## **SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q** 

(Mark One)

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

## FOR THE QUARTERLY PERIOD ENDED September 30, 2016,

OR

**o** 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)

(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 - x No - o

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 - x No - o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required

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

Large accelerated filer - o

Non-accelerated filer - o

(Do not check if a smaller reporting company)

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

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)

24,107,116 Outstanding at November 4, 2016

Accelerated filer - x

Smaller reporting company - o

94-3096597

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## **PART I - FINANCIAL INFORMATION**

Item 1. Financial Statements

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

	S	eptember 30, 2016	December 31, 2015
ASSETS			
Current assets:			
Cash	\$	8,880	\$ 14,581
Accounts receivable (net of allowance for doubtful accounts of \$97 and \$68, respectively)		7,871	10,919
Inventory		3,607	1,379
Other current assets		741	 464
Total current assets		21,099	27,343
Property and equipment, net		4,215	4,049
Intangible assets, net		2,708	2,917
Total assets	\$	28,022	\$ 34,309
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$	5,467	\$ 7,588
Accrued expenses		3,398	3,603
Revolving and term loan credit agreement, net of deferred costs of \$433		5,566	
Warrant liabilities		658	757
Short-term deferred rent		232	118
Other		39	42
Total current liabilities		15,360	 12,108
Long-term deferred rent		1,227	
Long term debt		42	71
Total liabilities		16,629	 12,179
COMMITMENTS AND CONTINGENCIES (Note 13)			
Shareholders' equity:			
Series A non-voting convertible preferred stock, no par value: shares authorized and reserved — 1; shares			
issued and outstanding — 1		3,150	3,150
Series B-2 voting convertible preferred stock, no par value: shares authorized and reserved — 39, shares issued and outstanding — 12		38,389	38,389
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 22,745 and 23,789, respectively		310,208	307,766
Treasury stock — 1,250 shares		(3,150)	(3,150)
Warrants		190	
Accumulated deficit		(337,394)	(324,025)
Total shareholders' equity		11,393	 22,130
Total liabilities and shareholders' equity	\$	28,022	\$ 34,309

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 End		ded September 30,							
		2016		2015		2015		2015 2016		2016	2016 2	
Revenues:												
Product sales	\$	10,929	\$	11,309	\$	37,860	\$	35,748				
Total revenues		10,929		11,309		37,860		35,748				
Costs and expenses:												
Cost of product sales		6,856		6,772		20,716		19,241				
Gross profit		4,073		4,537		17,144		16,507				
Research and development		3,443		3,740		11,037		11,486				
Selling, general and administrative		7,010		5,674		19,463		16,735				
Total operating expenses		10,453		9,414		30,500		28,221				
Loss from operations		(6,380)		(4,877)		(13,356)		(11,714)				
Other income (expense):												
Decrease (increase) in fair value of warrants		(203)		461		99		256				
Foreign currency translation (loss) gain		(6)		(5)		(17)		5				
Interest income		—		7		7		29				
Interest expense		(86)		(2)		(92)		(6)				
Other (income) expense		_		_		(10)						
Total other income (expense)		(295)		461		(13)		284				
Net loss	\$	(6,675)	\$	(4,416)	\$	(13,369)	\$	(11,430)				
Net loss per share attributable to common shareholders (Basic and Diluted) (see note 11)	\$	(0.38)	\$	(0.26)	\$	(0.84)	\$	(0.69)				
Weighted average number of common shares outstanding (Basic and Diluted)		22,744		23,788		22,678		23,786				

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,		
	2016		2015
Operating activities:			
Net loss	\$ (13,369	) \$	(11,430)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	1,393		1,182
Stock compensation expense	1,973		2,188
Change in fair value of warrants	(99	)	(256)
Inventory provision	98		621
Asset retirement obligation			(267)
Deferred rent expense	438		
Foreign currency translation loss	17		5
Gain on sales of fixed assets	_		(35)
Changes in operating assets and liabilities:			
Inventory	(2,325	)	(339)
Accounts receivable	3,048		552
Other current assets	(278	)	521
Accounts payable	(2,173	)	(899)
Accrued expenses	(205	)	(1,109)
Tenant improvement reimbursement	898		_
Other non-current assets and liabilities, net			(43)
Net cash used for operating activities	(10,584	)	(9,309)
Investing activities:		_	
Expenditures for property, plant and equipment	(1,314	)	(2,330)
Other			35
Net cash used in investing activities	(1,314	)	(2,295)
Financing activities:		<u> </u>	
Net proceeds from issuance of common stock	469		11
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	(28	·	(26)
Net cash provided by (used in) financing activities	6,197		(15)
Net decrease in cash	(5,701		(11,619)
Cash at beginning of period	14,581		30,343
Cash at end of period	\$ 8,880		18,724
		- -	10,724
Supplemental cash flow information (non-cash):			
Additions to equipment in process included in accounts payable	\$ 36		65
Warrants issued in connection with debt arrangement	\$ 190	\$	
Supplementary cash flows information:			
Interest paid, net of interest capitalized	\$ 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, 2016 (UNAUDITED)

#### 1. Organization

Vericel Corporation, a Michigan corporation, which was formerly known as Aastrom Biosciences, Inc. (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<sup>®</sup>, MACI<sup>®</sup>, and Epicel<sup>®</sup> 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 as well as 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-inclass 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.

Successful future operations are subject to several technical hurdles and risk factors, including satisfactory product development, timely initiation and completion of clinical trials, regulatory approval and market acceptance of the Company's products.

#### 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, 2016, are not necessarily indicative of the results to be expected for the full year or for any other period. The September 30, 2016 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, 2015, as filed with the SEC on March 14, 2016 (Annual Report).

The consolidated financial statements include the accounts of Vericel and its wholly-owned subsidiaries, Marrow Donation, LLC, located in San Diego, California, and Vericel Denmark ApS, in Kastrup, Demark (collectively, the Company). All inter-company transactions and accounts have been eliminated in consolidation. Aastrom Biosciences GmbH ceased operations in 2014 and Marrow Donation, LLC and Vericel Denmark ApS ceased operations in 2015.

#### Net Product Sales

On June 30, 2016, the Company terminated the agreement with its exclusive distributor for substantially all of its Carticel sales by reducing the scope of our agreement with this distributor. Prior to June 30, 2016, the distributor purchased and took title to Carticel upon shipment of the product and assumed credit and collection risk. 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 all responsibility for shipment of the product to the surgical suite. Effective July 1, 2016, the Company transitioned to a direct sales model whereby the Company retains credit and collection risk from the end customer. The Company's new provider, Dohmen Life Science Services, LLC (DLSS) provides a similar patient support services as the previous distributor but does not purchase and take title to Carticel.

The Company recognizes product revenues from sales of Carticel upon delivery to patients as long as (i) there is persuasive evidence that an arrangement exists between ourselves and the customer, (ii) collectability is reasonably assured and (iii) the price

is fixed or determinable. 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 recognizes the gross revenue. The estimates are updated on a recurring basis as new information becomes available.

#### 3. Recent Accounting Pronouncements

#### **Revenue Recognition**

In May 2014, the Financial Accounting Standards Board (FASB) issued authoritative guidance requiring entities to apply a new model for recognizing revenue from contracts with customers and the reporting of principal versus agent considerations. The guidance 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 is currently in the process of evaluating its revenue arrangements under the issued guidance and has not yet determined the impact to its consolidated financial statements.

#### **Going Concern Assessment**

The FASB has issued authoritative guidance for management on how to assess whether substantial doubt exists regarding an entity's ability to continue as a going concern and guidance on how to prepare related footnote disclosures. The guidance will require management to evaluate whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern for one year from the date the financial statements are issued. The guidance is effective for annual reporting periods beginning after December 15, 2016. The Company is currently reviewing the potential impact of adopting the new guidance.

#### Presentation and Subsequent Measurement of Debt Issuance Costs

The FASB issued guidance which requires entities to present debt issuance costs related to a recognized debt liability as a direct deduction from the carrying amount of that debt liability. For debt issuance costs related to line-of-credit arrangements, companies are able to defer and present debt issuance costs as an asset and subsequently amortize the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The guidance was effective for annual reporting periods beginning after December 15, 2015 and the Company adopted the guidance as of March 31, 2016 and for future periods.

#### **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 will be effective for us on January 1, 2017. We are currently evaluating the potential impact that this standard may have on our financial position, results of operations and statement of cash flows.

#### **Statement of Cash Flows Presentation**

The FASB issued guidance to address diversity in practice with respect to how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The updated guidance addresses eight specific cash flow issues with the objective of reducing the existing diversity that occurs in practice. The guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within 2017. The Company is currently reviewing the potential impact of adopting the new guidance.

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## 4. Selected Balance Sheet Components

Inventory as of September 30, 2016 and December 31, 2015:

(In thousands)	Septer	September 30, 2016		ıber 31, 2015
Raw materials	\$	3,214	\$	1,228
Work-in-process		373		131
Finished goods		20		20
Inventory	\$	3,607	\$	1,379

Property and equipment, net as of September 30, 2016 and December 31, 2015:

(In thousands)	Septe	mber 30, 2016	Dece	mber 31, 2015
Machinery and equipment	\$	3,207	\$	3,280
Furniture, fixtures and office equipment		931		931
Computer equipment and software		2,674		2,662
Leasehold improvements		3,319		2,393
Construction in process		810		421
Total property and equipment, gross		10,941		9,687
Less: Accumulated depreciation		(6,726)		(5,638)
	\$	4,215	\$	4,049

The leasehold improvements include \$0.9 million of tenant reimbursed improvements to our cleanrooms to replace a rooftop air handler unit. The leasehold improvement is accounted for as a lease incentive under lease accounting guidance.

Depreciation expense for the three and nine months ended September 30, 2016 was \$0.4 million and \$1.2 million, respectively, compared to \$0.4 million and \$1.0 million, respectively, for the same periods in 2015.

Intangible assets, net as of September 30, 2016 and December 31, 2015:

(In thousands)	September 3	0, 2016	December 31, 2015		
Commercial rights	\$	3,360	\$	3,360	
Less: accumulated amortization	\$	(652)	\$	(443)	
	\$	2,708	\$	2,917	

The calculated value of the commercial rights intangible assets are amortized using the straight line method over an estimated useful life of 12 years. Amortization expense for both the three and nine months ended September 30, 2016 and 2015 was \$0.1 million and \$0.2 million, respectively.

Estimated future amortization expense is as follows:

Calendar Years Ending December 31, (In thousands)	
2016	\$ 70
2017	280
2018	280
2019	280
2020	280
Thereafter	1,518
Total	\$ 2,708

Accrued expenses as of September 30, 2016 and December 31, 2015:

(In thousands)	September 30, 2016		December	December 31, 2015	
Bonus related compensation	\$	1,615	\$	1,956	
Employee related accruals		1,759		1,341	
Accrued expenses		24		306	
	\$	3,398	\$	3,603	

#### 5. 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 6. 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 requiring 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	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 6. 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 8 of the condensed consolidated financial statements.

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

August 2013 Warrants	September	September 30, 2016 Decen		ecember 31, 2015	
Closing stock price	\$	2.80	\$	2.58	
Expected dividend rate		%		—%	
Expected stock price volatility		90.0%		91.4%	
Risk-free interest rate		0.8%		1.3%	
Expected life (years)		1.88		2.63	

September 2016 Warrants	Septen	ıber 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

#### 6. Debt

On March 8, 2016, the Company entered into a \$15.0 million debt financing with Silicon Valley Bank (SVB) which on September 9, 2016, was replaced by an expanded term loan and revolving line of credit agreement with SVB and MidCap Financial Services, or MidCap, which together 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 must be drawn by March 31, 2017, a \$2.0 million term loan available upon the FDA's approval of the MACI BLA 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 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%. Monthly, the Company must remain in compliance with a minimum net revenue covenant (determined in accordance with GAAP), measured on a trailing twelve month basis. 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, 2016, there was an outstanding balance of \$4.0 million under the revolving line of credit, both recorded in current liabilities. The remaining capacity under the revolving line of credit, so f September 30, 2016 was \$4.3 million and we were, and continue to be, in compliance with our financial and non-financial debt covenants. In addition, warrants were issued in conjunction with the debt agreement as discussed in note 5.

In determining whether the debt replacement is to be accounted for as a debt extinguishment or a debt modification, the Company considered whether creditors remained the same or changed and whether the changes in debt terms are substantial. After performing the assessment in accordance with accounting guidance for the modification of debt arrangements, this transaction was determined to be accounted for as a debt modification. As a result, the unamortized deferred financing costs now include \$0.1 million from the original issue costs and lender fees and \$0.3 million, in new issue costs, lender fees and warrant issuance costs which will be deferred over the life of the new debt arrangement.

#### 7. 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, 2016, the Company granted 13,800 and 1,086,030 service-based options to purchase common stock, respectively. 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, 2016 was \$1.77 and \$2.15, respectively for 2016 and \$2.26 and \$2.23, respectively for the same periods in 2015.

The net compensation expense recorded for the service-based stock options related to employees and directors was \$0.6 million and \$1.8 million for the three and nine months ended September 30, 2016, respectively, and \$0.6 million and \$2.2 million for the three and nine months ended September 30, 2015, respectively. The compensation cost includes forfeiture adjustments.

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

	Nine Months Ended S	September 30,
Service-Based Stock Options	2016	2015
Expected dividend rate	—%	—%
Expected stock price volatility	78.7 – 92.2%	77.6 - 88.1%
Risk-free interest rate	1.1 - 1.8%	1.5 - 2.0%
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:



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Service-Based Stock Options	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	2,523,400	\$ 6.36	8.7	\$ 5,000
Granted	1,086,030	\$ 3.02		
Exercised	39,231	\$ 3.06		\$ 76,827
Expired	79,963	\$ 34.98		
Forfeited	126,631	\$ 3.80		
Outstanding at September 30, 2016	3,363,605	\$ 4.73	8.4	\$ 471,219
Exercisable at September 30, 2016	1,129,664	\$ 7.83	7.8	\$ 49,148

As of September 30, 2016 there was approximately \$2.9 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 2.9 years.

The total fair value of options vested during the three and nine months ended September 30, 2016 and 2015 was \$0.6 million and \$1.6 million, respectively, and \$0.4 million and \$1.3 million, respectively.

#### **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 3, 2016, employees purchased 62,000 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 three and nine months ended September 30, 2016 was less than \$0.1 million and \$0.2 million, respectively.

#### 8. 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).

The following table summarizes the valuation of the Company's investments and financial instruments that are measured at fair value on a recurring basis:

	September 30, 2016							December 31, 2015									
		Fair value measurement category										Fair va	alue n	neasurement	catego	ry	
(In thousands)		Total	Level 1 Level 2 Level 3			Total		Level 1		Level 2		Level 3					
Liabilities:																	
Warrant liabilities	\$	658	\$		\$	658	\$		\$	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, 2015	\$ 757
Decrease in fair value	(99)
Balance at September 30, 2016	\$ 658

## 9. Shareholders' Equity

On January 21, 2014, the Company entered into a purchase agreement (Purchase Agreement), together with a registration rights agreement, for the sale of up to \$15.0 million of shares of its common stock to Lincoln Park Capital Fund, LLC (Lincoln Park), subject to certain limitations, from time to time over a 30 months period, which began on April 3, 2014 and ends on November 1, 2016.

The Company may direct Lincoln Park, at its sole discretion, to purchase up to 50,000 shares of common stock in regular purchases, increasing to amounts of up to 100,000 shares depending upon the closing sale price of the common stock. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock equals or exceeds \$3.00 per share. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 10 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price of \$2.50, subject to adjustment. The Company controls the timing and amount of any sales of common stock to Lincoln Park. The Company's sales of shares of common stock to Lincoln Park under the Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the common stock. The remaining capacity under this agreement is \$11.2 million as of September 30, 2016. No shares were issued in 2015. In October 2016, 50,000 shares were purchased by Lincoln Park for \$0.1 million.

#### **Treasury Stock**

On December 23, 2015 Stonepine Capital, LLC (Stonepine) exchanged 1,250,000 shares of the Company's common stock held by Stonepine for 1,250 shares of Series A Convertible Preferred Stock. The common stock transferred from Stonepine to the Company during the share exchange is reserved as treasury shares. The value transferred to Series A Convertible Preferred Stock of \$3.2 million is equal to the fair market value of the common stock as of December 23, 2015. See further discussion in note 10 of the condensed consolidated financial statements.

#### **10. Preferred Stock**

#### Series B Convertible Preferred Stock

In 2012, the Company completed the sale of 12,308 shares of Series B-1 Non-Voting Convertible Preferred Stock (Series B-1 preferred stock) at an offering price of \$3,250 per share. In addition to the Series B-1 preferred stock, which was issued at the closing, the Company also authorized Series B-2 Voting Convertible Preferred Stock (Series B-2 preferred stock). The Series B-1 preferred stock and Series B-2 preferred stock collectively are referred to as the Series B preferred stock. The Series B preferred stock is convertible, at the option of the holder thereof at any time after the 5 years anniversary of the closing of the offering, (the Conversion date) into shares of common stock, at a conversion ratio of one share of preferred stock for fifty shares of common stock, subject to certain limitations. Stock dividends on the Series B preferred stock will be cumulative and compound daily, at a rate of 11.5% per annum, payable upon conversion, liquidation, redemption or other similar events, and payable in cash or Series B-1 preferred stock until the Conversion date. As of September 30, 2016, there are approximately 424,723 shares of accumulated but undeclared Series B-1 Stock dividends. Unless prohibited by Michigan law governing distributions to shareholders, the Series B-1 preferred stock shall be redeemable at the option of holder of the Series B-1 preferred stock commencing at any time after the Conversion date, liquidation, winding up, dissolution or other similar events, subject to certain terms and limitations.

In 2013, the Company amended the Series B preferred stock agreement to remove the cash redemption provision, modify the liquidation preferences for the Series B-2 preferred stock and to increase the redemption price for the Series B-1 preferred stock. The redemption price, prior to the five years anniversary, is now equal to \$7,430 multiplied by the number of Series B-1 preferred shares redeemed minus the Company's closing stock price multiplied by the number of common shares into which the outstanding Series B-2 preferred stock are convertible. The redemption price, after the five years anniversary, is the amount equal to the greater of the Series B offering price plus accrued dividends or the conversion value in common stock. As a result of the amendment to the agreement, the total amount of \$38.4 million Series B preferred stock is classified in shareholders' equity.

#### Series A Convertible Preferred Stock

On December 18, 2015, the Company entered into a Securities Exchange Agreement (Exchange Agreement) with Stonepine pursuant to which Stonepine exchanged an aggregate of 1,250,000 shares of its common stock for 1,250 shares of the Company's



Series A Convertible Preferred Stock (the Exchange). The Exchange closed on December 23, 2015. In connection with the Exchange, the Company designated 1,250 shares of its authorized and unissued preferred stock as Series A Convertible Preferred Stock. Each share of Series A Convertible Preferred Stock is convertible into 1,000 shares of its common stock at any time at the holder's option. The holder, however, will be prohibited from converting Series A Convertible Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the shares of the Company's common stock then issued and outstanding or, upon such holder's written election, 14.99% of the shares of the Company's common stock then issued and outstanding. In the event of our liquidation, dissolution, or winding up, holders of Series A Convertible Preferred Stock will receive a payment equal to any declared but unpaid dividends before any proceeds are distributed to the holder of our Series B-1 Non-Voting Convertible Preferred Stock and Series B-2 Voting Convertible Preferred Stock (together, the Series B Convertible Preferred Stock) and pari passu with any distributions to the holders of the Company's common stock. Shares of Series A Convertible Preferred Stock have no voting rights, except as required by law and except where the consent of holders of a majority of the outstanding Series A Convertible Preferred Stock would be required to amend the terms of the Series A Convertible Preferred Stock. Shares of Series A Convertible Preferred Stock are entitled to receive dividends at the same time as the shares of Common Stock.

#### 11.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 are 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:

	Т	hree months en	ded S	eptember 30,		Nine months end	led September 30,		
(Amounts in thousands except per share amounts)		2016		2015	2016			2015	
Numerator:									
Net loss	\$	(6,675)	\$	(4,416)	\$	(13,369)	\$	(11,430)	
Dividends accumulated on convertible preferred stock		(1,931)		(1,654)		(5,591)		(4,965)	
Net loss attributable to common shareholders	\$	(8,606)	\$	(6,070)	\$	(18,960)	\$	(16,395)	
Denominator:									
Denominator for basic and diluted EPS:									
Weighted-average common shares outstanding		22,744		23,788		22,678		23,786	
Net loss per share attributable to common shareholders (basic and diluted)	\$	(0.38)	\$	(0.26)	\$	(0.84)	\$	(0.69)	

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, 2016 and 2015 were 6.5 million and 4.2 million, respectively.

#### 12. Concentration of Credit Risk

On June 30, 2016, the Company terminated its agreement with the distributor for a significant portion of its Carticel sales. Prior to June 30, 2016, the Company sold Carticel to a distributor, which subsequently resold Carticel to patients and healthcare providers. The Company has transitioned to a new provider, Dohmen Life Science Services, LLC (DLSS) who provides a patient support services program but does not act as a distributor. The Company's receivables risk is now spread among various hospitals, individual patients, and third-party payers and therefore, the concentration of credit risk shifted for the Company.

Revenue from one customer, the distributor in the U.S., represented approximately 67% of total revenue during the three months ended September 30, 2015, and 46% and 66% of total revenue during the nine months ended September 30, 2016 and 2015, respectively. Accounts receivable from the same customer accounted for 76% of the outstanding accounts receivable as of December 31, 2015. The next largest customer represented 13% and 14% of total revenue during the nine months ended September 30, 2016 and 2015, respectively. No other customer accounted for more than 10% of revenue or accounts receivable in 2016 or 2015 reported in either period.

## 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, 2016, the Company has recorded a tenant improvement of \$0.9 million.

In addition to the property leases, the Company also leases an offsite warehouse, various vehicles and computer equipment. The Company's purchase commitments consists of minimum purchase amounts of material in manufacturing in addition to fees payable under the DLSS contract which provides a patient support services program for Carticel and MACI.

As of September 30, 2016, future minimum payments related to leases and other contractual obligations are as follows:

(In thousands)	Total	2016	2017	2018	2019	2020	M	ore than 5 Years
Operating leases	\$ 24,658	\$ 1,043	\$ 4,933	\$ 4,646	\$ 4,316	\$ 4,413	\$	5,307
Purchase commitments	4,610	440	1,668	1,668	834			—
Capital leases	86	11	43	32	—	—		—
Total	\$ 29,354	\$ 1,494	\$ 6,644	\$ 6,346	\$ 5,150	\$ 4,413	\$	5,307

Rent expense for the three and nine months ended September 30, 2016 was \$1.2 million and \$3.6 million, respectively, and \$1.3 million and \$3.8 million, respectively, for the three and nine months ended September 30, 2015.

## 14. Subsequent Events

On October 10, 2016, the Company entered into an At-the-Market Sales Agreement (ATM) with Cowen and Company, LLC (Cowen), pursuant to which the Company may sell shares of its common stock through Cowen, as sales agent, in registered transactions from its 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. No shares of common stock have been sold to date under the ATM.

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

#### **Overview**

Vericel Corporation is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. We market two autologous cell therapy products in the United States: Carticel<sup>®</sup> (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel<sup>®</sup> (cultured epidermal autografts), a permanent skin replacement 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. We are also developing MACI<sup>®</sup>, a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee, and ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy.

#### Manufacturing

We have a cell-manufacturing facility in Cambridge, Massachusetts which is used for U.S. manufacturing and distribution of Carticel, Epicel manufacturing and also manufacturing of MACI for the SUMMIT study conducted for approval in Europe. We also operate a centralized cell manufacturing facility in Ann Arbor, Michigan. The Ann Arbor facility supports the current open label extension portion of the ixCELL-DCM clinical trial being conducted in the United States and Canada and we believe we have sufficient capacity, with minor modifications, to supply our early commercialization requirements.

#### **Product Portfolio**

We market two autologous cell therapy products in the United States: Carticel® (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel® (cultured epidermal autografts), a permanent skin replacement 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). We are also developing MACI<sup>®</sup>, a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee and for which a BLA is under review by the FDA. Our product candidate portfolio also includes ixmyelocel-T, a patient-specific multicellular therapy currently in development for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy (DCM). We completed enrolling and treating patients in our Phase 2b ixCELL-DCM study in February 2015 and on March 10, 2016 announced the trial had met its primary endpoint of reduction in clinical cardiac events and that incidence of adverse events, including serious adverse events, in patients treated with ixmyelocel-T was comparable to patients in the placebo group.

#### Carticel

Carticel, a first-generation autologous chondrocyte implant product for the treatment and repair of cartilage defects in the knee, is the first and currently the only 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 Biologics License Application (BLA) approval in 1997 and is currently marketed in the U.S. It is generally used on patients with larger lesions (greater than 3 cm<sub>2</sub>).

In the U.S., we focus sales of Carticel on the sports-injury-targeted orthopedic physician target audience, which is very concentrated, with 60% of the current Carticel business originating from 25% of this audience, or approximately 110 physicians. We currently have an approximately 20-person field force calling on this sports-injury targeted orthopedic physician audience. For the three and nine months ended September 30, 2016, net revenues were \$8.3 million and \$26.1 million, respectively, for Carticel.

#### 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 Center for Biologics Evaluation and Research 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 three and nine months ended September 30, 2016, net revenues were \$2.6 million and \$11.7 million, respectively, for Epicel.

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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 the Company's 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.

We currently have a 5-person field force calling upon dedicated burn centers.

#### MACI

MACI is a third-generation autologous chondrocyte implant product for the treatment of focal chondral cartilage defects in the knee. MACI received marketing authorization in Europe in July 2013 by meeting the requirements of the Advanced Therapy and Medicinal Product (ATMP) guidelines. MACI had been commercially available in the European Union (EU) since 1998. As part of the June 2014 restructuring we temporarily suspended sales of MACI in August 2014, primarily due to low utilization and an unfavorable pricing environment. We believe that MACI has significant revenue potential in the U.S., if approved and reimbursed. On March 4, 2016, the FDA accepted our BLA seeking approval to market MACI as an autologous cellular treatment for symptomatic cartilage defects of the knee. The FDA provided a Prescription Drug User Fee Act goal date of January 3, 2017. In addition, the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.

#### 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. Our proprietary cell manufacturing process significantly expands the mesenchymal stromal cells (MSCs) and M2-like anti-inflammatory macrophages in the patient's bone marrow mononuclear cells while retaining many of the hematopoietic cells. These cell types are known to regulate the immune response and play a key role in tissue repair and regeneration by resolving pathologic inflammation, promoting angiogenesis, and remodeling ischemic tissue. The novelty and advantage of using ixmyelocel-T is the expansion of a unique combination of cell populations, including MSCs and M2-like macrophages, which secrete a distinct combination of angiogenic and regenerative factors, and possess the ability to remain anti-inflammatory in the face of inflammatory challenge.

Our lead clinical development program for ixmyelocel-T is focused on severe, chronic ischemic cardiovascular diseases. We have completed the doubleblind portion of the Phase 2b ixCELL-DCM study, which is a randomized, double-blind, placebo-controlled clinical trial for patients with advanced heart failure due to ischemic DCM. Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM. We also have conducted clinical studies for the treatment of critical limb ischemia and the treatment of craniofacial defects.

The Phase 2b ixCELL-DCM clinical study treated 114 patients at 28 sites in the U.S. and Canada. We completed enrolling and treating patients in February, 2015. Patients were followed for 12 months for the primary efficacy endpoint of major adverse cardiovascular events, defined as all-cause deaths, all-cause hospitalizations, and unplanned outpatient or emergency department visits for IV treatment of acute worsening heart failure. Secondary endpoints include clinical, functional, structural, symptomatic, quality of life, and biomarker measures at 3, 6 and 9 months. On March 10, 2016, we announced the trial had met its primary endpoint of reduction in clinical cardiac events, and that the full data results from the ixCELL-DCM trial were presented at the Late-Breaking Clinical Trial Sessions of the American College of Cardiology 65<sup>th</sup> Annual Scientific Session & Expo on April 4, 2016. On April 4, 2016, we announced that incidence of adverse events, including serious adverse events, in patients treated with ixmyelocel-T was comparable to or lower than patients in the placebo group. With respect to the secondary endpoints of the trial, the components of the primary endpoint were also analyzed using the Win ratio in a hierarchical manner to incorporate both the incidence and timing of the endpoint components. The Win ratio result of 1.56 showed that more often ixmyelocel-T was the "winner" in that the time to death, left ventricular assist device placement, heart transplantation or time to cardiovascular hospitalization was shorter for placebo-treated patients, but this difference did not reach statistical significance. The time to first

event was longer in the ixmyelocel-T group compared to placebo, but was not statistically significant. There were no significant structural changes in left ventricle cavity size or left ventricular ejection fraction as measured by echocardiogram in either the ixmyelocel-T or placebo groups. Both treatment groups had an improvement in the New York Heart Association class and six-minute walk test, with no statistical difference between the groups after 12 months using the last observation carried forward. Because the trial met the primary endpoint, patients who had been assigned to the placebo group or randomized to ixmyelocel-T in the double blind portion of the trial but did not receive ixmyelocel-T will be offered the option to receive treatment.

Future development plans for ixmyelocel-T are dependent upon input from our regulatory interactions and the availability of financing. We are focused on determining the most appropriate manner to fund future development of ixmyelocel-T, balancing risk to the overall business, dilution to current shareholders, and retaining a significant portion of the upside potential of the program for the company and our shareholders.

#### **Results of Operations**

#### Net Loss

Our net loss for the three and nine months ended September 30, 2016 totaled \$6.7 million or \$0.38 per share and \$13.4 million or \$0.84 per share, respectively. Our net loss for the three and nine months ended September 30, 2015 totaled \$4.4 million or \$0.26 per share and \$11.4 million and \$0.69 per share.

		Three Months En	ded S	September 30,		Nine Months End	ded September 30,		
(In thousands)	2016			2015		2016		2015	
Total revenues	\$	10,929	\$	11,309	\$	37,860	\$	35,748	
Cost of product sales		6,856		6,772		20,716		19,241	
Gross profit		4,073		4,537		17,144		16,507	
Total operating expenses		10,453		9,414		30,500		28,221	
Loss from operations		(6,380)		(4,877)		(13,356)		(11,714)	
Other expense		(295)		461		(13)		284	
Net loss	\$	(6,675)	\$	(4,416)	\$	(13,369)	\$	(11,430)	

#### Net Revenues

Net revenues decreased for the three months ended September 30, 2016 compared to the same period the previous year primarily due to lower average number of grafts per Epicel order resulting in lower sales in the current quarter and the closure of Marrow Donation, LLC in 2015. The decrease is offset by an increase in the price we charge for Carticel in 2016 which became effective in the three months ended March 31, 2016.

Net revenues increased for the nine months ended September 30, 2016 compared to the same period the previous year due primarily to an increase in Epicel sales and an increase in the price we charge for Carticel offset by the closure of Marrow Donation, LLC in 2015.

	-	Three Months En	ded Se	eptember 30,	 Nine Months En	ded September 30,		
Revenue by product (in thousands)		2016		2015	2016		2015	
Carticel	\$	8,319	\$	7,736	\$ 26,117	\$	23,917	
Epicel		2,610		3,246	11,743		11,159	
Bone Marrow		_		327			672	
	\$	10,929	\$	11,309	\$ 37,860	\$	35,748	

*Seasonality.* Carticel revenue is 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. Over the last five years ended December 31, 2015, the percentage of annual sales by quarter has ranged as follows: first quarter, 20% to 24%; second quarter, 24% to 26%; third quarter, 21% to 23%; and fourth quarter, 29% to 33%. During 2015, the percentage of annual sales by quarter was as follows: 20% in the first quarter; 26% in the second quarter; 22% 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 absent due to the extreme

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variability inherent with Epicel's low patient volume of fewer than 100 patients per year. Over the last five years ended December 31, 2015, the percentage of annual sales by quarter has ranged as follows: first quarter, 27%; second quarter, 25%; third quarter, 20%; and fourth quarter, 28%. The variability in graft volume between the same quarters in consecutive years has been as high as 65%. 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 En	nded Se	ptember 30,		ptember 30,			
(In thousands)	2016		2015		2016	2015		
Gross profit	\$ 4,073	\$	4,537	\$	17,144	\$	16,507	
Gross profit %	37%		40%		45%		46%	

Gross profit ratio decreased for the three months ended September 30, 2016 compared to the same period in 2015 due to a decrease in average order size for Epicel, an increase in certain material usage and increased facility expense. The gross profit ratio has remained substantially consistent for the nine months ended September 30, 2016 and 2015.

#### Research and Development Costs

	Three Months End	ed September 30,	Nine Months Ended	September 30,	
(In thousands)	2016	2015	2016	2015	
Research and development costs	3,444	3,740	11,037	11,486	

Research and development expenses for the three months ended September 30, 2016 were \$3.4 million versus \$3.7 million for the same period a year ago. The amount of trial expenses for the ixCELL-DCM clinical trial were consistent for both periods. Expenses for the three months ended September 30, 2016 are due to the preparation to treat patients who had been originally assigned to the placebo group in the double blind portion of the trial and are now being offered the option to receive ixmyelocel-T in the open label extension portion of the trial. The ixCELL-DCM clinical trial expenses for the three months ended September 30, 2015 also included the ongoing monitoring of the initial patients enrolled in January 2015.

Research and development expenses for the nine months ended September 30, 2016 were \$11.0 million versus \$11.5 million for the same period a year ago. Expenses related to the ixCELL-DCM clinical trial were lower due to decrease in consulting services offset by an increase in expenses associated with MACI, Carticel and Epicel research and development expenses.

		Three Months En	ided Se	Nine Months Ended September 30,				
(In thousands)	2016 2015					2016		2015
Dilated Cardiomyopathy	\$	1,875	\$	1,930	\$	5,732	\$	7,229
MACI		636		903		1,916		1,509
Carticel		462		409		1,828		1,409
Epicel		470		498		1,561		1,339
Total research and development expenses	\$	3,443	\$	3,740	\$	11,037	\$	11,486

Selling, General and Administrative Costs

	 Three Months En	ded Sep	ptember 30,		otember 30,		
(In thousands)	2016		2015		2016		2015
Selling, general and administrative costs	\$ 7,010	\$	5,674	\$	19,463	\$	16,735

Selling, general and administrative expenses for the three months ended September 30, 2016 were \$7.0 million compared to \$5.7 million for the same period a year ago. Selling, general and administrative expenses for the nine months ended September 30, 2016 were \$19.5 million compared to \$16.7 million for the same period a year ago. The increase in selling, general and administrative expenses in 2016 is due primarily to an increase in start-up costs with our new reimbursement and patient support services for Carticel of \$0.9 million for the nine months ended September 30, 2016, combined with professional services related to preparing for the potential launch of MACI, legal fees, shared facility fees and an increase in personnel costs.

Other Income (Expense)

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	Three Months Ended September 30,				Nine Months Ended September 30,				
(In thousands)		2016		2015		2016		2015	
(Increase) decrease in fair value of warrants	\$	(203)	\$	461	\$	99	\$	256	
Foreign currency translation (loss) gain		(6)		(5)		(17)		5	
Other income		_		_		(10)		_	
Net interest income		(86)		5		(85)		23	
Total other income (expense)	\$	(295)	\$	461	\$	(13)	\$	284	

The change in other income and expense for the three and nine months ended September 30, 2016 compared to 2015 is due primarily to the change in warrant value as a result of the fluctuations in our stock price and the reduction in the time to maturity and the expiration of the January Class A warrants and December 2010 warrants in 2015. 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:

	T	Three Months Ended September 30,			Nine Months Ended September 30,			
(In thousands)		2016		2015		2016		2015
Cost of goods sold	\$	117	\$	59	\$	330	\$	245
Research and development		133		109	\$	392	\$	467
Selling, general and administrative		404		406		1,251		1,476
Total non-cash stock-based compensation expense	\$	654	\$	574	\$	1,973	\$	2,188

The changes in stock-based compensation expense are due primarily to fluctuations in the fair value of the options granted in 2016 compared to 2015 in addition to additional expense recognized as a result of the Vericel Corporation Employee Stock Purchase Plan which was implemented effective October 1, 2015.

#### Adjusted Net Loss and Adjusted Net Loss Per Share

The reconciliation of reported numerator and denominator in net loss per share (GAAP) to adjusted net loss per share (non-GAAP measure) for the three and nine months ended September 30, 2016 and 2015 is below:

	Three Months Ended September 30,			Nine Months End			led September 30,	
(Amounts In thousands except per share amounts)	2016		2015		2016		2015	
Numerator:								
Numerator of basic and diluted EPS	\$	(8,606)	\$	(6,070)	\$	(18,960)	\$	(16,395)
Add: (Decrease) increase in fair value of warrants		203		(461)		(99)		(256)
Add: Dividends accumulated on convertible preferred stock		1,931		1,654		5,591		4,965
Adjusted net loss - Non-GAAP	\$	(6,472)	\$	(4,877)	\$	(13,468)	\$	(11,686)
Denominator:								
Denominator for basic and diluted EPS:								
Weighted-average common shares outstanding		22,744		23,788		22,678		23,786
Add: Treasury stock		1,250		—		1,250		
Adjusted denominator for basic and diluted EPS - Non-GAAP		23,994		23,788		23,928		23,786
Adjusted net loss per share (basic and diluted) - Non-GAAP	\$	(0.27)	\$	(0.21)	\$	(0.56)	\$	(0.49)

We believe that the presentation of Adjusted Net Loss and Adjusted Net Loss Per Share, non-GAAP financial measures, provide investors with additional information about our financial results. Adjusted Net Loss and Adjusted Net Loss Per Share are important supplemental measures used by our board of directors and management to evaluate our operating performance from period to

period on a consistent basis and as measures for planning and forecasting overall expectations and for evaluating actual results against such expectations.

The Adjusted Net Loss excludes the non-cash change in the fair value of warrants and the non-cash accumulated dividend on the Series B convertible preferred stock. The Adjusted Net Loss Per Share includes common shares reserved as treasury shares received in exchange for the Series A non-voting convertible preferred stock.

Adjusted Net Loss and Adjusted Net Loss Per Share are not in accordance with, or an alternative to, measures prepared in accordance with U.S. GAAP. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. As non-GAAP measures, Adjusted Net Loss and Adjusted Net Loss Per Share have limitations in that they do not reflect all of the amounts associated with our results of operations as determined in accordance with U.S. GAAP. Non-GAAP financial measures that we use may differ from measures that other companies may use. These non-GAAP financial measures that we disclose are not meant to be considered superior to or a substitute for results of operations prepared in accordance with GAAP, and should be viewed in conjunction with, GAAP financial measures.

#### 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. Until such time as we satisfy, if at all, applicable regulatory approval requirements for ixmyelocel-T and MACI, we expect the sales of Carticel and Epicel therapies to 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. While we believe that, based on our current cash on hand and availability under our term loan and revolving line of credit, we are well positioned to sustain operations twelve months beyond September 30, 2016; if actual results differ from our projections, we may need to access additional capital. We expect that we will require substantial additional capital resources to complete the development of ixmyelocel-T for the treatment of advanced heart failure due to ischemic DCM and for other strategic opportunities. Actual cash requirements may differ from projections and will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of possible acquisition or development of complementary business activities, and the cost of product launch and commercialization of newly approved products. If MACI receives the required FDA approvals, we may need to raise additional capital in anticipation of the introduction of MACI in the U.S. market.

We had access to certain amounts of financing through a 30 month agreement with Lincoln Park Capital Fund, LLC (Lincoln Park) which expired on November 1, 2016. Under that agreement we could direct Lincoln Park to purchase up to \$15.0 million worth of shares of our common stock over the 30-month period generally in amounts up to 50,000 shares of our common stock on certain business days under a Purchase Agreement. In October 2016, 50,000 shares were purchased by Lincoln Park for \$0.1 million.

At September 30, 2016, there was approximately \$7.8 million of net capacity remaining on the At-the-Market Sales Agreement with MLV & Co. LLC (formerly McNicoll, Lewis & Vlak and now owned by FBR & Co.), which allowed us to sell our common stock from time to time under a registration statement on Form S-3 filed in June 2011, pursuant to which we registered \$100 million of our securities for public sale. The Form S-3 registration statement filed in June 2011 expired in July 2014. If we choose to access the remaining capacity, we would need to file an updated Form S-3 registration statement.

On October 10, 2016, we entered into an At-the-Market Sales Agreement (ATM) with Cowen and Company, LLC (Cowen), pursuant to which we may sell shares of our common stock through Cowen, as sales agent, in registered transactions from its 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. We will pay up to 3% of the gross proceeds to Cowen as a commission.

On March 8, 2016, we entered into a \$15.0 million debt financing with Silicon Valley Bank (SVB) which on September 9, 2016 was replaced by an expanded term loan and revolving line of credit agreement with SVB and MidCap Financial Services (MidCap), providing 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 commitment which must be drawn by March 31, 2017, a \$2.0 million term loan available upon the FDA's approval of the MACI BLA 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 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%. Monthly, we must remain in compliance with a minimum net revenue covenant (determined in accordance with GAAP), measured on a trailing twelve month basis. SVB and MidCap have a shared first priority perfected security interest in all of our assets other than intellectual property. As of September 30, 2016, there was an outstanding balance of \$4.0 million under the term loan and \$2.0 million under the revolving line of credit. The remaining capacity under the revolving line of credit as of September 30, 2016 was \$4.3 million and we were, and continue to be, in compliance with our financial and non-financial debt covenants.

Our cash totaled \$8.9 million at September 30, 2016. During the nine months ended September 30, 2016, the cash used for operations was \$10.6 million. This use of funds was fueled largely by our operating loss adjusted by stock compensation expense of \$2.0 million, depreciation and amortization expense of \$1.4 million and cash receipts of \$0.9 million for tenant improvement reimbursements.

The decrease in cash used for investing activities was primarily due to a reduction in capital additions through September 30, 2016 compared to the same period in 2015. In 2015, the capital additions included an upgrade to our financial management/ERP software.

The change in cash provided from financing activities is primarily due to the cash proceeds of \$8.4 million from borrowings under the debt financing with SVB and MidCap offset by the repayment of \$2.4 million under the revolving credit portion of the debt financing in addition to the issuance of common stock of \$0.5 million as a result of the exercise of stock options and employee participation in the Vericel Corporation Employee Stock Purchase Plan which was implemented effective October 1, 2015.

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

At September 30, 2016, 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 (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, 2015 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, 2016.

#### **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, 2016, 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, 2015.

#### **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, 2016, our Certifying Officers concluded that the Company's disclosure controls and procedures were not effective because of the material weakness in our internal control over financial reporting as described below.

#### Management's Report on Internal Control over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. As previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our management identified a material weakness in our internal control over financial reporting relating to the design of controls to mitigate segregation of duties conflicts in our financial management/ERP software. Specifically, our Controller had access to modules in the financial management software beyond necessary to perform the job of Controller, and the controls that were designed and implemented to be performed by the Controller to mitigate the incompatible duties of other financial personnel were ineffective. Thus, the material weakness impacted substantially all financial statement accounts and all financial statement assertions. While the material weakness did not result in any financial statement adjustments during the three months ended September 30, 2016, it could result in misstatements to substantially all accounts and disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that this control deficiency constitutes a material weakness.

Notwithstanding the material weakness described above, we believe the Company's financial statements included in this Quarterly Report on Form 10-Q present fairly, in all material respects, the Company's financial position, results of operations and cash flows for the periods presented. The Certifying Officers have certified to their knowledge that this Quarterly Report on Form 10-Q does not contain any untrue statements of material fact or omit to state any 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 periods covered in this quarterly report.

## Plan for Remediation of Material Weakness

In January 2016, with the oversight of senior management and our audit committee, we have taken steps to begin to design a remediation plan. Planned steps and actions taken thus far are below.

- 1) Removed inappropriate permissions. Information Technology staff responsible for the maintenance of Active Directory Group assignments made changes to the Controller's permissions and the Controller's permissions were corrected to remove the incompatible access.
- 2) Enabled and designed a reporting functionality that provides an audit trail for journal entries, module access and other relevant user actions.
- 3) Reviewed remaining conflicts and permissions and documented the appropriate control that effectively mitigate the risk associated with the conflicts and/or permissions. In addition, we implemented a new control to review changes to personnel access in the financial reporting system.

Although the above remediation plan has been completed by June 30, 2016, we determined additional time was needed to assess the operating effectiveness of the aforementioned remediation plan to ensure the controls as designed are operating effectively through year end December 31, 2016 in order to conclude the material weakness has been fully remediated.

#### **Changes in Internal Control over Financial Reporting**

There have been no changes in internal control over financial reporting during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting, other than the material weakness and the related remediation plan discussed above in the section titled "Plan for Remediation of Material Weakness".

#### 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

Information regarding our risk factors is set forth in Part 1, Item 1A, "Risk Factors," on our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 14, 2016. Except for the following, there have been no material changes in our risk factors from those disclosed in Part 1, Item 1A, "Risk Factors" on our Annual Report on Form 10-K.

Due to recent changes with respect to the distribution of Carticel, we have decided to add the following risk factor:

# Failure to enter into written agreements with payers for reimbursement of our products and to obtain adequate reimbursement rates could have a material adverse effect on our financial condition and operating results.

On June 30, 2016, we terminated our agreement with our prior distributor for a significant portion of our Carticel sales by reducing the scope of our agreement with this distributor. Prior to June 30, 2016, we sold Carticel to such distributor, which subsequently resold Carticel to patients and healthcare providers. We have transitioned to a new provider, Dohmen Life Science Services, LLC (DLSS), who provides a patient support services program and reimbursement services. Failing to maintain and obtain written agreements from payers for reimbursement of our products or to obtain adequate reimbursement rates could have a material adverse effect on our financial condition and operating results. In addition, healthcare providers are under pressure to increase profitability and reduce costs. In response, certain healthcare providers are limiting coverage or reducing reimbursement rates for the products we provide. We cannot predict the extent to which reimbursement for our products will be affected by initiatives to reduce costs for healthcare providers. Failure to obtain or maintain written agreements with such payers or lower then estimated reimbursement for our products would adversely affect our business, financial conditions and results of operations.

#### 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, 2016.

## 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.

## SIGNATURE

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, 2016

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)

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## EXHIBIT INDEX

Exhibit No.	Description
5.1	Opinion of Dykema Gossett PLLC (incorporated by reference to Exhibit 5.1 on Form 8-K filed October 11, 2016).
10.1	Loan and Security Agreement, dated September 9, 2016, between the Company, as borrower, and Silicon Valley Bank, in its capacity as Administrative Agent, and Silicon Valley Bank, MidCap Financial Trust, MidCap Funding III Trust and other lenders listed therein as lenders (incorporated by reference to Exhibit 10.1 on Form 8-K filed September 14, 2016).
10.2	Form of Warrants issued by the Company to the Lenders (incorporated by reference to Exhibit 10.1 on Form 8-K filed September 14, 2016).
	Sales Agreement, dated October 10, 2016, among the Company and Cowen and Company, LLC (incorporated by reference to Exhibit 10.1 on Form 8-K filed October 11, 2016).
10.3	
10.4†**	Third Amendment to Services Agreement, dated October 12, 2016, by and between the Company and Dohmen Life Science Services, LLC.
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
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\*\* 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.

	GLOSSARY
TERM	DEFINITION
Adverse Event	Any adverse change in health or "side-effect" that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.
Autologous (Patient Specific)	Originating from the patient receiving treatment. (Vericel uses only autologous cells).
BLA — Biologics License Application	An application containing product safety, efficacy and manufacturing information required by the FDA to market biologics products in the U.S.
CLI — Critical Limb Ischemia	An atherosclerotic vascular disease characterized by insufficient blood flow in the lower extremities that causes severe pain, tissue loss or both.
Controlled Clinical Trial	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.
DCM — Dilated Cardiomyopathy	A chronic cardiac disease where expansion of the patient's heart reduces the pumping function to a point that the normal circulation of blood cannot be maintained.
Double-Blind Clinical Trial	Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo.
FDA — Food & Drug Administration	The U.S. FDA ensures that medicines, medical devices, and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of \$1 trillion worth of goods annually.
GMP — Good Manufacturing Practice	GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
Hematopoietic Cells	All of the cells in the blood system including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells).
Ischemia	A shortage or inadequate flow of blood to a body part (commonly an organ or tissue) caused by a constriction or obstruction of the blood vessels supplying it.
LVEF — Left Ventricular Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heartbeat.
Mesenchymal stromal cells	Connective tissue cells that, in the case of bone marrow derived MSCs, function to support blood forming cells and secrete anti-inflammatory factors.
M2 anti-inflammatory macrophages	Specialized blood cells that remove damaged tissue and bacteria and secrete anti-inflammatory factors.
Open-label Clinical Trial	A trial in which both the treating physician and the patient know whether they are receiving the experimental treatment or control/placebo treatment.
Orphan Drug Designation	"Orphan drug" refers to a drug or biologic that is intended for use in the treatment of a rare disease or condition. Orphan drug designation from the U.S. Food and Drug Association (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for developing the drug for a rare disease or condition. The drug must then go through the FDA marketing approval process like any other drug or biologic which evaluates for safety and efficacy. Usually a sponsor receives a quicker review time and lower application fees for an orphan product.
Phase 1 Clinical Trial	A Phase 1 trial represents an initial study in a small group of patients to test for safety and other relevant factors.
Phase 2 Clinical Trial	A Phase 2 trial represents a study in a moderate number of patients to assess the safety and efficacy of a product.
Phase 2b Clinical Trial	A Phase 2b trial is a moderately-sized Phase 2 trial that is more specifically designed assess the efficacy of a product than a Phase 2a trial.
Phase 3 Clinical Trial	Phase 3 studies are initiated to establish safety and efficacy in an expanded patient population at multiple clinical trial sites and are generally larger than trials in earlier phases of development.

Randomized Clinical Trial

A clinical trial in which the participants are assigned randomly to different treatment groups.

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

Exhibit 10.4

## THIRD AMENDMENT TO SERVICES AGREEMENT

This Third Amendment to Services Agreement (this "Amendment") is made and entered into as of October 12, 2016, by and between Vericel Corporation ("Client" or "Vericel") and Dohmen Life Science Services, LLC ("DLSS").

Client and DLSS are parties to that certain Services Agreement dated April 5, 2016 (the "Original Agreement"), as amended by (i) that certain First Amendment to Services Agreement dated as of May 31, 2016, and (ii) that certain Second Amendment to Services Agreement dated as of July 1, 2016 (collectively, the "Agreement"). The parties now wish to amend the Agreement as follows:

- 1. <u>Defined Terms</u>. Capitalized terms in this Amendment that are not defined in this Amendment have the meanings given to them in the Agreement. If there is any conflict between the Agreement and any provision of this Amendment, this Amendment will control.
- 2. <u>Guarantee</u>. If, with respect to any implant of the Product performed during a Guarantee Period for a Patient that is an eligible member of a Guaranteed Payer (a "Guaranteed Implant"), a Guaranteed Payer denies a claim for reimbursement or reimburses at a rate of less than [\*\*\*], DLSS agrees to guarantee reimbursement in an amount equal to [\*\*\*], subject to the payment terms set forth in Section 3 below. Notwithstanding anything to the contrary contained herein, (i) for purposes of this Amendment, all references to [\*\*\*] shall be fixed at an amount equal to \$[\*\*\*], and (ii) if, with respect to any Guaranteed Implant, a Guaranteed Payer reimburses at a rate of greater than [\*\*\*], such excess amount shall offset and reduce the aggregate guarantee obligation of DLSS arising under this Section 2.

The term "Guaranteed Payer" shall mean each Payer listed on <u>Exhibit D</u> of the Original Agreement; provided, however, that any such Payer shall cease to be a Guaranteed Payer upon the earlier of (i) the date upon which such Guaranteed Payer executes a written agreement that provides for reimbursement of Product, or (ii) September 30, 2016. For clarity, a wholesale order to a clinical institution on a direct bill basis does not constitute a written agreement that provides for reimbursement of Product.

The term "Guarantee Period" shall mean, for each Guaranteed Payer, that period of time commencing on July 1, 2016 and continuing until the earlier of (i) the date upon which such Guaranteed Payer executes such a written agreement that provides for reimbursement of Product, or (ii) September 30, 2016.

For purposes of clarity, if Payer ABC executes such a written agreement that provides for reimbursement of Product on August 25, 2016, then Payer ABC shall cease to be a Guaranteed Payer on August 25, 2016, the Guarantee Period shall end on August 25, 2016 for Payer ABC and the guarantee obligation of DLSS under this Section 2 with respect to Payer ABC shall only apply to implants of the Product performed between July 1, 2016 until August 25, 2016.

3. <u>Payment of Guarantee</u>. No later than March 15, 2017, DLSS shall pay to Client an amount equal to (i) the product of (A) the number of Guaranteed Implants, multiplied by (B) [\*\*\*], less (ii) any amounts collected by DLSS in connection with the Guaranteed Implants (including any amount paid by the Patient or reimbursement paid by the Guaranteed Payer) regardless of whether the amount collected for any particular Guaranteed Implant exceeds [\*\*\*]. In the event such calculation results in a negative number, no payment under this Amendment will be due to Client, and any amounts collected by DLSS in connection with the submission of claims for the Guaranteed Implants will be remitted to Client as set forth in Section 6 of the Agreement. Upon payment to Client pursuant

# 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.

to the foregoing, DLSS shall have no further obligations with respect to the guarantee set forth in Section 2 above and any amounts collected by DLSS in connection with the Guaranteed Implants (including any amount paid by the Patient or reimbursement paid by the Guaranteed Payer) at any time subsequent to the payment made to Client pursuant to the foregoing shall be retained in full by DLSS. Client acknowledges and agrees that under no circumstances shall DLSS be obligated to make any payment to Client pursuant to the Second Amendment to Services Agreement.

- 4. <u>Reimbursement Support</u>. DLSS shall use commercially reasonable efforts to contract directly with Payers, including but not limited to Medicare, Medicaid, commercial health plans and third party administrators, military facilities, and workers' compensation plans, based on the reimbursement rates and/or parameters set by Client for the Product as set forth on <u>Exhibit D</u> and <u>Exhibit E</u>. DLSS and Client agree that the foregoing hereby supersedes and replaces Section III(a)(4)(a) of <u>Exhibit B</u> of the Agreement in its entirety. Notwithstanding anything to the contrary, DLSS and Client acknowledge and agree that the obligations of DLSS under Section 3(g) of the Agreement, as amended, are hereby deemed to have been satisfied and that DLSS has no further commitments or obligations thereunder.
- <u>Administration of Program/Description of Services</u>. The Program is to be administered pursuant to DLSS SOP's and Client-specific SOP's mutually developed by DLSS and Vericel following implementation and in accordance with the Agreement. DLSS and Vericel are to re-evaluate <u>Exhibit B</u> of the Agreement, and mutually consider whether the DLSS SOP's and Client-specific SOP's should replace parts of <u>Exhibit B</u> of the Agreement.
- 6. <u>Exclusivity</u>. If there is a 3<sup>rd</sup> party organization that can provide direct contracting services for any payer that DLSS is not able to provide a direct contract, then DLSS and Vericel would be willing to permit an exception to the exclusivity provision contained in Section 4(a)(vi) of the Agreement with respect to reimbursement support/payer contracting, <u>but</u> only if such 3<sup>rd</sup> party organization agrees not to take title to the Product and can guarantee a direct contract with such payer. Following an evaluation of results of trial submissions by such 3<sup>rd</sup> party organization, DLSS and Vericel are to discuss possible exception to exclusivity provision, which would be set forth in an amendment to the Agreement as mutually agreed upon by the parties hereto under which Vericel would contract directly with such 3<sup>rd</sup> party organization. DLSS and Vericel mutually agree to discuss reimbursement support services for military Payers.
- 7. <u>Operational Metrics & Reporting</u>. Vericel is to review and evaluate the operational metrics proposed by DLSS. Following such evaluation, the parties hereto would update and revise any existing metrics based on mutually agreed operational metrics. DLSS and Vericel are to mutually evaluate and determine those reports that are important to the program. Following such evaluation, an amendment to the Agreement would update and revise the reporting obligations contained in <u>Exhibit C</u> of the Agreement.
- 8. <u>No Other Changes</u>. This Amendment, together with the Agreement, constitutes the entire agreement between the parties and supersedes all prior or contemporaneous discussions, negotiations, representations, warranties, or agreements relating to the subject matter hereof. All other terms and conditions contained in the Agreement will remain in full force and effect. In the event of any conflict between the Agreement and this Amendment, the terms of this Amendment shall prevail, and the Agreement shall be deemed amended to incorporate the provisions contained herein.

\* \* \* \* \*

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

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

## DOHMEN LIFE SCIENCE SERVICES, LLC

By: /<u>s/Joe Nolan</u> Name: Joe Nolan Title: President DLSS

## VERICEL CORPORATION

By: /<u>s/ Dominick C. Colangelo</u> Name: Dominick C. Colangelo Title: President and CEO

## 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, 2016

/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, 2016

/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, 2016, 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, 2016

/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, 2016, 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, 2016

/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.