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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED **June 30, 2016**,

OR

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

Commission file number **001-35280**

### **VERICEL CORPORATION**

(Exact name of registrant as specified in its charter)

**Michigan**

(State or other jurisdiction of  
incorporation or organization)

**94-3096597**

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

**64 Sidney Street**

**Cambridge, MA 02139**

(Address of principal executive offices, including zip code)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 -

Accelerated filer -

Non-accelerated filer -

Smaller reporting company -

(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 -  No -

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

**COMMON STOCK, NO PAR VALUE**

(Class)

**23,995,116**

Outstanding at August 5, 2016

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

## Item 1. Financial Statements

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

	June 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash	\$ 9,835	\$ 14,581
Accounts receivable (net of allowance for doubtful accounts of \$54 and \$68, respectively)	9,031	10,919
Inventory	2,393	1,379
Other current assets	1,046	464
Total current assets	22,305	27,343
Property and equipment, net	4,351	4,049
Intangible assets, net	2,778	2,917
Total assets	\$ 29,434	\$ 34,309
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,305	\$ 7,588
Accrued expenses	2,892	3,603
Revolving credit agreement, net of deferred costs of \$96	2,304	—
Warrant liabilities	455	757
Short-term deferred rent	460	118
Other	39	42
Total current liabilities	11,455	12,108
Long-term deferred rent	820	—
Long term debt	52	71
Total liabilities	12,327	12,179
<b>COMMITMENTS AND CONTINGENCIES (Note 13)</b>		
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 — 22,684 and 23,789, respectively	309,437	307,766
Treasury stock — 1,250 shares	(3,150)	(3,150)
Accumulated deficit	(330,719)	(324,025)
Total shareholders' equity	17,107	22,130
Total liabilities and shareholders' equity	\$ 29,434	\$ 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Revenues:</b>				
Product sales	\$ 12,823	\$ 13,590	\$ 26,931	\$ 24,439
Total revenues	12,823	13,590	26,931	24,439
<b>Costs and expenses:</b>				
Cost of product sales	7,300	6,901	13,860	12,469
Gross profit	5,523	6,689	13,071	11,970
Research and development	4,058	3,369	7,594	7,746
Selling, general and administrative	6,449	5,585	12,453	11,061
Total operating expenses	10,507	8,954	20,047	18,807
Loss from operations	(4,984)	(2,265)	(6,976)	(6,837)
<b>Other income (expense):</b>				
Decrease (increase) in fair value of warrants	1,942	112	302	(205)
Foreign currency translation (loss) gain	(1)	(6)	(11)	10
Interest income	2	9	7	22
Interest expense	(3)	(2)	(6)	(4)
Other expense	—	—	(10)	—
Total other income (expense)	1,940	113	282	(177)
Net loss	\$ (3,044)	\$ (2,152)	\$ (6,694)	\$ (7,014)
<b>Net loss per share attributable to common shareholders (Basic and Diluted)</b> (see note 11)				
	\$ (0.22)	\$ (0.16)	\$ (0.46)	\$ (0.43)
<b>Weighted average number of common shares outstanding (Basic and Diluted)</b>				
	22,684	23,786	22,644	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)

	Six Months Ended June 30,	
	2016	2015
<b>Operating activities:</b>		
Net loss	\$ (6,694)	\$ (7,014)
<b>Adjustments to reconcile net loss to net cash used for operating activities:</b>		
Depreciation and amortization	923	672
Stock compensation expense	1,319	1,614
Change in fair value of warrants	(302)	205
Inventory provision	86	—
Deferred rent expense	260	—
Tenant improvement reimbursement	607	—
Foreign currency translation loss	11	10
Gain on sales of fixed assets	—	(35)
<b>Changes in operating assets and liabilities:</b>		
Inventory	(1,099)	(157)
Accounts receivable	1,888	(789)
Other current assets	(385)	(1,235)
Accounts payable	(2,305)	(412)
Accrued expenses	(711)	(1,458)
Other non-current assets and liabilities, net	—	8
Net cash used for operating activities	<u>(6,402)</u>	<u>(8,591)</u>
<b>Investing activities:</b>		
Expenditures for property, plant and equipment	(1,074)	(1,555)
Other	93	35
Net cash used in investing activities	<u>(981)</u>	<u>(1,520)</u>
<b>Financing activities:</b>		
Net proceeds from issuance of common stock	352	3
Borrowings under revolving credit agreement	2,400	—
Deferred financing costs	(96)	—
Payments on long-term debt	(19)	(17)
Net cash provided by (used in) financing activities	<u>2,637</u>	<u>(14)</u>
Net decrease in cash	(4,746)	(10,125)
Cash at beginning of period	14,581	30,343
Cash at end of period	<u>\$ 9,835</u>	<u>\$ 20,218</u>
<b>Supplemental cash flow information (non-cash):</b>		
Additions to equipment in process included in accounts payable	\$ 11	\$ 700

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 JUNE 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-in-class therapies for patients with significant unmet medical needs.

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

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 six months ended June 30, 2016, are not necessarily indicative of the results to be expected for the full year or for any other period. The June 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.

## **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. As of June 30, 2016, the Company does not expect the guidance to impact future disclosures.

## 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 June 30, 2016.

## 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.

## 4. Selected Balance Sheet Components

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

(In thousands)	June 30, 2016	December 31, 2015
Raw materials	\$ 2,089	\$ 1,228
Work-in-process	276	131
Finished goods	28	20
Inventory	<u>\$ 2,393</u>	<u>\$ 1,379</u>

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

(In thousands)	June 30, 2016	December 31, 2015
Machinery and equipment	\$ 3,200	\$ 3,280
Furniture, fixtures and office equipment	931	931
Computer equipment and software	2,662	2,662
Leasehold improvements	3,291	2,393
Construction in process	593	421
Total property and equipment, gross	10,677	9,687
Less: Accumulated depreciation	(6,326)	(5,638)
	<u>\$ 4,351</u>	<u>\$ 4,049</u>

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 six months ended June 30, 2016 was \$0.4 million and \$0.8 million, respectively, compared to \$0.2 million and \$0.5 million, respectively, for the same periods in 2015.

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

(In thousands)	June 30, 2016	December 31, 2015
Commercial rights	\$ 3,360	\$ 3,360
Less: accumulated amortization	\$ (582)	\$ (443)
	<u>\$ 2,778</u>	<u>\$ 2,917</u>

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 six months ended June 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	\$ 141
2017	280
2018	280
2019	280
2020	280
Thereafter	1,517
<b>Total</b>	<u>\$ 2,778</u>

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

(In thousands)	June 30, 2016	December 31, 2015
Bonus related compensation	\$ 1,325	\$ 1,956
Employee related accruals	1,485	1,341
Accrued expenses	82	306
	<u>\$ 2,892</u>	<u>\$ 3,603</u>

## 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. The following warrants were outstanding at June 30, 2016, and include provisions that could require cash settlement of the warrants or have anti-dilution price protection provisions 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:

	August 2013 Warrants
Exercise price	\$4.80
Expiration date	August 16, 2018
Total shares issuable on exercise	724,950

The fair value of the August 2013 warrants 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	June 30, 2016		December 31, 2015	
Closing stock price	\$	2.25	\$	2.58
Expected dividend rate		—%		—%
Expected stock price volatility		85.9%		91.4%
Risk-free interest rate		0.6%		1.3%
Expected life (years)		2.13		2.63

## 6. Debt

On March 8, 2016, the Company entered into a \$15.0 million debt financing with Silicon Valley Bank (SVB). The debt financing consists of a \$3.0 million term loan available immediately upon the closing, \$2.0 million term loan available upon the FDA's approval of the MACI BLA and up to \$10.0 million revolving line of credit. The term loans are interest only (indexed to Wall Street Journal (WSJ) Prime plus 0.75%) until March 1, 2017 followed by 36 equal monthly payments of principal plus interest maturing February 1, 2020. The revolving credit is limited to a borrowing base calculated using eligible accounts receivable and maturing March 8, 2018 with an interest rate indexed to WSJ Prime plus 0.25% or 0.75%, depending on certain balance sheet ratios. Monthly, the Company must remain in compliance with an adjusted quick ratio greater than or equal to 1.10 to 1.0. The adjusted quick ratio is the ratio of (a) unrestricted cash and cash equivalents and net billed accounts receivable to (b) current liabilities minus the current portion of deferred revenue and warrant liabilities. SVB has a first priority perfected security interest in all assets of the Company other than intellectual property. As of June 30, 2016, there was an outstanding balance of \$2.4 million under the revolving line of credit recorded in current liabilities. The remaining capacity under the revolving line of credit as of June 30, 2016 was \$7.2 million and we were, and continue to be, in compliance with our financial and non-financial debt covenants.

## 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 six months ended June 30, 2016, the Company granted 236,750 and 1,072,230 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 six month periods ended June 30, 2016 was \$2.06 and \$2.16, respectively for 2016 and \$2.43 and \$2.22, respectively for the same periods in 2015.

The net compensation expense recorded for the service-based stock options related to employees and directors was \$0.7 million and \$1.2 million for the three and six months ended June 30, 2016, respectively, and \$0.7 million and \$1.6 million for the three and six months ended June 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.

Service-Based Stock Options	Six Months Ended June 30,	
	2016	2015
Expected dividend rate	—%	—%
Expected stock price volatility	78.7 – 92.2%	78.8 – 88.1%
Risk-free interest rate	1.2 – 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:

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	1,072,230	\$ 3.03		
Exercised	39,231	\$ 3.06		\$ 76,827
Expired	72,375	\$ 37.79		
Forfeited	113,686	\$ 3.81		
Outstanding at June 30, 2016	3,370,338	\$ 4.75	7.8	\$ 150,224
Exercisable at June 30, 2016	900,364	\$ 8.93	8.6	\$ 8,439

As of June 30, 2016 there was approximately \$3.5 million of total unrecognized compensation cost related to non-vested service-based stock options granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 3.1 years.

The total fair value of options vested during the three and six months ended June 30, 2016 and 2015 was \$0.6 million and \$1.0 million, respectively, and \$0.6 million and \$0.9 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 July 1, 2016, employees purchased 60,992 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 both the three and six months ended June 30, 2016 was approximately \$0.1 million for each period.

#### 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:

(In thousands)	June 30, 2016				December 31, 2015			
	Total	Fair value measurement category			Total	Fair value measurement category		
		Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
<b>Liabilities:</b>								
Warrant liabilities	\$ 455	\$ —	\$ 455	\$ —	\$ 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	(302)
Balance at June 30, 2016	\$ 455

## 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, subject to certain limitations, from time to time over a 30 months period, which began on April 3, 2014 and ends on October 3, 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 \$11.3 million as of June 30, 2016. No shares were issued in 2015 or 2016.

At June 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 & Vlasko and now owned by FBR & Co.) which allowed us to sell shares of 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 will file an updated Form S-3 registration statement.

### 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*

On March 9, 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. At any time after the Conversion date, the Company may elect to convert any or all outstanding shares of Series B preferred stock into 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 June 30, 2016, there are approximately 395,011 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.

The Series B preferred stock does not, in its entirety, require liability classification and was evaluated for embedded features to determine if those features require bifurcation and separate classification as derivative liabilities. The Series B preferred stock host contract was evaluated for equity or mezzanine classification based upon the nature of the redemption and conversion features. Generally, any feature that could require cash redemption for matters not within the Company's control, irrespective of probability of the event occurring, requires classification outside of shareholders' equity. The Series B preferred stock was initially recorded as mezzanine in the Condensed Consolidated Balance Sheets and was accreted to its redemption value through charges to accumulated deficit using the effective interest method.

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 was reclassified from mezzanine into 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 holders of common stock, after 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:

(Amounts in thousands except per share amounts)	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
<b>Numerator:</b>				
Net loss	\$ (3,044)	\$ (2,152)	\$ (6,694)	\$ (7,014)
Dividends accumulated on convertible preferred stock	(1,856)	(1,654)	(3,660)	(3,244)
Net loss attributable to common shareholders	\$ (4,900)	\$ (3,806)	\$ (10,354)	\$ (10,258)
<b>Denominator:</b>				
Denominator for basic and diluted EPS:				
Weighted-average common shares outstanding	22,684	23,786	22,644	23,786
Net loss per share attributable to common shareholders (basic and diluted)	\$ (0.22)	\$ (0.16)	\$ (0.46)	\$ (0.43)

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 June 30, 2016 and 2015 were 6.4 million and 4.3 million, respectively.

## 12. Concentration of Credit Risk

Revenue from one customer, a distributor in the U.S., represented approximately 69% and 63% of total revenue during the three months ended June 30, 2016 and 2015, respectively, and 65% and 63% of total revenue during the six months ended June 30, 2016 and 2015, respectively. Accounts receivable from the same customer accounted for 78% and 76% of the outstanding accounts receivable as of June 30, 2016 and December 31, 2015, respectively. The next largest customer represented approximately 13% and 15% of revenue for the three month period ended June 30, 2016 and 2015, respectively, and 15% and 16% of total revenue during the six months ended June 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 our consolidated balance sheet and is amortized to our consolidated statement of operations as reductions to rent expense over the lease term. As of June 30, 2016, we have 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.

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

(In thousands)	Total	2016	2017	2018	2019	2020	More than 5 Years
Operating leases	\$ 25,538	\$ 2,123	\$ 4,897	\$ 4,590	\$ 4,267	\$ 4,386	\$ 5,275
Purchase commitments	450	450	—	—	—	—	—
Capital leases	97	22	43	32	—	—	—
Total	\$ 26,085	\$ 2,595	\$ 4,940	\$ 4,622	\$ 4,267	\$ 4,386	\$ 5,275

Rent expense for the three and six months ended June 30, 2016 was \$1.2 million and \$2.4 million, respectively, and \$1.3 million and \$2.5 million, respectively, for the three and six months ended June 30, 2015.

## 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® (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. We are also developing MACI®, 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 ixmylocel-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 ixmylocel-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<sup>2</sup>).

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 approximately a 20-person field force calling on this sports-injury targeted orthopedic physician audience. For the three and six months ended June 30, 2016, net revenues were \$9.0 million and \$17.8 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 six months ended June 30, 2016, net revenues were \$3.8 million and \$9.1 million, respectively, for Epicel.

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

On February 18, 2016, the FDA approved 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 double-blind 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 six months ended June 30, 2016 totaled \$3.0 million or \$0.22 per share and \$6.7 million or \$0.46 per share, respectively. Our net loss for the three and six months ended June 30, 2015 totaled \$2.2 million or \$0.16 per share and \$7.0 million and \$0.43 per share.

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Total revenues	\$ 12,823	\$ 13,590	\$ 26,931	\$ 24,439
Cost of product sales	7,300	6,901	13,860	12,469
Gross profit	5,523	6,689	13,071	11,970
Total operating expenses	10,507	8,954	20,047	18,807
Loss from operations	(4,984)	(2,265)	(6,976)	(6,837)
Other expense	1,940	113	282	(177)
Net loss	\$ (3,044)	\$ (2,152)	\$ (6,694)	\$ (7,014)

### Net Revenues

Net revenues decreased for the three months ended June 30, 2016 compared to the same period the previous year primarily due to the downtime for the Carticel and Epicel cleanrooms to replace a rooftop air handler unit which resulted in a two-week, or approximately 16%, reduction in product shipment dates for both products during the second quarter. The decrease is offset by an increases 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 six months ended June 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.

Revenue by product (in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Carticel	\$ 8,987	\$ 9,063	\$ 17,798	\$ 16,181
Epicel	3,836	4,274	9,133	7,913
Bone Marrow	—	253	—	345
	\$ 12,823	\$ 13,590	\$ 26,931	\$ 24,439

*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 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 between the same quarters in consecutive years has been as high as 10% of the annual volume. While the number of patients treated per year remains low, we expect these large swings in revenue in some quarters to continue. These seasonal trends have caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

### Gross Profit and Gross Profit Ratio

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Gross profit	\$ 5,523	\$ 6,689	\$ 13,071	\$ 11,970
Gross profit %	43%	49%	49%	49%



Gross profit ratio decreased for the three months ended June 30, 2016 compared to the same period in 2015 due to the downtime for the Carticel and Epicel cleanrooms to replace a rooftop air handler unit which resulted in a two-week, or approximately 16%, reduction in product shipment dates for both products during the second quarter. The gross profit ratio has remained consistent for the six months ended June 30, 2016 and 2015.

#### Research and Development Costs

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development costs	4,058	3,369	7,594	7,746

Research and development expenses for the three months ended June 30, 2016 were \$4.1 million versus \$3.4 million for the same period a year ago. Trial expenses for the ixCELL-DCM clinical trial were higher in the three months ended June 30, 2016 due to consulting services related to completing the blinded portion of the trial, analyzing the data and preparing to treat patients who had been originally assigned to the placebo group in the double blind portion of the trial and will now be offered the option to receive ixmyelocel-T in the open label extension portion of the trial. In addition, MACI research and development consulting fees for the three months ended June 30, 2016 have increased compared to the same period a year ago.

Research and development expenses for the six months ended June 30, 2016 were \$7.6 million versus \$7.7 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.

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Dilated Cardiomyopathy	\$ 2,038	\$ 1,866	\$ 3,857	\$ 5,298
MACI	728	417	1,280	607
Carticel	719	522	1,366	1,000
Epicel	573	564	1,091	841
Total research and development expenses	\$ 4,058	\$ 3,369	\$ 7,594	\$ 7,746

#### Selling, General and Administrative Costs

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Selling, general and administrative costs	\$ 6,449	\$ 5,585	\$ 12,453	\$ 11,061

Selling, general and administrative expenses for the three months ended June 30, 2016 were \$6.4 million compared to \$5.6 million for the same period a year ago. Selling, general and administrative expenses for the six months ended June 30, 2016 were \$12.5 million compared to \$11.1 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, 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)

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Increase in fair value of warrants	\$ 1,942	\$ 112	\$ 302	\$ (205)
Foreign currency translation (loss) gain	(1)	(6)	(11)	10
Other income	—	—	(10)	—
Net interest income	(1)	7	1	18
Total other income (expense)	\$ 1,940	\$ 113	\$ 282	\$ (177)

The change in other income and expense for the three and six months ended June 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:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of goods sold	\$ 131	\$ 67	\$ 214	\$ 187
Research and development	179	145	\$ 258	\$ 357
Selling, general and administrative	521	480	847	1,070
Total non-cash stock-based compensation expense	\$ 831	\$ 692	\$ 1,319	\$ 1,614

The increase in stock-based compensation expense is due primarily to an increase in the fair value of the options granted in 2016 compared to 2015 in addition to the 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 six months ended June 30, 2016 and 2015 is below:

(Amounts in thousands except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Numerator:</b>				
Numerator of basic and diluted EPS	\$ (4,900)	\$ (3,806)	\$ (10,354)	\$ (10,258)
Add: (Decrease) increase in fair value of warrants	(1,942)	(112)	(302)	205
Add: Dividends accumulated on convertible preferred stock	1,856	1,654	3,660	3,244
Adjusted net loss - Non-GAAP	\$ (4,986)	\$ (2,264)	\$ (6,996)	\$ (6,809)
<b>Denominator:</b>				
Denominator for basic and diluted EPS:				
Weighted-average common shares outstanding	22,684	23,786	22,644	23,786
Add: Treasury stock	1,250	—	1,250	—
Adjusted denominator for basic and diluted EPS - Non-GAAP	23,934	23,786	23,894	23,786
Adjusted net loss per share (basic and diluted) - Non-GAAP	\$ (0.21)	\$ (0.10)	\$ (0.29)	\$ (0.29)

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 June 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 have access to certain amounts of financing through an agreement with Lincoln Park Capital Fund, LLC (Lincoln Park). We may direct Lincoln Park to purchase up to \$15.0 million worth of shares of our common stock over a 30-month period generally in amounts up to 50,000 shares of our common stock on certain business days under a Purchase Agreement. However, there are certain factors, such as volume of trading in our common stock and our stock price, which limit the amount that can be raised in a short period of time. The extent to which we rely on the Lincoln Park Equity Line as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. The remaining capacity under this agreement is \$11.3 million as of June 30, 2016.

At June 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 will file an updated Form S-3 registration statement.

On March 8, 2016, we entered into a \$15.0 million debt financing with SVB. The debt financing consists of a \$3.0 million term loan available immediately upon the closing, \$2.0 million term loan available upon the FDA's approval of the MACI BLA and up to \$10.0 million revolving line of credit. The term loans are interest only (indexed to WSJ Prime plus 0.75%) until March 1, 2017 followed by 36 equal monthly payments of principal plus interest maturing February 1, 2020. The revolving credit is limited to a borrowing base calculated using eligible accounts receivable and maturing March 8, 2018 with an interest rate indexed to WSJ Prime plus 0.25% or 0.75%, depending on certain balance sheet ratios. Monthly, the Company must remain in compliance with an adjusted quick ratio greater than or equal to 1.10 to 1.0. The adjusted quick ratio is the ratio of (a) unrestricted cash and cash equivalents and net billed accounts receivable to (b) current liabilities minus the current portion of deferred revenue and warrant liabilities. SVB has a first priority perfected security interest in all assets of the Company other than intellectual property. As of June 30, 2016, there was an outstanding balance of \$2.4 million under the revolving line of credit. The remaining capacity under the revolving line of credit as of June 30, 2016 was \$7.2 million and we were, and continue to be, in compliance with our financial and non-financial debt covenants.

Our cash totaled \$9.8 million at June 30, 2016. During the six months ended June 30, 2016, the cash used for operations was \$6.4 million. This use of funds was fueled largely by our operating loss adjusted by stock compensation expense of \$1.3 million, depreciation and amortization expense of \$0.9 million and cash receipts of \$0.6 million for tenant improvement reimbursements.

The decrease in cash used for investing activities was primarily due to a reduction in capital additions through June 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 \$2.4 million from borrowings under the debt financing with SVB in addition to the issuance of common stock of \$0.4 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 June 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 six months ended June 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 June 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 June 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 June 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 June 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. 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.

### **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 June 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: August 8, 2016

VERICEL CORPORATION

/s/ DOMINICK C. COLANGELO

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

/s/ GERARD MICHEL

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

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
10.1†**	Amended and Restated Contract Manufacturing and Supply Agreement, dated April 20, 2016 between the Company and Vention Medical Inc. (formerly ATEK Medical, LLC).
10.2**	First Amendment to the Services Agreement, dated April 5, 2016 between the Company and Dohmen Life Science Services, LLC, dated May 31, 2016.
10.3†**	Second Amendment to the Services Agreement, dated April 5, 2016 between the Company and Dohmen Life Science Services, LLC, dated July 1, 2016.
10.4**	Seventh Amendment to Transition Services Agreement, dated as of May 28, 2016, by and between the Company and Genzyme Corporation.
31.1**	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document

\*\* Filed herewith.

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



## GLOSSARY

<b>TERM</b>	<b>DEFINITION</b>
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.

Prospective Clinical Trial

A clinical trial in which participants are identified and then followed throughout the study going forward in time.

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.

## AMENDED AND RESTATED

### CONTRACT MANUFACTURING AND SUPPLY AGREEMENT

This Amended and Restated Contract Manufacturing and Supply Agreement (the "Agreement") amends and restates in its entirety as of April 20, 2016 (the "Amendment Effective Date") the agreement made and entered into as of November 8, 2010 by and between Vericel Corporation (formerly Aastrom Biosciences, Inc.), a Michigan corporation having a principal place of business at Domino's Farms, Lobby K, 24 Frank Lloyd Wright Drive, Ann Arbor, MI, 48105 ("Vericel") and Vention Medical Inc. (formerly ATEK Medical, LLC), having its principal place of business at 620 Watson SW, Grand Rapids, MI, 49504 ("Supplier").

#### RECITALS

WHEREAS, Vericel manufactures a stem cell product for use in clinical trials;

WHEREAS, Supplier desires to manufacture Vericel's proprietary cell cassette (the "Product") for use in their manufacturing process; and

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and agreements hereinafter set forth, and subject to the terms and conditions of this Agreement, the parties agree as follows:

#### 1. PRODUCTS

Vericel shall purchase from Supplier and Supplier shall manufacture for Vericel the Product as further set forth on Appendix A attached hereto at the facility specified therein, (the "Facility"), and assemble, package, label, and coordinate the sterilization of the Product in facilities approved by Vericel, in accordance with the terms of this Agreement.

#### 2. OBLIGATIONS

##### 2.1 Supplier's Obligations.

2.1.1 Sterilization Cost. Supplier will include the cost of gamma sterilization in the Product unit cost. Supplier shall arrange for initial sterilization validations and Vericel requested re-validations using mutually approved protocols. The cost for development of protocols, execution of the validation, and writing of the sterilization final report shall be paid for by Vericel at a pre-approved cost. Supplier will coordinate sterilization schedules and will generate purchase orders for sterilization to a Vericel approved contract sterilization company. Subsequent certificates of sterilization will be provided by the contract sterilization company to Supplier. Supplier shall forward such certificates to Vericel upon shipment of Product and will be included in the Product unit price. In the event of a failed sterilization, Vention shall be responsible for the sterilization costs of such product.

2.1.2 Quarterly Dose Audits. Supplier will coordinate the execution of quarterly dose audits related to sterilized Product using a mutually approved standard operating procedure. Vericel will provide a purchase order for the periodic dose audits with associated bioburden and sterility testing. Any Supplier requested modifications requiring re-validation will be performed at Supplier's expense.

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- 2.1.3 Purchasing. Supplier is responsible for obtaining all Vericel approved components pertaining to the Product including those for manufacturing, assembly, packaging, labeling and sterilization in accordance with the schedule and quantities outlined on Appendix A attached hereto and Sections 10.1 and 10.2, unless otherwise noted in Appendix A of this Agreement. Supplier will order components against pre-approved purchase specifications and will receive components against pre-approved incoming inspection plans.
- 2.1.4 Schedule. Supplier will ship the Product in accordance with Sections 10.1 and 10.2 of this Agreement.
- 2.1.5 Production Affecting Events. Supplier will notify Vericel of any plant shut down, manufacturing delay, or other event about which Supplier is aware that would result in the inability of Supplier to provide Product. Vericel will be notified within two days of any shutdown or other information that may impede Supplier in the manufacture of the Product.
- 2.1.6 Sustaining. Supplier shall provide reasonable ongoing manufacturing support of the Product in order to satisfy production requirements outlined in Appendix A and Section 10.
- 2.2 Vericel Obligations.
  - 2.2.1 Purchasing. Vericel shall order and purchase the Product from Supplier as provided in Appendix A attached hereto and Section 10, as amended from time to time by mutual consent.
  - 2.2.2 Engineering Support. Vericel shall provide Supplier with reasonable engineering support to initiate, maintain and ramp up manufacturing of the Product, including training, substitute part validation and sterilization validation.
  - 2.2.3 Obsolescence. If Vericel decides to make obsolete a component of the Product, Vericel shall reimburse Supplier at cost for any remaining inventory of such component and work in process to the extent that such inventory and work in process can be converted into finished Products, but not to exceed [\*\*\*] months of the Forecast (as defined in Section 10) Product demand or as agreed to in writing by both parties.
  - 2.2.4 Tooling for External Suppliers. Vericel shall be responsible for costs in connection to routine tooling maintenance performed by any external supplier appointed by Vericel.

### **3. EQUIPMENT & CALIBRATION**

All manufacturing equipment will be supplied by Vericel. Supplier's calibration group will calibrate all applicable equipment within its capabilities. Calibration requirements for each piece of equipment will be agreed upon individually and provided in writing to Supplier by Vericel. For all special equipment or processes requiring calibration, Supplier will consult with Vericel on requirements prior to taking action towards setup and routine calibration. Additional expenses required for special calibration requirements will be agreed upon in advance and submitted to Vericel for payment.

### **4. CONFIDENTIALITY**

It is anticipated that Vericel and Supplier will need to exchange confidential information. All such information concerning the subject matter of this Agreement is to be considered confidential by the receiving party whether received orally, visually, or in written form. In the event of any conflict

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between this Section 4 and any prior confidentiality agreement entered into between the parties, the confidentiality provisions herein shall control.

During the Term (as defined in Section 8) all confidential information disclosed hereunder shall be used by the recipient solely for the purpose of this Agreement and shall not be used in any way for its own account or for the account of any third party, or disclosed to third parties, nor to those within the recipient's company who do not have a need to know such information.

Said obligations of confidentiality shall not apply to any information which:

- a) was in the possession of the recipient before disclosure hereunder as evidenced by written records; or
- b) is or becomes known to the public through no fault of the recipient party; or
- c) is information received by the recipient from a third party who is under no obligation to the disclosing party to maintain such information as confidential; or
- d) is developed by the recipient independent of any disclosure hereunder as evidenced by written records.

All confidential information shall at all times remain the property of the disclosing party, and shall be returned to the disclosing party along with all copies thereof, immediately upon request by the disclosing party.

No disclosure of confidential information shall be deemed to vest in the receiving party any rights in any patents, trade secrets, or intellectual property or other property of the disclosing party, other than as set forth in this Agreement.

## **5. DESIGN CONTROL AND SPECIFICATIONS; RECORDS; REGULATORY CONTACT**

- 5.1 **General.** Supplier shall only manufacture the Product to Vericel's specifications and shall not change materials, specifications, design/configuration, procedures, packaging or labeling without Vericel's prior written consent. Vericel may reject any Product lots that are defective or otherwise do not conform to Vericel's specifications, drawings, or to Vericel's purchase orders.
- 5.2 **Changes by Vericel.** Vericel may change specifications from time to time as needed, (e.g. to meet market requirements, comply with regulatory requirements, improve Product function or quality, or lower Product cost). Any changes in specifications shall be conveyed to Supplier in writing. Supplier shall confirm, in writing, its receipt of Vericel's changes and shall use its commercial best efforts to implement the documented changes within forty-five (45) days of notification unless otherwise agreed upon. Once changes are implemented, Supplier shall immediately advise Vericel in writing of the first Product lot to contain the changes.

Vericel shall purchase from Supplier any affected finished goods that are in a usable condition and comply with all Vericel specifications, components or raw materials inventory and work in process to the extent that such inventory and work in process can be converted into finished Products, that Supplier has purchased or completed at Supplier's actual cost, in aggregate quantities not to exceed the actual accumulated monthly production from Vericel purchase orders for [\*\*\*] days preceding

notice of discontinuation of the affected components of the Product or unless otherwise mutually agreed in writing. However, Supplier agrees to make commercially best efforts to minimize the financial impact to Vericel by optimizing the procurement of materials for minimal scrap once Vericel notifies Supplier of such changes.

If any Vericel specification change directly affects the prices or schedule of the Product, a reasonable adjustment for such increased costs of Supplier shall be made, provided that Supplier makes and Vericel accepts a written claim for an adjustment prior to manufacturing the Product. Price adjustments shall be limited to the affected component or process and shall not constitute an opportunity to renegotiate any other aspects of this Agreement or the manufacture of the Product. If the parties are unable to agree upon the amount of the adjustment, Vericel may, without liability to Supplier, terminate this Agreement as to all or part of the affected Products.

- 5.3 Changes by Supplier. Supplier may recommend design or specification changes to Vericel but no such changes will be incorporated into the Product without Vericel's prior written approval and without following appropriate documentation change procedures. Such Supplier proposed changes shall be made at Vericel's expense.
- 5.4 Discontinuation of Product. Vericel may discontinue the manufacture of the Product at its sole discretion. In the event Vericel decides to discontinue the manufacture of the Product, Vericel shall use commercially reasonable efforts to notify Supplier at least one hundred eighty (180) days prior to Vericel's intention to discontinue manufacture of the Product. Failure to provide Supplier prior notice shall not be a breach of this Agreement; provided, however, if Vericel does not give Supplier one hundred eighty (180) days prior notice, Vericel agrees to purchase from Supplier any finished goods that are in a usable condition and comply with all Vericel specifications, component or raw materials inventory and work in process to the extent that such inventory and work in process can be converted into finished Products, that Supplier has purchased or completed at Supplier's actual cost, in aggregate quantities not to exceed the actual accumulated monthly production from Vericel purchase orders for [\*\*\*] days preceding notice of discontinuation of the Product.
- 5.5 Records. Supplier will keep complete and accurate records (including reports, accounts, notes, raw data, and records of all information and results obtained from performance of services) of all work done by it under this Agreement, in form and substance as specified in the applicable Quality Agreement and this Agreement (collectively, the "Records"). All such Records will be the property of Vericel. Supplier will not transfer, deliver or otherwise provide any such Records to any party other than Vericel, without the prior written approval of Vericel. Records will be available at reasonable times for inspection, examination and copying by or on behalf of Vericel. All original Records of the Manufacture of Product under this Agreement will be retained and archived by Supplier in accordance with cGMP (if applicable) and Applicable Law, but in no case for less than a period of five (5) years. Upon Vericel's request, Supplier will promptly provide Vericel with copies of such Records. Five (5) years after completion of services, all of the aforementioned Records will be sent to Vericel or Vericel's designee; provided, however, that Vericel may elect to have such Records retained in Supplier's archives for an additional period of time at a reasonable charge to Vericel.
- 5.6 Regulatory Approvals. Vericel will be responsible for obtaining, at its expense, all regulatory and governmental approvals and permits necessary for Vericel's use of any Product developed and/or manufactured under this Agreement, including investigational new drug application, biologics license application, new drug application, and abbreviated new drug application submissions and

any analogous submissions filed with the appropriate regulatory authority of a country other than the United States. Supplier will be responsible for providing Vericel with all supporting data and information relating to the development and/or manufacture of Product necessary for obtaining such approvals, including all (i) Records, (ii) batch documentation, (iii) authorizations, certificates, methodologies, raw material specifications, SOPs, standard test methods, and other documentation (collectively, "Supporting Documentation") in the possession or under the control of Supplier relating to the development and manufacture of Product (or any intermediate or component of Product).

5.7 Regulatory Inspections. Supplier will promptly notify Vericel of any visit or inspection by any regulatory authority of the Facility. Supplier will provide Vericel with a copy of any report or other written communication received from such regulatory authority in connection with such visit or inspection (assuming the same relates to Product), and any written communication received from any regulatory authority relating to any Product, the Facility (if it relates to or affects the development and/or manufacture of Product) or the manufacturing process, within [\*\*\*] after receipt, and will consult with Vericel prior to submitting a response to the applicable regulatory authority; provided, however, that the response specifically relates to Product. Supplier will provide Vericel with a copy of its final responses within [\*\*\*] business days after submission.

## **6. FACILITY; QUALITY**

6.1 Supplier will perform all services at the Facility, provide all staff necessary to perform the services in accordance with the terms of this Agreement, and hold at such Facility all equipment, Vericel materials and other items used in the services. Supplier will not change the location of such Facility or use any additional facility for the performance of services under this Agreement without at least one hundred eighty (180) days prior written notice to, and prior written consent from, Vericel, which consent will not be unreasonably withheld or delayed (it being understood and agreed that Vericel may withhold consent pending satisfactory completion of a quality assurance audit and/or regulatory impact assessment of the new location or additional facility, as the case may be). Supplier will maintain, at its own expense, the Facility and all equipment required for the manufacture of Product in a state of repair and operating efficiency consistent with the requirements of cGMP (if applicable) and all applicable law. For clarification, no Facility shall be located outside of the continental United States.

6.1.1 Validation. Supplier will be responsible for performing all validation of the Facility, equipment and cleaning and maintenance processes employed in the manufacturing process in accordance with cGMP (if applicable), Supplier's SOPs, the applicable Quality Agreement (if any), applicable law, and in accordance with any other validation procedures established by Vericel and made known in writing to Supplier. Supplier will also be responsible for ensuring that all such validated processes are carried out in accordance with their terms.

6.1.2 Licenses and Permits. Supplier will be responsible for obtaining, at its expense, any Facility or other licenses or permits, and any regulatory and government approvals necessary for the performance of services by Supplier under this Agreement. At Vericel's request, Supplier will provide Vericel with copies of all such approvals and submissions to regulatory authorities, and Vericel will have the right to use any and all information contained in such approvals or submissions in connection with regulatory approval and/or commercial development of Product.

6.2 Access to Facility. Supplier will permit Vericel or its duly authorized representatives to observe and consult with Supplier during the performance of services under this Agreement, including the

manufacturing of any batch of Product. Supplier also agrees that Vericel and its duly authorized agents will have reasonable access upon advance prior notice, at a mutually agreeable date and time, during operational hours and during active manufacturing, to inspect the Facility and manufacturing process to ascertain compliance by Supplier with the terms of this Agreement, including inspection of (i) the equipment and materials used in the performance of services; (ii) the warehouse facilities for such materials and Equipment; and (iii) all Records directly relating to such services and the Facility. Vericel will also have the right, at its expense (including payment for the time and expenses incurred by Vention personnel in supporting the "mock" pre-approval audits ("Mock Audits"), to be invoiced by Vention and paid by Vericel), to conduct Mock Audits upon reasonable prior notice, and upon a date and time agreed to by Supplier, and Supplier agrees to cooperate with Vericel in such Mock Audits at Vericel's expense.

6.3 Quality Agreement. A separate written Quality Agreement will be drafted and mutually agreed upon between Vericel and Supplier.

## 7. **PRICING**

7.1 General. The Product shall be purchased and sold in US dollars. Prices per unit of Product are listed in Appendix A.

7.2 Extension Option; Quarterly Charge. As of the Amendment Effective Date, Vericel hereby exercises its right to extend the Term for an additional five (5) years subject to the terms of this Section 7.2. Commencing with the calendar quarter in which the initial QDA/Sterility production runs are shipped and for each calendar quarter thereafter during the Term, Vericel shall pay Supplier a quarterly charge equal to [\*\*\*] Dollars (\$[\*\*\*]), provided Supplier is not in material breach of its supply obligations as provided hereunder, subject to Supplier's right to cure as provided in Section 9. The first such quarterly charge shall be pro-rated based upon the date of the shipment of the QDA/Sterility production runs required to re-qualify the Supplier's cleanroom and production processes.

7.3 Annual Price Adjustment Notification. At least forty-five (45) days prior to the end of the first year of the Term and each year thereafter that this Agreement remains in effect, Supplier shall notify Vericel of any proposed Product unit price increase or decrease for the next succeeding year. Any increase or decrease in Product unit price shall be applicable only to those production lots of the Product of which the production process is completed after the change and cost becomes effective and shall remain in effect until another price change occurs. Additionally, any increase shall be limited to actual, documented increases in materials costs or shall not exceed the then current consumer price index for non-material related costs, without Vericel's prior approval.

7.4 Justification of Price Increases. Supplier will provide written rationale for its price increases for the Product any year during the Term upon Vericel's request. Vericel and Supplier will work collaboratively and in good faith to mitigate any potential cost increases.

7.5 Scrap. Supplier unit cost shall assume a scrap rate of [\*\*\*]%. If during the Term, actual scrap rate exceeds [\*\*\*]% for a period of thirty (30) days or more, Supplier will notify Vericel in writing of the actual scrap rate and failure mode. Supplier and Vericel will work collaboratively to determine root cause of the increased scrap. When the supplier and Vericel agree on the root cause, financial responsibility shall remain with the party at cause. Best efforts shall be made by both parties to resolve all scrap issues within ninety (90) days from occurrence.



7.6 Cost Reduction. Both parties shall continuously work towards reducing costs. Any cost reduction efforts researched and implemented by both parties shall result in a 50/50 gain sharing of the savings realized. When a cost saving measure is solely driven by Vericel the savings will benefit Vericel 100%. Vericel and Supplier will meet periodically to review cost reduction efforts and define an action plan for driving improvement.

## 8. TERM

The term of this Agreement shall commence on November 8, 2010 and shall expire on November 7, 2021 (the "Term"). At the end of the Term, this Agreement shall terminate automatically without notice, unless, prior to that time, the Term is extended by mutual written consent of the parties delivered at least six (6) months prior to the termination date. Sections 4, 5.5, 5.6, 5.7 (with the exception of the first sentence), 9.4, and 11 through 28 shall survive the expiration or termination of this Agreement.

## 9. TERMINATION

9.1 Procedure for Termination: This Agreement may be terminated as follows:

- Either party may terminate this Agreement if the other party materially defaults in the performance of any provision of this Agreement. Should any such default occur, and then the non-defaulting party may give written notice to the defaulting party that if the default is not cured within forty-five (45) days, the Agreement will be terminated. If the non-defaulting party gives such notice and the default is not cured during the forty-five (45) day period, then the Agreement shall automatically terminate at the end of such period unless an extension is mutually agreed to by both parties.
- In addition to other remedies, either party may terminate the Agreement at any time if either breaches its confidentiality obligations under Section 4, in which case termination shall be effective immediately upon receipt of notice of the breach and of termination.
- Commencing on the first anniversary of the Amendment Effective Date, Vericel shall have the right to terminate this Agreement in its sole discretion upon twelve (12) months' prior written notice to Supplier.
- Commencing on the first anniversary of the Amendment Effective Date, Vention shall have the right to terminate this Agreement in its sole discretion upon eighteen (18) months' prior written notice to Vericel.
- Either party may immediately terminate this Agreement by written notice upon the occurrence of any of the following events: (i) the other party is or becomes insolvent or unable to pay its debts as they become due within the meaning of the United States Bankruptcy Code (or any successor statute) or any analogous foreign statute; or (ii) the other party appoints or has appointed a receiver for all or substantially all of its assets, or makes an assignment for the benefit of its creditors; or (iii) the other party files a voluntary petition under the United States Bankruptcy Code (or any successor statute) or any analogous foreign statute; or (iv) the other party has filed against it an involuntary petition under the United States Bankruptcy Code (or any successor statute) or any analogous foreign statute, and such petition is not dismissed within ninety (90) days.

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.

- 9.2 Return of Confidential Information and Equipment. Upon termination of this Agreement for any reason, each party shall return all confidential information, including, but not limited to technical information, and any equipment belonging to Vericel, each party shall make no further use of such information.
- 9.3 Inventory and Equipment Purchase Upon Termination. If the Agreement is terminated by Supplier for material breach by Vericel then Vericel shall purchase: (a) finished Products that are in a usable condition and comply with all Vericel specifications, including sterility on the date of termination; and (b) ninety (90) day work in process and component and raw materials inventory to the extent that such work in process and inventory can be converted into finished Products, all based on Vericel's Forecast needs. Such purchases shall be made within sixty (60) days following the effective date of the termination.
- 9.4 Other Termination. If the Agreement terminates by mutual agreement of both parties, then both parties will mutually agree upon the purchase and/or disposition of raw component materials, Product and/or equipment. Supplier shall provide reasonable technical support to transition Product to new manufacturing facility. Such technical support will be provided at Supplier's published engineering rates and shall be at Vericel's expense. If the Agreement terminates by Vericel for material breach by Supplier, then Vericel shall have the option to purchase any raw materials, inventory or Products at any stage of assembly as long as all materials are within current Vericel specification.

## **10. FORECAST, ORDERS AND QUANTITY**

- 10.1 Purchase Orders. Orders by Vericel shall be initiated by purchase orders executed by an authorized representative of Vericel. Supplier shall provide written confirmation to Vericel within 3 business days. If Supplier is unable to meet requested delivery date Supplier will provide alternative delivery date based on current manufacturing schedule. Supplier will make best efforts to achieve Vericel requested delivery date.
- 10.2 Delivery. Supplier shall use best efforts to ship the Product for delivery by the requested date on the Vericel purchase order. In order for shipment to be considered timely, a delivery must be shipped no earlier than three (3) days prior or no days later to the requested date.
- 10.3 Production Forecast. Vericel will provide to Supplier a [\*\*\*] month rolling forecast ("Forecast") upon the placement of initial production order. At all times the first [\*\*\*] months will represent a firm production demand.

## **11. SHIPMENT, RISK OF LOSS AND PAYMENT TERMS**

Supplier shall ship the Product in accordance with Vericel's delivery instructions specified in Vericel's purchase orders. Delivery shall be FOB Supplier's dock in Grand Rapids, MI. Supplier shall deliver all Products ordered by Vericel in accordance with the requested delivery dates as indicated in Vericel's purchase orders. Vericel shall be responsible for shipping costs.

All Products delivered by Supplier pursuant to this Agreement shall be packed as per standard operating procedure for the designated carrier. All Product shipped will include the Certificate of Conformance and will specify Vericel part number, lot number and quantity. All Product will be shipped with appropriate shipping documentation and clearly marked with part number, order

number, and quantity.

Payments for Products are due within thirty (30) days of the invoice date. In the event that any terms and conditions on any Supplier invoice or Vericel purchase order conflict with the terms of this Agreement, the terms of this Agreement shall govern.

**12. INTELLECTUAL PROPERTY RIGHTS**

All confidential information, including technical data and intellectual property rights, including without limitation, patents, patents pending, patent applications, trademarks, service marks, trade secrets and copyrights (the "Intellectual Property"), associated with the development, design, and manufacture of the Product are and shall remain the exclusive property of Vericel, and may be used by Supplier only as specifically set forth in this Agreement. Vericel reserves to itself and retains all right, title and interest in and to the Intellectual Property embodied in the Product and to any modifications, enhancements, improvements and upgrades thereto.

Supplier understands and agrees that it has no license to any Vericel product, technology, Intellectual Property or other property, except as set forth in this Agreement.

**13. WARRANTY AND REMEDIES FOR NON-CONFORMANCE**

13.1 Warranty. Supplier warrants that upon delivery as provided for hereunder and for the shelf life period ([\*\*\*]months) of the Product after delivery that (i) the Product shall be manufactured in compliance with document at ion provided and certified by Vericel; (ii) the Product delivered shall conform to documented specifications, including component inspection, test, and product release testing; (iii) any components or parts shall be sourced from Vericel approved vendors and inspected by mutually approved incoming inspection plans; (iv) the Product will be free of defects related to internal sterilization, workmanship, or material; (v) it shall not manufacture Product in advance of confirmed purchase orders so that the Product is delivered with the longest possible expiration date; and (vi) it shall manufacture the Product in a workmanlike manner and in accordance with industry standards, applicable law and, to the best of its knowledge, not in violation or infringement of any patent, copyright or trademark laws (the "Product Warranty"). Should any failure to conform to the Product Warranty become apparent, Vericel shall notify Supplier in writing, and Supplier will either correct such nonconformity by replacement of the defective Product or credit Vericel for any payments made with respect to the value of any defective Product, including direct expenses to Vericel.

13.2 Vericel warrants that to Vericel's knowledge the specifications and license contemplated herein do not violate or infringe any applicable laws, regulations or standards, including any patent copyright or trademark laws. Supplier's Product Warranty does not extend to (i) any Product rendered defective by a component provided by Vericel, unless Supplier is aware of the defect at or before the time the Product is assembled, or (ii) to defects caused by improper sterilization, use, transportation, maintenance or storage; third party negligence; or unauthorized repair, service or modification; in each case unless and to the extent caused by Supplier. EXCEPT FOR THE WARRANTIES SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

13.3 Remedies for Non-Conformance. In case of any disagreement between the parties as to whether Product conforms to the applicable specifications or cGMP (if applicable), warranties, or was manufactured in accordance with the manufacturing process, the quality assurance and/or engineering representatives of the parties will attempt in good faith to resolve any such disagreement and Vericel and Supplier will follow their respective SOPs to determine the conformity of the Product to the specifications and cGMP (if applicable) and manufacture in compliance with the manufacturing process. If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not exceed thirty (30) days), a representative sample of such Product and/or relevant documentation will be submitted to an independent testing laboratory (in the case of an alleged failure to meet Specifications) and/or independent cGMP consultant (in the case of an alleged failure to comply with cGMP or the manufacturing process), as appropriate, that are mutually agreed upon by the parties for tests and final determination of whether such Product conforms with such specifications and/or cGMP (if applicable). The laboratory must meet cGMP (if applicable). The laboratory and consultant, as applicable, must be of recognized standing in the industry, and consent to the appointment of such laboratory and consultant will not be unreasonably withheld or delayed by either party. Such laboratory will use the test methods contained in the applicable specifications. The determination of conformance by such laboratory and/or cGMP consultant, as applicable, with respect to all or part of such Product will be final and binding on the parties absent manifest error. The fees and expenses of the laboratory and/or consultant, as applicable, incurred in making such determination will be paid by the party against whom the determination is made.

13.4 Product Non-Compliance and Remedies. If a lot of Product fails to conform to the specifications or was not manufactured in compliance with cGMP (if applicable) and the manufacturing process, then Supplier will, at Vericel's sole option: (a) at Supplier's cost and expense, replace the Product by manufacture of a new lot as soon as reasonably possible; or (b) refund in full the fees and expenses paid by Vericel for such lot.

Moreover, the parties will meet to discuss, evaluate and analyze the reasons for and implications of the failure to comply with cGMP (if applicable) and/or the manufacturing process and will decide whether to proceed with the services via a change order, or to terminate such services.

13.5 Disposition of Non-Conforming Product. The ultimate disposition of non-conforming Product will be the responsibility of Vericel's quality assurance and/or engineering departments.

#### **14. INDEMNIFICATION AND LIMITATION OF LIABILITY**

14.1 Indemnification. Each party (the "Indemnifying Party") will indemnify and hold harmless the other party (the "Indemnified Party") from any claims, actions, proceedings, awards, demands, losses, damages or expenses suffered by the Indemnified Party ("Losses"), whether or not such Losses relate to any liability to a third party, to the extent claimed or arising from or relating to a material breach of the Indemnifying Party's representations, warranties or covenants under this Agreement or the Indemnifying Party's negligence or willful misconduct.

Supplier shall not indemnify Vericel for any Losses claimed or arising from or relating to (A) the Intellectual Property provided by Vericel for the manufacture of or incorporation into the Product, or (B) the use of the Product by customers in any manner inconsistent with the Product's intended purposes; in each case except and to the extent such Losses result from Supplier's gross negligence or willful misconduct.

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.

- 14.2 **Procedure.** To obtain indemnification, the Indemnified Party shall: (a) provide prompt notice in writing of any such Losses claimed to the Indemnifying Party and permit the Indemnifying Party, through counsel chosen by the Indemnifying Party, the opportunity to answer and defend such claims; and (b) provide the Indemnifying Party information, assistance and authority, at the Indemnifying Party's expense, to assist the Indemnifying Party in defending such claims. Neither party shall be responsible for any settlement made by the other party without the other party's prior written approval. Neither party shall admit any liability of the other party without the other party's prior written approval.
- 14.3 **Limitation of Liability.** Notwithstanding any other provision of this Agreement, neither party shall be liable to the other for, nor obligated to allow claims for, special, incidental, consequential, or other indirect damages or expenses of any kind.

**15. ADDITIONAL REPRESENTATIONS AND WARRANTIES OF THE PARTIES**

15.1 Vericel hereby represents and warrants to Supplier that:

15.1.1 Vericel is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Michigan, and has all corporate power and authority to own, lease and operate its properties and to carry on its businesses as it is currently being conducted. Vericel has all necessary corporate power and authority to enter into this Agreement and to perform its obligations hereunder. This Agreement has been duly authorized, executed and delivered by Vericel.

15.1.2 Vericel is the lawful owner of all right, title and interest in and to the applicable Intellectual Property incorporated in the Product, free and clear of all liens, claims, security interests or other restrictions or encumbrances.

15.2 Supplier hereby represents and warrants to Vericel that:

15.2.1 Supplier is a company duly organized and existing under the laws of the State of Minnesota, and has all power and authority to own, lease and operate its properties and to carry on its businesses as currently conducted. Supplier has all necessary power and authority to enter into this Agreement and to perform its obligations hereunder. This Agreement has been duly authorized, executed and delivered by Supplier.

15.2.2 Supplier has the manufacturing and assembly facilities and personnel reasonably necessary to perform its functions and otherwise carry out its obligations under the terms of this Agreement.

15.2.3 All Products manufactured, sold and shipped pursuant to this Agreement shall, upon delivery, have been manufactured and shipped by Supplier in compliance with applicable law and regulations, including the U.S. Food and Drug Administration regulations and current Good Manufacturing Practices requirements set forth in the Quality System promulgated under the U.S. Food, Drug & Cosmetic Act.

15.2.4 The conduct and the provision of the services will not, to the best of its knowledge, violate any patent, trade secret or other proprietary or intellectual property rights of any third party and Supplier will promptly notify Vericel in writing should it become aware of any claims asserting such violation.

15.2.5 Supplier, its affiliates, approved subcontractors, and each of their respective officers and directors,

as applicable, and any person used by Supplier, its affiliates or approved subcontractors to perform services under this Agreement: (i) have not been debarred and are not subject to a pending debarment pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (ii) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)); (iii) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (iv) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. Supplier will notify Vericel immediately if Supplier, its affiliates, or approved subcontractors, or any person used to perform services under this Agreement, or any of their respective officers or directors, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of Supplier's knowledge, is threatened.

**16. RELATIONSHIP OF THE PARTIES**

The parties understand and agree that Supplier is a vendor to Vericel and that neither party is an agent of the other nor are the parties to be legal partners, joint venturers or otherwise. Except as expressly set forth in this Agreement, no rights or licenses are granted by either party to the other. Neither party shall be entitled to participate in any plans, arrangements or distributions offered by the other party to its employees, including without limitation any bonus, profit sharing, insurance or similar benefits. Each party shall be solely responsible to purchase any required insurance on behalf of its employees and to pay any applicable taxes. Neither party has authority to bind the other by contract or agreement, of any kind, nor to undertake any obligation on behalf of the other party.

**17. SUCCESSORS, ASSIGNS AND SUBCONTRACTORS**

This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. Neither party may assign rights nor delegate duties, including to a subcontractor, under this Agreement without the prior written consent of the other party except in the event of a merger, consolidation or sale of all or substantially all of its assets relating to this Agreement and the assignee agrees to be bound to the terms of this Agreement. Any assignee or delegate must agree to be bound by the terms of this Agreement.

**18. NO WAIVER**

None of the terms of this Agreement shall be deemed to be waived by any party unless such waiver is in writing duly executed by the party to be charged with such waiver and such writing recites specifically that it is a waiver of the terms of this Agreement. The waiver by either party of any breach of any agreement, warranty or covenant contained in this Agreement shall not be construed to act as a waiver of any subsequent breach. The failure or delay of either party to exercise any right, power or remedy shall not operate as a waiver thereof, and all rights, powers and remedies shall continue in full force and effect. All rights, powers and remedies of both parties provided for in this Agreement are cumulative and non-exclusive, except as otherwise expressly provided.

**19. NO INVALIDITY**

The unenforceability or invalidity of any one or more provisions hereof shall not render any other provision herein contained unenforceable or invalid.

**20. ENTIRE AGREEMENT; NO OTHER AGREEMENTS**

This Agreement constitutes the entire agreement between the parties relating to the subject matter herein, and all oral or written, prior and contemporaneous proposals, understandings, course of conduct and writings by and between the parties and relating to the subject matter herein is superseded hereby.

Neither party has any other Agreement of any kind or nature with any other person, corporation or entity which would or might prevent it from entering into this Agreement with the other party hereto.

**21. MODIFICATION**

This Agreement may be modified or altered through written instrument duly executed by Supplier and Vericel.

**22. NOTICES**

All notices must be in writing and sent to the address for the recipient set forth in this Agreement below or at such other address as the recipient may specify in writing under this procedure. All notices must be given by (a) personal delivery, with receipt acknowledged; or (b) prepaid certified or registered mail, return receipt requested; or (c) prepaid recognized next business day or express delivery service. Notices will be effective upon receipt or at a later date stated in the notice:

If to Vericel, to: Vericel Corporation

24 Frank Lloyd Wright Drive Ann Arbor, Michigan 48105

Attn: Director of Engineering

Attn: Director, Supply Chain

With a copy to: General Counsel

Vericel Corporation

64 Sidney Street

Cambridge, MA 02139

If to Supplier, to:

Vention Medical, LLC 620 Watson SW

Grand Rapids, MI 49504-6393

Attn: VP Business Development

Facsimile: 616 643-1044

With a copy to:

Vention Medical

29 Northwestern Drive

Salem, NH 03079  
Attention: Corporate Counsel

**23. CHOICE OF LAW**

This Agreement will be governed, construed and enforced in accordance with the laws of the State of Michigan, without regard to the principles of conflicts of laws.

**24. DISPUTE RESOLUTION**

Final and binding arbitration of any dispute shall be conducted in the State of Michigan. Except with respect to any disputes relating to the provisions on confidentiality and Vericel's intellectual property rights, any disputes arising hereunder, if not resolved after good faith negotiation between the parties, shall be finally settled by binding arbitration in accordance with the commercial rules and under the auspices of one arbitrator of the American Arbitration Association. The award thereof shall be final and binding upon both parties. Each party shall bear its own expenses of the arbitration, unless the arbitration award states that the expense shall be otherwise assessed, including its own attorneys' fees and costs. The parties shall share equally the expenses of the arbitration, including payment to the arbitrator(s).

Notwithstanding the foregoing, in the event both parties hereto are named as defendants by an arm's length third party plaintiff asserting a claim against both parties, then and in such event, either party may seek the resolution of their respective indemnity rights and obligations as herein set forth, arising from such claim in said proceedings.

Notwithstanding the foregoing, both parties acknowledge that any breach by it of its confidentiality obligations or of the provisions governing Vericel's intellectual property rights will cause Vericel irreparable harm for which injunctive relief is the only adequate remedy. Supplier therefore agrees that Vericel shall have the right to seek injunctive or other immediate relief from any United States court or tribunal of competent jurisdiction to prevent or stop any violations of those Supplier obligations. Should Vericel desire to seek injunctive relief after an arbitration proceeding is commenced by either party, Supplier hereby agrees to the filing of such action according to the terms of this paragraph.

**25. FORCE MAJEURE**

Failure of either party to perform its obligations under this Agreement shall not subject such party to any liability to the other party if such failure is caused by any cause beyond the reasonable control of such nonperforming party, including, but not limited to, acts of God, fire, explosion, flood, drought, war, riot, terrorism, sabotage, embargo, strikes or other labor trouble or a national health emergency.

**26. RISK MITIGATION**

Upon termination of Agreement, Supplier agrees to provide reasonable technical support at Supplier's published engineering rates for the transfer of manufacturing technology to an alternative manufacturer chosen by Vericel to conduct final manufacture, package and test of the Product, in the event that:



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.

(a) Supplier, for a period of one hundred and fifty (150) days from the date of receipt of the associated purchase order, is unable to manufacture all of Vericel's orders for any reason, or

(b) Supplier fails or refuses to meet Vericel's orders for the Product pursuant to the terms of this Agreement.

27. **INSURANCE**

Supplier shall maintain during the Term, and for a reasonable period thereafter, general liability insurance and product liability insurance, which insurances shall be in amounts and of a type customarily maintained by companies similarly situated. Each such insurance shall provide at least [\*\*\*] (\$[\*\*\*]) U.S. Dollars in coverage per occurrence combined single limit, bodily injury/property damage and [\*\*\*] (\$[\*\*\*]) U.S. Dollars aggregate liability limits. Additionally, Supplier warrants that such insurance will not be changed or canceled without at least thirty (30) days prior written notice to Vericel.

28. **APPENDIX TO THIS AGREEMENT**

Included in this Agreement are the following Appendices:

Appendix A - Schedule

\* \* \*

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 have caused this Agreement to be executed and delivered by their respective duly authorized officers on the day and year first above written.

**VERICEL CORPORATION**

By: /s/ Dominick Colangelo

Name: Dominick Colangelo

Title: President and CEO

**VENTION MEDICAL INC.**

By: /s/ Bill Flaherty

Name: Bill Flaherty

Title: President

**APPENDIX A**

1) Facilities:

- a. [\*\*\*]
  - 1. [\*\*\*]
  - 2. [\*\*\*]
  
- b. [\*\*\*]
  - 3. [\*\*\*]
  - 4. [\*\*\*]
  - 5. [\*\*\*]

2) Supplier Molded Components: [\*\*\*]:

- a. [\*\*\*]
- b. [\*\*\*].
- c. [\*\*\*]

3) Pricing: [\*\*\*]

- a. [\*\*\*]
  - i. [\*\*\*]
- b. [\*\*\*]
  - i. [\*\*\*]

Additional facilities: [\*\*\*]

**FIRST AMENDMENT TO  
SERVICES AGREEMENT**

This First Amendment to Services Agreement (this “Amendment”) is between Vericel Corporation (“Client”) and Dohmen Life Science Services, LLC (“DLSS”). This Amendment is effective as of May 31, 2016 (the “Amendment Effective Date”).

Client and DLSS are parties to a Services Agreement dated April 5, 2016 (the “Agreement”), under which Client appointed DLSS as its exclusive specialty pharmacy provider of Carticel® effective July 1, 2016 and MACI (upon approval of the Biologics License Application for MACI submitted by Client). The parties now wish to amend the Agreement as follows:

1. Defined Terms. 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. Section 17 - Miscellaneous. Section 17 is hereby amended to add the following subsection:
  - (g) **This contractor (Client) and subcontractor (DLSS) shall abide by the requirements of 41 CFR §§ 60-1.4(a), 60-300.5(a) and 60-741.5(a). These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, sexual orientation, gender identity or national origin. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, protected veteran status or disability.**
3. No Other Changes. 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.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment by their duly authorized representatives as of the Amendment Effective Date.

**DOHMEN LIFE SCIENCE SERVICES, LLC**

By: s/ Marie E. Lamont

Name: Marie E. Lamont

Title: President, Patient Services

**VERICEL CORPORATION**

By: s/ Dominick C. Colangelo

Name: Dominick C. Colangelo

Title: Chief Executive Officer

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

## SECOND AMENDMENT TO SERVICES AGREEMENT

This Second Amendment to Services Agreement (this "Amendment") is made and entered into as of July 1, 2016, by and between Vericel Corporation ("Client") and Dohmen Life Science Services, LLC ("DLSS").

Client and DLSS are parties to that certain Services Agreement dated April 5, 2016, as amended (the "Agreement"). The parties now wish to amend the Agreement as follows:

1. Defined Terms. Capitalized terms in this Amendment that are not defined in this Agreement 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. Amendment of Section 3(g). Section 3(g) of the Agreement is hereby amended and restated in its entirety as follows:
 

(g) DLSS shall, no later than August 1, 2016, (i) have a payer agreement or similar arrangement with each Payer listed in **Exhibit D** attached hereto and incorporated herein regardless of whether such payer agreement includes reimbursement for the Product (each, an "Initial Payer"), (ii) initiate discussions with each Initial Payer, (iii) commence negotiations with each Initial Payer for the reimbursement of the Product on the terms set forth in **Exhibit D**, and (iv) present to Client the proposed rate of reimbursement by each Initial Payer, which terms shall be subject to Client's review and approval or review and further direction, as applicable.
3. Amendment of Exhibit D. **Exhibit D** of the Agreement is hereby superseded and replaced in its entirety with **Exhibit D** attached hereto.
4. Guarantee. If, with respect to any implant of the Product performed during a Guarantee Period, a Guaranteed Payer denies a claim for reimbursement or reimburses at a rate of less than [\*\*\*], DLSS agrees to guarantee the payment of such reimbursement in an amount equal to (i) [\*\*\*], less (ii) any amounts collected by DLSS in connection with the implant (including any amount paid by the patient or reimbursement paid by the Guaranteed Payer). DLSS shall be required to pay any guarantee amount due hereunder on or prior to December 31, 2016. If, with respect to any implant of the Product performed during a Guarantee Period, a Guaranteed Payer reimburses at a rate of greater than [\*\*\*], DLSS agrees to promptly remit to Client the payment of such reimbursement in an amount equal to (i) any amounts collected by DLSS in connection with the implant (including any amount paid by the patient or reimbursement paid by the Guaranteed Payer), less (ii) [\*\*\*].

The term "Guaranteed Payer" shall mean each Initial Payer that DLSS has not presented to Client a proposed rate of reimbursement as of July 1, 2016. An Initial Payer shall cease to be a Guaranteed Payer upon the earlier of (i) the date upon which DLSS presents to Client a proposed rate of reimbursement for such Initial Payer, or (ii) July 31, 2016.

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 DLSS presents to Client a

proposed rate of reimbursement for such Guaranteed Payer, or (ii) July 31, 2016.

For purposes of clarity, if DLSS presents to Client a proposed rate of reimbursement for Payer ABC on July 10, 2016 and a proposed rate of reimbursement for Payer XYZ on July 25, 2016, then (i) Payer ABC shall cease to be a Guaranteed Payer on July 10, 2016, the Guarantee Period shall end on July 10, 2016 for Payer ABC and the guarantee obligation of DLSS under this Section 4 with respect to Payer ABC shall only apply to implants of the Product performed between July 1, 2016 until July 10, 2016; and (ii) Payer XYZ shall cease to be a Guaranteed Payer on July 25, 2016, the Guarantee Period shall end on July 25, 2016 for Payer XYZ and the guarantee obligation of DLSS under this Section 4 with respect to Payer XYZ shall only apply to implants of the Product performed between July 1, 2016 and July 25, 2016.

5. Military Payers. The Parties agree that notwithstanding anything to the contrary in the Agreement, in particular Sections 2(a) and 4(a)(vi), US Bioservices Corporation will continue to provide Client with reimbursement support services for military Payers for a transition period after the date hereof as determined by Client.
6. No Other Changes. 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.

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: s/ Marie E. Lamont

Name: Marie E. Lamont

Title: President, Patient Services

**VERICEL CORPORATION**

By: s/ Daniel R. Orlando

Name: Daniel R. Orlando

Title: Chief Operating Officer



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

## **Reimbursement**

Client shall be responsible for setting the pricing strategy and allowable reimbursement amount for each Initial Payer. The amount of reimbursement for the Product by each Initial Payer shall be subject to review and approval by Client.

Payment Terms to be offered to Initial Payers on behalf of the Client are [\*\*\*] days. Should an Initial Payer request extended payment terms, DLSS will secure advance approval from the Client.



**SEVENTH AMENDMENT TO TRANSITION SERVICES AGREEMENT**

This Seventh Amendment (the “Seventh Amendment”), effective as of the date last signed by both parties (the “Amendment Effective Date”) is by and between Genzyme Corporation, a Massachusetts corporation (“Service Provider”), and Vericel Corporation, formerly known as Aastrom Biosciences Inc., a Michigan corporation (“Service Recipient” or “Vericel”) (collectively, the “Parties”).

WHEREAS, effective as of May 30, 2014, Service Provider and Service Recipient entered into that certain Transition Services Agreement, as amended from time to time (collectively, the “Agreement”) which described transition services that Service Provider agreed to provide to Service Recipient in support of the sale of three (3) products (Carticel®, Epicel® and Matrix Applied Characterized Autologous Cultured Chondrocytes (“MACI®”), and collectively the “Products”) to Service Recipient (the terms of the sale are memorialized in a separate Asset Purchase Agreement between Sanofi, a French Société anonyme and Service Provider Affiliate (“Sanofi”) and Vericel, dated as of April 19, 2014 (the “Asset Purchase Agreement”));

WHEREAS, the Agreement will expire on June 30, 2016;

WHEREAS, certain of the services provided by Service Provider to Service Recipient under the Agreement, including without limitation,

- 1) IT services related to data transfer,
- 2) Data Controller and data hosting services until such time as data controller responsibility may be legally transferred, and
- 3) Transferred Intellectual Property missing residual documentation,

require additional time and support for wind-down activities; and

WHEREAS, Service Provider has agreed to provide these wind-down activities services, subject to certain dependencies and limitations specified in this Seventh Amendment; and

NOW, THEREFORE, in consideration of the above-recitals, the mutual benefits to be derived by the Parties, and other good and valuable consideration, the receipt and satisfaction of which are acknowledged, Service Provider and Service Recipient agree to amend the Agreement as follows:

1. All capitalized terms not defined herein shall have the same meaning as set forth in the Agreement. For purposes of clarity, the Agreement in certain instances relies on definitions as set forth in the Asset Purchase Agreement, and all capitalized terms defined in neither this Seventh Amendment nor the Agreement shall have the same meaning as set forth in the Asset Purchase Agreement.

2. Section 4.1, Term. Section 4.1 is hereby stricken and replaced in its entirety by the following:

“4.1. Term. This Agreement will commence on the Effective Date and remain in effect until the earlier of completion of all Services hereunder or December 31, 2016 (the “Term”), unless earlier terminated under this ARTICLE 4. With respect to each Service, such Service will begin upon the applicable start date set forth in the Transition Services Schedule, unless earlier terminated under this ARTICLE 4. This Agreement may be extended by the Parties in writing, either in whole or with respect to one or more of the Services.”

3. Miscellaneous. The Parties acknowledge that, as set forth in Section 7.22 of the Asset Purchase Agreement, all transition services were to end by May 29, 2015. Service Provider hereby confirms that Service Provider has received approval from its Affiliate to continue certain transition services beyond May 29, 2015. The Parties hereby agree that, notwithstanding the term limit to the transition services set forth in Section 7.22 of the Asset Purchase Agreement, the Services will be extended as set forth in this Seventh Amendment.

The rights and obligations of the Parties or any dispute arising out of this Seventh Amendment will be interpreted, construed and enforced in accordance with the laws of the State of New York, excluding its conflict of laws rules to the extent such rules would apply the law of another jurisdiction.

This Seventh Amendment will terminate in accordance with the terms set forth in the Agreement.

Except as set forth in this Seventh Amendment, the terms of the Agreement shall remain in full force and effect; provided however, that in the event of a conflict between a term contained in this Seventh Amendment and a term contained in the Agreement, the term contained in this Seventh Amendment shall prevail. The Agreement, as amended, together with the Asset Purchase Agreement and the other Ancillary Agreements, constitutes the entire agreement between and among the Parties with regard to the subject matter of this Agreement, and supersedes all prior agreements and understandings with regard to such subject matter. Except for the Confidentiality Agreement, there are now no agreements, representations or warranties between or among the Parties other than those set forth in the Agreement, the Asset Purchase Agreement or the Ancillary Agreements.

IN WITNESS WHEREOF, Service Provider and Service Recipient have caused this Seventh Amendment to the Agreement to be executed by their duly authorized representatives as of the Amendment Effective Date.

GENZYME CORPORATION

VERICEL CORPORATION

Signature: s/ Steven Couldwell

Signature: s/ Dominick C. Colangelo

Name: Steven Couldwell

Name: Dominick C. Colangelo

Title: COO

Title: President & CEO

Date: May 28, 2016

Date: April 26, 2016

## 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.

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: August 8, 2016

/s/ DOMINICK C. COLANGELO

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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.

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: August 8, 2016

/s/ GERARD MICHEL

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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 June 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: August 8, 2016

/s/ DOMINICK C. COLANGELO

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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 June 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: August 8, 2016

/s/ GERARD MICHEL

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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.