

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-Q

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED: March 31, 2019**

**OR**

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

Commission file number 001-35280

### VERICEL CORPORATION

(Exact name of registrant as specified in its charter)

**Michigan**

(State or other jurisdiction of  
incorporation or organization)

**94-3096597**

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

**64 Sidney Street**

**Cambridge, MA 02139**

(Address of principal executive offices, including zip code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes -  No -

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

Large accelerated filer -

Non-accelerated filer -

Accelerated filer -

Smaller reporting company -

Emerging growth company -

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	VCEL	NASDAQ

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

**COMMON STOCK, NO PAR VALUE**

(Class)

43,911,316

Outstanding at May 3, 2019

**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)

	March 31, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 35,084	\$ 18,286
Short term investments	49,001	64,638
Accounts receivable (net of allowance for doubtful accounts of \$669 and \$514, respectively)	18,774	23,454
Inventory	4,063	3,558
Other current assets	2,679	2,847
Total current assets	109,601	112,783
Property and equipment, net	6,445	5,906
Right-of-use assets	25,183	—
Total assets	\$ 141,229	\$ 118,689
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,201	\$ 7,108
Accrued expenses	4,179	6,930
Current portion of operating lease liabilities	2,385	—
Other liabilities	176	754
Total current liabilities	12,941	14,792
Operating lease liabilities	25,100	—
Other long-term liabilities	133	1,666
Total liabilities	38,174	16,458
<b>COMMITMENTS AND CONTINGENCIES (Note 12)</b>		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 43,825 and 43,578, respectively	474,806	471,180
Other comprehensive gain (loss)	3	(39)
Warrants	104	104
Accumulated deficit	(371,858)	(369,014)
Total shareholders' equity	103,055	102,231
Total liabilities and shareholders' equity	\$ 141,229	\$ 118,689

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

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

	Three Months Ended March 31,	
	2019	2018
Product sales, net	\$ 21,810	\$ 18,027
Cost of product sales	8,640	7,666
Gross profit	13,170	10,361
Research and development	3,008	3,729
Selling, general and administrative	13,520	10,954
Total operating expenses	16,528	14,683
Loss from operations	(3,358)	(4,322)
Other income (expense):		
Increase in fair value of warrants	—	(2,907)
Interest income	480	—
Interest expense	(2)	(432)
Other income	36	2
Total other income (expense)	514	(3,337)
Net loss	\$ (2,844)	\$ (7,659)
Net loss per share (Basic and Diluted)	\$ (0.07)	\$ (0.21)
Weighted average number of common shares outstanding (Basic and Diluted)	43,725	36,140

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

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

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Net loss	\$ (2,844)	\$ (7,659)
Other comprehensive loss:		
Unrealized gain on investments	42	—
Comprehensive loss	<u>\$ (2,802)</u>	<u>\$ (7,659)</u>

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

**VERICEL CORPORATION**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY**  
(Unaudited, amounts in thousands)

	Common Stock		Warrants	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Amount			
BALANCE, DECEMBER 31, 2018	43,578	\$ 471,180	\$ 104	\$ (39)	\$ (369,014)	\$ 102,231
Net loss					(2,844)	(2,844)
Compensation expense related to stock options and restricted stock units granted, net of forfeitures		2,628	—		—	2,628
Stock option exercises	228	780				780
Shares issued under the Employee Stock Purchase Plan	19	218				218
Unrealized gain on investments				42	—	42
BALANCE, MARCH 31, 2019	43,825	\$ 474,806	\$ 104	\$ 3	\$ (371,858)	\$ 103,055

	Common Stock		Warrants	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Amount			
BALANCE, DECEMBER 31, 2017	35,861	\$ 383,020	\$ 397	\$ —	\$ (360,877)	\$ 22,540
Net loss					(7,659)	(7,659)
Compensation expense related to stock options granted, net of forfeitures		1,348				1,348
Stock option exercises	253	851				851
Shares issued under the Employee Stock Purchase Plan	28	127				127
Exercise of warrants resulting in the issuance of common stock	360	3,728				3,728
BALANCE MARCH 31, 2018	36,502	\$ 389,074	\$ 397	\$ —	\$ (368,536)	\$ 20,935

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

	Three Months Ended March 31,	
	2019	2018
<b>Operating activities:</b>		
Net loss	\$ (2,844)	\$ (7,659)
<b>Adjustments to reconcile net loss to net cash used for operating activities:</b>		
Depreciation and amortization expense	324	427
Stock compensation expense	2,628	1,342
Change in fair value of warrants	—	2,907
Loss on sale of fixed assets	—	22
Foreign currency translation loss	6	44
Amortization of premiums and discounts on marketable securities	(215)	—
Amortization of right-of-use assets	387	—
<b>Change in operating assets and liabilities:</b>		
Inventory	(505)	(112)
Accounts receivable	4,680	5,108
Prepaid and other current assets	168	223
Accounts payable	(1,368)	(229)
Accrued expenses	(2,751)	(1,566)
Operating lease liabilities	(310)	—
Other assets and liabilities, net	(46)	(102)
Net cash provided by operating activities	<u>154</u>	<u>405</u>
<b>Investing activities:</b>		
Purchases of short term investments	(10,686)	—
Maturities of short term investments	26,580	—
Expenditures for property, plant and equipment	(232)	(184)
Net cash provided by (used in) investing activities	<u>15,662</u>	<u>(184)</u>
<b>Financing activities:</b>		
Net proceeds from common stock issuance due to stock option exercises	998	985
Proceeds from exercise of warrants	—	1,727
Other	(16)	(18)
Net cash provided by financing activities	<u>982</u>	<u>2,694</u>
Net increase in cash and cash equivalents	16,798	2,915
Cash and cash equivalents at beginning of period	18,286	26,862
Cash and cash equivalents at end of period	<u>\$ 35,084</u>	<u>\$ 29,777</u>

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE QUARTER ENDED MARCH 31, 2019 (UNAUDITED)**

**1. Organization**

Vericel Corporation, a Michigan corporation (together with its consolidated subsidiaries referred to herein as the Company, Vericel, we, us or our), was incorporated in March 1989 and began employee-based operations in 1991. On May 30, 2014, Vericel completed the acquisition of certain assets and assumed certain liabilities of Sanofi, a French *société anonyme* (Sanofi), including all of the outstanding equity interests of Genzyme Biosurgery ApS (Genzyme Denmark or the Danish subsidiary) (now known as Vericel Denmark ApS), a wholly-owned subsidiary of Sanofi, and a portfolio of patents and patent applications of Sanofi and certain of its subsidiaries for purposes of acquiring the portion of the cell therapy and regenerative medicine business related to the MACI<sup>®</sup>, Epicel<sup>®</sup> and Carticel<sup>®</sup> products. The Company is a fully integrated, commercial-stage biopharmaceutical company and currently markets MACI and Epicel in the U.S. The Company is a leader in advanced cell therapies for the sports medicine and severe burn care markets.

MACI (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. At the end of the second quarter of 2017, the Company removed Carticel (autologous cultured chondrocytes), an earlier generation autologous chondrocyte implant (ACI) product, from the market. The Company also markets Epicel (cultured epidermal autografts), a permanent skin replacement Humanitarian Use Device (HUD) for the treatment of adult and pediatric patients with deep-dermal or full-thickness burns comprising greater than or equal to 30 percent of total body surface area (TBSA). The Company operates its business primarily in the U.S. in one reportable segment — the research, product development, manufacture and distribution of advanced cellular therapies for use in the treatment of specific diseases.

The accompanying condensed consolidated financial statements have been prepared on a basis, which assumes that the Company will continue as a going concern and contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of March 31, 2019, the Company has an accumulated deficit of \$371.9 million and had a net loss of \$2.8 million during the quarter ended March 31, 2019. The Company had cash and cash equivalents of \$35.1 million, and short term investments of \$49.0 million as of March 31, 2019. The Company expects that existing cash, cash equivalents and short term investments will be sufficient to support the Company's current operations through at least May 2020. The Company may seek additional funding through debt or equity financings. However, the Company may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's shareholders.

**2. Basis of Presentation**

The condensed consolidated financial statements included herein have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). The preparation of condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States of America (U.S. GAAP) requires management to make estimates, judgments, and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the three months ended March 31, 2019, are not necessarily indicative of the results to be expected for the full year or for any other period. The March 31, 2019 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, 2018, as filed with the SEC on February 26, 2019 (Annual Report).

*Consolidated Statement of Cash Flows*

The following table presents certain supplementary cash flows information for the three months ended March 31, 2019 and 2018:

(In thousands)	Three Months Ended March 31,	
	2019	2018
Supplementary Cash Flows information:		
Warrants exercised for common stock	\$ —	\$ 2,000
Interest paid (net of interest capitalized)	2	357
Additions to equipment in process included in accounts payable	455	401
Right-of-use asset recognized	185	—

### 3. Recent Accounting Pronouncements

#### 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. The leasing Accounting Standard Update 2016-02, became effective for the Company on January 1, 2019, and was adopted using the modified retrospective method. See note 7 for further discussion.

#### Measuring Credit Losses on Financial Instruments

The FASB issued updated guidance on measuring credit losses on financial instruments. The guidance removes the thresholds that companies apply to measure credit losses on financial instruments measured at amortized cost, such as loans, receivables, and held-to-maturity debt securities. Prior to the updated guidance, credit losses are recognized when it is probable that the loss has been incurred. The revised guidance removes all recognition thresholds and requires companies to recognize an allowance for credit losses for the difference between the amortized cost basis of a financial instrument and the amount of amortized cost that a company expected to collect over the instrument's contractual life. The guidance is effective for annual reporting periods beginning after December 15, 2019. The Company is currently in the process of evaluating the impact to its consolidated financial statements.

### 4. Revenue

#### Revenue Recognition and Net Product Sales

The Company recognizes product revenue from sales of MACI kits, MACI implants and Epicel grafts following the five step model in Accounting Standards Codification 606 *Revenue Recognition* (ASC 606).

##### *MACI Kits*

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

##### *MACI Implants*

The Company recognizes product revenues from sales of MACI implants upon delivery at which time the customer is in control of the implant and the claim is billable. Prior authorization or confirmation of coverage level by the patient's private insurance plan, hospital or government payer is a prerequisite to the shipment of product to a patient. Depending upon the type of contract and payer for the MACI implant, the Company's net product revenues are based on contracted rates or estimated based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or past payer precedents. Changes in estimates are recorded through revenue in the period such change occurs. Net product revenues from sales to distributors may include a prompt pay discount.

On July 25, 2018 and August 10, 2018, the Company entered into amendments to its distribution agreement with Orsini Pharmaceutical Services, Inc. (Orsini). The amendments modified certain payment terms for surgeries after June 15, 2018. In addition, under the revised agreement, the parties agreed to limit Orsini's right to serve as the Company's exclusive distributor for MACI to a specified set of payers as the Company moved to a limited expanded network of distributors. The agreement with

Orsini includes a provision whereby the Company retains the credit and collection risk from the end customer on implants after June 15, 2018. Orsini performs the collection activities. The net product revenues for these cases are based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or past payer precedents. Changes in estimates are recorded through revenue in the period in which such change occurs.

On April 18, 2019, the Company entered into an amendment with Orsini that extended the term of the agreement until May 2022, modified the per case dispensing fee, and eliminated Orsini's exclusivity for all payers.

On July 26, 2018, the Company entered into a Dispensing Agreement (Dispensing Agreement) with AllCare Plus Pharmacy, Inc. (AllCare). Pursuant to the Dispensing Agreement, the Company appoints AllCare as a non-exclusive specialty pharmacy provider of MACI. The Company pays AllCare a fee for each patient to whom MACI is dispensed. Under the Dispensing Agreement, the Company retains the credit and collection risk from the end customer on all implants. Depending upon the type of contract and payer for the MACI implant, the Company's net product revenues are based on contracted rates or estimated based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or past payer precedents. Changes in estimates are recorded through revenue in the period such change occurs. On May 1, 2019, the Company entered into an amendment with AllCare that extended the term of the Dispensing Agreement until May 2022 and modified the per case dispensing fee.

### *Epistel*

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

### *Revenue by Product and Customer*

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

Revenue by product (in thousands)	Three Months Ended March 31,	
	2019	2018
<b>MACI implants and kits</b>		
Implants based on contracted rate sold through a specialty pharmacy <sup>(a)</sup>	9,787	7,792
Implants subject to third party reimbursement sold through a specialty pharmacy <sup>(b)</sup>	2,743	1,008
Implants sold direct based on contracted rates <sup>(c)</sup>	3,226	2,674
Implants sold direct subject to third party reimbursement <sup>(d)</sup>	322	283
Biopsy kits - direct bill	542	436
Change in estimates related to prior periods	(37)	(138)
<b>Epistel</b>		
Direct bill (hospital)	5,227	5,972
<b>Total revenue</b>	<b>21,810</b>	<b>18,027</b>

(a) Represents implants sold through Orsini or AllCare in which such specialty pharmacy has entered into a direct contract with the underlying insurance provider. The amount of reimbursement is known at the time of sale supported by the pharmacy's direct contract.

(b) Represents implants sold through Orsini or AllCare in which such specialty pharmacy does not have a direct contract with the underlying payer. The amount of reimbursement is established based on a payer or state fee schedule and/or payer history.

(c) Represents implants sold directly from the Company to the facility based on a contract and known price agreed upon prior to the surgery date.

(d) Represents implants sold directly from the Company to the facility based on a contract and known price agreed upon prior to the surgery date. The payment terms are subject to third party reimbursement from an underlying insurance provider.

## Concentration of Credit Risk

On May 15, 2017, the Company entered into a distribution agreement with Orsini Pharmaceutical Services, Inc. as a specialty pharmacy distributor of MACI and has engaged a third party services provider to provide the patient support program to manage patient cases for MACI. The Company's receivables risk and credit risk became more concentrated from June 30, 2017 through June 15, 2018 due to the shift to Orsini. Beginning June 16, 2018, the concentration of risk decreased because the Company retains the credit and collection risk from the end customer on implants after June 15, 2018. The Company sells Epicel directly to hospitals and not through a distributor.

The Company includes concentration percentages for both revenue and accounts receivable for any customers which represent 10% or more of total revenue. The Company's concentration percentages were comprised of the following for MACI and Epicel:

	Revenue Concentration		Accounts Receivable Concentration	
	Three Months Ended March 31,		March 31,	December 31,
	2019	2018	2019	2018
MACI	11%	43%	9%	2%
Epicel	38%	14%	2%	4%

## 5. Selected Balance Sheet Components

Inventory as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019	December 31, 2018
Raw materials	\$ 3,324	\$ 2,872
Work-in-process	687	638
Finished goods	52	48
Inventory	\$ 4,063	\$ 3,558

Property and equipment, net as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019	December 31, 2018
Machinery and equipment	\$ 2,200	\$ 1,536
Furniture, fixtures and office equipment	775	775
Computer equipment and software	3,829	3,712
Leasehold improvements	4,631	4,587
Construction in process	2,664	2,801
Financing right-of-use lease	175	—
Total property and equipment, gross	14,274	13,411
Less: Accumulated depreciation	(7,829)	(7,505)
	\$ 6,445	\$ 5,906

Depreciation expense for the three months ended March 31, 2019 was \$0.3 million and \$0.4 million for the same period in 2018.

Accrued expenses as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019	December 31, 2018
Bonus related compensation	\$ 798	\$ 5,161
Employee related accruals	2,782	1,559
Other accrued expenses	599	210
	\$ 4,179	\$ 6,930

## 6. Stock Purchase Warrants

The Company has historically issued warrants to purchase shares of the Company's common stock in connection with certain of its common stock offerings and in December 2017 the Company issued warrants in connection with a previous loan agreement. The following table describes the outstanding warrants classified in equity as of March 31, 2019:

	<u>December 2017 Warrants</u>
Exercise price	\$4.27
Expiration date	December 6, 2023
Total shares issuable on exercise	26,951

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

## 7. Leases

The Company leases facilities in Ann Arbor, Michigan and Cambridge, Massachusetts. The Cambridge facility includes clean rooms, laboratories for MACI and Epicel manufacturing and office space. The Company also leases offsite warehouse space, vehicles and computer equipment.

The Company adopted the new leasing standards using the modified retrospective transition approach, as of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. Certain of the Company's lease agreements include lease payments that are adjusted periodically for an index or rate. The leases are initially measured using the projected payments adjusted for the index or rate in effect at the commencement date. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants. Upon adoption all operating lease commitments with a lease term greater than 12 months that were previously assessed under previous lease guidance, were recognized as right to use assets and liabilities, on a discounted basis on the balance sheet. Leases with an initial term of 12 months or less are not recorded on the balance sheet and for the three months ended March 31, 2019, lease expense of less than \$0.1 million was recorded related to short-term leases.

Adoption of ASU 2016-02 resulted in the recording of additional net lease assets and lease liabilities of approximately \$25.6 million and \$27.8 million, respectively, as of January 1, 2019. There was an immaterial impact on the Company's consolidated net earnings and cash flows upon adoption. The contribution toward the cost of tenant improvements is recorded as a reduction of the operating lease assets and reclassified from deferred rent to lease operating assets. For the three months ended March 31, 2019, the Company recognized \$1.3 million and less than \$0.1 million of operating and financing lease expense, respectively. During the three months ended March 31, 2018, the Company recognized \$1.4 million in lease expense under the prior leasing guidance. The Company's leases contain non-lease components and activities that do not transfer a good or service to the Company which were not considered to be components of the contract and therefore were not included in the net lease assets or lease liabilities.

Total leased assets and liabilities as reassessed under the updated guidance and classified on the balance sheet, as of March 31, 2019 are as follows:

(In thousands)	Classification	March 31, 2019
<b>Assets</b>		
Operating	Right-of-use assets	\$ 25,183
Finance	Property and equipment, net	175
		<u>\$ 25,358</u>
<b>Liabilities</b>		
<i>Current</i>		
Operating	Current portion of operating lease liabilities	2,385
Finance	Other liabilities	33
		<u>\$ 2,418</u>
<i>Non-current</i>		
Operating	Operating lease liabilities	25,100
Finance	Other long-term liabilities	133
		<u>\$ 25,233</u>

An explicit rate is not provided for some of the Company's leases, therefore the Company uses a mix of incremental borrowing rate based on the information available at commencement date, as well as implicit and explicit rates in determining the present value of lease payments.

Maturity of lease liabilities as of March 31, 2019 are as follows:

(In thousands)	Operating Leases	Finance Leases	Total
2019	\$ 3,661	\$ 21	\$ 3,682
2020	4,799	41	4,840
2021	4,805	41	4,846
2022	4,929	41	4,970
2023	4,901	41	4,942
2024	4,968	—	4,968
Thereafter	11,269	—	11,269
Total lease payments	39,332	185	39,517
Less: Interest	(11,847)	(19)	(11,866)
Present value of lease liabilities	<u>\$ 27,485</u>	<u>\$ 166</u>	<u>\$ 27,651</u>

The Company has options to renew lease terms for facilities and other assets. The exercise of lease renewal options is generally at the Company's sole discretion. The Company evaluates renewal and termination options at the lease commencement date to determine if it is reasonably certain to exercise the option on the basis of economic factors. For certain leases, the Company's exercise of the renewal option was determined to be probable and it was accordingly included in the lease term and related calculations. Lease terms and discount rates as of March 31, 2019 are as follows:

	March 31, 2019
<b>Weighted average remaining lease term (years)</b>	
Operating leases	7.54
Finance leases	4.25
<b>Weighted average discount rate</b>	
Operating leases	9.56%
Finance leases	5.00%

Future minimum payments related to operating and capital leases, as reflected under the prior guidance, disclosed in note 16 in our Form 10-K for the fiscal year ended December 31, 2018, are as follows with no changes from prior disclosure:

(In thousands)	Total	2018	2019	2020	2021	2022	More than 5 years
Operating leases	\$ 15,386	\$ 4,879	\$ 4,719	\$ 4,754	\$ 966	\$ 68	\$ —
Capital leases	205	41	41	41	41	41	—
Total	<u>\$ 15,591</u>	<u>\$ 4,920</u>	<u>\$ 4,760</u>	<u>\$ 4,795</u>	<u>\$ 1,007</u>	<u>\$ 109</u>	<u>\$ —</u>

## **8. Stock-based Compensation**

### ***Stock Option, Restricted Stock Units and Equity Incentive Plans***

The Company has historically had various stock incentive plans and agreements that provide for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants.

Options and restricted stock units granted to employees and non-employees under these plans expire no later than ten years from the date of grant and generally become exercisable over a four year period, under a graded-vesting methodology for stock options and annually on the anniversary grant date for restricted stock units, following the date of grant. The Company generally issues new shares upon the exercise of stock options or vesting of restricted stock units. For certain non-employee consultants, stock option awards continue to vest post-termination. The guidance for non-employee stock compensation accounting for equity-classified awards was updated, and these awards are now subject to fixed grant date fair value principles which eliminates the variable mark-to-market accounting. The options were valued as of the adoption date July 1, 2018.

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

As of March 31, 2019, there were 1,304,357 shares available for future grant under the 2017 Plan.

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

Employees are able to purchase stock under the Vericel Corporation Employee Stock Purchase Plan (ESPP). The ESPP allows for the issuance of an aggregate of 1,000,000 shares of common stock of which 540,248 have been granted since the inception of the plan in 2015. Participation in this plan is available to substantially all employees. The ESPP is a compensatory plan accounted for under the expense recognition provisions of the share-based payment accounting standards. Compensation expense is recorded based on the fair market value of the purchase options at the grant date, which corresponds to the first day of each purchase period and is amortized over the purchase period. On April 1, 2019, employees purchased 14,228 shares resulting in proceeds from the sale of common stock of \$0.2 million under the ESPP.

### ***Service-Based Stock Options***

During the three months ended March 31, 2019, the Company granted 1,486,010 service-based options to purchase common stock. The options have an exercise price equal to the fair market value per share of common stock on the grant date, generally vest over four years (other than non-employee director options which vest over one year) and have a term of ten years. The Company issues new shares upon the exercise of stock options. The weighted average grant-date fair value of service-based options granted under the 2017 Plan for the three month periods ended March 31, 2019 and 2018 was \$12.82 and \$6.63, respectively.

### ***Restricted Stock Units***

During the three months ended March 31, 2019, the Company granted 176,422 service-based restricted stock units. The restricted stock units vest annually over four years in equal installments commencing on the first anniversary of the grant date and have a term of ten years. The Company issues new shares upon the vesting of restricted stock units. Restricted stock awards are recorded at fair value at the date of grant, which is based on the closing share price on the grant date. Compensation expense is recorded for restricted stock units that are expected to vest based on their fair value at grant date, and is amortized over the expected vesting period. The weighted average grant-date fair value of restricted stock units awarded for the three month periods ended March 31, 2019 was \$17.77. The aggregate fair value of restricted stock units as of March 31, 2019 was \$3.1 million. No restricted stock units were granted in 2018.

### ***Stock Compensation Expense***

Non-cash stock-based compensation expense (employee stock purchase plan, service-based stock options and restricted stock units) included in cost of goods sold, research and development expenses and selling, general and administrative expenses is summarized in the following table:

(In thousands)	Three Months Ended March 31,	
	2019	2018
Cost of goods sold	\$ 260	\$ 142
Research and development	525	475
Selling, general and administrative	1,843	725
Total non-cash stock-based compensation expense	\$ 2,628	\$ 1,342

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

Service-Based Stock Options	Three Months Ended March 31,	
	2019	2018
Expected dividend rate	—%	—%
Expected stock price volatility	84.5-85.5%	82.3-84.4%
Risk-free interest rate	2.4 – 2.7%	2.4-2.8%
Expected life (years)	6.1-6.3	6.1-6.3

## 9. Cash Equivalents and Investments

Marketable debt securities are classified as available-for-sale and carried at fair value in the accompanying consolidated balance sheets on a trade date basis. The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019			
	Amortized Cost	Gains	Losses	Fair Value
Money market funds	\$ 21,947	\$ —	\$ (2)	\$ 21,945
Repurchase agreements	5,000	—	—	5,000
Commercial paper	19,505	—	—	19,505
Corporate notes	15,332	2	—	15,334
U.S. government securities	3,498	—	—	3,498
U.S. asset-backed securities	10,661	3	—	10,664
	\$ 75,943	\$ 5	\$ (2)	\$ 75,946
Classified as:				
Cash equivalents				\$ 26,945
Short-term investments				49,001
				\$ 75,946

December 31, 2018

Gross Unrealized

(In thousands)	Amortized Cost	Gains	Losses	Fair Value
Money market funds	\$ 5,838	\$ —	\$ —	\$ 5,838
Repurchase agreements	5,000	—	—	5,000
Commercial paper	30,710	—	—	30,710
Corporate notes	13,168	—	(24)	13,144
U.S. government securities	10,167	—	(1)	10,166
U.S. asset-backed securities	10,632	—	(14)	10,618
	<u>\$ 75,515</u>	<u>\$ —</u>	<u>\$ (39)</u>	<u>\$ 75,476</u>
Classified as:				
Cash equivalents				\$ 10,838
Short-term investments				64,638
				<u>\$ 75,476</u>

At March 31, 2019 and December 31, 2018, the Company invested \$5.0 million in overnight repurchase agreement securities classified as cash equivalents on the balance sheet.

There were no marketable securities that the Company considers to be other-than-temporarily impaired as of March 31, 2019. The Company's investment strategy is to buy short-duration marketable securities with a high credit rating. As of March 31, 2019, all marketable securities held by the Company had remaining contractual maturities of one year or less.

If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary," including the Company's intention to sell and, if so, mark the investment to market through a charge to our consolidated statements of operations. There have been no impairments of the Company's assets measured and carried at fair value during the three months ended March 31, 2019.

## 10. Fair Value Measurements

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

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

There was no movement between level 1 and level 2 or between level 2 and level 3. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The commercial paper, corporate notes, government securities and asset-backed securities are classified as Level 2 as they were valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. The following table summarizes the valuation of the Company's financial instruments that are measured at fair value on a recurring basis:

(In thousands)	March 31, 2019				December 31, 2018			
	Total	Fair value measurement category			Total	Fair value measurement category		
		Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
<b>Assets:</b>								
Money market funds	\$ 21,945	\$ 21,945	\$ —	\$ —	\$ 5,838	\$ 5,838	\$ —	\$ —
Repurchase agreements	5,000	—	5,000	—	5,000	—	5,000	—
Commercial paper	19,505	—	19,505	—	30,710	—	30,710	—
Corporate notes	15,334	—	15,334	—	13,144	—	13,144	—
U.S. government securities	3,498	—	3,498	—	10,166	—	10,166	—
U.S. asset-backed securities	10,664	—	10,664	—	10,618	—	10,618	—
	<u>\$ 75,946</u>	<u>\$ 21,945</u>	<u>\$ 54,001</u>	<u>\$ —</u>	<u>\$ 75,476</u>	<u>\$ 5,838</u>	<u>\$ 69,638</u>	<u>\$ —</u>

## 11. Net Loss Per Common Share

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

(Amounts in thousands except per share amounts)	Three Months Ended March 31,	
	2019	2018
<b>Numerator:</b>		
Net loss	\$ (2,844)	\$ (7,659)
<b>Denominator for basic and diluted EPS:</b>		
Weighted-average common shares outstanding	43,725	36,140
Net loss per share attributable to common shareholders (basic and diluted)	<u>\$ (0.07)</u>	<u>\$ (0.21)</u>

Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The number of common equivalent shares (options of 6.0 million, restricted stock unit awards of 0.2 million and less than 0.1 million of warrants) that have been excluded from the computations of diluted net loss per common share at March 31, 2019 and 2018 were 6.2 million in the aggregate for both periods.

## 12. Commitments and Contingencies

The Company leases facilities in Ann Arbor, Michigan and Cambridge, Massachusetts. The Cambridge facility includes clean rooms, laboratories for MACI and Epicel manufacturing and office space. The Company also pays for use of an offsite warehouse space and leases various vehicles and computer equipment.

In March 2016, the Company amended its current lease in Cambridge to, among other provisions, extend the term until February 2022. Under the amendment, the landlord will contribute approximately \$2.0 million toward the cost of tenant improvements. The contribution toward the cost of tenant improvements is recorded as part of the operating lease assets under the new leasing guidance described below, on the Company's condensed consolidated balance sheet. As of March 31, 2019, the Company has recorded \$1.9 million of leasehold improvements funded by the tenant improvement allowance.

The Company adopted the updated leasing guidance as described in note 7, as of January 1, 2019. Upon adoption all operating lease commitments with a lease term greater than 12 months that were previously assessed under previous lease guidance, were recognized as right to use assets and liabilities, on a discounted basis on the balance sheet. Leases with an initial term of 12 months or less are not recorded on the balance sheet and lease expense is recorded on a straight-line basis over the lease term.

The Company's purchase commitments consist of minimum purchase amounts of materials used in the Company's cell manufacturing process to manufacture its marketed cell therapy products.

## 13. Subsequent Events

On May 6, 2019, the Company entered into exclusive license and supply agreements with MediWound Ltd. (MediWound) to commercialize NexoBrid<sup>®</sup> and any improvements to Nexobrid in all countries of North America (the Territory). NexoBrid is a topically-administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns.

NexoBrid is currently in clinical development in the Territory, and pursuant to the terms of the License Agreement, MediWound will continue to conduct all clinical activities described in the development plan to support the filing of a biologics license application (BLA) with the United States Food and Drug Administration under the supervision of a Central Steering Committee comprised of members of each party.

Within ten days from May 7, 2019, the Company is obligated to pay MediWound \$17.5 million. The Company is also obligated to pay MediWound \$7.5 million upon U.S. regulatory approval of the BLA for NexoBrid and up to \$125 million contingent upon meeting certain sales milestones. The first sales milestone of \$7.5 million would be triggered when NexoBrid annual net sales in North America exceed \$75 million. The Company also will pay MediWound tiered royalties on net sales ranging from single-digit to low double-digit percentages, subject to customary reductions. The U.S. Biomedical Advanced Research and Development Authority (BARDA) has committed to procure NexoBrid, and the Company will pay a percentage of gross profits to MediWound on initial committed amounts and a royalty on any additional BARDA purchases of NexoBrid beyond the initial committed amount. The Company also entered into a supply agreement with MediWound under which MediWound will manufacture NexoBrid for the Company on a unit price basis which may be increased based on a published index.

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

### **Overview**

Vericel Corporation is a leader in advanced cell therapies for the sports medicine and severe burn care markets, and a developer of cell therapies for use in the treatment of patients with severe diseases and conditions. We currently market two FDA approved autologous cell therapy products in the United States. MACI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. We also market Epicel® (cultured epidermal autografts), a permanent skin replacement Humanitarian Use Device (HUD) for the treatment of adult and pediatric patients with deep-dermal or full-thickness burns comprising greater than or equal to 30 percent of total body surface area (TBSA).

### **Manufacturing**

We have a cell-manufacturing facility in Cambridge, Massachusetts which is used for U.S. manufacturing and distribution of MACI and Epicel.

### **Product Portfolio**

Our approved and marketed products include two approved autologous cell therapy products: MACI, a third generation autologous implant for the repair of symptomatic, full-thickness cartilage defects of the knee in adult patients and Epicel, a permanent skin replacement for full thickness burns in adults and pediatrics with greater than or equal to 30% of TBSA, both of which are currently marketed in the U.S. We also own Carticel which is no longer marketed in the U.S. Until 2017, our active product candidate portfolio included ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to dilated cardiomyopathy, or DCM. We have no current plans to continue the development of ixmyelocel-T.

#### **MACI**

MACI is a third generation autologous implant for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. MACI replaced Carticel, an earlier generation ACI product for the treatment and repair of cartilage defects in the knee and was the first FDA-approved autologous cartilage repair product.

In the U.S., the physician target audience which repairs cartilage defects is very concentrated and is comprised of a group of physicians who self-identify as or have the formal specialty of sports medicine physicians. We believe this target audience is approximately 2,500 to 3,000 physicians. In addition to these physicians there is a population of 4,000 to 8,000 general orthopedic surgeons who treat cartilage injuries, although typically at a much lower average volume relative to the sports medicine physicians. As we look to more effectively engage this customer base, we expanded our field force from 40 to 48 representatives, whom we anticipate to be in the field in the second quarter of 2019. Most private payers have a medical policy that covers treatment with MACI with all of the top 30 largest commercial payers having a formal medical policy for MACI or ACI in general. For those private payers which have not yet approved a medical policy for MACI, for medically appropriate cases we can often obtain approval on a case by case basis. For the three months ended March 31, 2019 and 2018, net revenues for MACI were \$16.6 million and \$12.1 million, respectively.

#### **Epicel**

Epicel is a permanent skin replacement for full thickness burns greater than or equal to 30% of TBSA. Epicel is regulated by the Center for Biologics Evaluation and Research, or CBER of the U.S. Food and Drug Administration, or FDA under medical device authorities, and is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was designated as a HUD in 1998 and a Humanitarian Device Exception (HDE) application for the product was submitted in 1999. HUDs are devices that are intended for diseases or conditions that affect fewer than 8,000 individuals annually in the U.S. Under an HDE approval, a HUD cannot be sold for an amount that exceeds the cost of research and development, fabrication and distribution unless certain conditions are met.

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

On February 18, 2016, the FDA approved our HDE supplement to revise the labeled indications of use to specifically include pediatric patients and to add pediatric labeling. The revised product label also now specifies that the probable benefit of Epicel, mainly related to survival, was demonstrated in two Epicel clinical experience databases and a physician-sponsored study comparing outcomes in patients with massive burns treated with Epicel relative to standard care. Due to the change in the label to specifically include use in pediatric patients, Epicel is no longer subject to the HDE profit restrictions. In conjunction with adding the pediatric labeling and meeting the pediatric eligibility criteria, the FDA has determined the ADN number for Epicel is 360,400 which is approximately 45 times larger than the volume of grafts sold in 2018. We currently have a 5-person field force. For the three months ended March 31, 2019 and 2018, net revenues for Epicel were \$5.2 million and \$6.0 million, respectively.

### **Ixmyelocel-T**

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

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

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

## **Results of Operations**

### *Net Loss*

Our net loss for the three months ended March 31, 2019 and 2018 totaled \$2.8 million and \$7.7 million, respectively.

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Total revenues	\$ 21,810	\$ 18,027
Cost of product sales	8,640	7,666
Gross profit	13,170	10,361
Total operating expenses	16,528	14,683
Loss from operations	(3,358)	(4,322)
Other income (expense)	514	(3,337)
Net loss	\$ (2,844)	\$ (7,659)

### *Net Revenues*

Net revenues increased for the three months ended March 31, 2019 compared to the same period the previous year as an increase in cartilage implants more than offset a reduction in Epicel grafts in the quarter compared to the prior year.

<b>Revenue by product (in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
MACI	\$ 16,583	\$ 12,055
Epicel	5,227	5,972
Total Revenue	\$ 21,810	\$ 18,027

*Seasonality.* Over the last four years ACI (MACI and Carticel prior to its replacement) sales volumes from the first through the fourth quarter have on average represented 20%, 24%, 22% and 35% respectively, of total annual volumes. MACI orders are stronger in the fourth quarter due to a number of factors including insurance copay limits and the time of year patients prefer to start rehabilitation. Epicel revenue is also subject to seasonal fluctuations mostly associated with the use of heating elements during the colder months, with stronger sales occurring in the winter months of the first and fourth quarters, and weaker sales occurring in the hot summer months of the third quarter. However, in any single year, this trend can be absent due to the extreme variability inherent with Epicel's patient volume. Over the last four years the percentage of annual product orders for Epicel has on average been 28%, 25%, 21% and 27% from the first to the fourth quarters.

#### *Gross Profit and Gross Profit Ratio*

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Gross profit	\$ 13,170	\$ 10,361
Gross profit %	60%	57%

Gross profit increased for the three months ended March 31, 2019 compared to the same period in 2018 due primarily to an increase in MACI sales combined with our highly fixed manufacturing cost structure which consists mainly of labor and facility costs that do not materially fluctuate with volume increases.

#### *Research and Development Costs*

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Research and development costs	\$ 3,008	\$ 3,729

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

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Dilated Cardiomyopathy	\$ 32	\$ 556
MACI	2,130	2,456
Epicel	846	717
Total research and development costs	\$ 3,008	\$ 3,729

Research and development costs for the three months ended March 31, 2019 were \$3.0 million versus \$3.7 million for the same period a year ago. These expenses include research costs associated with manufacturing process improvement activities, the ongoing MACI pediatric trial, pharmacovigilance and other reporting and compliance requirements, as well as medical affairs and external grants. The reduction was driven by clinical study start-up costs related to the MACI pediatric trial incurred in 2018 and a reduction to other outside expenditures compared to prior year.

#### *Selling, General and Administrative Costs*

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Selling, general and administrative costs	\$ 13,520	\$ 10,954

Selling, general and administrative costs for the three months ended March 31, 2019 were \$13.5 million compared to \$11.0 million for the same period a year ago. The increase in selling, general and administrative costs for the three months ended March 31, 2019 is due primarily to a \$1.1 million increase in stock based compensation expenses, an incremental \$0.6 million in MACI sales force expenses driven by the expansion in the second quarter of 2018 and a \$0.6 million increase in selling expenses and patient reimbursement support services. The increase in selling expenses and patient reimbursement support services is primarily driven by higher MACI sales volume and the revision to our distributor model as of June 15, 2018, compared to the same period a year ago.

*Other Income (Expense)*

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Decrease (increase) in fair value of warrants	\$ —	\$ (2,907)
Other income	36	2
Net interest income (expense)	478	(432)
Total other expense	\$ 514	\$ (3,337)

The change in other income and expense is due to the increase in our stock price in 2018 resulting in an increase in the fair value of warrants compared to no expense or income due to a change in the fair value of warrants in 2019. We did not experience a change in warrant value for the three months ended March 31, 2019 due to the expiration of the 2013 warrants in 2018 which contributed to the valuation change. In addition, all outstanding debt was repaid in December 2018. The interest income for the three months ended March 31, 2019 is a result of our investments in various marketable debt securities.

*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:

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Cost of goods sold	\$ 260	\$ 142
Research and development	525	475
Selling, general and administrative	1,843	725
Total non-cash stock-based compensation expense	\$ 2,628	\$ 1,342

The changes in stock-based compensation expense are due primarily to fluctuations in the fair value of the options granted in 2019 compared to 2018 as a result in the increase in stock price. In addition, we granted restricted stock units in 2019 and none in 2018.

## Liquidity and Capital Resources

Since the acquisition in 2014 of MACI, Epicel and Carticel from Sanofi, our primary focus has been to invest in our existing commercial business with the goal of growing revenue. 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. At present revenue levels, we do not currently anticipate the need to finance our operations through the sales of equity securities.

Our cash and cash equivalents totaled \$35.1 million, and short term investments totaled \$49.0 million as of March 31, 2019. The cash provided by operations of \$0.2 million was a result of a net loss of \$2.8 million, offset largely by collections on prior quarter sales and by noncash charges including \$2.6 million of stock compensation expense, \$0.2 million due to the amortization of premiums and discounts on marketable securities and \$0.3 million of depreciation expense.

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

The change in cash used for investing activities as of March 31, 2019 is the result of \$10.7 million in short term investments purchases offset by \$26.6 million of short term investment maturities and property plant and equipment purchases of \$0.2 million primarily for manufacturing upgrades and leasehold improvements through March 31, 2019. The change in cash used for investing activities is the result of the purchases of \$0.2 million of property plant and equipment for manufacturing upgrades through March 31, 2018.

The change in cash provided from financing activities is the result of net proceeds from the exercise of stock options of \$1.0 million during the three months ended March 31, 2019. The change in cash provided from financing activities is the result of proceeds from the exercise of stock options of \$1.0 million and exercise of warrants of \$1.7 million during the three months ended March 31, 2018.

We believe that, based on current revenue levels, cash on hand, cash equivalents and short term investments we are in a position to operate our business without the need to finance our operations through the sales of equity securities. If revenues decline for a sustained period of time, we may need to access additional capital; however, we may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of our shareholders. Actual cash requirements may differ from projections and will depend on many factors, including the level of future research and development, the scope and results of ongoing and potential clinical trials, the costs involved in filing, prosecuting and enforcing patents, the need for additional manufacturing capacity, competing technological and market developments, costs of possible acquisition or development of complementary business activities, and the cost to market our products.

## Off-Balance Sheet Arrangements

At March 31, 2019, we were not party to any off-balance sheet arrangements.

## Critical Accounting Policies

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The preparation of these condensed consolidated financial statements requires the application of appropriate technical accounting rules and guidance, as well as the use of estimates. The application of these policies necessarily involves judgments regarding future events. These estimates and judgments, in and of themselves, could materially impact the condensed consolidated financial statements and disclosures based on varying assumptions. The accounting policies discussed in our Form 10-K for the fiscal year ended December 31, 2018 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 three months ended March 31, 2019.

## Forward-Looking Statements

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

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

- manufacturing and facility capabilities;
- potential strategic collaborations with others;
- future capital needs and financing sources;
- adequacy of existing capital to support operations for a specified time;
- reimbursement for our products;

- product development and marketing plans;
- features and successes of our cellular therapies;
- clinical trial plans, including publication thereof;
- anticipation of future losses;
- replacement of manufacturing sources;
- commercialization plans; or
- revenue expectations and operating results.

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

As of March 31, 2019, 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, 2018.

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

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

Management of the Company, with the participation of its Certifying Officers, evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation as of March 31, 2019, our Certifying Officers concluded that the Company's disclosure controls and procedures were effective.

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

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We implemented internal controls to ensure management properly assessed the impact of the new lease accounting standards on our condensed consolidated financial statements to facilitate adoption of the new leasing standards effective January 1, 2019. There were no significant changes to our internal control over financial reporting due to the adoption of the new standards.

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

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

### Item 1B. Unresolved Staff Comments

Not applicable.

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

The Company did not have any repurchases or unregistered issuances of its equity securities during the quarter ended March 31, 2019.

### Item 3. Defaults Upon Senior Securities

Not applicable.

### Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

Not applicable.

### Item 6. Exhibits

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

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
31.1**	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2**	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1**	<a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2**	<a href="#">Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS**	<a href="#">XBRL Instance Document</a>
101.SCH**	<a href="#">XBRL Taxonomy Extension Schema Document</a>
101.CAL**	<a href="#">XBRL Taxonomy Extension Calculation Linkbase Document</a>
101.LAB**	<a href="#">XBRL Taxonomy Extension Label Linkbase Document</a>
101.PRE**	<a href="#">XBRL Taxonomy Extension Presentation Linkbase Document</a>
101 DEF**	<a href="#">XBRL Taxonomy Extension Definition Linkbase Document</a>

\*\* Filed herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 7, 2019

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)*

## CERTIFICATION

I, Dominick C. Colangelo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vericel Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2019

/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; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2019

/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 March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

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

Date: May 7, 2019

/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 March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

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

Date: May 7, 2019

/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.