
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: September 30, 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 every Interactive Data File required to be submitted 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 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 -

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)

43,347,348

Outstanding at November 2, 2018

VERICEL CORPORATION
QUARTERLY REPORT ON FORM 10-Q
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 53,289	\$ 26,862
Short term investments	44,462	—
Accounts receivable (net of allowance for doubtful accounts of \$286 and \$249, respectively)	15,528	18,270
Inventory	3,638	3,793
Other current assets	2,339	1,581
Total current assets	119,256	50,506
Property and equipment, net	5,207	4,071
Total assets	\$ 124,463	\$ 54,577
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,580	\$ 5,552
Accrued expenses	5,592	5,573
Deferred rent	534	420
Current portion of term loan credit agreement (net of deferred costs of \$69 and \$67, respectively)	4,097	350
Warrant liabilities	—	1,014
Other	189	181
Total current liabilities	14,992	13,090
Revolving and term loan credit agreement (net of deferred costs of \$150 and \$196, respectively)	13,183	16,888
Deferred rent	1,813	2,059
Total liabilities	29,988	32,037
COMMITMENTS AND CONTINGENCIES (Note 13)		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 43,170 and 35,861, respectively	468,447	383,020
Other comprehensive loss	(18)	—
Warrants	302	397
Accumulated deficit	(374,256)	(360,877)
Total shareholders' equity	94,475	22,540
Total liabilities and shareholders' equity	\$ 124,463	\$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product sales, net	\$ 22,484	\$ 14,260	\$ 59,522	\$ 40,574
Cost of product sales	8,138	7,186	23,531	21,965
Gross profit	14,346	7,074	35,991	18,609
Research and development	3,113	2,919	10,581	9,357
Selling, general and administrative	12,569	8,186	35,314	25,427
Total operating expenses	15,682	11,105	45,895	34,784
Loss from operations	(1,336)	(4,031)	(9,904)	(16,175)
Other income (expense):				
Decrease (increase) in fair value of warrants	420	(1,060)	(2,524)	(512)
Foreign currency translation loss	—	(6)	(49)	(20)
Interest income	307	2	390	6
Interest expense	(460)	(317)	(1,340)	(878)
Other income	—	5	48	6
Total other income (expense)	267	(1,376)	(3,475)	(1,398)
Net loss	\$ (1,069)	\$ (5,407)	\$ (13,379)	\$ (17,573)
Net loss per share attributable to common shareholders (Basic and Diluted)	\$ (0.02)	\$ (0.16)	\$ (0.34)	\$ (0.54)
Weighted average number of common shares outstanding (Basic and Diluted)	42,925	33,667	39,163	32,783

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

VERICEL CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited, amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	\$ (1,069)	\$ (5,407)	\$ (13,379)	\$ (17,573)
Other comprehensive loss:				
Net change in unrealized loss on investments	\$ (18)	\$ —	\$ (18)	\$ —
Comprehensive loss	\$ (1,087)	\$ (5,407)	\$ (13,397)	\$ (17,573)

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)

	Nine Months Ended September 30,	
	2018	2017
Operating activities:		
Net loss	\$ (13,379)	(17,573)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization expense	1,133	1,186
Stock compensation expense	5,739	2,053
Change in fair value of warrants	2,524	512
Inventory provision	303	232
Loss on sale of fixed assets	23	—
Foreign currency translation loss	49	20
Change in operating assets and liabilities:		
Inventory	(148)	(793)
Deferred rent	(132)	91
Accounts receivable	2,742	1,663
Prepaid and other current assets	(758)	(202)
Accounts payable	(1,212)	(1,068)
Accrued expenses	19	(9)
Other assets and liabilities, net	74	(129)
Net cash used for operating activities	<u>(3,023)</u>	<u>(14,017)</u>
Investing activities:		
Purchases of short term investments	(44,480)	—
Expenditures for property, plant and equipment	(2,101)	(792)
Net cash used in investing activities	<u>(46,581)</u>	<u>(792)</u>
Financing activities:		
Net proceeds from equity offering	70,028	—
Net proceeds from common stock issuance due to stock option exercises	3,310	7,549
Proceeds from exercise of warrants	2,716	—
Other	(23)	(252)
Net cash provided by financing activities	<u>76,031</u>	<u>7,297</u>
Net increase (decrease) in cash and cash equivalents	26,427	(7,512)
Cash and cash equivalents at beginning of period	26,862	22,978
Cash and cash equivalents at end of period	<u>\$ 53,289</u>	<u>\$ 15,466</u>

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 SEPTEMBER 30, 2018 (UNAUDITED)**

1. Organization

Vericel Corporation, a Michigan corporation (together with its consolidated subsidiaries referred to herein as 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), related to the MACI[®], Carticel[®] and Epicel[®] products. The Company is a fully integrated, commercial-stage biopharmaceutical company and currently markets MACI[®] 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. 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, the Company 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). The Company also markets 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). 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 September 30, 2018, the Company has an accumulated deficit of \$374.3 million and had a net loss of \$1.1 million during the quarter ended September 30, 2018. The Company had cash and cash equivalents of \$53.3 million, and short term investments of \$44.5 million as of September 30, 2018. The Company expects that existing cash, cash equivalents and short term investments 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 November 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 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. As of September 30, 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. 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.

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 and nine months ended September 30, 2018, are not necessarily indicative of the results to be expected for the full year or for any other period. The September 30, 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 the nine months ended September 30, 2018 and 2017:

(In thousands)	Nine Months Ended September 30, 2018	
	2018	2017
Supplementary Cash Flows information:		
Warrants exercised for common stock	\$ 3,538	\$ —
Interest paid (net of interest capitalized)	1,161	691
Shares converted to common from preferred stock	—	38,389
Additions to equipment in process included in accounts payable	191	486

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 superseded the then-applicable 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 has evaluated its leasing arrangements under the issued guidance and determined all leases are classified as operating leases and will be recognized as assets and future payments as liabilities on the balance sheet. Based on the Company's evaluation to date, the Company expects that the adoption of the new leasing standards will result in the recognition of material right-to-use assets and liabilities in the Company's condensed consolidated balance sheet. The adoption of the new leasing standards is not expected to have a material impact to the Company's condensed consolidated statements of income.

Accounting for Non-Employee Share Based Payment Arrangements

The FASB issued guidance to expand the scope of stock compensation guidance to include stock compensation granted to nonemployees. Previously, stock compensation granted to nonemployees was subject to vesting date, as opposed to grant date, fair value principles that required companies to re-measure fair value at each reporting period until settlement for equity classified awards. The guidance for non-employee stock compensation accounting for equity-classified awards was updated, and these awards are now subject to fixed grant date fair value principles which eliminates the variable mark-to-market accounting. The non-employee stock awards granted by the Company have a service condition but no performance condition, each of which is measured using the Black-Scholes valuation model. The guidance was adopted early and applied as of July 1, 2018 and reflected in the Company's financial statements. The impact upon adoption was not material and no cumulative adjustment was recorded.

Measuring Credit Losses on Financial Instruments

The FASB issued updated guidance on measuring credit losses on financial instruments. The guidance removes the thresholds that companies apply to measure credit losses on financial instruments measured at amortized cost, such as loans, receivables, and held-to-maturity debt securities. Prior to the updated guidance, credit losses are recognized when it is probable that the loss has been incurred. The revised guidance removes all recognition thresholds and requires companies to recognize an allowance for credit losses for the difference between the amortized cost basis of a financial instrument and the amount of amortized cost that

a company expected to collect over the instrument's contractual life. The guidance is effective for annual reporting periods beginning after December 15, 2019. The Company is currently in the process of evaluating the impact to its consolidated financial statements.

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. For the three and nine months ended September 30, 2018, the timing and amount of revenue recognized under ASC 606 is not materially different from that under the previous guidance.

The Company recognizes 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 this 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 September 30, 2018; however, in certain limited cases the Company will accept a product return if a surgery is canceled. Revenue is not recognized in these cases, and historically such amounts have been insignificant.

Currently, for MACI, MACI kits and Epicel there are no variable pricing arrangements related to warranties or rebates offered to customers. The majority of orders are due within 60 days of delivery. Shipping and handling fees 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 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, MACI kits, or Epicel as of September 30, 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. As noted above, the Company's net product revenues are based on contracted rates or estimated based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or 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.

On July 25, 2018 and August 10, 2018, the Company entered into amendments to its distribution agreement with Orsini Pharmaceutical Services, Inc. (Orsini). The amendments modified certain payment terms for surgeries after June 15, 2018. In addition, under the revised agreement, the parties agreed to eliminate Orsini's right to serve as the Company's exclusive distributor for MACI as the Company is moving to a limited expanded network of distributors. Orsini remains the exclusive pharmacy supplying MACI for only an enumerated list of payers. The amended agreement includes a provision whereby the Company retains the credit and collection risk from the end customer on implants after June 15, 2018. Orsini performs the collection activities. The net product revenues for these cases are based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or past payer precedents. Changes in estimates are recorded through revenue in the period such change occurs.

Pursuant to the revised arrangement, the Company will pay Orsini a dispensing fee on a per implant basis. In addition, in consideration of Orsini's future administrative services related to the amendment, the Company has agreed to pay Orsini an incremental fee of approximately \$1.3 million which will be paid as a service fee based on a fixed number of MACI cases subsequent to the date of amendment with any unpaid amount due to Orsini at June 30, 2019 or upon termination of the agreement by the Company, if earlier.

On July 26, 2018, the Company entered into a Dispensing Agreement (Dispensing Agreement) with AllCare Plus Pharmacy, Inc. (AllCare). Pursuant to the Dispensing Agreement, the Company appoints AllCare as a non-exclusive specialty pharmacy provider of MACI. The Company will pay to AllCare a fee for each patient to whom MACI is dispensed. Under the Dispensing Agreement, the Company retains the credit and collection risk from the end customer on all implants. The net product revenues for these cases are based on contracted rates stated in the approved contract or other documentation with the insurance provider, hospital or patient.

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
MACI and Carticel implants and kits				
Implants - based on contracted rate	\$ 243	\$ 8,046	\$ 18,354	\$ 11,145
Implants - subject to third party reimbursement	15,593	1,079	23,156	15,172
Biopsy kits - direct bill	488	412	1,392	1,274
Change in estimates related to prior periods	125	372	(273)	230
Epicel				
Direct bill (hospital)	6,035	4,351	16,893	12,753
Total revenue	\$ 22,484	\$ 14,260	\$ 59,522	\$ 40,574

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 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 because 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 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 and credit risk became more concentrated from June 30, 2017 through June 15, 2018 due to the shift from DLSS to Orsini. Beginning June 16, 2018, the concentration of risk decreased because the Company retains the credit and collection risk from the end customer on implants after June 15, 2018. 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 from its largest customers of Carticel, MACI and Epicel, as follows:

	Revenue Concentration				Accounts Receivable Concentration	
	Three Months Ended September 30,		Nine Months Ended September 30,		September 30,	December 31,
	2018	2017	2018	2017	2018	2017
MACI and Carticel ¹	<10%	55%	24%	25%	<10%	46%
Epicel	<10%	10%	<10%	13%	<10%	<10%

¹ Carticel was removed from the market at the end of the second quarter of 2017.

5. Selected Balance Sheet Components

Inventory as of September 30, 2018 and December 31, 2017:

(In thousands)	September 30, 2018	December 31, 2017
Raw materials	\$ 3,130	\$ 3,532
Work-in-process	456	226
Finished goods	52	35
Inventory	\$ 3,638	\$ 3,793

Property and equipment, net as of September 30, 2018 and December 31, 2017:

(In thousands)	September 30, 2018	December 31, 2017
Machinery and equipment	\$ 1,424	\$ 1,249
Furniture, fixtures and office equipment	757	872
Computer equipment and software	3,695	3,536
Leasehold improvements	4,459	4,213
Construction in process	2,084	822
Total property and equipment, gross	12,419	10,692
Less: Accumulated depreciation	(7,212)	(6,621)
	\$ 5,207	\$ 4,071

Depreciation expense for the three and nine months ended September 30 2018 was \$0.3 million and \$1.1 million, respectively, and \$0.4 million and \$1.2 million, for the same periods in 2017.

Accrued expenses as of September 30, 2018 and December 31, 2017:

(In thousands)	September 30, 2018	December 31, 2017
Bonus related compensation	\$ 2,180	\$ 2,693
Employee related accruals	2,955	2,389
Other accrued expenses	457	491
	<u>\$ 5,592</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) expired in August 2018, and included anti-dilution price protection provisions that required cash settlement of the warrants and accordingly required 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 September 30, 2018:

	September 2016 Warrants	December 2017 Warrants
Exercise price	\$2.25	\$4.27
Expiration date	September 9, 2022	December 6, 2023
Total shares issuable on exercise	58,537	53,902

During the nine months ended September 30, 2018, the Company issued 565,895 and 45,625 shares of common stock upon the exercise of August 2013 and September 2016 Warrants with an exercise price of \$4.80 and \$2.25 per share, respectively for proceeds of \$2.7 million. As of September 30, 2018, the unexercised August 2013 warrants expired and no August 2013 warrants are outstanding.

The fair value of the warrants described in the table above were initially 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.

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 loan is 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 September 30, 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 \$0.2 million). The weighted average interest rate on the outstanding term and revolving credit loans as of September 30, 2018 was 9.07% 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 September 30, 2018 was \$7.5 million. The Company was, and continues to be, in compliance with its financial and non-financial debt covenants.

Annual principal payments on debt at September 30, 2018, are as follows:

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

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 to employees and non-employees under these plans expire no later than ten years from the date of grant and 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.

For certain non-employee consultants, stock option awards continue to vest post-termination. The guidance for non-employee stock compensation accounting for equity-classified awards was updated, and these awards are now subject to fixed grant date fair value principles which eliminates the variable mark-to-market accounting. The options were valued as of the adoption date July 1, 2018.

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 September 30, 2018, there were 2,917,614 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 507,613 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 October 1, 2018, employees purchased 21,937 shares resulting in proceeds from the sale of common stock of \$0.2 million under the ESPP.

Service-Based Stock Options

During the three and nine months ended September 30, 2018, the Company granted 147,000 and 1,629,760 service-based options to purchase common stock, respectively. 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 for the three and nine month periods ended September 30, 2018 was \$10.90 and \$9.62, respectively, and \$2.53 and \$1.99, for the same periods in 2017.

Stock Compensation Expense

Non-cash stock-based compensation expense (employee stock purchase plan and service-based stock options) 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of goods sold	\$ 284	\$ 119	\$ 820	\$ 316
Research and development	365	177	1,282	391
Selling, general and administrative	1,283	459	3,637	1,346
Total non-cash stock-based compensation expense	\$ 1,932	\$ 755	\$ 5,739	\$ 2,053

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	Nine Months Ended September 30,	
	2018	2017
Expected dividend rate	—%	—%
Expected stock price volatility	82.3 – 88.3%	80.1 – 88.2%
Risk-free interest rate	2.4 – 2.9%	1.8 – 2.3%
Expected life (years)	5.3 – 6.3	5.5 – 6.3

9. Cash Equivalents and Investments

Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase and consist primarily of demand deposits, money market funds, overnight repurchase agreements and short duration agency bonds and commercial paper.

Investments

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than one year as of the balance sheet date. All investments are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a component of accumulated other

comprehensive loss. The cost of available-for-sale securities sold is based on the specific-identification method. Realized gains and losses are included in earnings, and are derived for specific-identification method for determining the costs of investments sold. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is reclassified from accumulated other comprehensive income (loss) to the statements of operations. Realized gains and losses are determined on the specific identification method and are included in investment and other income, net.

During the quarter ended September 30, 2018, the Company purchased marketable debt securities, which are classified as available-for-sale and carried at fair value in the accompanying consolidated balance sheets on a trade date basis. The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of September 30, 2018:

(In thousands)	September 30, 2018				Fair Value
	Amortized Cost	Gains	Losses		
Money market funds	\$ 18,684	\$ —	\$ —	\$ 18,684	
Repurchase agreements	10,002	—	—	10,002	
Commercial paper	21,832	—	—	21,832	
Corporate notes	13,058	—	(11)	13,047	
U.S. government securities	3,174	—	(1)	3,173	
U.S. asset-backed securities	8,430	—	(6)	8,424	
	<u>\$ 75,180</u>	<u>\$ —</u>	<u>\$ (18)</u>	<u>\$ 75,162</u>	
Classified as:					
Cash equivalents				\$ 30,700	
Short-term investments				44,462	
				<u>\$ 75,162</u>	

As of September 30, 2018, the Company invested \$10.0 million in overnight repurchase agreement securities classified as cash equivalents on the balance sheet.

The Company's portfolio of marketable securities had an average AA- credit rating and there were no marketable securities that the Company considers to be other-than-temporarily impaired as of September 30, 2018. The Company's investment strategy is to buy short-duration marketable securities with a high credit rating. As of September 30, 2018, all marketable securities held by the Company had remaining contractual maturities of one year or less.

If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary," including the Company's intention to sell and, if so, mark the investment to market through a charge to our consolidated statements of comprehensive loss. There have been no impairments of the Company's assets measured and carried at fair value during the nine months ended September 30, 2018.

10. 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 and level 2 or between level 2 and level 3. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The commercial paper, corporate notes, government securities and asset-backed securities are classified as Level 2 as they were valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. The following table summarizes the valuation of the Company's financial instruments that are measured at fair value on a recurring basis:

(In thousands)	September 30, 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
Assets:								
Money market funds	\$ 18,684	\$ 18,684	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Repurchase agreements	10,002	—	10,002	—	—	—	—	—
Commercial paper	21,832	—	21,832	—	—	—	—	—
Corporate notes	13,047	—	13,047	—	—	—	—	—
U.S. government securities	3,173	—	3,173	—	—	—	—	—
U.S. asset-backed securities	8,424	—	8,424	—	—	—	—	—
	\$ 75,162	\$ 18,684	\$ 56,478	\$ —	\$ —	\$ —	\$ —	\$ —
Liabilities:								
Warrant liabilities	\$ —	\$ —	\$ —	\$ —	\$ 1,014	\$ —	\$ 1,014	\$ —

The following table summarizes the change in the estimated fair value of the Company's outstanding warrant liabilities as of September 30, 2018:

Warrant Liabilities (In thousands)	
Balance at December 31, 2017	\$ 1,014
Increase in fair value (net of expired warrants)	2,524
Warrant exercise	(3,538)
Balance at September 30, 2018	\$ —

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

Revolving and Term Loan Credit Agreements

At each of September 30, 2018 and December 31, 2017, the Company had a total of \$17.3 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.

11. Shareholders' Equity

At-the-Market Sales Agreement

On October 10, 2016, the Company entered into an at-the-market sales agreement with Cowen (ATM Agreement), pursuant to which the Company could 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 were sold at market prices. The Company was required to pay up to 3% of the gross proceeds to Cowen as a commission. A total of 2,340,879 shares of common stock were 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). There were no shares sold under the ATM Agreement during the nine months ended September 30, 2018. Effective May 29, 2018, the Company terminated the ATM Agreement and no further sales pursuant to the ATM Agreement will be made following such date of termination.

Public Equity Offering

In June 2018, the Company sold 5,750,000 shares of its common stock in an underwritten public offering at a price per share of \$13.00 per share. The Company received proceeds of \$70.1 million, net of \$4.7 million of underwriters' discount and issuance costs consisting primarily of legal and accounting fees. The Company recorded these proceeds as a common stock issuance.

12. 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	\$ (1,069)	\$ (5,407)	\$ (13,379)	\$ (17,573)
Denominator for basic and diluted EPS:				
Weighted-average common shares outstanding	42,925	33,667	39,163	32,783
Net loss per share attributable to common shareholders (basic and diluted)	\$ (0.02)	\$ (0.16)	\$ (0.34)	\$ (0.54)

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 September 30, 2018 and 2017 were 5.3 million and 5.4 million, respectively.

13. 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 the Company's condensed consolidated statement of operations as reductions to rent expense over the lease term. As of September 30, 2018, the Company has recorded \$1.9 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. The Company's agreement with Orsini includes certain minimum administrative fees included in purchase commitments below.

As of September 30, 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	\$ 16,915	\$ 1,273	\$ 4,908	\$ 4,902	\$ 4,811	\$ 957	\$ 64
Debt and interest related payments	20,860	814	6,290	5,817	7,939	—	—
Purchase commitments	3,206	526	711	681	644	644	—
Total	\$ 40,981	\$ 2,613	\$ 11,909	\$ 11,400	\$ 13,394	\$ 1,601	\$ 64

Rent expense for the three and nine months ended September 30, 2018 was \$1.3 million and \$4.1 million, respectively, and \$1.5 million and \$4.1 million for the same periods in 2017.

14. 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, is 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. Throughout 2016 and early 2017, we also operated a centralized cell manufacturing facility in Ann Arbor, Michigan.

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. Until 2017, our active product candidate portfolio included ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to dilated cardiomyopathy, or DCM. We have no current plans to continue the development of ixmyelocel-T unless funded by a partner.

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. We expanded our field force from 28 to 40 representatives in 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 and nine months ended September 30, 2018, net revenues for MACI were \$16.4 million and \$42.6 million, respectively.

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 a Humanitarian Device Exception (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 U.S. 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 and nine months ended September 30, 2018, net revenues for Epicel were \$6.0 million and \$16.9 million, respectively.

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 Annual Distribution Number (ADN). The ADN is defined as the number of devices reasonably needed to treat a population of 8,000 individuals per year in the U.S.

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 occurred 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, at this time we have no current plans to initiate or fund a Phase 3 trial on our own unless funded by a partner.

Results of Operations

Net Loss

Our net loss for the three and nine months ended September 30, 2018 totaled \$1.1 million and \$13.4 million, respectively and \$5.4 million and \$17.6 million for the same periods in 2017.

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Total revenues	\$ 22,484	\$ 14,260	\$ 59,522	\$ 40,574
Cost of product sales	8,138	7,186	23,531	21,965
Gross profit	14,346	7,074	35,991	18,609
Total operating expenses	15,682	11,105	45,895	34,784
Loss from operations	(1,336)	(4,031)	(9,904)	(16,175)
Other income (expense)	267	(1,376)	(3,475)	(1,398)
Net loss	\$ (1,069)	\$ (5,407)	\$ (13,379)	\$ (17,573)

Net Revenues

Net revenues increased for the three months ended September 30, 2018 compared to the same period the previous year due primarily to significant volume increases for both MACI and Epicel.

Net revenues increased for the nine months ended September 30, 2018 compared to the same period the previous year due primarily to significant volume increases for both MACI and Epicel. During the nine months ended September 30, 2017, we recorded a reduction to revenue of \$0.6 million related to a dispute between a third party payer and our distributor of MACI and Carticel.

Revenue by product (in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Carticel and MACI	\$ 16,449	\$ 9,909	\$ 42,629	\$ 27,821
Epicel	6,035	4,351	16,893	12,753
Total Revenue	\$ 22,484	\$ 14,260	\$ 59,522	\$ 40,574

Seasonality. Between 2014 to 2017, 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 and Carticel revenue has historically been 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. Since the launch of MACI the seasonality trends have become less predictable and have been impacted by the underlying growth in sales. 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Gross profit	\$ 14,346	\$ 7,074	\$ 35,991	\$ 18,609
Gross profit %	64%	50%	60%	46%

Gross profit ratio increased for the three and nine months ended September 30, 2018 compared to the same period in 2017 due primarily to an increase in MACI and Epicel sales combined with a significant portion of our manufacturing costs being fixed.

Research and Development Costs

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development costs	\$ 3,113	\$ 2,919	\$ 10,581	\$ 9,357

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Dilated Cardiomyopathy	\$ 153	\$ 909	\$ 1,119	\$ 4,050
MACI	2,095	1,430	7,169	3,678
Epicel	865	580	2,293	1,629
Total research and development costs	\$ 3,113	\$ 2,919	\$ 10,581	\$ 9,357

Research and development costs for the three months ended September 30, 2018 were \$3.1 million versus \$2.9 million for the same period a year ago, primarily due to a reduction in the ixCELL-DCM clinical trial expenses compared to the same period in 2017, which are partially offset by the MACI pediatric clinical study, a post-approval FDA commitment, in the U.S. in 2018.

Research and development costs for the nine months ended September 30, 2018 were \$10.6 million versus \$9.4 million for the same period a year ago. The increase was due primarily 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. There was also an additional \$0.9 million in stock compensation expense for the nine months ended September 30, 2018 compared to the same period a year ago.

Selling, General and Administrative Costs

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Selling, general and administrative costs	\$ 12,569	\$ 8,186	\$ 35,314	\$ 25,427

Selling, general and administrative costs for the three months ended September 30, 2018 were \$12.6 million compared to \$8.2 million for the same period a year ago. The increase in selling, general and administrative costs for the three months ended September 30, 2018 is due primarily to \$1.2 million in service fees paid to MACI pharmacy distributors, a \$1.0 million increase in reimbursement support services resulting from increased MACI demand, a \$1.0 million increase in MACI sales force employee expenses as a result of the sales force expansion in 2018 as compared to 2017 and an additional \$0.8 million in stock compensation expense.

Selling, general and administrative costs for the nine months ended September 30, 2018 were \$35.3 million versus \$25.4 million for the same period a year ago. The increase in selling, general and administrative costs for the nine months ended September 30, 2018 is due primarily to a \$3.2 million increase in MACI sales force employee expenses as a result of the sales force expansion as compared to 2017, a \$2.1 million increase in reimbursement support services resulting from increased MACI demand and \$1.2 million in service fees paid to MACI pharmacy distributors. There was also an additional \$2.2 million in stock compensation expense.

Other Income (Expense)

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Decrease (increase) in fair value of warrants	\$ 420	\$ (1,060)	\$ (2,524)	\$ (512)
Foreign currency translation loss	—	(6)	(49)	(20)
Other income	—	5	48	6
Net interest expense	(153)	(315)	(950)	(872)
Total other expense	\$ 267	\$ (1,376)	\$ (3,475)	\$ (1,398)

The change in other income and expense for the three and nine months ended September 30, 2018 compared to 2017 is due primarily to the change in warrant value as a result of the increase in our stock price and the reduction in the time to maturity.

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of goods sold	\$ 284	\$ 119	\$ 820	\$ 316
Research and development	365	177	1,282	391
Selling, general and administrative	1,283	459	3,637	1,346
Total non-cash stock-based compensation expense	\$ 1,932	\$ 755	\$ 5,739	\$ 2,053

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 as a result in the increase in stock price.

Liquidity and Capital Resources

Since the acquisition in 2014 of the CTRM Business of Sanofi, our primary focus has been to invest in our existing commercial business with the goal of growing revenue. In June 2018, we sold 5,750,000 shares of our common stock in an underwritten public offering at a price of \$13.00 per share. We received proceeds of \$70.1 million, net of \$4.7 million of underwriters' discount and issuance costs consisting primarily of legal and accounting fees. We recorded these proceeds as a common stock issuance. We currently intend to use the net proceeds from this offering primarily for general corporate purposes, as well as to expand our business by in-licensing or acquiring, as the case may be, product candidates, technologies, other assets, commercial products or businesses which would be complementary to our existing commercial franchises or our advanced cell therapy platform; however, we have no current commitments or obligations to do so.

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, and funds from the SVB-Mid-Cap facility.

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. Any ATM Shares sold were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-205336). Effective May 29, 2018, we terminated the ATM Agreement and no further sales pursuant to the ATM Agreement will be made.

Our cash and cash equivalents totaled \$53.3 million, and short term investments totaled \$44.5 million as of September 30, 2018. During the nine months ended September 30, 2018, the cash used for operations was \$3.0 million. The cash used for operations was driven largely by our operating loss of \$13.4 million offset by noncash charges including \$5.7 million of stock compensation expense, \$2.5 million due to the change in fair value of warrants and \$1.1 million of depreciation expense.

The change in cash used for investing activities is the result of the purchases of \$2.1 million of property plant and equipment for manufacturing upgrades and \$44.5 million in short term investments through September 30, 2018.

The change in cash provided from financing activities is the result of net proceeds from our recent follow-on public offering of common stock of \$70.0 million, proceeds from the exercise of stock options of \$3.3 million and the exercise of warrants of \$2.7 million during the nine months ended September 30, 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 loan is 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 September 30, 2018, there was an outstanding balance of \$15.0 million under the term loan and \$2.5 million under the revolving line of credit.

We believe that, based on our current cash on hand, we are in a position to sustain operations through at least November 2019. In the future, we may need to access additional capital; 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. Actual cash requirements may differ from projections and will depend on many factors, including the level of future research and development, the scope and results of ongoing and potential clinical trials, the costs involved in filing, prosecuting and enforcing patents, the need for additional manufacturing capacity, competing technological and market developments, costs of possible acquisition or development of complementary business activities, and the cost to market our products.

Off-Balance Sheet Arrangements

At September 30, 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 standards for stock compensation and revenue which has been discussed in notes 3 and 4 to these financial statements, respectively, there have been no material changes to that information disclosed in our Annual Report during the nine months ended September 30, 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,” “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;
- 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 September 30, 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 September 30, 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 September 30, 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

There have been no material changes from the risk factors previously disclosed in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and the risk factors found in Part I, Item 1A, "Risk Factors," of the Company's Annual Report on Form 10-K for the year ended December 31, 2017. The risks described in the Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 are not the only risks the Company faces. Additional risks and uncertainties not currently known or currently deemed to be immaterial also may materially and adversely affect the Company's business, financial condition, results of operations or cash flows.

Item 1B. Unresolved Staff Comments

Not applicable.

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

The Company did not have any repurchases or unregistered issuances of its equity securities during the quarter ended September 30, 2018.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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>Fourth Amendment to Distribution Agreement between Orsini Pharmaceutical Services, Inc. and the Company, dated July 25, 2018.</u>
10.2**†	<u>Dispensing Agreement by and between AllCare Plus Pharmacy and the Company, dated July 26, 2018.</u>
10.3**†	<u>Fifth Amendment to Distribution Agreement between Orsini Pharmaceutical Services, Inc. and the Company, dated October 18, 2018.</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: November 6, 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.

FOURTH AMENDMENT TO DISTRIBUTION AGREEMENT

This Fourth Amendment to the Distribution Agreement ("Fourth Amendment") is between Vericel Corporation ("Vericel") and Orsini Pharmaceutical Services, Inc. ("Orsini"). This Fourth Amendment is entered into as of July 25, 2018 ("Effective Date").

Whereas, Vericel and Orsini are parties to a Distribution Agreement dated May 15, 2017 (as amended, the "Agreement"), under which Vericel appointed Orsini as a specialty pharmacy distributor for Carticel[®] and MACI[®];

Whereas, the Parties entered into the First Amendment to the Agreement effective August 10, 2017;

Whereas, the Parties entered into the Second Amendment to the Agreement effective October 13, 2017;

Whereas, the Parties entered into the Third Amendment to the Agreement effective November 14, 2017; and

Whereas, the Parties desire to modify certain terms of the Agreement, including the revision and restatement of Exhibit A;

Now therefore, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to amend the Agreement as follows:

1. **Section 1.1 Distribution.** Section 1.1 shall be modified to add the following at the end of the first paragraph: “A Payor is defined as a Healthcare Provider, Healthcare Facility, or insurer. The Parties agree that any cases [***] shall not be processed under the Agreement.” In addition, the second and third paragraphs of Section 1.1 shall be deleted, with the exception of the first sentence of the second paragraph which shall remain.
2. **Section 1.3 Shipment of Product.** This Section shall be deleted.
3. **Section 1.5 Data.** The last sentence of Section 1.5 shall be deleted.
4. **Section 2 Obligations of Vericel.** This Section shall be deleted and be replaced with [Intentionally omitted].
5. **Section 7.1 Term.** The first two sentences of Section 7.1 shall remain, but the last sentence of the Section shall be deleted and replaced with the following:

During the Term, Orsini shall be the exclusive pharmacy supplying the Product for the cases covered by Section 1.1 for: (i) Payors for which Orsini [***]; or (ii) where the Payor is identified as [***]. Orsini shall not enter into any agreement with a Payor covering the Product unless Vericel [***]. Unless otherwise agreed to in writing by Vericel, the minimum reimbursement amount for the Product shall be the Product’s

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[***]. Vericel shall review and approve any proposed material modifications to the conditions for reimbursement for the Product relating to Payors on Exhibit B and/or for the proposed addition of Payors to Exhibit B, which approval shall not be unreasonably withheld or delayed. Exhibit B will be modified from time to time in writing by the Parties as additional Payors are contracted with Orsini and approved by Vericel. Upon execution of this Fourth Amendment, Orsini shall provide to Vericel the [***]. Should a Payor request extended payment terms in excess of [***], Orsini will secure advance approval from Vericel. If Vericel refuses to approve a Payor it shall notify Orsini in writing specifying the reason for its disapproval.

6. **Exhibit A.** The Parties agree that Exhibit A to the Agreement – Payment Terms and Pricing shall be deleted and replaced with the attached revised and restated Exhibit A.
7. **No Other Changes.** To the extent terms in the Fourth Amendment conflict with the Agreement and/or any of the amendments to the Agreement, the terms of this Fourth Amendment shall prevail. Except as provided in this Fourth Amendment, the terms and conditions of the Agreement will continue in full force.
8. **Counterparts/Signatures.** This Fourth Amendment may be executed in multiple counterparts, each of which constitutes an original, and all of which, collectively, constitute only one agreement. The signatures of the parties need not appear on the same counterpart, and delivery of an executed counterpart signature page by facsimile or other form of electronic transmission shall be as effective as executing and delivering this Fourth Amendment in the presence of the other parties to this Fourth Amendment.

IN WITNESS WHEREOF, the parties executed this Fourth Amendment as of its Effective Date.

Vericel Corporation

Orsini Pharmaceutical Services, Inc.

By: /s/ Daniel Orlando

By: /s/ Michael Fieri

Name: Daniel Orlando
Title: Chief Operating Officer

Name: Michael Fieri
Title: President and CEO

Date: 25 July 2018

Date: 25 July 2018

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EXHIBIT A -- PAYMENT TERMS AND PRICING

1. Product.

Product, under this Agreement is defined as:

<u>Product</u>	<u>NDC Number</u>
MACI	69866-1030-01
MACI	69866-1030-02

2. Orsini Counseling and Dispensing.

- A. Orsini, when acting as the dispensing specialty pharmacy for Product, shall [***]. Vericel shall provide Orsini, through its vendors or its web-based data-sharing platform (“Vericel Central”), with daily data feeds regarding cases, [***].
- B. Vericel shall, [***], arrange for Product to be shipped to Orsini so that Orsini may label and dispense the Product [***] by the surgery date. Vericel shall also be responsible [***].
- C. By [***], Orsini, in coordination with Vericel, shall use commercially reasonable efforts to determine the feasibility of dispensing from a facility near Vericel’s Cambridge, Massachusetts manufacturing facility. [***]. Orsini shall have no liability under the Agreement if it determines use of another facility is not feasible.
- D. In order to perform its specialty pharmacy services, Orsini shall take title to the Product upon receipt of the Product at its facility. [***].

3. Claim Submittal, Contracting and Payment Coordination between Parties.

- A. The Parties agree that Orsini shall dedicate at least one full-time experienced person to the Product (“Vericel Program Manager”). The Vericel Program Manager shall work exclusively on Product cases and serve as the point of contact for Vericel and Vericel’s contractor. In consideration of the Vericel Program Manager, Vericel shall pay Orsini a fee of [***] each month. Orsini shall screen and select a candidate for the Vericel Program Manager position and present such a candidate to Vericel for approval, which shall not be unreasonably withheld. Upon hiring of the Vericel Program Manager, the fee is due the first of each month and shall be applied to such [***] service.
- B. To the extent permitted by Orsini’s Payor agreements, the Parties agree that they will work together to manage reimbursement issues regarding the Product. Orsini, working with Vericel’s contractor, shall submit claims for Products [***] of Product implantation. [***]. Orsini shall appeal or resubmit for payment all denied and otherwise rejected claims for

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which a good faith basis exists to do so, [***] from Orsini’s receipt of such notice of denial or rejection. [***]. Orsini shall notify Vericel daily of denials or claims otherwise rejected and the reason for the denial or rejection.

- C. When reasonably determined by Vericel representatives and Orsini, Orsini will consult with Vericel and its designated representatives with [***].
- D. [***]. Orsini agrees to provide to Vericel representatives the payment history for the Product. If required for Vericel’s financial reporting purposes under generally accepted accounting principles, Orsini agrees to provide redacted portions of the relevant agreements or other payment arrangements between a Payor and Orsini to the extent allowed by the confidentiality provisions of such agreements.

4. Payment Terms.

- A. The Payment Terms outlined in this Fourth Amendment shall apply to (i) any existing case listed on Exhibit C, and (ii) any case for which an order is accepted by Orsini in Vericel Central and for which a claim is submitted to a Payor after June 15, 2018. Other cases will be handled in accordance with the terms of the Agreement in place at the time of the claim submission.
- B. Vericel shall pay Orsini for each Product dispensed by Orsini, regardless of the Product NDC, [***] (“Dispensing Fee”). Orsini shall invoice Vericel for the Dispensing Fee weekly for claims submitted during the week, and such payment is due to Orsini [***] of Vericel’s receipt of the invoice. Vericel’s obligation to pay this fee shall survive the termination of the Agreement.
- C. The Parties agree that Vericel, in consideration of Orsini’s administrative services relating to the submission and collection of claims relating to the Product, shall pay Orsini an administrative fee [***] (“Administrative Fee”) for [***] that are Eligible Cases (as defined below). The Administrative Fee applies to [***] cases (i) listed on Exhibit C, or (ii) for which an order is accepted by Orsini in Vericel Central and for which a claim is submitted to a Payor after June 15, 2018 (collectively, “Eligible Cases”); provided, however, cases shall not be deemed Eligible Cases and will not count [***] if a Payor denies payment for an otherwise Eligible Case. Vericel shall notify Orsini at the end of each calendar quarter the number of Eligible Cases remaining [***] cases. Orsini shall be allowed to deduct from each Payor reimbursement for an Eligible Case the amount of the Administrative Fee.
- D. Within [***] of receipt of payment from a Payor related to the Product, Orsini shall remit to Vericel all reimbursements related to Products dispensed by Orsini except as provided above. The payments shall be deposited into a bank account maintained by and in the name and sole control of Vericel (the “Vericel Account”). In conjunction with each deposit, Orsini shall remit to Vericel a schedule detailing the cases for which a payment was deposited into the account including the case number and the amount deposited for each case.
- E. On a [***] basis, Orsini shall remit to Vericel a schedule which includes the gross reimbursements received [***] related to Products dispensed by Orsini, including whether

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the payments were deposited into the Vericel Account and the date of payment into the Vericel Account. Such schedule of payments shall include the case number and other identifiers agreed to by the Parties. In addition, Orsini shall provide to Vericel and its agent [***] for each reimbursed case.

- F. In addition to the remitting of payment to Vericel as set forth above, Orsini shall update, [***], the payment status of submitted cases to Vericel and its contractors through Vericel Central or other mutually agreed upon method.
- G. Subject to the terms of the Agreement, as amended, Vericel acknowledges that it retains the risk of [***].
- H. Except as provided herein, all payments (including interest payments, if any) for the Product received by Orsini during the Term and after the expiration or termination of the Agreement shall be the sole property of Vericel and shall be remitted to Vericel in accordance with the Agreement. In the event of a termination or expiration of the Agreement, Orsini shall continue to collect on claims covered by the Agreement, consistent with the terms of the Agreement, for a period [***] following the expiration or termination of the Agreement.
- I. If Vericel terminates the Agreement for any reason other than the reasons contained in Section 7.2(b)(1) of the Agreement or a failure of Orsini to submit claims for payment and/or resubmit or appeal pursuant to Paragraph 3B of this Exhibit (except that this shall not apply to the failure of Orsini to submit claims within the timelines set forth in Paragraph 3B, unless such failure is repeated and results in the denial of claims by Payors) or Paragraph 4D of this Exhibit regarding the payment to Vericel of amounts received from Payors or Orsini has not been paid an Administrative Fee on [***] by June 30, 2019, Orsini shall continue to receive the Administrative Fees associated with the unpaid cases, and the Administrative Fee on both paid and unpaid Eligible Cases shall be increased [***]. Within the earlier of thirty (30) days of the effective date of the termination or June 30, 2019, Vericel shall pay Orsini [***].
[***]:
[***]:
[***].
[***].

In the event Orsini terminates the Agreement, Vericel shall not owe any Administrative Fees on any cases implanted but not paid by the Payors as of the effective date of termination.

- J. Orsini represents and warrants that each of Orsini’s Payor agreements set forth on Exhibit B are in full force and effect and apply to the Product.
- K. If a Payor recoups any payment on a case for which Orsini has made payment to Vericel, Orsini shall notify Vericel and shall be entitled to deduct from Vericel funds a sum equal to the amount of the recoupment. If there are insufficient Vericel Funds, Orsini shall invoice

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Vericel for the amount of the recoupment and Vericel shall pay Orsini within [***] of receipt of the invoice. Vericel’s obligation under this Paragraph K shall survive the termination of the Agreement. The Parties shall discuss appealing and/or disputing the proposed recoupment with the Payor. If an appeal is successful, Orsini shall treat the payment in accordance with the terms of this Fourth Amendment.

L. The Parties agree that fees paid hereunder are not designed nor constitute inducements for Orsini to utilize or recommend the utilization of Vericel Products under federal and/or similar state laws. Orsini shall properly disclose and otherwise comply with applicable law.

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EXHIBIT B – EXCLUSIVE PAYORS

Contract Payers for MACI

[***]

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Exhibit C – Existing Eligible Cases

Lot #
[***]

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Dispensing Agreement

This Dispensing Agreement (“Agreement”) is made as July 26, 2018 (“Effective Date”) between Vericel Corporation (“Vericel”) and AllCare Plus Pharmacy, 50 Bearfoot Rd, Northborough, MA 01532 (“AllCare”).

Whereas, Vericel is a manufacturer of autologous cell chondrocyte products, including MACI® (autologous cultured chondrocytes on porcine collagen membrane);

Whereas, AllCare, as a specialty pharmacy, provides dispensing services; and

Whereas, Vericel would like to utilize AllCare’s dispensing services for MACI (collectively referred to herein as the “Product” or “Products”) in the United States and Puerto Rico (“Territory”) pursuant to this Agreement.

Therefore, the Parties agree as follows.

1. **Claim Submission and Management.** Vericel hereby appoints AllCare as a non-exclusive specialty pharmacy provider of the Products to physicians and other healthcare providers (“Healthcare Providers”) for the purpose of implanting the Products in patients, and to the hospitals, outpatient surgical centers or other similarly licensed facilities (“Healthcare Facilities”) in which surgical procedures involving the Products are performed.
 - 1.1 AllCare acknowledges and agrees that [***], Vericel’s [***], will use certain AllCare identifiers including, but not limited to, provider name, address, National Provider Identifier (NPI), taxonomy, and other information necessary to perform [***] related to the Product. AllCare acknowledges and agrees that [***] may use the following: AllCare Plus Pharmacy, 50 Bearfoot Rd, Northborough, MA 01532; NPI 1902167596 and any other required identifiers.
 - 1.2 AllCare authorizes Vericel’s contractor, [***], with which it will enter into a Business Associate Agreement, to act as an authorized representative of AllCare with respect to [***] services for the Product. If required by Healthcare Providers, Healthcare Facilities, or insurers (collectively “Payors”), AllCare agrees to provide [***] with a Designation of Authorized Representative letter which [***] may provide to Payors.
 - 1.3 Vericel’s contractor shall conduct [***], which shall also include [***] required by Payors, including [***] and/or other relevant materials (collectively “Case Materials”). AllCare agrees that Vericel’s contractor may utilize any [***] to make submissions of Case Materials to Payors.
 - 1.4 AllCare agrees and authorizes Vericel and its contractor to [***] as a medical benefit. Vericel shall not modify existing agreements between AllCare and Payors concerning pharmacy benefits.
 - 1.5 AllCare agrees that Vericel’s contractor shall [***] which arise regarding the Product, including the [***].

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- 1.6 Vericel's contractor shall advise [***] upon the implantation of the Product. After the Product is implanted into a patient, AllCare shall be responsible for the [***]. The Parties shall coordinate the manner of communications to the patient regarding the [***].
 - 1.7 AllCare shall cooperate with and work with Vericel and [***] regarding claim submission and any claim appeal procedures. Such cooperation shall include AllCare notifying Vericel within [***] day of receiving notices of denials or claims otherwise rejected. If any Payor notifies AllCare that it plans to recoup any payment previously made for a Product, AllCare shall notify Vericel within [***] day.
 - 1.8 AllCare, consistent with Exhibit A, shall collect and pass-on to Vericel, [***]. In order for the Parties to segregate payments made to AllCare for the Product, AllCare agrees to utilize a billing system for the Product that is either separate or walled-off from other funds it receives. The Parties shall agree on the specifics of such a system and Vericel shall have access to such a system for the purpose of determining compliance with this Agreement.
 - 1.9 AllCare agrees to utilize Vericel's web-based data hosting portal and to cooperate with Vericel and its vendors to ensure the complete, orderly, and secure transfer of data between Vericel (including Vericel's vendors) and AllCare. At a frequency, format, and detail level agreed upon by the Parties, Vericel may provide reports to AllCare or other information from the Vericel's web-based platform.
 - 1.10. Vericel shall be responsible for any acts or omissions by its contractor.
2. **Dispensing and Shipment of Product**. AllCare will coordinate with Vericel to ensure the dispensing of Product by AllCare on the [***] day Product is received by AllCare. From Monday to Saturday, AllCare, in coordination with Vericel, shall pick-up Product at Vericel's manufacturing facility at 64 Sidney Street, Cambridge, MA 02139 and transport the Product to AllCare's pharmacy location in Northborough, MA. During such transport, [***] shall bear the risk of loss. On Sundays, [***] shall be responsible for transporting Product to AllCare's pharmacy and shall bear the risk of loss during such transport. Upon dispensing the Product, which shall be the [***] day as the Product is received by AllCare, AllCare shall coordinate for the Product's pick-up by Vericel or its agent at AllCare's pharmacy. [***] shall be responsible for shipping the dispensed Product to the customer identified in the order and shall bear the risk of loss during transport from AllCare's pharmacy to the customer. For purpose of dispensing the Product, the title to the Product shall transfer to AllCare upon AllCare's possession of the Product.
 3. **Standard of Care**. AllCare shall maintain all applicable licenses or certifications, including DEA numbers, and will dispense the Product in accordance with applicable professional standards and applicable federal, state and local laws, rules, regulations and guidelines (collectively, "Standards and Legal Requirements"). AllCare shall maintain internal controls to facilitate compliance with its obligations under this Agreement. In the event AllCare receives a notice from any governmental authority regarding its obligations pertaining to Standards and Legal Requirements that have a material adverse effect on its ability to

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comply with this Agreement, AllCare shall notify Vericel and provide Vericel with any non-confidential documentation reasonably related to such inquiry.

4. Obligation of the Parties.

- 4.1. Financial and Credit Position. Each Party will maintain a financial condition reasonably satisfactory to the other. If, during the Term, the financial condition of a Party is impaired or unsatisfactory, the other Party may require such Party to perform its obligations in advance or provide other reasonable adequate assurances of performance.
- 4.2. Compliance with Laws. Each Party shall maintain all federal, state and local registrations necessary to comply with this Agreement and will immediately notify the other Party of any denial, revocation or suspension of any such registration. Each Party will comply with all Standards and Legal Requirements applicable to performance of its obligations under this Agreement, including without limitation, (i) Drug Quality and Security Act, (ii) federal and state Food, Drug and Cosmetics Acts; (iii) federal and state Anti-kickback laws; (iv) any federal, state or local statutes, regulations, rules, guidelines or manuals relating to dispensing pharmaceutical products; (v) guidelines of the Joint Commission on Accreditation of Healthcare Organizations; (vi) federal, state or local laws relating to billing or sales practices; (vii) Health Insurance Portability and Accountability Act of 1996 and applicable regulations. In the event there is any change in law, regulation or interpretation thereof that has the effect of prohibiting any right or obligation of a Party under the Agreement that is material to the Party's rights and obligations under this Agreement or materially and adversely affects such right or obligation, the Parties shall meet in good faith to mutually agree on an appropriate amendment to this Agreement to reflect the changed circumstances.

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

- 4.3 Debarment/Exclusion. Each Party represents and certifies that it and any person or entity employed or engaged by it including, without limitation, employees, contractors, or agents who will provide Services in connection with this Agreement (collectively, “Personnel”) are not currently:
- (i) excluded, debarred, suspended or otherwise ineligible to participate in federal health care programs as defined in 42 U.S.C. § 1320a-7b or in federal procurement or non procurement activities as defined in Executive Order 12689 (collectively, “Ineligible”);
 - (ii) debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), as amended, or any similar state law or regulation (“Debarred”);

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- (iii) excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7, et seq. or any state agency from participation in any federal or state health care program as defined in 42 U.S.C. § 1320a-7 and 42 U.S.C. § 1320a-7b (“Excluded”); and/or
- (iv) otherwise disqualified or restricted by the FDA pursuant to 21 CFR § 312.70 or any other regulatory authority (“Disqualified”).

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

- 4.4 Proper Handling and Storage. Vericel and AllCare agree to handle and store Product in a manner which will assure that the quality of Product is maintained.
- 4.5 Adverse Event and Product Complaint Reporting. During the course of this Agreement, if AllCare becomes aware of an adverse event associated with use of a Vericel product (whether or not expected or labeled), Consultant shall report the adverse event to Vericel within 1 working day, by email at PatientSafety@vcel.com or by telephone at 1-800-453-6948 or in any of the following forms: (i) CIOMS I; (ii) Med Watch; or (iii) adverse event reporting form (electronic or hardcopy). Information reported shall include: patient identifiers, reporter (including reporter name and contact information), the suspect product information (drug, dose, route, date of administration), and details regarding the adverse event. If Vericel concludes that the AllCare should be trained on Vericel’s Adverse Event Reporting policy, AllCare agrees to cooperate to complete such training.
- 4.6 Product Informational Materials. If requested by AllCare, Vericel shall provide AllCare, at no cost, reasonable amounts of applicable supplies of materials describing the Product as prepared by Vericel in the ordinary course of Vericel's marketing of the Product, including for example, Product FAQs and fact sheets. AllCare shall not make any changes or provide supplemental information to any descriptive, educational, promotional or other Product-related materials supplied by Vericel without the prior written authorization of Vericel. Moreover, AllCare shall not distribute any descriptive, educational, promotional or other Product-related materials created or developed by AllCare or any third Party without the prior written authorization of Vericel.
- 4.7 Records Retention and Audit. The Parties shall maintain complete and accurate records of all transactions related to the conduct of business under this Agreement. During the Term of this Agreement and for a period of [***] thereafter both Parties shall retain records pertaining to transactions undertaken pursuant to this Agreement

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and permit inspection of these records by a mutually acceptable third Party auditor subject to a mutually agreeable nondisclosure agreement. Any audit shall be upon reasonable prior written notice, at the expense of the initiating Party and shall be conducted during regular business hours in a manner so as not to unduly interfere with the other Party's normal business operations. Such audit and inspection must be reasonable in time and in scope, and shall be conducted no more than once annually (unless for reasonable cause). If based on any such inspection or audit it is determined that a Party has: (i) received excess credits; (ii) taken any unearned discounts; or (iii) been underpaid, the Party against whom such finding has been made shall immediately pay any such sums, subject to the other Party's right to offer evidence to dispute such inspection or audit finding.

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

- 4.8 Recalls. In the event that (i) any governmental agency or authority issues a request or directive or orders that the Product be recalled or retrieved, (ii) a court of competent jurisdiction orders that the Product be recalled or retrieved, or (iii) Vericel reasonably determines that the Product should be recalled, retrieved or a "dear doctor" letter is required relating to restrictions on use of Product, AllCare will provide Vericel with any reasonable assistance requested by Vericel, and the Parties will take all agreed to corrective actions. Vericel will be responsible for all of the expenses of such activities, except to the extent the event causing the recall results from a breach of any of AllCare's obligations under this Agreement or AllCare's negligence or willful misconduct. For purposes of this Agreement, the expenses may include, but are not limited to, the expenses of notification and return or destruction (if authorized by Vericel) of the Product, the cost of replacement of the Product, and any costs directly associated with the distribution of replacement Product. AllCare and Vericel will cooperate fully with one another in conducting any activity contemplated by this provision. AllCare will arrange for the destruction of Product lawfully recalled only upon Vericel's (or any regulatory authority's) written instruction to arrange for the destruction of such Product.

5. Warranty/Indemnification.

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

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5.2 Indemnification by Vericel. Vericel agrees to indemnify and hold harmless AllCare, its Affiliates and the officers, directors and employees of each of them, from and against all damages, expenses, claims, judgments and liabilities including, reasonable attorneys' fees ("Claims"), incurred by AllCare arising from or in connection with (1) Vericel's manufacturing, processing, labeling, marketing, storage, handling or sale of Product; (2) third Party Claims that the Product [***] or any other standards and legal requirements; (3) label, promotional literature, or other information concerning the Product provided by Vericel; (4) Payor claims for recoupment of any payments to Vericel for Products; or (4) any negligent, grossly negligent, or willful act or omission by Vericel in the performance of its obligations under this Agreement, except to the extent subject to AllCare's Indemnification obligations.

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

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

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

6. **Taxes.** Each Party shall be responsible to pay or collect any federal, state or local taxes, including excise, sales, use or other taxes ("Taxes") arising from the Party's performance under this Agreement.

7. **Term/Termination.**

7.1 Term. The term of this Agreement will commence on the Effective Date and continue for a period of two (2) years thereafter (the "Term"). The Parties may renew

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the agreement for two (2) additional two (2) year terms, upon mutual agreement providing ninety (90) days' notice of their intention to renew or terminate.

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

- a. Either Party may terminate this Agreement for any reason upon ninety (90) days' written notice to the other Party.
- b. In addition to other available remedies, either Party may immediately terminate this Agreement for cause upon written notice to the other Party upon the other Party's:
 1. (i) filing an application for or consenting to appointment of a trustee, receiver or custodian of its assets; (ii) having an order for relief entered in Bankruptcy Code proceedings; (iii) making a general assignment for the benefit of creditors; (iv) having a trustee, receiver, or custodian of its assets appointed unless proceedings and the person appointed are dismissed within thirty (30) days; (v) insolvency within the meaning of Uniform Commercial Code Section 1-201 or failing generally to pay its debts as they become due within the meaning of Bankruptcy Code Section 303(h)(l), as amended; or, (vi) certification in writing of its inability to pay its debts as they become due (and either Party may periodically require the other to certify its ability to pay its debts as they become due) (collectively, "Bankruptcy"); or
 2. failure to perform any material obligation and such failure continues for sixty (60) days after it receives notice of such breach from the non-breaching Party; provided, however, if the other Party has commenced to cure such breach within such sixty (60) days, but such cure is not completed within such sixty (60) days, it will have a reasonable time to complete its cure if it diligently pursues the cure until completion.

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

- a. Each Party will immediately pay the other Party all amounts due under any invoice or credit memo;
- b. The Parties agree to cooperate with one another and use commercially reasonable efforts to ensure a smooth transition up to and through the termination date, including complying with the terms of this Agreement regarding the submission and collection of claims. The Parties also agree that the terms of this Agreement related to the collection of claims shall continue for a period of [***] following the expiration or termination of the Agreement.

8. General Provisions

8.1 Neither Vericel nor AllCare will be liable to the other for failing or delaying the performance of any obligations under this Agreement where such failure or delay arises out of a cause beyond the reasonable control of the Party claiming relief, including, without limitation, storms, floods, other acts of nature, fires, explosions,

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riots, war or civil disturbance, national strikes or other industry wide labor unrest, embargoes and other governmental actions or regulations that would prevent a Party from performing an obligations hereunder (“Force Majeure”). The Party claiming to be delayed by reason of an event of Force Majeure shall promptly notify the other Party in writing of any actual or anticipated delays and take all necessary steps to avoid, overcome or end delays without additional cost to the other Party. The notice shall contain particulars as to the nature of the claimed event of Force Majeure, the date of commencement of the event and the anticipated date on which the event is anticipated to cease. The Party claiming to be delayed by reason of an event of Force Majeure shall take all reasonable steps to mitigate the effect of delays. Such steps shall include advanced planning and contingency planning.

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

- (1) is in the public domain at the time of disclosure or afterward, other than by breach of this Agreement by the Party receiving the Information;
- (2) the receiving Party can establish by documentary evidence was in its lawful possession at the time of disclosure by the other Party;
- (3) is in the possession of the receiving Party from third Parties not under an obligation to maintain its confidentiality;
- (4) is independently developed by employees of the receiving Party where such employees had no access to Information as shown by documentary evidence; or

8.3 If either party (with respect to the other party’s Confidential Information) is required or requested to disclose the same by law, court or Regulatory Authority order, subpoena, interrogatory, request for admission, demand or other similar process of Law, such disclosure shall be permitted; provided, however, that the receiving party shall promptly notify the disclosing party of the existence and terms of such legal process and provide the disclosing party a copy of the demand or request, and reasonably assist (at the disclosing party’s cost and expense) the disclosing party’s efforts to obtain a protective order or such other relief as may be available to prevent or limit such disclosure.

8.4 This Agreement is the entire and only understanding between the Parties as to its subject matter and supersedes all prior promises, agreements or understandings between the Parties. This Agreement may be executed in counterparts. All attachments to this Agreement are incorporated by this reference. This Agreement

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may be amended only in a writing signed by duly authorized representatives of Vericel and AllCare. Any waiver or delay by any Party in enforcing this Agreement will not deprive that Party of the right to take appropriate action at a later time or due to another breach. All provisions of this Agreement will be deemed to be severable.

- 8.5 This Agreement may not be assigned by either Party without the written consent of the other Party, whose consent shall not be unreasonably withheld.
- 8.6 All notices, claims, certificates, requests, demands and other communications under this Agreement must be in writing and delivered personally or sent by facsimile transmission, nationally-recognized express courier, or United States registered or certified mail, return receipt requested, addressed as follows. Items delivered personally will be deemed delivered on the date of actual delivery. Items sent by facsimile will be deemed delivered on the day sent if sent during normal business hours of the receiving Party (or, otherwise, on the first business day after the date of transmission). Items sent by certified or registered mail will be deemed delivered three (3) business days after mailing. Either Party may change its contact information by a written notice delivered pursuant to this Section.

If to Vericel:

With a Copy to:

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

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

If to AllCare:

AllCare Plus Pharmacy Inc.
50 Bearfoot Road
Northborough, MA 01532
Attn: Mark Janian, CCO

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

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- 8.8 Neither party shall issue or release any announcement, statement, press release or other publicity or marketing materials relating to this Agreement without the prior consent of the other party (which consent shall not unreasonably be withheld or delayed); provided, however that either Vericel or AllCare may identify the other as a provider or customer of services hereunder without obtaining the consent of the other party. If Vericel files a copy of this Agreement with any regulatory authority or any stock exchange, Vericel shall, to the extent permitted by law or the rules of any applicable stock exchange, redact or otherwise obtain confidential treatment of any of the pricing or other confidential terms set forth in this Agreement.
- 8.9 Neither Party's failure to insist on performance of any term, condition, or instruction nor failure to exercise any right or privilege or its waiver of any breach, shall thereafter be construed to constitute a waiver of such term, condition, instruction, right or privilege. No consent or waiver, expressed or implied, by a Party to the performance by the other Party or of any breach or default by the other Party of its obligations hereunder shall be deemed or construed to be a consent or waiver to or of any other breach or default in the performance by such other Party of the same or any other obligations of such other Party hereunder. The giving of consent by a Party in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance. No waiver of any rights under this Agreement shall be binding unless it is in writing and signed by the Party waiving such rights.
- 8.10 This Agreement shall be governed by the laws of the Commonwealth of Massachusetts.

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

Vericel Corporation

AllCare Plus Pharmacy

/s/ Daniel Orlando

/s/ Daniel Apelian

Dan Orlando, Chief Operating Officer

President & CEO

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EXHIBIT A -- PAYMENT TERMS AND PRICING

1. Product.

Product, under this Agreement is defined as:

<u>Product</u>	<u>NDC Number</u>
MACI	69866-1030-01
MACI	69866-1030-02

2. Payment Terms.

- A. Vericel shall pay AllCare [***] for each Patient to whom Product is dispensed. If a customer receives more than one Product within the same order, AllCare shall receive [***].
- B. At the end of each [***], AllCare shall invoice Vericel for Product dispensed during the [***]. Vericel shall pay the undisputed amounts of the invoice within [***] days of its receipt.
- C. On a [***] basis, AllCare shall remit to Vericel all reimbursement [***] related to the Product received by AllCare. Such payments shall include the case number and other identifiers agreed to by the Parties.
- D. All [***] payments for the Product (“Vericel Funds”) shall be deposited into a bank account maintained by and in the name and sole control of Vericel (the “Vericel Account”). In conjunction with each deposit, AllCare shall remit to Vericel a schedule detailing the cases for which a payment was deposited into the account including the case number and the amount deposited for each case..
- E. In addition to the remitting of payment into the Vericel Account, AllCare shall update, on a [***] basis, the payment status of submitted Cases to Vericel and its contractors through the web-based data sharing platform or other mutually agreed upon method.
- F. All payments (including interest payments, if any) for the Product received by AllCare after the expiration or termination of this Agreement shall be the sole property of Vericel and shall be remitted to Vericel in accordance with this Agreement.
- G. AllCare represents and warrants that the billing and collection procedures set forth in this Agreement comply with all applicable laws and with each of AllCare’s Payor agreements.
- H. The Parties agree that such fees are not designed nor constitute inducements for AllCare to utilize or recommend the utilization of Vericel Products under federal and/or similar state laws. AllCare shall properly disclose and otherwise comply with applicable law.

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.

- I. In the event that any Payor recoups any amounts paid to AllCare for Products, whether by requiring payment from AllCare or by offsetting the recoupment amount from amounts owed by a Payor to AllCare for pharmacy benefits, Vericel shall reimburse AllCare for the amount of such recoupment.

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.

FIFTH AMENDMENT TO DISTRIBUTION AGREEMENT

This Fifth Amendment to the Distribution Agreement ("Fifth Amendment") is between Vericel Corporation ("Vericel") and Orsini Pharmaceutical Services, Inc. ("Orsini"). This Fifth Amendment is entered into as of August 10, 2018 ("Effective Date").

Whereas, Vericel and Orsini are parties to a Distribution Agreement dated May 15, 2017 (as amended, the "Agreement"), under which Vericel appointed Orsini as a specialty pharmacy distributor for Carticel® and MACI®;

Whereas, the Parties entered into the First Amendment to the Agreement effective August 10, 2017;

Whereas, the Parties entered into the Second Amendment to the Agreement effective October 13, 2017;

Whereas, the Parties entered into the Third Amendment to the Agreement effective November 14, 2017;

Whereas, the Parties entered into the Fourth Amendment to the Agreement effective July 25, 2018; and

Whereas, the Parties desire to modify certain terms of the Agreement, including the revision and restatement of Exhibit A;

Now therefore, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to amend the Agreement as follows:

1. **Exhibit A.** The Parties agree that Section 4(A) of Exhibit A to the Agreement – Payment Terms and Pricing shall be modified to state the following:

The Payment Terms outlined in the Fourth Amendment shall apply to all surgeries after [***], 2018. Other cases are subject to the terms of the Third Amendment to the Distribution Agreement.
2. **Exhibit B.** The Parties agree that Exhibit B to the Agreement – Exclusive Payors shall be deleted and replaced with the attached revised Exhibit B.
3. **Exhibit C.** The Parties agree that Exhibit C to the Agreement – Existing Eligible Cases shall be deleted.
4. **No Other Changes.** To the extent terms in the Fifth Amendment conflict with the Agreement and/or any of the amendments to the Agreement, the terms of this Fifth Amendment shall prevail. Except as provided in this Fifth Amendment, the terms and conditions of the Agreement will continue in full force.
5. **Counterparts/Signatures.** This Fifth Amendment may be executed in multiple counterparts, each of which constitutes an original, and all of which, collectively, constitute only one agreement. The signatures of the parties need not appear on the same counterpart, and delivery of an executed counterpart signature page by facsimile or other form of electronic transmission shall

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.

be as effective as executing and delivering this Fifth Amendment in the presence of the other parties to this Fifth Amendment.

IN WITNESS WHEREOF, the parties executed this Fifth Amendment as of its Effective Date.

Vericel Corporation

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

Date: 10 August 2018

Orsini Pharmaceutical Services, Inc.

By: /s/Carla Sawa
Name: Carla Sawa
Title: Chief Financial Officer

Date: 10 August 2018

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 B – EXCLUSIVE PAYORS

Consistent with Section 1.1 and Section 7.1 of the Agreement, the Exclusive Payors listed on this Exhibit shall only apply to covered [***] lives. For the sake of clarity, if one of the Payors on this Exhibit B has a plan covering [***] lives, Vericel is not required to process such claims via Orsini.

[***]

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: November 6, 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: November 6, 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 September 30, 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: November 6, 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 September 30, 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: November 6, 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.