# 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, 2017

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 -  $\boxtimes$  No -  $\square$ 

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

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

Large accelerated filer -

Non-accelerated filer -  $\Box$ (Do not check if a smaller reporting 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)

Smaller reporting company - □ Emerging growth company -

Accelerated filer - 🗵

Outstanding at November 3, 2017

34,907,789

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

PART I —	FINANCIAL	INFORMATION
----------	-----------	-------------

Item 1.	Financial Statements (Unaudited):	<u>3</u>
	Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016	<u>3</u>
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017 and 2016	<u>4</u>
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016	<u>5</u>
	Notes to Condensed Consolidated Financial Statements	<u>6</u>
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>15</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>21</u>
Item 4.	Controls and Procedures	<u>21</u>
PART II —	- OTHER INFORMATION	
Item 1.	Legal Proceedings	<u>22</u>
Item 1A.	Risk Factors	<u>22</u>
Item 1B.	Unresolved Staff Comments	<u>22</u>
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	<u>22</u>
Item 6.	Exhibits	<u>22</u>
<u>Exhibit Ind</u>	lex	<u>23</u>
<u>Signature</u>		<u>25</u>
	i	

### PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30,		,	
		2017		2016
ASSETS				
Current assets:				
Cash	\$	15,466	\$	22,978
Accounts receivable (net of allowance for doubtful accounts of \$226 and \$225, respectively)		15,430		17,093
Inventory		4,049		3,488
Other current assets		1,366		1,164
Total current assets		36,311		44,723
Property and equipment, net		3,967		3,875
Total assets	\$	40,278	\$	48,598
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	5,972	\$	6,535
Accrued expenses		4,514		4,523
Current portion of term loan credit agreement (net of deferred costs of \$110)		2,557		779
Warrant liabilities		1,269		757
Other		216		259
Total current liabilities		14,528		12,853
Revolving and term loan credit agreement (net of deferred costs of \$211 and \$293, respectively)		7,400		9,318
Long term deferred rent		1,613		1,687
Other long term debt		_		32
Total liabilities		23,541		23,890
COMMITMENTS AND CONTINGENCIES (Note 13)				
Shareholders' equity:				
Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved $-39$ , shares issued and outstanding $-0$ and 12, respectively				38,389
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 34,852 and 31,595, respectively		377,711		329,720
Warrants		190		190
Accumulated deficit		(361,164)		(343,591)
Total shareholders' equity		16,737		24,708
Total liabilities and shareholders' equity	\$	40,278	\$	48,598

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,				
		2017		2016		2017		2016
Product sales, net	\$	14,260	\$	10,929	\$	40,574	\$	37,860
Cost of product sales		7,186		6,856		21,965		20,716
Gross profit		7,074		4,073		18,609		17,144
Research and development		2,919		3,443		9,357		11,037
Selling, general and administrative		8,186		7,010		25,427		19,463
Total operating expenses		11,105		10,453		34,784		30,500
Loss from operations		(4,031)		(6,380)		(16,175)		(13,356)
Other income (expense):								
(Increase) decrease in fair value of warrants		(1,060)		(203)		(512)		99
Foreign currency translation loss		(6)		(6)		(20)		(17)
Interest income		2		—		6		7
Interest expense		(317)		(86)		(878)		(92)
Other income (expense)		5				6		(10)
Total other income (expense)		(1,376)		(295)		(1,398)		(13)
Net loss	\$	(5,407)	\$	(6,675)	\$	(17,573)	\$	(13,369)
Net loss per share attributable to common shareholders (Basic and Diluted) (see note 12)	\$	(0.16)	\$	(0.38)	\$	(0.54)	\$	(0.84)
Weighted average number of common shares outstanding (Basic and Diluted)		33,667		22,744		32,783		22,678

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,		
		2017		2016
Operating activities:				
Net loss	\$	(17,573)		(13,369
Adjustments to reconcile net loss to net cash used for operating activities:				
Depreciation and amortization		1,186		1,393
Stock compensation expense		2,053		1,973
Change in fair value of warrants		512		(99
Inventory provision		232		98
Foreign currency translation loss		20		17
Changes in operating assets and liabilities:				
Inventory		(793)		(2,325
Accounts receivable		1,663		3,048
Other current assets		(202)		(278
Accounts payable		(1,068)		(2,173
Accrued expenses		(9)		(205
Tenant improvement reimbursement		89		898
Deferred rent expense		2		438
Other assets and liabilities, net		(129)		_
Net cash used for operating activities		(14,017)		(10,584
Investing activities:				
Expenditures for property, plant and equipment		(792)		(1,314
Net cash used in investing activities		(792)		(1,314
Financing activities:		<u>, , , , , , , , , , , , , , , , , , , </u>		
Net proceeds from issuance of common stock		7,549		469
Deferred financing costs				(244
Borrowings under revolving credit agreement and term loan		_		8,400
Repayments of short-term debt		_		(2,400
Payments on long-term debt		(252)		(28
Net cash provided by financing activities		7,297		6,197
Net decrease in cash		(7,512)		(5,701
Cash at beginning of period		22,978		14,581
Cash at end of period	\$	15,466	\$	8,880
	Ψ	10,100	Ψ	
Supplemental cash flow information (non-cash):				
Additions to equipment in process included in accounts payable	\$	486	\$	36
Conversion of preferred stock into common stock	\$	38,389		_
Warrants issued in connection with debt arrangement	\$		\$	190
Supplementary cash flows information:				
Interest paid, net of interest capitalized	\$	691	\$	73

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, 2017 (UNAUDITED)

#### 1. Organization

Vericel Corporation, a Michigan corporation (the Company, Vericel, we, us or our), was incorporated in March 1989 and began employee-based operations in 1991. On May 30, 2014, Vericel completed the acquisition of certain assets and assumed certain liabilities of Sanofi, a French société anonyme (Sanofi), including all of the outstanding equity interests of Genzyme Biosurgery ApS (Genzyme Denmark or the Danish subsidiary) (now known as Vericel Denmark ApS), a wholly-owned subsidiary of Sanofi, and over 250 patent applications of Sanofi and certain of its subsidiaries for purposes of acquiring the portion of the cell therapy and regenerative medicine business (the CTRM Business), which researches, develops, manufactures, markets and sells the Carticel®, MACI®, and Epicel® products. The Company is a fully integrated, commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of innovative therapies that enable the body to repair and regenerate damaged tissues and organs to restore normal structure and function. Vericel has marketed products and developmental stage product candidates, and the Company's goal is to become the leader in cell therapy and regenerative medicine by developing, manufacturing and marketing best-in-class therapies for patients with significant unmet medical needs.

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 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, 2017, the Company has an accumulated deficit of \$361.2 million and had a net loss of \$5.4 million during the quarter ended September 30, 2017. The Company had cash of \$15.5 million as of September 30, 2017. The Company expects that existing cash together with its term loan and revolving line of credit agreement with Silicon Valley Bank (SVB) and MidCap Financial Services (MidCap) (the SVB-MidCap facility), will be sufficient to support the Company's current operations through at least twelve months following the filing of this Form 10-Q. In connection with the SVB-MidCap facility, the Company must remain in compliance with minimum monthly net revenue covenants (determined in accordance with U.S. GAAP), measured on a trailing twelve month basis. SVB and MidCap also have the ability to call debt based on material adverse change clauses which are subjectively determinable and result in a subjective acceleration clause. If the Company's cash requirements exceed its current expectations, or if it is not in compliance with the monthly net revenue covenants or the subjective acceleration clauses are triggered under the SVB-MidCap facility, then SVB may call the debt resulting in the Company immediately needing additional funds. As of September 30, 2017, the Company was in compliance with the minimum revenue covenant set forth in the Second Loan Modification Agreement between the Company, SVB and MidCap. The Company may seek additional funding through debt or equity financings including the at-the-market sales agreement in place with Cowen and Company, LLC. However, the Company may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company needs additional funds and is unable to obtain funding on a timely basis, the Company may need to significantly curtail its operations including its research and development programs in an effort to provide sufficient funds to continue its operations, which could adversely affect its business prospects.

#### 2. Basis of Presentation

The condensed consolidated financial statements included herein have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). The preparation of condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States of America (U.S. GAAP) requires management to make estimates, judgments, and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the three and nine months ended September 30, 2017, are not necessarily indicative of the results to be expected for the full year or for any other period. The September 30, 2017 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, 2016, as filed with the SEC on March 13, 2017 (Annual Report).

#### 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. The guidance will supersede the current revenue recognition guidance and require 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 is currently effective for annual reporting periods beginning after December 15, 2017 and may be adopted using a full or modified retrospective application. The Company does not expect a material impact to its consolidated financial statements following its initial evaluation of its revenue arrangements under the issued guidance. The Company will implement the guidance under the modified retrospective approach.

#### 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 2018. The Company is currently reviewing the potential impact of adopting the new guidance.

#### **Share-based Payment Accounting**

The FASB issued guidance to simplify the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard became effective and was implemented for the Company beginning January 1, 2017. Consistent with prior periods, the Company will continue to estimate forfeitures and therefore, the guidance did not have an impact on the Company's consolidated financial statements.

#### 4. Revenue

#### Revenue Recognition and Net Product Sales

The Company sells Epicel and surgical kits directly to the customer based on contracted amounts. Revenue from sales to the customers is recognized in accordance with ASC 605, *Revenue Recognition* and SAB Topic 104, *Revenue Recognition*, when (i) persuasive evidence of an arrangement exists, (ii) the goods are shipped or delivered and implanted, depending on shipping terms, (iii) title and risk of loss pass to the customer and (iv) collectability is reasonably assured. Shipping and handling costs are included as a component of revenue.

Prior to July 1, 2016, the Company sold Carticel to a distributor and followed ASC 605, *Revenue Recognition* and SAB Topic 104 *Revenue Recognition* to record revenue. This distributor purchased and took title to Carticel upon shipment of the product and assumed credit and collection risk related to the end customers. The distributor worked with the payers on behalf of patients and surgeons to ensure medical coverage and to obtain reimbursement for Carticel implantation procedures. The Company retained responsibility for shipment of the product to the surgical suite. Revenue was recorded for Carticel upon occurrence of the surgery, net of provisions for rebates and cash discounts. Such rebates and discounts were \$0.5 million for the nine months ended September 30, 2016. There were no rebates or cash discounts for the three months ended September 30, 2016. These rebates and prompt payment cash discounts were established by the Company at the time of sale, based on actual experience adjusted to reflect known changes in the factors that impact such reserves. Adjustments to these reserves have historically not been significant.

On June 30, 2016, the Company reduced the scope of the agreement with its exclusive distributor by terminating their services for a significant portion of its Carticel sales. On July 1, 2016, the Company transitioned to a direct sales model for Carticel and MACI after launch whereby the Company retained credit and collection risk from the patient as the end customer. The Company utilized a new provider, Dohmen Life Science Services, LLC (DLSS), to provide patient support services but this provider did not purchase and take title to Carticel or MACI. On May 15, 2017, the Company and DLSS mutually terminated the agreement effective June 30, 2017. In addition, the Company utilized Vital Care Inc. and its franchisees as a second provider to expand the available network of contracted third-party payers for Carticel and MACI. Under this direct sales model, the patient bears the ultimate financial responsibility for the purchase of Carticel or MACI and as such the Company recognized revenue in accordance with ASC 954-605, *Health Care Entities - Revenue Recognition*. The third party payer (insurance company, government, etc.) pays all or some of the product price on the patient's behalf.



Under the direct sales model, the Company recognized product revenues from sales of Carticel and MACI upon implantation at which time the claim is billable to patient's insurance provider on behalf of the patient and is billed by either DLSS or Vital Care. The Company assumed counterparty risk for the third party reimbursement payment from the payer and from the patient co-pay. Prior authorization or confirmation of coverage level by the patient's private insurance plan, hospital or government payer is a prerequisite to the shipment of product to a patient. The Company's net product revenues are calculated by estimating expected payments for insurance, hospital or patient payments at the time it invoices and recognizes revenue. To support this direct sales model, the Company utilized DLSS to provide administrative services associated with case management and reimbursement support and to provide billing and collection services. The Company utilized Vital Care to provide similar billing and collection services for a subset of insurance payers and patients.

In April 2017, the Company was notified of a contractual dispute between Vital Care and a third-party payer and as a result, during the three months ended March 31, 2017, the Company increased its estimated revenue allowances, reducing revenue by \$2.1 million related to 2016 sales and \$0.7 million related to 2017 sales to reflect the lower reimbursement that would be obtained if the claims are ultimately required to be treated as out-of-network. During the three months ended June 30, 2017, the dispute was resolved and the negotiated reimbursement resulted in the Company's ability to reduce its estimated sales allowances by \$1.4 million which resulted in additional revenue in the second quarter related to sales which originated primarily in 2016. As a result of the continuing evaluation and assessment of these expected payments, our estimates for expected payments could change.

On May 15, 2017, the Company entered into a distribution agreement with Orsini Pharmaceutical Services, Inc. (Orsini) to appoint Orsini as a specialty pharmacy distributor of MACI to patients' physicians and other healthcare providers. The initial term of the distribution agreement will end on May 15, 2019 with the option of two additional two-year terms. The Company ships the product directly to the surgical suite. Orsini purchases and takes title to MACI upon shipment of the product at which point the Company recognizes revenue. Orsini assumes credit and collection risk related to the end customers. In 2017, there are no material chargebacks, rebates or other types of sales incentives that would impact revenue under the agreement with Orsini. The Company and Orsini amended their agreement in August 2017, and further amended the agreement in October 2017 to provide Orsini with a prompt pay discount beginning on January 1, 2018. Under the Orsini arrangement, Orsini is the customer and the Company is recognizing revenue in accordance with ASC 605 and SAB 104.

#### Concentration of Credit Risk

On May 15, 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 as a specialty pharmacy distributor of MACI and has engaged a third party services provider to provide the patient support program previously provided by DLSS and to manage patient cases for MACI. The Company's receivables risk is now more concentrated, and the concentration of credit risk also shifted for the Company.

Revenue from one customer, the MACI distributor in the U.S., represented approximately 55% and 25% during the three and nine months ended September 30, 2017, respectively. Accounts receivable from the same customer accounted for 48% of the outstanding accounts receivable as of September 30, 2017. For the three and nine months ended September 30, 2016, the Company's largest customer represented 67% and 46% of total revenue, respectively. The next largest customer represented approximately 10% and 13% of revenue for the three and nine ended September 30, 2017, respectively, and 8% and 13% of total revenue during the three and nine months ended September 30, 2016, respectively. No other customer accounted for more than 10% of revenue or accounts receivable in 2017 or as of December 31, 2016.

#### 5. Selected Balance Sheet Components

Inventory as of September 30, 2017 and December 31, 2016:

(In thousands)	Septen	September 30, 2017		nber 31, 2016
Raw materials	\$	3,727	\$	3,214
Work-in-process		279		257
Finished goods		43		17
Inventory	\$	4,049	\$	3,488

Property and equipment, net as of September 30, 2017 and December 31, 2016:

(In thousands)	September 30, 2017		December 31, 2016	
Machinery and equipment	\$	3,264	\$	3,150
Furniture, fixtures and office equipment		981		931
Computer equipment and software		3,485		3,147
Leasehold improvements		3,908		3,332
Construction in process		608		408
Total property and equipment, gross		12,246		10,968
Less: Accumulated depreciation		(8,279)		(7,093)
	\$	3,967	\$	3,875

Depreciation expense for both the three months ended September 30, 2017 and September 30, 2016 was \$0.4 million and depreciation expense for both the nine months ended September 30, 2017 and September 30, 2016 was \$1.2 million.

Accrued expenses as of September 30, 2017 and December 31, 2016:

(In thousands)	September 30, 2017	Dec	ember 31, 2016
Bonus related compensation	\$ 1,608	\$	2,433
Employee related accruals	2,021		1,668
Clinical trial related accruals	379		422
Other	506		_
	\$ 4,514	\$	4,523

### 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 the Company issued warrants in connection with the updated debt agreement (September 2016 Warrants) discussed in note 7. The warrants issued in August 2013 (August 2013 Warrants) include anti-dilution price protection provisions that could require cash settlement of the warrants and accordingly require the warrants to be recorded as liabilities of the Company at the estimated fair value at the date of issuance, 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 September 2016 Warrants meet the requirements for equity classification. The following table describes the outstanding warrants:

	August 2013 Warrants	Sontombor 2016 Woments
	warrants	September 2016 Warrants
Exercise price	\$4.80	\$2.48
Expiration date	August 16, 2018	September 9, 2022
Total shares issuable on exercise	724,950	117,074

On September 9, 2016, the Company issued 117,074 warrants to two holders in conjunction with the loan agreement described in note 7. The initial valuation of the September 2016 Warrants was recorded as debt issuance costs and is being amortized over the remaining life of the loan agreement to interest expense. The September 2016 Warrants are treated as equity instruments recorded at fair value with no subsequent remeasurement. Pursuant to the warrants, the holders may exercise their warrants for an aggregate of 117,074 shares of the Company's common stock.

The fair value of the warrants described in the table above is measured using the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero. See further detail in note 9 of the condensed consolidated financial statements.



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

August 2013 Warrants	September 30, 2017		Decem	ber 31, 2016
Closing stock price	\$	6.00	\$	3.00
Expected dividend rate		%		%
Expected stock price volatility		50.6%		97.9%
Risk-free interest rate		1.3%		1.0%
Expected life (years)		0.88		1.62

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

#### 7. Debt

On March 8, 2016, the Company entered into a \$15.0 million debt financing with SVB which on September 9, 2016, was replaced by an expanded term loan and revolving line of credit agreement with SVB and MidCap, which together initially provided access to up to \$20 million. The updated debt financing consists of a \$4.0 million term loan which was drawn at the closing, a \$4.0 million term loan which was drawn upon in November 2016, a \$2.0 million term loan which is no longer available as it was not drawn upon by April 12, 2017 and up to \$10.0 million of a revolving line of credit. The term loans are interest only (indexed to Wall Street Journal (WSJ) Prime plus 5.00%) until September 1, 2017 followed by 36 equal monthly payments of principal plus interest maturing September 9, 2020. The revolving line of credit is limited to a borrowing base calculated using eligible accounts receivable and maturing September 9, 2020 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 monthly minimum net revenue covenants (determined in accordance with U.S. 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. The Company has not been informed of any material adverse changes that have occurred. 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, 2017, there was an outstanding balance of \$7.8 million under the term loan and \$2.5 million under the revolving line of credit (net of total deferred costs of \$0.3 million). The weighted average interest rate on the outstanding term and revolving credit loans as of September 30, 2017 was 7.8%. On December 30, 2016, the Company entered into an amendment to the SVB-MidCap facility to amend certain financial covenants and to modify the final payment of the term loan advance. The Company further amended the SVB-MidCap facility on May 9, 2017 to update the monthly net revenue requirement covenants, measured on a trailing twelve month basis. The amendment decreased the monthly 12 month trailing minimum revenue covenant and revised the December 31, 2017 minimum revenue covenant to \$51.7 million. As of September 30, 2017, the Company was in compliance with the minimum revenue covenant. As of September 30, 2017, there was \$3.3 million remaining capacity under the revolving line of credit.

#### 8. Stock-based Compensation

#### Stock Option and Equity Incentive Plans

The Company can issue nonqualified and incentive stock options as well as other equity awards pursuant to its Second Amended and Restated 2009 Omnibus Incentive Plan (Option Plan). Such awards pursuant to the Option Plan may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants.

During the three and nine months ended September 30, 2017, the Company granted 127,200 and 1,677,760, respectively, service-based options to purchase common stock. The options were granted with exercise prices equal to the fair market value of the Company's stock at the grant date, and other than those granted to non-employee directors, vest over four years, under a graded-vesting methodology, following the date of grant, and expire after ten years. The Company issues new shares upon the exercise of stock options. The weighted average grant-date fair value of service-based options granted under the Option Plan during the three and nine month periods ended September 30, 2017 was \$2.53 and \$1.99, respectively and, \$1.77 and \$2.15, respectively for the same periods in 2016.



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:

	Thi	Three Months Ended September 30,				Nine Months Ended September 30,			
(In thousands)		2017		2016		2017		2016	
Cost of goods sold	\$	119	\$	117	\$	316	\$	330	
Research and development		177		133	\$	391	\$	392	
Selling, general and administrative		459		404		1,346		1,251	
Total non-cash stock-based compensation expense	\$	755	\$	654	\$	2,053	\$	1,973	

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 optionpricing model using the weighted average assumptions noted in the following table.

	Nine Months Ended	September 30,
Service-Based Stock Options	2017	2016
Expected dividend rate		%
Expected stock price volatility	80.1 - 88.2%	78.7 - 92.2%
Risk-free interest rate	1.8 - 2.3%	1.1 - 1.8%
Expected life (years)	5.5 - 6.3	5.5 - 6.3

The following table summarizes the activity for service-based stock options for the indicated periods:

Service-Based Stock Options	Options	Weighted Average Exercise Price	Aggregate Intrinsic Value	
Outstanding at December 31, 2016	3,355,692	\$ 4.66	8.2	\$ 610
Granted	1,677,760	\$ 2.82		
Exercised	(165,678)	\$ 3.12		\$ 362
Expired	(100,131)	\$ 16.31		
Forfeited	(190,766)	\$ 3.35		
Outstanding at September 30, 2017	4,576,877	\$ 3.84	8.2	\$ 13,336
Exercisable at September 30, 2017	1,870,011	\$ 5.18	7.5	\$ 4,988

As of September 30, 2017 there was approximately \$3.4 million of total unrecognized compensation cost related to non-vested service-based stock options granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 3.0 years.

The total fair value of options vested during the three and nine months ended September 30, 2017 was \$0.6 million and \$1.8 million, respectively, and \$0.6 million and \$1.6 million, respectively, for the same periods in 2016.

#### **Employee Stock Purchase Plan**

Employees are able to purchase stock under the Vericel Corporation Employee Stock Purchase Plan (ESPP), which was implemented effective October 1, 2015. Participation in this plan is available to substantially all employees. 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 2, 2017, employees purchased 40,683 shares resulting in proceeds from the sale of common stock of \$0.1 million under the ESPP. The total share-based compensation expense for the ESPP for the nine months ended September 30, 2017 was approximately \$0.1 million.

#### 9. Fair Value Measurements

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

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

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

	 September 30, 2017					December 31, 2016									
			Fair va	r value measurement category							Fair va	alue n	neasurement	categ	ory
(In thousands)	Total		Level 1	Level 2 Level 3				Total		Level 1	Level 2			Level 3	
Liabilities:															
Warrant liabilities	\$ 1,269	\$		\$	1,269	\$	—	\$	757	\$	—	\$	757	\$	—

The following table summarizes the change in the estimated fair value of the Company's warrant liabilities:

Warrant Liabilities (In thousands)	
Balance at December 31, 2016	\$ 757
Increase in fair value	512
Balance at September 30, 2017	\$ 1,269

#### **Revolving and Term Loan Credit Agreements**

At September 30, 2017 and December 31, 2016, we had a total of \$10.0 million and \$10.1 million, respectively, outstanding under our revolving and term loan credit agreements, which are variable rate loans. The fair value of these loans approximates book value based on the borrowing rates currently available for variable rate loans obtained from third party lending institutions. These fair values represent Level 2 under the three-tier hierarchy described above.

#### 10. Shareholders' Equity

#### At-the-Market Sales Agreement

On October 10, 2016, the Company entered into our at-the-market sales agreement with Cowen (ATM Agreement), pursuant to which the Company may sell shares of our common stock through Cowen, as sales agent, in registered transactions from our shelf registration statement filed in June 2015, for aggregate proceeds of up to \$25.0 million. Shares of common stock sold under the ATM are to be sold at market prices. The Company will pay up to 3% of the gross proceeds to Cowen as a commission. A total of 2,222,240 shares of common stock have been sold under the ATM Agreement of which 1,864,384 were sold in 2017 for proceeds of \$6.7 million (net of \$0.3 million in commission and issuance costs) and as of September 30, 2017 had remaining capacity of approximately \$17.2 million. We currently intend to use the net proceeds for research, development, manufacturing, and general and administrative expenses, and for other general corporate purposes.

#### 11. Preferred Stock

#### Series B Convertible Preferred Stock

On February 10, 2017, the Company sent notice to Eastern Capital Limited (Eastern), an existing holder of shares of the Company's Series B-1 Non-Voting Convertible Preferred Stock or Series B-2 Voting Convertible Preferred Stock (Preferred Stock), informing Eastern of the Company's election to convert all 12,308 of the outstanding shares of Preferred Stock held by Eastern, plus 9,570 shares of Preferred Stock in accumulated but undeclared dividends thereon, into 1,093,892 shares of the Company's common stock pursuant to the terms of the Amended and Restated Certificate of Designations, Preferences and Rights of Series B-1 Non-Voting Preferred Stock and Series B-2 Voting Preferred Stock of the Company (Mandatory Conversion). After the Mandatory Conversion on March 9, 2017, no shares of Preferred Stock of the Company remain outstanding as of September 30, 2017.

#### 12.Net Loss Per Common Share

Basic earnings (loss) per share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (loss) per share for the holders of the Company's common shares and holders of the Series B Preferred Stock. The Series B Preferred Stock shares contain participation rights in undistributed earnings, but do not share in the losses of the Company. The dividends on the Series B Preferred Stock were treated as a reduction of earnings attributable to common shareholders.

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:

	1	Three months end	ded Se	ptember 30,	Nine months ended September 30,				
(Amounts in thousands except per share amounts)		2017		2016		2017		2016	
Numerator:									
Net loss	\$	(5,407)	\$	(6,675)	\$	(17,573)	\$	(13,369)	
Dividends accumulated on convertible preferred stock				(1,931)		—		(5,591)	
Net loss attributable to common shareholders	\$	(5,407)	\$	(8,606)	\$	(17,573)	\$	(18,960)	
Denominator:									
Denominator for basic and diluted EPS:									
Weighted-average common shares outstanding		33,667		22,744		32,783		22,678	
Net loss per share attributable to common shareholders (basic and diluted)	\$	(0.16)	\$	(0.38)	\$	(0.54)	\$	(0.84)	

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, 2017 and 2016 were 5.4 million and 6.5 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 terms 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 consolidated balance sheet and is amortized to our consolidated statement of operations as reductions to rent expense over the lease term. As of September 30, 2017, the Company has recorded \$1.0 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 material in manufacturing.

As of September 30, 2017, future minimum payments related to leases and other contractual obligations are as follows:

(In thousands)	Total	2017	2018	2019	2020	2021	re than 5 Years
Operating leases	\$ 20,378	\$ 1,317	\$ 4,806	\$ 4,473	\$ 4,475	\$ 4,546	\$ 761
Purchase commitments	2,940	45	681	576	546	546	546
Capital leases	43	11	32				
Total	\$ 23,361	\$ 1,373	\$ 5,519	\$ 5,049	\$ 5,021	\$ 5,092	\$ 1,307

Rent expense for the three and nine months ended September 30, 2017 was \$1.5 million and \$4.1 million, respectively, and \$1.2 million and \$3.6 million, respectively, for the three and nine months ended September 30, 2016.

#### 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 Vericel product portfolio in Greater China, South Korea, Singapore, and other countries in Asia. ICT will acquire an exclusive license to certain patent rights, know-how and intellectual property relating to Carticel, MACI, ixmyelocel-T, and Epicel as well as enter into a warrant purchase agreement. As part of the license and warrant purchase agreements, the Company will receive an upfront payment of \$6.0 million, less any applicable taxes, within 60 days of the effective date of the License Agreement. The initiation of the technology transfer, the license grants in the License Agreement and the warrant purchase are contingent upon Vericel's receipt of the upfront payment. Vericel is eligible to receive approximately \$8.0 million in development and commercial milestones. ICT has also agreed to pay tiered royalties to Vericel equal to a percentage of net sales of each Licensed Product in the low double digits for the commercial life of the applicable Licensed Product. ICT will be responsible for funding the development of the programs and manufacturing of the products for commercialization in China and the rest of the territory. The funding transfer is subject to approval by the State Administration of Foreign Exchange of the People's Republic of China and has not occurred as of issuance date of the financial statements. As a result, the parties have amended the agreement monthly to provide additional time for ICT to pay and reset certain terms of the warrant. The initiation of the technology transfer, the license grants in the License Agreement and the warrant purchase have not occurred. As partial consideration for an amount included in the withholding tax payable thereon divided by \$4.90 currently (formerly \$3.05), with a strike price of \$0.01 per share.

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

#### Overview

Vericel Corporation is a leading developer of patient-specific expanded cell therapies for use in the treatment of patients with severe diseases and conditions. We currently have two U.S. Food and Drug Administration (FDA) marketed 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, MACI replaced Carticel® (autologous cultured chondrocytes), 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). Our development stage portfolio includes ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM).

#### Manufacturing

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

#### **Product Portfolio**

Our approved and marketed products include two approved autologous cell therapy products: MACI (autologous cultured chondrocytes on a porcine collagen membrane), a third generation autologous implant for the repair of symptomatic, full-thickness cartilage defects of the knee in adult patients and Epicel (cultured epidermal autografts), a permanent skin replacement for full thickness burns in adults and pediatrics with greater than or equal to 30% of total body surface area (TBSA) also currently marketed in the U.S. We also own Carticel (autologous cultured chondrocytes), a first-generation product for autologous chondrocyte implantation (ACI) which is no longer marketed in the U.S. Our product candidate portfolio included ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to DCM. On September 29, 2017, the FDA indicated we would be required to conduct an additional clinical study to support a Biologics License Application (BLA) for ixmyelocel-T. We have decided we will not conduct any additional clinical studies for ixmyelocel-T unless fully 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 is 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 such as debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft. Carticel received a BLA approval in 1997 and is no longer marketed in the U.S. It was generally used on patients with larger lesions (greater than 3 cm<sub>2</sub>). 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 orthopedic physician target audience is very concentrated, with two thirds of our 2016 Carticel business originating from approximately 150 physicians. Our target Carticel and MACI audience is a group of physicians who self-identify as or have the formal specialty of sports medicine physicians. We believe this target audience is approximately 500 physicians. At the end of 2016 we expanded our field force from 21 to 28 representatives. Most private payers have a medical policy that allows treatment with Carticel and we are actively working with payers to ensure reimbursement for MACI. 28 of the top 30 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 nine months ended September 30, 2017, net revenues were \$27.8 million for Carticel and MACI.

#### Epicel

Epicel (cultured epidermal autografts) is a permanent skin replacement for full thickness burns greater than or equal to 30% of TBSA. Epicel is regulated by the CBER under medical device authorities, and is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was designated as a HUD in 1998 and an HDE application for the product was submitted in 1999. HUDs are devices that are intended for diseases or conditions that affect fewer than 4,000 individuals annually in the United States. Under an HDE approval, a HUD cannot be sold for an amount that exceeds the cost of research and development, fabrication and distribution unless certain conditions are met. Currently, fewer than 100 patients are treated with Epicel in the U.S. each year. For the nine months ended September 30, 2017, net revenues were \$12.8 million for Epicel.

A HUD is eligible to be sold for profit after receiving HDE approval if the device meets certain eligibility criteria, including where the device is intended for the treatment of a disease or condition that occurs in pediatric patients and such device is labeled for use in pediatric patients. If the FDA determines that a HUD meets the eligibility criteria, the HUD is permitted to be sold for profit as long as the number of devices distributed in any calendar year does not exceed the annual distribution number (ADN). The ADN is defined as the number of devices reasonably needed to treat a population of 4,000 individuals per year in the United States.

On February 18, 2016, the FDA approved our HDE supplement to revise the labeled indications of use to specifically include pediatric patients and to add pediatric labeling. The revised product label also now specifies that the probable benefit of Epicel, mainly related to survival, was demonstrated in two Epicel clinical experience databases and a physician-sponsored study comparing outcomes in patients with massive burns treated with Epicel relative to standard care. Due to the change in the label to include use in pediatric patients, Epicel is no longer subject to the HDE profit restrictions. In conjunction with 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 2016. We currently have a 5-person field force.

#### Ixmyelocel-T

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

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

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

#### **Results of Operations**

#### Net Loss

Our net loss for the three and nine months ended September 30, 2017 totaled \$5.4 million and \$17.6 million, respectively. Our net loss for the three and nine months ended September 30, 2016 totaled \$6.7 million and \$13.4 million, respectively.

	Three Months En	ded Sept	Nine Months Ended September 30,				
(In thousands)	 2017		2016		2017		2016
Total revenues	\$ 14,260	\$	10,929	\$	40,574	\$	37,860
Cost of product sales	7,186		6,856		21,965		20,716
Gross profit	 7,074		4,073		18,609		17,144
Total operating expenses	11,105		10,453		34,784		30,500
Loss from operations	 (4,031)		(6,380)		(16,175)		(13,356)
Other income (expense)	(1,376)		(295)		(1,398)		(13)
Net loss	\$ (5,407)	\$	(6,675)	\$	(17,573)	\$	(13,369)
						_	

#### Net Revenues

Net revenues increased for the three months ended September 30, 2017 compared to the same period the previous year due primarily to an increase in MACI and Epicel sales units and an increase in average sales price per unit.

Net revenues increased for the nine months ended September 30, 2017 primarily due to higher Carticel, MACI and Epicel sales units and higher average price per unit. In April 2017, we were informed of a contractual dispute between Vital Care, Inc. (Vital Care) and the third-party payer related to certain insurance reimbursement claims associated with Carticel and MACI surgeries performed in 2016 and 2017. This contractual dispute between Vital Care and the third-party payer was resolved. The negotiated reimbursement and related change in estimate, for sales that were originally recorded in 2016, resulted in a decrease of \$0.6 million to revenue for the nine months ended September 30, 2017.

	Т	hree Months En	ded Se	 Nine Months End	led Se	ptember 30,	
Revenue by product (in thousands)		2017		2016	2017		2016
Carticel and MACI	\$	9,909	\$	8,319	\$ 27,821	\$	26,117
Epicel		4,351		2,610	12,753		11,743
	\$	14,260	\$	10,929	\$ 40,574	\$	37,860

Seasonality. Carticel revenue was subject to seasonal fluctuations with stronger sales occurring in the fourth quarter and second quarter due to a number of factors including insurance copay limits and the time of year patients prefer to start rehabilitation, and MACI revenue is expected to be subject to these seasonal fluctuations as well. Over the last five years, the percentage of annual sales by quarter has ranged as follows: first quarter, 20% to 23%; and fourth quarter, 28% to 33%. During 2016, the percentage of annual sales by quarter was as follows: 24% in the first quarter; 24% in the second quarter; 20% in the third quarter; and 32% in the fourth quarter. 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 absend due to the extreme variability inherent with Epicel's low patient volume of fewer than 100 patients per year. Over the last five years, the percentage of annual sales by quarter, 23% to 33%. The variability between the same quarter, 22% to 35%; second quarter, 22% to 28%; third quarter, 17% to 24%; and fourth quarter, 23% to 30%. The variability between the same quarters in consecutive years has been as high as 11% of the annual volume. While the number of patients treated per year remains low, we expect these large swings in revenue in some quarters to continue. These seasonal trends have caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

#### Gross Profit and Gross Profit Ratio

		Three Months Er	nded S	eptember 30,	Nine Months Ended September 30,					
(In thousands)	2017			2016		2017	2016			
Gross profit	\$	7,074	\$	4,073	\$	18,609	\$	17,144		
Gross profit %		50%		37%	46%			45%		

Gross profit ratio increased for the three and nine months ended September 30, 2017 compared to the same period in 2016 due primarily to an increase in Carticel and MACI sales described above.

#### Research and Development Costs

	Three Months En	ded Se	eptember 30,	Nine Months Ended September 30,			
(In thousands)	2017		2016	2017	2016		
Research and development costs	\$ 2,919	\$	3,443	9,357	11,037		

Research and development costs for the three months ended September 30, 2017 were \$2.9 million versus \$3.4 million for the same period a year ago, primarily due to a reduction in the ixCELL-DCM clinical trial expenses. 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 were offered the option to receive ixmyelocel-T beginning in 2016. We successfully treated the last patients in February 2017 and lower expenses were incurred in the current period. MACI research and development costs increased related to activity incurred as a result of the FDA approval received in December 2016.

Research and development costs for the nine months ended September 30, 2017 were \$9.4 million versus \$11.0 million for the same period a year ago. As described above, the trial expenses for the ixCELL-DCM clinical trial decreased as the trial completed treatment of the patients who received the placebo. Carticel-related expenses decreased as a result of the approved MACI product in December 2016. Additional costs were incurred related to MACI upon the approval.

	1	Three Months En	ded Se	eptember 30,	Nine Months Ended September 30,				
(In thousands)		2017		2016		2017		2016	
Dilated Cardiomyopathy	\$	909	\$	1,875	\$	4,050	\$	5,732	
MACI		1,385		636		3,309		1,916	
Carticel		45		462		369		1,828	
Epicel		580		470		1,629		1,561	
Total research and development costs	\$	2,919	\$	3,443	\$	9,357	\$	11,037	

Selling, General and Administrative Costs

	Three Months En	ded Se	eptember 30,	Nine Months Ended September 30,			
(In thousands)	 2017		2016		2017		2016
Selling, general and administrative costs	\$ 8,186	\$	7,010	\$	25,427	\$	19,463

Selling, general and administrative costs for the three months ended September 30, 2017 were \$8.2 million compared to \$7.0 million for the same period a year ago. The increase in selling, general and administrative costs for the three months ended September 30, 2017 is due primarily to an increase in personnel and employee costs of \$0.9 million related to an increase in the MACI sales force.

Selling, general and administrative costs for the nine months ended September 30, 2017 were \$25.4 million compared to \$19.5 million for the same period a year ago. The increase in selling, general and administrative costs in 2017 is driven by an increase in personnel costs of \$1.6 million primarily related to an increase in the MACI sales force, consulting and agency fees of \$3.0 million related to the launch of MACI and costs associated with our reimbursement and patient support services for MACI of \$0.9 million.

Other Income (Expense)

	Three Months Ended September 30,			Nine Months Ended September 30,				
(In thousands)		2017		2016		2017		2016
Decrease in fair value of warrants	\$	(1,060)	\$	(203)	\$	(512)	\$	99
Foreign currency translation (loss)		(6)		(6)		(20)		(17)
Other income (expense)		5		—		6		(10)
Net interest (expense) income		(315)		(86)		(872)		(85)
Total other income (expense)	\$	(1,376)	\$	(295)	\$	(1,398)	\$	(13)

The change in other income and expense for the three and nine months ended September 30, 2017 compared to 2016 is due primarily to interest expense on the outstanding revolving credit agreement and term loans, the change in warrant value as a result of the fluctuations in our stock price and the reduction in the time to maturity. Fluctuations in the fair value of the warrants in



future periods could result in significant non-cash adjustments to the condensed consolidated financial statements; however, any income or expense recorded will not impact our cash, operating expenses or cash flow.

#### Stock Compensation

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

	Thr	Three Months Ended September 30,			Nine Months Ended September 30,			
(In thousands)	2	2017		2016		2017		2016
Cost of goods sold	\$	119	\$	117	\$	316	\$	330
Research and development		177		133	\$	391	\$	392
Selling, general and administrative		459		404		1,346		1,251
Total non-cash stock-based compensation expense	\$	755	\$	654	\$	2,053	\$	1,973

The changes in stock-based compensation expense are due primarily to fluctuations in the fair value of the options granted in 2017 compared to 2016.

### Liquidity and Capital Resources

We are currently focused on utilizing our technology to identify, develop and commercialize innovative therapies that enable the body to repair and regenerate damaged tissues and organs to restore normal structure and function. Since the acquisition in 2014 of the CTRM Business of Sanofi, the sales of Carticel and Epicel therapies have constituted nearly all of our product sales revenues. With the approval of MACI and replacement of Carticel with MACI, we expect the sales of MACI and Epicel therapies will constitute nearly all of our product sales revenues. Additionally, we are focusing significant resources to grow our commercial business.

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 including the net proceeds of approximately \$18.0 million we received from our December 2016 public offering and the availability of funds under the SVB-Mid-Cap Facility. While we believe that, based on our current cash on hand, we are in a position to sustain operations through at least November 2018, if actual results differ from our projections, we may need to access additional capital.

On October 10, 2016 we entered into an at-the-market sales agreement (ATM Agreement) with Cowen and Company, LLC (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 (ATM Offering). The ATM Shares will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-205336). We filed a prospectus supplement, dated October 10, 2016, with the Securities and Exchange Commission in connection with the offer and sale of the ATM Shares sold under the ATM Agreement. We are obliged to pay 3% of the gross proceeds to Cowen as a commission. As of September 30, 2017, approximately \$17.2 million of net capacity remained under the ATM Agreement.

Our cash totaled \$15.5 million as of September 30, 2017. During the nine months ended September 30, 2017, the cash used for operations was \$14.0 million. This use of funds was fueled largely by our operating loss of \$17.6 million reduced by noncash charges including \$2.1 million of stock compensation expense, \$1.2 million of depreciation expense and \$0.5 million due to the change in fair value of warrants.

The change in cash used for investing activities is the result of material property plant and equipment purchases of \$0.8 million for manufacturing upgrades and leasehold improvements through September 30, 2017.

The change in cash provided from financing activities is the result of the ATM activity during the nine months ended September 30, 2017 which did not occur during the nine months ended September 30, 2016. In 2016, we had net borrowings of \$6.0 million under our term loan and revolving credit agreements and no additional borrowings in 2017.

On March 8, 2016, we entered into a \$15.0 million debt financing with SVB which we replaced on September 9, 2016 with an expanded term loan and revolving line of credit agreement with SVB and MidCap Financial Services, or MidCap, which initially provide access to up to \$20 million. The updated debt financing consists of a \$4.0 million term loan which was drawn at the closing, a \$4.0 million term loan which was drawn upon in November 2016, a \$2.0 million term loan which is no longer available

as it was not drawn on by April 12, 2017 and up to \$10.0 million of a revolving line of credit. The term loans are interest only (indexed to Wall Street Journal (WSJ) Prime plus 5.00%) until September 1, 2017 followed by 36 equal monthly payments of principal plus interest maturing September 9, 2020. Per the initial terms of the agreement, the revolving credit is limited to a borrowing base calculated using eligible accounts receivable which was further reduced in the amendment described below and maturing September 9, 2020 with an interest rate indexed to WSJ Prime plus 1.25%. We are subject to various financial and nonfinancial covenants including but not limited to a monthly minimum net revenue covenant (determined in accordance with U.S. GAAP), measured on a trailing twelve month basis. The December 31, 2017 minimum revenue covenant is set at \$51.7 million. SVB and MidCap also have the ability to call debt based on material adverse change chauses which are subjectively determinable and result in a subjective acceleration clause. The Company does not believe any material adverse change shave 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 revolving blance of \$7.8 million under the term loan and \$2.5 million under the tervolving line of credit.

On December 30, 2016, we entered into an amendment to the SVB-MidCap facility to amend certain financial covenants and to modify the final payment of the term loan advance. We further amended the SVB-MidCap facility on May 9, 2017 to update the monthly net revenue requirement covenants, measured on a trailing twelve month basis. The amendment decreased the 12 month trailing minimum revenue covenant as of June 30, 2017 and revised the December 31, 2017 minimum revenue covenant to \$51.7 million. As of September 30, 2017, we were in compliance with the minimum revenue covenant. The amount of eligible account receivables used to calculate the availability under the revolving line of credit is no longer reduced by the \$3.0 million per the terms of an amendment, as our revenue met minimum revenue targets for two (2) consecutive quarters. As of September 30, 2017, there was \$3.3 million remaining capacity under the revolving line of credit. The distribution agreement with Orsini discussed in note 4 and the concentration of credit limitations in the calculation of eligible account receivables could further reduce our ability to borrow under the revolving line of credit.

While we believe that, based on our current cash on hand, we are in a position to sustain operations through at least November 2018, if actual results differ from our projections or we pursue other strategic opportunities, we may need to access additional capital. In addition, if our revenues do not meet the existing threshold set forth in the debt covenants, and we are unable to renegotiate those thresholds, SVB could call the debt immediately. Such events could result in the need for additional funds. However, we may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of our shareholders. If we need additional funds and we are unable to obtain funding on a timely basis, we may need to significantly curtail our operations including our research and development programs in an effort to provide sufficient funds to continue our operations, which could adversely affect our business prospects. Actual cash requirements may differ from projections and will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of product launch and market acceptance of those products and commercialization of newly approved products.

#### **Off-Balance Sheet Arrangements**

At September 30, 2017, 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, 2016 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. There have been no material changes to that information disclosed in our Annual Report during the nine months ended September 30, 2017.

#### **Forward-Looking Statements**

This report, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange



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

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

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

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of September 30, 2017, 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, 2016.

#### 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, 2017, 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, 2017 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, 2017 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, 2016. The risks described in the Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 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

On August 11, 2017, we received a comment letter from the staff of the SEC with respect to our Form 10-K for the fiscal year ended December 31, 2016. We responded to the SEC's comments on September 11, 2017, and received one follow-up comment from the SEC on October 4, 2017, regarding the applicable accounting policies used for revenue recognition and product sales. On October 18, 2017, we submitted our response to the SEC regarding this comment. As of November 7, 2017 we are still waiting for a response from the SEC to clear the unresolved comment.

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

The Company did not repurchase any of its equity securities during the quarter ended September 30, 2017.

#### Item 6. Exhibits

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

# EXHIBIT INDEX

Exhibit No. Description		
10.1	First Amendment to Executive Employment Agreement by and between Dominick C. Colangelo and the Company, dated September 14, 2017, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 19, 2017, incorporated herein by reference.	
10.2	Amended and Restated Employment Agreement by and between Daniel Orlando and the Company, dated September 14, 2017, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 19, 2017, incorporated herein by reference.	
10.3	Amended and Restated Employment Agreement by and between Gerard Michel and the Company, dated September 15, 2017, filed as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on September 19, 2017, incorporated herein by reference.	
10.4**	<u>Amendment No. 1 to License Agreement between Vericel Corporation and Innovative Cellular Therapeutics CO., LTD., dated</u> <u>August 3, 2017.</u>	
10.5**	Amendment No. 2 to License Agreement between Vericel Corporation and Innovative Cellular Therapeutics CO., LTD., dated September 5, 2017.	
10.6**	Amendment No. 1 to Side Letter between Vericel Corporation and Innovative Cellular Therapeutics CO., LTD., dated August 3, 1017.	
10.7**	Amendment No. 2 to Side Letter between Vericel Corporation and Innovative Cellular Therapeutics CO., LTD., dated September 5, 2017.	
10.8†**	First Amendment to Distribution Agreement between Orsini Pharmaceutical Services, Inc. and the Company, dated August 10, 2017.	
31.1**	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	
31.2**	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
101.INS**	XBRL Instance Document	
101.SCH**	XBRL Taxonomy Extension Schema Document	
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document	
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document	
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document	
101 DEF**	XBRL Taxonomy Extension Definition Linkbase Document	

\*\* 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 7, 2017

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)

# **AMENDMENT NO. 1 TO LICENSE AGREEMENT**

This Amendment No 1 ("Amendment") to the License Agreement (as defined below) dated as of August 3, 2017 (the "Amendment Date"), is entered into by and between "上海斯丹赛生物"技术有限公司" (Innovative Cellular Therapeutics CO., LTD.), a corporation organized and existing under the laws of China ("ICT"), and Vericel Corporation, a corporation organized and existing under the laws of the State of Michigan ("Vericel"). Terms used, but not defined, herein shall have the meaning ascribed to them in the License Agreement.

# RECITALS

WHEREAS, Vericel and ICT are parties to that certain License Agreement, dated as of May 9, 2017 (the "License Agreement"); and

**WHEREAS**, the Parties desire to amend the License Agreement on the terms and subject to the conditions set forth herein, with this Amendment becoming effective on August 7, 2017 at 4:00 pm Eastern Daylight Time (the "Effective Time") if the Upfront Payment is not received by Vericel from ICT at or before the Effective Time (the "Nonpayment Condition").

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

# 1. AMENDMENTS

**1.1** Section 12.2.4 of the License Agreement is hereby deleted in its entirety and replaced with the following:

**12.2.4 Termination of Agreement for Failure to Pay Upfront Payment.** ICT shall use its commercially reasonable efforts to pay the Upfront Payment within sixty (60) days after the Effective Date. In the event the default of its timely payment is caused by the related regulatory approval process, ICT shall immediately notify Vericel by a written notice and ICT will be granted a grace period of sixty (60) days after Vericel's receipt of such notice to fulfill ICT's payment obligation with regards to Upfront Payment. Subject to <u>Section 13.12</u>, Vericel shall have the right to terminate this Agreement in its entirety, immediately upon written notice to ICT, if ICT fails to pay the Upfront Payment within such sixty (60) day grace period, <u>provided</u> that Vericel's right to terminate this Agreement under this <u>Section 12.2.4</u> shall expire on the earlier of (a) the date that is one hundred twenty (120) days after the Effective Date or (b) the Upfront Payment Receipt Date.

### 2. MISCELLANEOUS

2.1 This Amendment shall become effective at the Effective Time if, and only if, the Nonpayment Condition has occurred.

**2.2** Except to the extent modified herein, the terms and conditions of the License Agreement shall remain in full force and effect.

**2.3** This Amendment shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Amendment to the substantive law of another jurisdiction.

**2.4** This Amendment may be executed in two or more counterparts, including by facsimile or PDF signature pages, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 1 to the License Agreement as of the Amendment Date.

Innovative Cellular Therapeutics Co., Ltd.	Vericel Corporation
BY:/s/Lei Xiao	BY:/s/Dominick Colangelo
NAME:Lei Xiao	NAME: _Dominick Colangelo
TITLE:Chairman	TITLE: _Chief Executive Officer

# **AMENDMENT NO. 2 TO LICENSE AGREEMENT**

This Amendment No 2 ("Amendment") to the License Agreement (as defined below) dated as of September 5, 2017 (the "Amendment Date"), is entered into by and between "上海斯丹赛生物"技术有限公司" (Innovative Cellular Therapeutics CO., LTD.), a corporation organized and existing under the laws of China ("ICT"), and Vericel Corporation, a corporation organized and existing under the laws of the State of Michigan ("Vericel"). Terms used, but not defined, herein shall have the meaning ascribed to them in the License Agreement.

# RECITALS

WHEREAS, Vericel and ICT are parties to that certain License Agreement, dated as of May 9, 2017 (the "License Agreement"); and

**WHEREAS**, the Parties desire to amend the License Agreement on the terms and subject to the conditions set forth herein, with this Amendment becoming effective on September 6, 2017 at 4:00 pm Eastern Daylight Time (the "Effective Time") if the Upfront Payment is not received by Vericel from ICT at or before the Effective Time (the "Nonpayment Condition").

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

# 1. AMENDMENTS

**1.1** Section 12.2.4 of the License Agreement is hereby deleted in its entirety and replaced with the following:

**12.2.4 Termination of Agreement for Failure to Pay Upfront Payment.** ICT shall use its commercially reasonable efforts to pay the Upfront Payment within sixty (60) days after the Effective Date. In the event the default of its timely payment is caused by the related regulatory approval process, ICT shall immediately notify Vericel by a written notice and ICT will be granted a grace period of sixty (60) days after Vericel's receipt of such notice to fulfill ICT's payment obligation with regards to Upfront Payment. Subject to <u>Section 13.12</u>, Vericel shall have the right to terminate this Agreement in its entirety, immediately upon written notice to ICT, if ICT fails to pay the Upfront Payment within such sixty (60) day grace period, <u>provided</u> that Vericel's right to terminate this Agreement under this <u>Section 12.2.4</u> shall expire on the earlier of (a) the date that is one hundred twenty (120) days after the Effective Date or (b) the Upfront Payment Receipt Date.

### 2. MISCELLANEOUS

2.1 This Amendment shall become effective at the Effective Time if, and only if, the Nonpayment Condition has occurred.

**2.2** Except to the extent modified herein, the terms and conditions of the License Agreement shall remain in full force and effect.

**2.3** This Amendment shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Amendment to the substantive law of another jurisdiction.

**2.4** This Amendment may be executed in two or more counterparts, including by facsimile or PDF signature pages, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 2 to the License Agreement as of the Amendment Date.

Innovative Cellular Therapeutics Co., Ltd.	Vericel Corporation
BY:/s/Lei Xiao	BY:/s/Dominick Colangelo
NAME:Lei Xiao	NAME: _Dominick Colangelo
TITLE:Chairman	TITLE: _Chief Executive Officer

### EXHIBIT 10.6

### **CONFIDENTIAL**

# AMENDMENT NO. 1 TO LETTER AGREEMENT

This Amendment No 1 ("**Amendment**") to the Letter Agreement (as defined below) dated as of August 3, 2017 (the "**Amendment Date**"), is entered into by and between "上海斯丹赛生物"技术有限公司" (Innovative Cellular Therapeutics CO., LTD.), a corporation organized and existing under the laws of China ("**ICT**"), and Vericel Corporation, a corporation organized and existing under the laws of the State of Michigan ("**Vericel**"). Terms used, but not defined, herein shall have the meaning ascribed to them in the Letter Agreement. ICT and Vericel are each referred to herein as a "**Party**" or collectively the "**Parties**".

# RECITALS

WHEREAS, Vericel and ICT are parties to that certain License Agreement, dated as of May 9, 2017 (the "License Agreement"); and

WHEREAS, in connection with entering into the License Agreement, Vericel and ICT entered into that certain letter agreement, dated as of May 9, 2017 (the "Letter Agreement"); and

WHEREAS, the Parties desire to amend the Letter Agreement on the terms and subject to the conditions set forth herein, with this Amendment becoming effective on August 7, 2017 at 4:00 pm Eastern Daylight Time (the "Effective Time") if the Upfront Payment (as defined in the License Agreement) is not received by Vericel from ICT at or before the Effective Time (the "Nonpayment Condition").

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

# 1. AMENDMENTS

1.1 The third  $(3^{rd})$  sentence of the second  $(2^{nd})$  full paragraph of the Letter Agreement is hereby deleted in its entirety and replaced with the following:

As consideration for an amount included in the Upfront Payment equal to (a) \$5,000,000.00 minus (b) the Withholding Income Taxes (such amount, the "**Warrant Purchase Price**"), Vericel hereby agrees to issue to ICT, effective as of and contingent upon Vericel's receipt of the Upfront Payment, a warrant (the "**Common Stock Warrant**") in substantially the form attached hereto as <u>Exhibit A</u>, exercisable for the number of shares of Vericel's Common Stock equal to (x) the Warrant Purchase Price divided by (y) the closing price of a share of Vericel's Common Stock on the Nasdaq Stock Market on August 3, 2017, rounded down to the nearest whole number.

1.2 The third (3<sup>rd</sup>) full paragraph of the Letter Agreement is hereby deleted in its entirety and replaced with the following:

If ICT fails to pay the Upfront Payment to Vericel pursuant to the terms of the License Agreement by September 6, 2017, Vericel's obligation to issue the Common Stock Warrant to ICT pursuant to the terms hereof shall terminate in its entirety and shall be of no further force or effect.

# 2. MISCELLANEOUS

2.1 This Amendment shall become effective at the Effective Time if, and only if, the Nonpayment Condition has occurred.

**2.2.** Except to the extent modified herein, the terms and conditions of the Letter Agreement shall remain in full force and effect.

**2.3** This Amendment shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Amendment to the substantive law of another jurisdiction.

**2.4** This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Electronic copies or facsimiles of signatures shall be deemed originals.

\* \* \* \* \*

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 1 to the Letter Agreement as of the Amendment Date.

Innovative Cellular Therapeutics Co., Ltd.	Vericel Corporation
BY:/s/Lei Xiao	BY:/s/Dominick Colangelo
NAME:Lei Xiao	NAME:Dominick Colangelo
TITLE:Chairman	TITLE:Chief Executive Officer

[Signature Page to Amendment No 1 to Letter Agreement]

### EXHIBIT 10.7

### **CONFIDENTIAL**

# **AMENDMENT NO. 2 TO LETTER AGREEMENT**

This Amendment No 2 ("Amendment 2") to the Letter Agreement (as defined below) dated as of September 5, 2017 (the "Amendment Date"), is entered into by and between "上海斯丹赛生物"技术有限公司" (Innovative Cellular Therapeutics CO., LTD.), a corporation organized and existing under the laws of China ("ICT"), and Vericel Corporation, a corporation organized and existing under the laws of the State of Michigan ("Vericel"). Terms used, but not defined, herein shall have the meaning ascribed to them in the Letter Agreement. ICT and Vericel are each referred to herein as a "Party" or collectively the "Parties".

# RECITALS

WHEREAS, Vericel and ICT are parties to that certain License Agreement, dated as of May 9, 2017 (the "License Agreement"); and

WHEREAS, in connection with entering into the License Agreement, Vericel and ICT entered into that certain letter agreement, dated as of May 9, 2017 (the "Letter Agreement"); and

WHEREAS, the Parties desire to amend the Letter Agreement on the terms and subject to the conditions set forth herein, with this Amendment 2 becoming effective on September 6, 2017 at 4:00 pm Eastern Daylight Time (the "Effective Time") if the Upfront Payment (as defined in the License Agreement) is not received by Vericel from ICT at or before the Effective Time (the "Nonpayment Condition").

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

# 1. AMENDMENTS

1.1 The third  $(3^{rd})$  sentence of the second  $(2^{nd})$  full paragraph of the Letter Agreement is hereby deleted in its entirety and replaced with the following:

As consideration for an amount included in the Upfront Payment equal to (a) \$5,000,000.00 minus (b) the Withholding Income Taxes (such amount, the "**Warrant Purchase Price**"), Vericel hereby agrees to issue to ICT, effective as of and contingent upon Vericel's receipt of the Upfront Payment, a warrant (the "**Common Stock Warrant**") in substantially the form attached hereto as <u>Exhibit A</u>, exercisable for the number of shares of Vericel's Common Stock equal to (x) the Warrant Purchase Price divided by (y) \$4.30 the closing price of a share of Vericel's Common Stock on the Nasdaq Stock Market on September 5, 2017, rounded down to the nearest whole number.

1.2 The third (3<sup>rd</sup>) full paragraph of the Letter Agreement is hereby deleted in its entirety and replaced with the following:

If ICT fails to pay the Upfront Payment to Vericel pursuant to the terms of the License Agreement by October 6, 2017, Vericel's obligation to issue the Common Stock Warrant to ICT pursuant to the terms hereof shall terminate in its entirety and shall be of no further force or effect.

# 2. MISCELLANEOUS

2.1 This Amendment 2 shall become effective at the Effective Time if, and only if, the Nonpayment Condition has occurred.

**2.2.** Except to the extent modified herein, the terms and conditions of the Letter Agreement shall remain in full force and effect.

**2.3** This Amendment 2 shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Amendment to the substantive law of another jurisdiction.

**2.4** This Amendment 2 may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Electronic copies or facsimiles of signatures shall be deemed originals.

\* \* \* \* \*

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 2 to the Letter Agreement as of the Amendment Date.

Innovative Cellular Therapeutics Co., Ltd.	Vericel Corporation
BY:/s/Lei Xiao	BY:/s/Dominick Colangelo
NAME:Lei Xiao	NAME:Dominick Colangelo
TITLE:Chairman	TITLE:Chief Executive Officer

[Signature Page to Amendment No 2 to Letter Agreement]

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.

# FIRST AMENDMENT TO DISTRIBUTION AGREEMENT

This First Amendment to the Distribution Agreement ("Amendment") is between Vericel Corporation ("Vericel") and Orsini Pharmaceutical Services, Inc. ("Orsini"). This Amendment is effective as of August 10, 2017 ("Effective Date").

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

Whereas, Vericel has discontinued the sale of Carticel and added an additional National Drug Code for MACI;

Whereas, the Parties now wish to update the Distribution Agreement to reflect these changes;

Therefore, the Parties agree to amend the Distribution Agreement as follows:

1. <u>Exhibit A</u>. In order to remove Carticel and add an additional NDC for MACI (corresponding to an order of two cases per pack, with each case containing one implant), the Parties agree to delete and replace in its entirety the table "Products and Prices" with the following:

Product	<u>NDC Number</u>	List Price*
MACI	69866-1030-01	[***]
MACI	69866-1030-02	[***]

2. <u>No Other Changes</u>. Except as provided in this Amendment, the terms and conditions of the Distribution Agreement will continue in full force.

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

### **Vericel Corporation**

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

Date: 11 August 2017

### Orsini Pharmaceutical Services, Inc.

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

Date: 08.10.2017

#### 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 7, 2017

/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 7, 2017

/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, 2017, 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 7, 2017

/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, 2017, 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 7, 2017

/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.