints a third arbitrator who is to be the chairman of the arbitration tribunal. If a party fails to appoint an arbitrator within thirty (30) days of having filed or received a request for arbitration, the Chamber shall appoint such arbitrator. The award rendered shall be final and binding upon both parties. Such arbitration shall be held in Geneva, Switzerland, and be conducted in the English language. This arbitration agreement set forth herein shall be without prejudice to the right of a party to seek any interim or conservatory measure as it deems appropriate to enforce Section 8 of the ACI-Maix Supply Agreement. Each party shall pay for the arbitrator it selects with the cost of the third arbitrator being split equally between the parties. All other costs shall also be split equally between the parties.

KEY: M = Matricel, V = Vericel

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.

8.0 Table of Contents

1.0	Quality Service Agreement Signatures	2
2.0	Date of Issue	2
3.0	Scope	2
4.0	Procedures for Revision	3
5.0	Document Revision History	3
6.0	Definitions	3
7.0	Quality Requirements	4
8.0	Table of Contents	11
9.0	Quality Responsibility Matrix (See Attachment 1)	11

9.0 Quality Responsibility Matrix (See Attachment 1)

Attachment 1	12	
1.0	Quality System Requirements	12
2.0	Regulatory Affairs (Actions, and Inspections)	12
3.0	Production and Validation	12
4.0	Design/Change Control	13
5.0	Deviations and Out of Specification Management	13
6.0	Materials	13
7.0	Lot Number Assignment and Expiration Dating Assignment	14
8.0	Testing, Analysis, and Assay Validation	14
9.0	Product Release	14
10.0	Records Required for Release and submitted to Vericel	15
11.0	Product Complaints and Adverse Events	15
12.0	Product Recall and Product Withdrawal	15
13.0	Storage, Transportation, and Distribution	15
14.0	Contract Manufacturing/Testing	15
Attachment 2 - Certificate of Analysis and Certificate of Compliance	17	
Appendix 1 - List of Contacts	19	

KEY: M = Matricel, V = Vericel

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.

Attachment 1

1.0 Quality System Requirements

Both Parties agree to the following listed responsibilities for all the operations that are marked with “√” in the respective column that bears their name.

Ref	Description of Activity	M	V
1.1	[***]		
1.2	[***]		
1.3	[***]		
1.4	[***]		

2.0 Regulatory Affairs (Actions, and Inspections)

Ref	Description of Activity	M	V
2.1	[***]		
2.2	[***]		
2.3	[***]		
2.4	[***]		

3.0 Production and Validation

Ref	Description of Activity	M	V
3.1	[***]		
3.2	[***]		
3.3	[***]		
3.4	[***]		
3.5	[***]		
3.6	[***]		
3.7	[***]		
3.8	[***]		
3.9	[***]		
3.10	[***]		
3.11	[***]		

4.0 Design/Change Control

Ref	Description of Activity	M	V
4.1	[***]		
4.2	[***]		

5.0 Deviations and Out of Specification Management

KEY: M = Matricel, V = Vericel

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.

Ref	Description of Activity	M	V
5.1	[***]		
5.2	[***]		
5.3	[***]		
5.4	[***]		
5.5	[***]		

6.0 Materials

Ref	Description of Activity	M	V
6.1	[***]		
6.2	[***]		
6.3	[***]		
6.4	[***]		
6.5	[***]		

7.0 Lot Number Assignment & Expiration Dating Assignment

Ref	Description of Activity	M	V
7.1	[***]		
7.2	[***]		
7.3	[***]		

8.0 Testing, Analysis and Assay Validation

Ref	Description of Activity	M	V
8.1	[***]		
8.2	[***]		
8.3	[***]		
8.4	[***]		
8.5	[***]		
8.6	[***]		

9.0 Product Release

Ref	Description of Activity	M	V
9.1	[***]		
9.2	[***]		
9.3	[***]		
9.4	[***]		
9.5	[***]		
9.6	[***]		

KEY: M = Matricel, V = Vericel

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.

10.0 Records Required for Release and submitted to Vericel

Ref	Description of Activity	M	V
10.1	[***]		
10.2	[***]		1

11.0 Product Complaints and Adverse Events

Ref	Description of Activity	M	V
11.1	[***]		
11.2	[***]		
11.3	[***]		
11.4	[***]		
11.5	[***]		

12.0 Product Recall and Withdrawal

Ref	Description of Activity	M	V
12.1	[***]		
12.2	[***]		
12.3	[***]		

13.0 Storage, Transportation, and Distribution

Ref	Description of Activity	M	V
13.1	[***]		
13.2	[***]		
13.3	[***]		

14.0 Contract Manufacturing/Testing

Ref	Description of Activity	M	V
14.1	[***]		
14.2	[***]		
14.3	[***]		
14.4	[***]		

KEY: M = Matricel, V = Vericel

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.

**Attachment 2
Certificate of Analysis**

NON-STERILE FINISHED PRODUCT TESTING

Test	Specification	Result
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	

STERILE FINISHED PRODUCT TESTING

Test	Specification	Result
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	

KEY: M = Matricel, V = Vericel

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.

Attachment 3

Certificate of Compliance
ACI-Maix collagen membrane

Lot number: ACIMAIX- Expiration date: _____

[***]

[***]

[***]

[***]

[***]

[***]

[***]

Head of Manufacturing: _____ Date:

Head of Quality Management: _____ Date:

KEY: M = Matricel, V = Vericel

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.

Appendix 1 - List of Contacts

Vericel				
	Name	Telephone Number	e-mail	Title
1				[***]
2				[***]

Matricel				
	Name	Telephone Number	e-mail	Title
1				[***]
2				[***]
3				[***]

KEY: M = Matricel, V = Vericel

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.

Annex 2: Shrinkage

The Parties hereby agree to the following provisions regarding shrinkage:

- (a) Dry ACI-Maix-Membrane Products are [***]. To be acceptable for use in the Final Product ("**Usable ACI-Maix-Membrane Product**"), the minimum acceptable surface area of ACI-Maix-Membrane Products after hydration and before cell seeding is [***] ("**Minimum Acceptable Surface Area After Hydration**"). [***] cannot be utilized in Final Product and will need to be discarded ("**Unusable ACI-Maix-Membrane Product**").
- (b) At the time of execution of this Agreement, an appropriate shrinkage specification for inclusion in the Quality Service Agreement has not been determined by the Parties.
- (c) Vericel and Matricel will jointly develop a work plan [***]. At the successful completion of this work, the Specifications and Quality Service Agreement shall be amended to include the jointly defined shrinkage release criterion.
- (d) For the time period between the execution of this Agreement and the execution of the amendment to the Specifications and Quality Service Agreement [***] the following provisions shall apply:
 - (i) [***].
 - (ii) [***].
 - (iii) [***]
 - a. [***].
 - b. [***].

[***].

KEY: M = Matricel, V = Vericel

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.

Annex 3: [***]

[***].

Annex 4: Initial Forecast

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

KEY: M = Matricel, V = Vericel

CERTIFICATION

I, Dominick C. Colangelo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vericel Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2018

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Gerard Michel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vericel Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2018

/s/ GERARD MICHEL

Gerard Michel

*Chief Financial Officer and Vice President, Corporate Development
(Principal Financial Officer)*

**18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Vericel Corporation (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

- (1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2018

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Vericel Corporation and will be retained by Vericel Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

**18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Vericel Corporation (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

- (1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2018

/s/ GERARD MICHEL

Gerard Michel

*Chief Financial Officer and Vice President, Corporate Development
(Principal Financial Officer)*

A signed original of this written statement required by Section 906 has been provided to Vericel Corporation and will be retained by Vericel Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

