UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

FOR THE QUARTERLY PERIOD ENDED: June 30, 2020

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	**94-3096597**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

64 Sidney Street
Cambridge, MA 02139
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(617) 588-5555**

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

Title of Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock (No par value)	VCEL	NASDAQ

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

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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

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	☒	Accelerated filer	☐
Non-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. o

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

As of July 31, 2020, 45,250,402 shares of Common Stock, no par value per share, were outstanding.

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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,704	$ 26,889
Short term investments	25,086	42,829
Accounts receivable (net of allowance for doubtful accounts of $207 and $306, respectively)	23,655	32,168
Inventory	8,417	6,816
Other current assets	2,900	2,953
Total current assets	115,762	111,655
Property and equipment, net	7,040	7,144
Restricted cash	89	89
Right-of-use leased assets	23,800	25,103
Long term investments	—	9,247
Total assets	$ 146,691	$ 153,238
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,535	$ 6,345
Accrued expenses	7,975	7,948
Current portion of operating lease liabilities	5,570	5,461
Other liabilities	41	41
Total current liabilities	18,121	19,795
Operating lease liabilities	20,881	22,242
Other long-term liabilities	93	110
Total liabilities	$ 39,095	$ 42,147
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 45,194 and 44,864, respectively	$ 499,103	$ 489,749
Other comprehensive gain	146	21
Accumulated deficit	(391,653)	(378,679)
Total shareholders' equity	107,596	111,091
Total liabilities and shareholders' equity	$ 146,691	$ 153,238

The accompanying Notes to the 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,	
	2020	2019	2020	2019
Product sales, net	$ 20,014	$ 26,151	$ 46,692	$ 47,961
Cost of product sales	8,660	9,022	18,582	17,662
Gross profit	11,354	17,129	28,110	30,299
Research and development	3,226	21,070	6,989	24,078
Selling, general and administrative	16,486	16,259	34,555	29,779
Total operating expenses	19,712	37,329	41,544	53,857
Loss from operations	(8,358)	(20,200)	(13,434)	(23,558)
Other income (expense):				
Interest income	147	428	453	908
Interest expense	(1)	(2)	(3)	(4)
Other income (expense)	(57)	(18)	10	18
Total other income (expense)	89	408	460	922
Net loss	$ (8,269)	$ (19,792)	$ (12,974)	$ (22,636)
Net loss per share attributable to common shareholders (Basic and Diluted)	$ (0.18)	$ (0.45)	$ (0.29)	$ (0.52)
Weighted average number of common shares outstanding (Basic and Diluted)	45,137	43,956	45,031	43,841

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (8,269)	$ (19,792)	$ (12,974)	$ (22,636)
Other comprehensive loss:				
Unrealized gain on investments	84	35	125	38
Comprehensive loss	$ (8,185)	$ (19,757)	$ (12,849)	$ (22,598)

The accompanying Notes to the 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, 2019	44,864	$ 489,749	—	$ 21	$ (378,679)	$ 111,091
Net loss	—	—	—	—	(4,705)	(4,705)
Compensation expense related to stock options and restricted stock units granted, net of forfeitures	—	3,768	—	—	—	3,768
Stock option exercises	57	196	—	—	—	196
Shares issued under the Employee Stock Purchase Plan	20	224	—	—	—	224
Issuance of stock upon restricted stock unit vesting	36	—	—	—	—	—
Restricted stock withheld for employee tax remittance	(14)	(163)	—	—	—	(163)
Unrealized gain on investments	—	—	—	41	—	41
BALANCE, MARCH 31, 2020	44,963	$ 493,774	$ —	$ 62	$ (383,384)	$ 110,452
Net loss	—	—	—	—	(8,269)	(8,269)
Compensation expense related to stock options and restricted stock units granted, net of forfeitures	—	4,376	—	—	—	4,376
Stock option exercises	188	696	—	—	—	696
Shares issued under the Employee Stock Purchase Plan	32	257	—	—	—	257
Issuance of stock for restricted stock unit vesting	11	—	—	—	—	—
Unrealized gain on investments	—	—	—	84	—	84
BALANCE, JUNE 30, 2020	45,194	$ 499,103	$ —	$ 146	$ (391,653)	$ 107,596

	Common Stock		Warrants	Accumulated Other Comprehensive Income (Loss)	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
Net loss	—	—	—	—	(19,792)	(19,792)
Compensation expense related to stock options and restricted stock units granted, net of forfeitures	—	4,183	—	—	—	4,183
Stock option exercises	227	850	—	—	—	850
Shares issued under the Employee Stock Purchase Plan	14	211	—	—	—	211
Unrealized gain on investments	—	—	—	35	—	35
BALANCE, JUNE 30, 2019	44,066	$ 480,050	$ 104	$ 38	$ (391,650)	$ 88,542

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

	Six Months Ended June 30,	
	2020	**2019**
Operating activities:		
Net loss	$ (12,974)	$ (22,636)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation and amortization expense	1,079	698
Stock compensation expense	8,144	6,810
Foreign currency translation loss	45	13
Loss on sale of fixed assets	30	—
Amortization of premiums and discounts on marketable securities	(25)	(408)
Amortization and interest accretion related to operating leases	1,603	1,139
Changes in operating assets and liabilities:		
Inventory	(1,601)	(1,230)
Accounts receivable	8,513	2,370
Prepaid and other current assets	53	680
Accounts payable	(1,692)	(2,238)
Accrued expenses	27	(2,229)
Operating lease liabilities	(1,537)	(1,007)
Other non-current assets and liabilities, net	—	(187)
Net cash provided by (used for) operating activities	1,665	(18,225)
Investing activities:		
Purchases of short term investments	(5,657)	(32,402)
Maturities of short term investments	32,797	45,477
Expenditures for property, plant and equipment	(1,186)	(1,224)
Net cash provided by investing activities	25,954	11,851
Financing activities:		
Net proceeds from common stock issuance due to stock option exercises	1,373	2,059
Payments on employee's behalf for taxes related to vesting of restricted stock unit awards	(163)	—
Other	(14)	(9)
Net cash provided by financing activities	1,196	2,050
Net increase in cash, cash equivalents, and restricted cash	28,815	(4,324)
Cash, cash equivalents, and restricted cash at beginning of period	26,978	18,286
Cash, cash equivalents, and restricted cash at end of period	$ 55,793	$ 13,962

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

VERICEL CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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. The Company is a fully-integrated, commercial-stage biopharmaceutical company and is a leader in advanced cell therapies for the sports medicine and severe burn care markets. Vericel currently markets two cell therapy products, MACI® and Epicel®, in the United States. Vericel obtained both products in May 2014, as part of the acquisition of certain assets and the assumption of certain liabilities from Sanofi, a French *société anonyme* (Sanofi).

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. 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 biopharmaceuticals for use in the treatment of specific diseases.

COVID-19

The novel coronavirus (COVID-19) outbreak was first reported by China in late December 2019 and rapidly spread globally. The World Health Organization (WHO) declared the outbreak a pandemic on March 11, 2020 and the President of the United States declared a national health emergency two days later. Subsequently most states' governments, including those in Massachusetts and Michigan where the Company's operations are located, issued orders requiring businesses that do not conduct essential services to temporarily close their physical workplaces to employees and customers. The status of such orders varies on a state-by-state basis and is likely to continue to vary. Because Vericel is deemed an essential business, the Company is exempt from these state orders in their current form.

Notwithstanding being an essential business, the Company’s business and operations have been, and are expected to continue to be, adversely impacted by the effects of COVID-19 as a result of various factors including, without limitation, patients’ potential reluctance to undergo elective surgical procedures, healthcare facility restrictions regarding elective surgical procedures, the recent economic downturn due to the pandemic, the imposition of related public health measures and travel and business restrictions and disruptions to the ability of the Company’s employees to perform their jobs.

The implantation of MACI is an elective surgical procedure. On March 13, 2020 and March 14, 2020, the American College of Surgeons and United States Surgeon General, respectively, recommended that each hospital, health system, and surgeon minimize, postpone, or cancel electively scheduled surgeries, which has resulted in a reduction in MACI sales. The stated purpose for these recommendations was that every elective surgery could spread COVID-19 within a facility, use up personal protective equipment (PPE) which may be needed by healthcare workers treating COVID-19 patients, and burden hospital workforce who may be needed to respond to COVID-19. These recommendations were followed by numerous state level executive orders either banning or partially banning elective surgeries. As a result of these restrictions, beginning in mid-March 2020, the Company started to experience a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders. By early April 2020, 45 states, representing over 95% of total U.S. surgical capacity had issued either mandates or recommendations and guidelines suspending elective surgical procedures. These restrictions began to ease in May and, by the end of June 2020, states representing an estimated 90% total U.S. surgical capacity had lifted restrictions suspending elective procedures. It is likely that restrictions will continue to be both lifted and re-imposed as regional COVID 19 cases rates fall and rise. The Company’s MACI business will continue to be negatively impacted so long as multiple state orders and/or facilities restrict elective surgical procedures.

Going Concern

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 the satisfaction of liabilities and commitments in the normal course of business. As of June 30, 2020, the Company had an accumulated deficit of $391.7 million and incurred a net loss of $8.3 million and $13.0 million for the three and six months ended June 30, 2020, respectively. The Company had cash and cash equivalents of $55.8 million and investments of $25.1 million as of June 30, 2020. The Company expects that existing cash, cash equivalents and investments will be sufficient to support the Company's current operations through at least 12 months from the issuance of these financial statements. However, the continuing effects of the COVID-19 pandemic may require the Company to engage in layoffs, furloughs and/or reductions in salary, all of which may result in irrecoverable losses of customers and significantly impact long-term liquidity. If elective surgery restrictions are reinstated on a widespread basis, significantly impacting the Company's business, the Company may need to access additional capital; however, the Company may not be able to obtain financing on acceptable terms or at all, particularly in light of the impact of COVID-19 on the global economy and financial markets. The terms of any financing may adversely affect the holdings or the rights of the Company's shareholders.

2. Basis of Presentation

The accompanying condensed consolidated financial statements as of June 30, 2020 and for the three and six months ended June 30, 2020 are unaudited and 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 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. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to continue to contain it or treat COVID-19, as well as the economic impact on our customers. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results may differ from these estimates. As of June 30, 2020, the Company has not recorded impairments to investments, inventory, other current assets or long-lived assets as a result of the COVID-19 pandemic and does not expect material impairments in the future. The Company has assessed the impact of COVID-19 on accounts receivables (see note 4).

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, 2019 as filed with the SEC on February 25, 2020 (Annual Report).

Consolidated Statement of Cash Flows

The following table presents certain supplementary cash flows information for the six months ended June 30, 2020 and 2019:

(In thousands)	Six Months Ended June 30, 2020	2019
Supplementary Cash Flows information:		
Non-cash information:		
Right-of-use asset and lease liability recognized	$ 429	$ 560
Additions to property, plant and equipment included in accounts payable	55	365
Cash information:		
Interest paid (net of interest capitalized)	$ 3	$ 4

Total cash, cash equivalents, and restricted cash of $55.8 million as of June 30, 2020, shown in the statement of cash flows is comprised of cash and cash equivalents of $55.7 million and restricted cash of $0.1 million which is included in other long term assets on the consolidated balance sheet. As of June 30, 2019, cash and cash equivalents were $14.0 million and the Company did not have any restricted cash.

3. Recent Accounting Pronouncements

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 Accounting Standard Update (ASU) 2016-13, *Financial Instruments-Credit Losses (Topic 326)*, became effective for the Company January 1, 2020. See note 4 and note 8 for further discussion.

Fair Value Measurement Disclosure

The FASB issued updated guidance through ASU 2018-13, *Fair Value Measurement (Topic 820) Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement.* The revised guidance is intended to develop a more consistent disclosure framework that will increase clarity, remove, modify and add certain fair value disclosures to improve the effectiveness of the Company's disclosures in the notes of the financial statements. This guidance became effective for the Company January 1, 2020 and had no impact to its condensed consolidated financial statements.

Simplifying the Accounting for Income Taxes

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes (ASC 740).* The ASU enhances and simplifies various aspects of the income tax accounting guidance in ASC 740, including requirements related to hybrid tax regimes, the tax basis step-up in goodwill obtained in a transaction that is not a business combination, separate financial statements of entities not subject to tax, the intra-period tax allocation exception to the incremental approach, ownership changes in investments, changes from a subsidiary to an equity method investment, interim-period accounting for enacted changes in tax law, and the year-to-date loss limitation in interim-period tax accounting. This guidance is effective for the Company for annual and interim periods beginning after December 31, 2020; however, early adoption is permitted. The Company is currently in the process of evaluating the impact to its condensed 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 facility) 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 contracts with two specialty pharmacies, Orsini Pharmaceutical Services, Inc. (Orsini) and AllCare Plus Pharmacy, Inc. (AllCare) to distribute its MACI product in arrangements whereby the Company retains the credit and collection risk from the end customer. The Company pays both specialty pharmacies a fee for each patient to whom MACI is dispensed. Both Orsini and AllCare perform collection activities to receive payment from customers. The Company has engaged a third-party to provide services in connection with a patient support program to manage patient cases and to ensure complete and correct billing information is provided to the insurers and hospitals. In addition, the Company also sells MACI directly to DMS Pharmaceutical (DMS) for military implants. The sales directly to DMS are sold at a contracted rate.

Prior authorization and confirmation of coverage level by the patient's private insurance plan, hospital or government payer is a prerequisite to the shipment of product to a patient. The Company recognizes product revenues from sales of all MACI implants upon delivery at which time the customer obtains control of the implant and the claim is billable. The total consideration which the Company expects to collect in exchange for MACI implants (the transaction price) may be fixed or variable. Direct sales to hospitals or distributors are recorded at a contracted price, and other than customary prompt pay discounts, there are typically no forms of variable consideration.

When the Company sells MACI the patient is responsible for payment, however, the Company is typically reimbursed by a third-party insurer or government payer, subject to a patient co-pay amount. Reimbursements from third-party insurers and government payers vary by patient and payer and are based on either contracted rates, publicly available rates or a fee schedule. Net product revenue is recognized net of contractual allowances, which considers historical collection experience from both the payer and patient and the terms of the Company's contractual arrangements. The Company estimates expected collections for these transactions using the portfolio approach. These estimates include the impact of contractual allowances, which considers historical collection experience from both the payer and patient, denial rates and the terms of the Company's contractual arrangements. The Company records a reduction to revenue at the time of sale for its estimate of the amount of consideration that will not be collected. In addition, potential credit risk exposure has been evaluated for the Company's accounts receivable in accordance with *ASC 326, Financial Instruments - Credit Losses.* The Company assesses risk and determines a loss percentage by pooling account receivables based on similar risk characteristics. The loss percentage is based on current and historical information as well as reasonable and supportable forecasts. This loss percentage was applied to the accounts receivables as of June 30, 2020. The total allowance for uncollectible consideration was $4.4 million as of June 30, 2020 and $3.9 million at December 31, 2019. The allowance includes less than $0.1 million of which is related to COVID-19 potential impacts on accounts receivable from third-party insurers, government payers, hospitals and patients. Changes to the estimate of the amount of consideration that will not be collected could have a material impact to the revenue recognized. A 0.5% change to the estimated uncollectible percentage could result in approximately a $0.1 million decrease in the revenue recognized for the six months ended June 30, 2020.

Changes in estimates of the transaction price are recorded through revenue in the period in which such change occurs. Changes in estimates related to prior period sales for the three and six months ended June 30, 2020 resulted in a decrease to revenue of $0.2 million and increase to revenue of $1.1 million, respectively, and an increase to revenue of $0.09 million and $0.05 million, respectively for the same period in 2019. The changes in estimates recorded during the three and six months ended June 30, 2020, were primarily due to completion of the billing claims process for implants that occurred in late 2019. Upon completion of the billing claims process, the Company concluded that it was probable that a significant reversal in the amount of revenue recognized would not occur.

Epicel

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

Revenue by Product and Customer

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Revenue by product (in thousands)	**2020**	**2019**	**2020**	**2019**
MACI implants and kits				
Implants based on contracted rate sold through a specialty pharmacy (a)	$ 9,790	$ 12,989	$ 21,218	$ 22,776
Implants subject to third party reimbursement sold through a specialty pharmacy (b)	2,819	3,459	6,335	6,202
Implants sold direct based on contracted rates (c)	1,806	3,450	4,916	6,676
Implants sold direct subject to third party reimbursement (d)	589	281	1,016	603
Biopsy kits - direct bill	348	557	811	1,099
Change in estimates related to prior periods (e)	(248)	87	1,095	50
Epicel				
Direct bill (hospital)	4,910	5,328	11,301	10,555
Total revenue	$ 20,014	$ 26,151	$ 46,692	$ 47,961

(a) Represents implants sold through Orsini and AllCare in both 2020 and 2019 in which such specialty pharmacies have entered into a direct contract with the underlying insurance provider. The amount of reimbursement is based on contracted rates at the time of sale supported by the pharmacy's direct contracts. Also represents direct sales under a contract to the specialty distributor DMS.

(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.

(e) Primarily represents changes in estimates related to implants sold through Orsini or AllCare in which such specialty pharmacy does not have a direct contract with the underlying payer. The initial estimate of the amount of reimbursement is established based on a payer or state fee schedule and/or payer history. The change in estimates is a result of additional information or actual cash collections received in the current period.

Concentration of Credit Risk

The table below shows the Company's total Epicel revenue and accounts receivable balances from customers whose revenue or accounts receivable concentration is greater than 10% in any of the periods disclosed below. The Company did not have MACI revenue or accounts receivable concentrations greater than 10% in any of the periods disclosed below.

	Revenue Concentration				Accounts Receivable Concentration	
	Three Months Ended June 30,		Six Months Ended June 30,		June 30,	December 31,
	2020	2019	2020	2019	2020	2019
Epicel	6 %	6 %	10 %	8 %	3 %	2 %

5. Selected Balance Sheet Components

Inventory

Inventory as of June 30, 2020 and December 31, 2019:

(In thousands)	June 30, 2020	December 31, 2019
Raw materials	$ 7,853	$ 6,085
Work-in-process	513	541
Finished goods	51	190
Inventory	$ 8,417	$ 6,816

Property and Equipment

Property and Equipment, net as of June 30, 2020 and December 31, 2019:

(In thousands)	June 30, 2020	December 31, 2019
Machinery and equipment	$ 3,279	$ 3,152
Furniture, fixtures and office equipment	810	775
Computer equipment and software	6,393	6,174
Leasehold improvements	5,256	5,256
Construction in process	1,311	859
Financing right-of-use lease	129	148
Total property and equipment, gross	17,178	16,364
Less accumulated depreciation	(10,138)	(9,220)
	$ 7,040	$ 7,144

Depreciation expense for the three and six months ended June 30, 2020 was $0.5 million and $1.1 million, respectively, and $0.4 million and $0.7 million for the same periods in 2019.

Accrued Expenses

Accrued Expenses as of June 30, 2020 and December 31, 2019 are as follows:

(In thousands)	June 30, 2020	December 31, 2019
Bonus related compensation	$ 2,872	$ 5,116
Employee related accruals	2,578	1,785
Other accrued expenses	2,525	1,047
Accrued expenses	$ 7,975	$ 7,948

6. Leases

The Company leases facilities in Ann Arbor, Michigan and Cambridge, Massachusetts. The Ann Arbor facility includes office space, and 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. 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. All operating lease commitments with a lease term greater than 12 months are 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 both the three and six months ended June 30, 2020 and 2019, lease expense of less than $0.1 million was recorded related to short-term leases.

The contribution toward the cost of tenant improvements is recorded as a reduction of the operating lease assets. For the three and six months ended June 30, 2020, the Company recognized $1.4 million and $2.9 million of operating lease expense and $1.3 million and $2.6 million for the same periods in 2019.

For both the three and six months ended June 30, 2020 and 2019, the Company recognized less than $0.1 million of financing lease expense. The Company's leases contain non-lease components and activities that do not transfer a good or service to the Company. The Company elected not to combine lease and non-lease components and therefore non-lease costs 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 June 30, 2020 and December 31, 2019 are as follows:

(In thousands)	Classification	June 30, 2020	December 31, 2019
Assets			
Operating	Right-of-use assets	$ 23,800	$ 25,103
Finance	Property and equipment, net	129	148
		$ 23,929	$ 25,251
Liabilities			
Current			
Operating	Current portion of operating lease liabilities	$ 5,570	$ 5,461
Finance	Other liabilities	41	41
		$ 5,611	$ 5,502
Non-current			
Operating	Operating lease liabilities	$ 20,881	$ 22,242
Finance	Other long-term liabilities	93	110
		$ 20,974	$ 22,352

7. 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 and restricted stock units 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.

The 2019 Omnibus Incentive Plan (2019 Plan) was approved on May 1, 2019 and 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 2019 Plan shall not be less than the fair market value of the Company's common stock on the date of grant. The 2019 Plan replaced the 1992 Stock Option Plan, the 2001 Stock Option Plan, the Amended and Restated 2004 Equity Incentive Plan, the 2009 Second Amended and Restated Omnibus Incentive Plan and the 2017 Omnibus Incentive Plan (Prior Plans), and no new grants have been granted under the Prior Plans after approval. However, the expiration or forfeiture of options previously granted under the Prior Plans will increase the number of shares available for issuance under the 2019 Plan.

The Amended and Restated 2019 Omnibus Incentive Plan (Amended and Restated 2019 Plan) was approved on April 29, 2020. Amendments to the Amended and Restated 2019 Omnibus Plan included increasing the total number of shares of the Company's common stock reserved for issuance under the 2019 Plan by 2,400,000 shares, a revised ratio at which "full- value" awards are counted against the share reserve from 1.25 to 1.4, and extending the term of the plan to April 29, 2030.

As of June 30, 2020, there were 4,267,255 shares available for future grant under the Amended and Restated 2019 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 672,907 have been issued since the inception of the benefit 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. In July 2020, employees purchased 44,137 shares resulting in proceeds from the sale of common stock of $0.3 million under the ESPP for the second quarter of 2020.

Service-Based Stock Options

During the three and six months ended June 30, 2020, the Company granted service-based options to purchase common stock of 110,750 and 1,296,890, respectively, and 152,500 and 1,638,510, respectively, for the same periods in 2019. The exercise price of the options is 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 during the three and six months ended June 30, 2020 was $8.82 and $8.66, respectively and $11.94 and $12.74, respectively, for the same periods in 2019.

Restricted Stock Units

During the three and six months ended June 30, 2020 and 2019, the Company granted 10,700 and 196,836, service-based restricted stock units, respectively and 10,500 and 186,922, respectively, for the same periods in 2019. The restricted stock units vest annually over four years in equal installments commencing on the first anniversary of the grant date (other than non-employee director options which vest over one year from the grant date). 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 granted during the three and six months ended June 30, 2020 was $14.49 and $11.41, respectively and $16.62 and $17.71, respectively, for the same periods in 2019. The aggregate fair value of restricted stock units granted in the three and six months ended June 30, 2020 was $0.2 million and $2.2 million, respectively and $0.2 million and $3.3 million, respectively, for the same periods in 2019.

As a result of 36,212 units vesting during the three months ended March 31, 2020, 13,872 shares were withheld for payment of taxes on the employee's behalf and retired from the 2019 Plan. During the three months ended June 30, 2020, 10,500 units vested and no shares were withheld for payment of taxes, as no shares are withheld at vesting for shares awarded to the Company's Board of Directors.

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:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Cost of goods sold	$ 568	$ 716	$ 997	$ 976
Research and development	484	886	$ 1,060	1,410
Selling, general and administrative	3,325	2,581	$ 6,087	4,424
Total non-cash stock-based compensation expense	$ 4,377	$ 4,183	$ 8,144	$ 6,810

8. Cash Equivalents and Investments

Marketable debt securities held by the Company are classified as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*, and carried at fair value in the accompanying consolidated balance sheets on a settlement date basis. The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of June 30, 2020 and December 31, 2019:

	June 30, 2020				
		Gross Unrealized			
	Amortized Cost	Gains	Losses	Credit Losses	Estimated Fair Value
Money market funds	$ 44,985	$ —	$ —	—	$ 44,985
Commercial paper	3,685	—	—	—	3,685
Corporate notes	8,840	55	—	—	8,895
U.S. government securities	7,776	67	—	—	7,843
U.S. asset-backed securities	4,640	23	—	—	4,663
	$ 69,926	$ 145	$ —	$ —	$ 70,071
Classified as:					
Cash equivalents					$ 44,985
Short term investments					25,086
					$ 70,071

	December 31, 2019			
		Gross Unrealized		
(In thousands)	Amortized Cost	Gains	Losses	Estimated Fair Value
Money market funds	$ 5,381	$ —	$ —	$ 5,381
Commercial paper	11,892	—	—	11,892
Corporate notes	18,369	11	—	18,380
U.S. government securities	11,291	4	—	11,295
U.S. asset-backed securities	10,503	6	—	10,509
	$ 57,436	$ 21	$ —	$ 57,457
Classified as:				
Cash equivalents				$ 5,381
Short-term investments				42,829
Long term investments				9,247
				$ 57,457

As of June 30, 2020 and December 31, 2019, we held both short-term and long-term investments. Investments classified as short-term have maturities of less than one year. Investments classified as long-term are those that: (i) have a maturity of greater than one year, and (ii) we do not intend to liquidate within the next twelve months, although these funds are available for use and, therefore, are classified as available-for-sale. The Company's investment strategy is to buy short-duration marketable securities with a high credit rating. As of June 30, 2020, all marketable securities held by the Company had remaining contractual maturities of three years or less.

Unrealized gains are included as a component of accumulated other comprehensive income in the condensed consolidated balance sheets and statements of stockholders' equity and a component of total comprehensive loss in the condensed consolidated statements of comprehensive loss, until realized. Unrealized losses are evaluated for impairment under ASC 326, *Financial Instruments - Credit Losses*, to determine if the impairment is credit-related or non credit-related. Credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings, and non credit-related impairment is recognized in other comprehensive income, net of taxes. There were no material realized losses on marketable securities for the three and six months ended June 30, 2020 and 2019.

The Company evaluated its investments for impairment under ASC 326. Any allowance for credit losses are recorded at the lower of either the fair market value less book value or the difference between the present value of future cash flows and the book value. As of June 30, 2020, the analysis under ASU 2016-13 and the current macroeconomic impact of the COVID-19 pandemic did not result in material allowances for credit losses. There have been no impairments of the Company's assets measured and carried at fair value as of June 30, 2020.

9. Fair Value Measurements

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

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;
- 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 from December 31, 2019 to June 30, 2020. 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, U.S. 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:

	June 30, 2020				December 31, 2019			
		Fair value measurement category				Fair value measurement category		
(In thousands)	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Assets:								
Money market funds	$ 44,985	$ 44,985	$ —	$ —	$ 5,381	$ 5,381	$ —	$ —
Commercial paper	3,685	—	3,685	—	11,892	—	11,892	—
Corporate notes	8,895	—	8,895	—	18,380	—	18,380	—
U.S. government securities	7,843	—	7,843	—	11,295	—	11,295	—
U.S. asset-backed securities	4,663	—	4,663	—	10,509	—	10,509	—
	$ 70,071	$ 44,985	$ 25,086	$ —	$ 57,457	$ 5,381	$ 52,076	$ —

The fair values of the cash equivalents and marketable securities are based on observable market prices. See note 8 for impact of ASU 2016-13 on the investment valuation.

10. 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 June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Numerator:				
Net loss	$ (8,269)	$ (19,792)	$ (12,974)	$ (22,636)
Denominator:				
Basic and diluted EPS: weighted-average common shares outstanding	45,137	43,956	45,031	43,841
Net loss per share attributable to common shareholders (basic and diluted)	$ (0.18)	$ (0.45)	$ (0.29)	$ (0.52)
Anti-dilutive shares excluded from the calculation of diluted earnings per share[(a)] (amounts in millions):				
Stock options	6.0	5.6	6.0	5.6
Restricted stock unit awards	0.3	0.2	0.3	0.2
Warrants	—	0.1	—	0.1

(a) Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive.

11. NexoBrid License and Supply Agreements

On May 6, 2019, the Company entered into exclusive license and supply agreements with MediWound Ltd. (MediWound) to commercialize NexoBrid® and any improvements to NexoBrid in all countries of North America. 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 North America, 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 BLA filing with the United States Food and Drug Administration (FDA) under the supervision of a Central Steering Committee comprised of members of each party. On June 30, 2020, the Company announced the submission of the BLA to the FDA seeking the approval of NexoBrid. NexoBrid is approved in the European Union and other international markets and has been designated as an orphan biologic in the United States, European Union and other international markets.

In May 2019, the Company paid MediWound $17.5 million in consideration of the license. The $17.5 million upfront payment was recorded to research and development expense during 2019, as the license was considered in process research and development. 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 annual net sales of NexoBrid or improvements to it in North America exceed $75 million. The Company also will pay MediWound tiered royalties on net sales ranging from mid-high single-digit to mid-teen 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. MediWound is obligated to supply the Company with NexoBrid for sale in North America on an exclusive basis for the first five years of the term of the supply agreement. After the exclusivity period or upon supply failure, the Company will be permitted to establish an alternate source of supply. As of June 30, 2020, the milestone payments are not yet probable and therefore, not considered a liability.

12. Commitments and Contingencies

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.

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

Overview

Vericel Corporation is a leader in advanced cell therapies and specialty biologics 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). We hold an exclusive license for North America commercial rights to NexoBrid, a registration-stage biological orphan product for debridement of severe thermal burns.

COVID-19

The novel coronavirus (COVID-19) outbreak was first reported by China in late December 2019 and rapidly spread globally. The World Health Organization (WHO) declared the outbreak a pandemic on March 11, 2020 and the President of the United States declared a national health emergency. Subsequently most states' governments, including those in Massachusetts and Michigan where the Company's operations are located, issued orders requiring businesses that do not conduct essential services to temporarily close their physical workplaces to employees and customers. The status of such orders varies on a state-by-state basis and is likely to continue to vary. Because Vericel is deemed an essential business the Company is exempt from these state orders in their current form.

Notwithstanding being an essential business, the Company's business and operations have been, and are expected to continue to be, adversely impacted by the effects of COVID-19 as a result of various factors including, without limitation, patients' potential reluctance to undergo elective surgical procedures, healthcare facility restrictions regarding elective surgical procedures, the recent economic downturn due to the pandemic, the imposition of related public health measures and travel and business restrictions and disruptions to the ability of the our employees to perform their jobs.

The implantation of MACI is an elective surgical procedure. On March 13, 2020 and March 14, 2020, the American College of Surgeons and the United States Surgeon General, respectively, recommended that each hospital, health system, and surgeon minimize, postpone, or cancel electively scheduled surgeries, which has resulted in a significant reduction in MACI sales. The stated purpose for these recommendations was that every elective surgery could spread COVID-19 within a facility, use up personal protective equipment (PPE) which may be needed by healthcare workers treating COVID-19 patients, and burden hospital workforce who may be needed to respond to COVID-19. These recommendations were followed by numerous state level executive orders either banning or partially banning elective surgeries. By early April 2020, 45 states, representing over 95% of total U.S. surgical capacity had issued either mandates or recommendations and guidelines suspending elective procedures. These restrictions began to ease in May and, by the end of June 2020, states representing an estimated 90% total U.S. surgical capacity had lifted restrictions suspending elective procedures. As a result of these restrictions, beginning in mid-March 2020, the Company started to experience a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders. The impact has varied over time and has been heavily correlated with the amount of surgical capacity under restrictions.

Although many states have eased restrictions, as the COVID-19 virus has spread across the country other states have implemented or re-imposed restrictions on elective surgical procedures, and certain facilities, independent of state restrictions, have imposed restrictions on elective surgeries. The restrictions that currently are in force vary significantly. Some states and facilities have put in place restrictions which apply only to surgeries which require an overnight stay in a hospital and thus have little impact on MACI as over 95% of MACI surgeries do not result in an overnight stay. However, other state and facility restrictions do cover all elective surgeries. Similarly, some restrictions do not cover ambulatory surgery centers where approximately 50% of MACI procedures are performed, while others cover all elective surgeries regardless of site. It is likely that restrictions will continue to be both lifted and re-imposed as regional COVID-19 rates fall and rise. The Company's MACI business will continue to be negatively impacted so long as multiple state orders and/or facilities restrict elective surgical

procedures. Although we believe Epicel may be less directly impacted by COVID-19 given the critical nature of severe burn injuries, trauma injury admissions have reportedly been reduced as a result of the various COVID-19 related restrictions and potential reluctance on the part of patients to seek care in light of COVID-19. In addition, any prolonged material disruption of the Company's employees, distributors, suppliers or customers will impact its sales and operating results that could lead to potential inventory write-offs, credit losses in accounts receivable, or impairment of long-lived assets.

We have implemented a number of initiatives to maintain our near-term and future growth opportunities while supporting patients and reducing non-essential discretionary spending, including the imposition of a temporary moratorium on new employee hiring. In March 2020, we initiated protective measures in response to the COVID-19 outbreak including the canceling of all business-related international travel, requesting employees limit non-essential personal travel, enhancing our facilities' janitorial and sanitary procedures and the provision of certain personal protective equipment to employees working in our offices, encouraging employees to work from home to the extent their job function enables them to do so, limiting third-party access to our facilities, encouraging the use of virtual meetings, and modifying the manner and schedule of on-site production activities. We have also instituted daily health screening for all of our employees. We are reviewing all of these measures on a daily basis as the situation evolves, and we will take additional actions to the extent they are needed in the future.

We continue to manufacture MACI and Epicel and are maintaining a significant safety stock of all key raw materials. We do not expect current supply chain interruptions will impact the Company's ongoing manufacturing operations. With respect to customer delivery, MACI final product has an established shelf life of 6 days and established shipping shelf life of 3 days. Currently, MACI is picked up by courier and shipped by commercial air or ground transportation to our customer's location. Epicel final product has an established shelf life of 24 hours and is hand carried to customer hospital sites by courier. Transportation is primarily commercial or charter airline. Although we have not experienced material shipping delays or increased costs to date, significant disruption of air travel could result in the inability to deliver MACI or Epicel final products to customer sites within appropriate timeframes, which could further adversely impact our business. There is no expected impact of COVID-19 on the Company's distributors or third-party service providers' ability to manage patient cases.

For a discussion of additional risks associated with COVID-19, please see Item 1A. Risk Factors.

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 marketed products include two FDA-approved autologous cell therapies: 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 adult and pediatric patients with deep dermal or full thickness burns greater than or equal to 30% of TBSA. Both products are currently marketed in the U.S. In addition, we have entered into exclusive license and supply agreements with MediWound to commercialize NexoBrid in all countries of North America. NexoBrid is currently in clinical development in North America. 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 product for autologous chondrocyte implantation (ACI), a class of methods for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults.

In the U.S., the physician target audience which repairs cartilage defects is concentrated and is partly comprised of a group of orthopedic surgeons who self-identify and/or have a formal specialty as sports medicine physicians. We believe this target audience is approximately 3,000 physicians. In addition to sports medicine physicians there is a population of approximately 8,000 general orthopedic surgeons who treat cartilage injuries, although typically at a much lower average volume relative to the sports medicine segment. As of June 30, 2020, we have expanded the number of MACI sales representatives to 76 to enable the sales force to call on 2,000 of the general orthopedic surgeons. Amid the COVID-19 outbreak, the sales representatives and clinical support specialists are adapting their practices to support physician education initiatives using virtual tools in regions where executive orders or hospital restrictions preclude their physical presence. MACI sales and clinical representatives are continuing to provide on-site assistance for MACI surgical procedures, so long at the representative's presence is in accordance with governmental orders and the policies and procedures of the relevant hospital or surgical center. Most private payers have a

medical policy that covers treatment with MACI with the top 30 largest commercial payers having a formal medical policy for MACI or ACI in general. Even for private payers which have not yet approved a medical policy for MACI, for medically appropriate cases, we often obtain approval on a case-by-case basis. For the three and six months ended, June 30, 2020, net revenues for MACI were $15.1 million and $35.4 million, respectively, and $20.8 million and $37.4 million, respectively, for the same periods in 2019.

Epicel

Epicel is a permanent skin replacement for deep dermal or full thickness burns greater than or equal to 30% of total body surface area (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 cultured epidermal autograft product available for large total surface area burns. Epicel was designated as a Humanitarian Use Device (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 so 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. 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. Because of 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 ten-person field force comprised of 7 sales representatives and 3 clinical support specialists which is adapting its practices to support physician education initiatives using virtual tools in regions where executive orders or hospital restrictions preclude their physical presence. Epicel sales and clinical representatives are continuing to provide on-site assistance for Epicel surgical procedures, so long at the representative's presence is in accordance with governmental orders and the policies and procedures of the relevant hospital or surgical center. For the three and six months ended June 30, 2020, net revenues for Epicel were $4.9 million and $11.3 million, respectively and $5.3 million and $10.6 million, respectively, for the same periods in 2019.

NexoBrid

Our preapproval stage portfolio includes NexoBrid, 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 North America, and on June 30, 2020, we announced the submission of a BLA to the FDA seeking the approval of NexoBrid. NexoBrid is approved in the European Union and other international markets and has been designated as an orphan biologic in the United States, European Union and other international markets. Pursuant to the terms of our existing license agreement, MediWound will continue to conduct all clinical activities described in the development plan to support the BLA with the FDA under the supervision of a Central Steering Committee comprised of members of each party.

Ixmyelocel-T

Our preapproval stage portfolio also 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.

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 and six months ended June 30, 2020 totaled $8.3 million and $13.0 million, respectively, and $19.8 million and $22.6 million, respectively, for the same periods in 2019.

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2020**	**2019**	**2020**	**2019**
Net revenues	$ 20,014	$ 26,151	$ 46,692	$ 47,961
Cost of product sales	8,660	9,022	18,582	17,662
Gross profit	11,354	17,129	28,110	30,299
Total operating expenses	19,712	37,329	41,544	53,857
Loss from operations	(8,358)	(20,200)	(13,434)	(23,558)
Other income	89	408	460	922
Net loss	$ (8,269)	$ (19,792)	$ (12,974)	$ (22,636)

Net Revenues

Net revenues decreased for the three and six months ended June 30, 2020 compared to the same periods in 2019 primarily due to the effects of the COVID-19 pandemic. Beginning in mid-March 2020, the Company experienced a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders. Due to state and local restrictions on elective surgery the majority of US surgical capacity was unavailable during April 2020 with some recovery occurring in May in certain geographies. The decrease in MACI volume largely tracked with the available surgical capacity across the country in April and May. By June, the restrictions on elective surgeries had been eased across most states but capacity still lagged pre-COVID levels due to new procedures in place at hospitals such as testing patients before treatment and increased cleaning time between patient treatments.

Net revenues for the three and six months ended June 30, 2020 and 2019 are shown below.

	Three Months Ended June 30,		Six Months Ended June 30,	
Revenue by product (In thousands)	**2020**	**2019**	**2020**	**2019**
MACI	$ 15,104	$ 20,823	$ 35,391	$ 37,406
Epicel	4,910	5,328	11,301	10,555
	$ 20,014	$ 26,151	$ 46,692	$ 47,961

Seasonality. Over the last four years ACI sales volumes from the first through the fourth quarter have on average represented 19% (16%-24% range), 23% (21%-25% range), 22% (20%-23% range) and 36% (32%-38% range) respectively, of total annual volumes. MACI orders are consistently stronger in the fourth quarter due to several factors including insurance deductible limits and the time of year patients prefer to start rehabilitation. However, given the disruption due to COVID-19 related elective surgery restrictions seasonality patterns in 2020 are not expected to follow historical trends. Due to the low incidence and sporadic nature of severe burns, Epicel revenue has inherent variability from quarter to quarter and does not exhibit significant seasonality. Over the past four years, Epicel revenue in a single quarter has ranged from as high as 34% to as low as 17% of annual revenue.

Gross Profit and Gross Profit Ratio

(In thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Gross profit	$ 11,354	$ 17,129	$ 28,110	$ 30,299
Gross profit %	57 %	66 %	60 %	63 %

Gross profit decreased for the three and six months ended June 30, 2020 compared to the same period in 2019 primarily due to the decrease in revenue caused by the COVID-19 pandemic.

Research and Development Costs

(In thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Research and development costs	$ 3,226	$ 21,070	$ 6,989	$ 24,078

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

(In thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
ACI	$ 1,657	$ 2,231	$ 3,753	4,390
Epicel	686	1,091	1,713	1,937
Nexobrid	876	17,748	1,507	17,748
Other	7	—	16	3
Total research and development costs	$ 3,226	$ 21,070	$ 6,989	$ 24,078

Research and development expenses for the three months ended June 30, 2020 were $3.2 million compared to $21.1 million for the same period in 2019. The prior period included $17.5 million for the upfront payment to MediWound for the North American rights to NexoBrid.

Research and development expenses for the six months ended June 30, 2020 were $7.0 million compared to $24.1 million for the same period in 2019. The prior period included $17.5 million for the upfront payment to MediWound for the North American rights to NexoBrid.

Selling, General and Administrative Costs

(In thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Selling, general and administrative costs	$ 16,486	$ 16,259	$ 34,555	$ 29,779

Selling, general and administrative expenses for the three months ended June 30, 2020 were $16.5 million compared to $16.3 million for the same period in 2019. The increase in selling, general and administrative expenses during the three months ended June 30, 2020 is due primarily to an incremental $0.9 million in MACI sales force expenses due to the sales force expansion in the second quarter of 2020 and $0.7 million of additional stock compensation expenses, which were largely offset by a reduction in variable and discretionary spend as a result of the COVID-19 pandemic.

Selling, general and administrative expenses for the six months ended June 30, 2020 increased to $34.6 million from $29.8 million for the same period in 2019. The increase in selling, general and administrative expenses during the six months ended June 30, 2020 is due primarily to an incremental $1.6 million in MACI sales force expenses driven by the sales force expansion in the second quarter of 2020 and the full quarter impact of hires made in the second quarter of 2019, $1.6 million of additional stock compensation expense and $0.6 million of incremental reimbursement support costs.

Other Income (Expense)

(In thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Net interest income	$ 146	$ 426	$ 450	$ 904
Other income (expense)	(57)	(18)	10	18
Total other income (expense)	$ 89	$ 408	$ 460	$ 922

The decrease in interest income for the three and six months ended June 30, 2020 compared to the same period in 2019 is due primarily to a decrease in interest income as a result of lowering our investment balance and decreasing rates of returns on our investments in various marketable debt securities compared to the prior period.

Stock Compensation

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

(in thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Cost of goods sold	$ 568	$ 716	$ 997	$ 976
Research and development	484	886	$ 1,060	1,410
Selling, general and administrative	3,325	2,581	$ 6,087	4,424
Total non-cash stock-based compensation expense	$ 4,377	$ 4,183	$ 8,144	$ 6,810

The increase in stock-based compensation expense for the three and six months ended June 30, 2020 is due primarily to fluctuations in stock prices which impacts the fair value of the options and restricted stock units awarded and the expense recognized in the period.

Liquidity and Capital Resources

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 to market and commercialize our products. To date, we have financed our operations primarily through cash received through Epicel and MACI sales and public and private sales of our equity securities.

Our cash and cash equivalents totaled $55.7 million and short-term investments totaled $25.1 million as of June 30, 2020. The $1.7 million of cash provided by operations during the six months ended June 30, 2020 was the result of cash collections and a decrease in accounts receivable of $8.5 million from a decrease in sales volume from prior quarter and collections on prior period sales, including noncash charges of $8.1 million in stock compensation expense and $1.1 million in depreciation and amortization expense offset by a $13.0 million net loss.

Our cash and cash equivalents totaled $14.0 million and short term investments totaled $52.0 million at June 30, 2019. The $18.2 million of cash used by operations during the six months ended June 30, 2020 was largely the result of our net loss of $22.6 million which included a cash outflow of $17.5 million for the upfront payment for the NexoBrid License. The net loss was offset by noncash charges including $6.8 million in stock compensation expense, and $0.7 million in depreciation and amortization expense.

The change in cash provided by investing activities during the six months ended June 30, 2020 is the result of $32.8 million of investment maturities offset by $5.7 million in short term investment purchases and property plant and equipment purchases of $1.2 million primarily for manufacturing upgrades through June 30, 2020. The cash provided by investing activities for the six months ended June 30, 2019 is the result of $32.4 million in short term investments purchases offset by $45.5 million of maturities and property plant and equipment purchases of $1.2 million primarily for manufacturing upgrades and leasehold improvements.

The change in cash provided from financing activities is the result of net proceeds from the exercise of stock options of $1.4 million, slightly offset by the payment of employee withholding taxes related to the vesting of restricted stock units of $0.2 million during the six months ended June 30, 2020. The change in cash provided from financing activities is the result of proceeds from the exercise of stock options of $2.1 million during the six months ended June 30, 2019.

We believe that, based on our current cash on hand, cash equivalents and investments will be sufficient to support our current operations through at least 12 months from the issuance of these financial statements. However, the continuing effects of the COVID-19 pandemic may require us to engage in layoffs, furloughs, and/or reductions in salary, all of which may result in irrecoverable losses of customers and significantly impact long-term liquidity. We have implemented a number of initiatives to maintain our near-term and future growth opportunities while supporting patients and reducing non-essential discretionary spending.

If elective surgery restrictions are reinstated, we may need to access additional capital; however, we may not be able to obtain financing on acceptable terms or at all. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access financing as and when needed. 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 ultimate duration of the effects of the COVID-19 pandemic, 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 June 30, 2020, 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, filed with the SEC on February 25, 2020 (Annual Report), for the fiscal year ended December 31, 2019 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, 2020.

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,” “target,” “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;
- submission of a BLA for NexoBrid to the FDA;
- product development and marketing plans;
- features and successes of our therapies;
- clinical trial plans, including publication thereof;
- the effects of the COVID-19 pandemic on our business, including economic slowdowns or recessions, impact to our operations or to the healthcare industry generally, which could reduce demand for our products;
- 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, 2020, we held marketable debt securities, which are classified as available-for-sale and carried at fair value in the accompanying consolidated balance sheet included in this Form 10-Q. The fair value of our cash equivalents and marketable securities is subject to changes in market interest rates. Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable debt securities. We do not believe we are materially exposed to changes in interest rates related to our investments, and we do not currently use interest rate derivative instruments or hedging transactions to manage exposure to interest rate changes of our investments. We estimate that a 100 basis point, or 1%, unfavorable change in interest rates would have resulted in approximately a $0.1 million and $0.3 million decrease in the fair value of our investment portfolio as of June 30, 2020 and December 31, 2019, respectively.

We have evaluated the potential credit risk exposure for our accounts receivable and available-for sale investment securities in accordance with *ASC 326, Financial Instruments - Credit Losses.* See note 4 and note 8, for further discussion.

We operate in the United States only. We are primarily exposed to foreign exchange risk with respect to recognized assets and liabilities due to vendors in countries outside the United States which are typically paid in Euro. We do not enter into hedging transactions and do not purchase derivative instruments.

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

Evaluation of Disclosure Controls and Procedures

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, 2020, the Company’s certifying officers concluded that the Company’s disclosure controls and procedures were effective.

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 Securities and Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the Commission’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.

Changes in Internal Control over Financial Reporting

During the three months ended June 30, 2020, there were no material changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). The effects of the COVID-19 pandemic did not have a material impact on our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. ***Legal Proceedings***

We are currently not party to any material legal proceedings, although from time to time we may become involved in disputes in connection with the operation of our business.

Item 1A. ***Risk Factors***

Certain risks described below update the risk factors discussed in Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and expound upon and amend the specific risks resulting from the COVID-19 pandemic, which were first discussed by the Company in its Form 8-K filed on April 2, 2020, and which were updated in its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020. Each of these risks, as well as those discussed in our previous filings could materially affect our business, financial condition, results of operations, or cash flows. The risks described below and in our previous filings are not the only risks we face. Additional risks and uncertainties not currently known or currently deemed to be immaterial also may materially and adversely affect our business, financial condition, results of operations or cash flows.

The current pandemic of COVID-19 and the future outbreak of other highly infectious or contagious diseases, could seriously harm our research, development and commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research, development and commercialization activities. For example, in December 2019, an outbreak of a novel strain of coronavirus originated in Wuhan, China, and has since spread globally. To date, the COVID-19 pandemic has caused significant disruptions to the U.S. and global economy and has contributed to significant volatility in financial markets. The global impact of the outbreak is continually evolving and, as the virus spreads and additional cases are identified, many countries, including the U.S., have reacted by instituting quarantines, restrictions on travel and mandatory closures of businesses. Since March 2020, certain states and cities, including where we or the third parties with whom we engage operate, have reacted by instituting quarantines, restrictions on travel, "shelter in place" rules, restrictions on types of business that may continue to operate, and/or restrictions on the types of construction projects that may continue. For example, on March 23, 2020, the Governor of Massachusetts ordered all individuals living in the Commonwealth of Massachusetts to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID-19 pandemic. The Governor of Michigan issued a substantially similar executive order applicable to Michigan residents on March 23, 2020. In both instances, the executive orders exempted certain individuals needed to maintain continuity of operations of critical infrastructure sectors as determined by the federal government, and the governors of both Massachusetts and Michigan have clarified that biopharmaceutical research and development is essential and exempt. Since March, the steps taken by many state and local officials have helped to slow the spread of the virus in certain regions of the United States. As a result, some states – including Massachusetts and Michigan – have instituted plans to ease the restrictions on workplaces and individuals in an effort to reopen the economies of those regions. On May 18, 2020, the governor of Massachusetts issued an order and report outlining the phased reopening of physical workplaces. Similarly, on May 18, 2020, the State of Michigan issued Executive Orders 2020-91 and 2020-92 allowing the re-opening of some businesses that had been formerly ordered to be closed. Both state orders require businesses to implement mandatory training and protection measures for their employees who continue to work in the office setting.

In March 2020, we put in place a comprehensive workplace protection plan, which institutes protective measures in response to the COVID-19 pandemic. These measures include mandatory employee training on social distancing and hygiene protocols, conducting daily health screenings of all employees, vendors and visitors entering our facilities, canceling of all commercial international travel, requesting that employees limit non-essential personal travel, enhancing our facilities' janitorial and sanitary procedures, making certain physical modifications and enhancements to our facilities to enable effective social distancing among employees, providing certain personal protective equipment to employees working in our offices, encouraging employees to work from home to the extent their job function enables them to do so, limiting third-party access to our facilities, encouraging the use of virtual employee meetings, modifying the manner and schedule of on-site production activities, and providing guidance to our field-based commercial teams concerning their communications and contact with customers and healthcare professionals. We are reviewing these measures regularly as the situation evolves, and we are likely to take additional actions as we learn more and as instruction is provided by national, state and local governmental agencies. Both these existing measures and any future actions we take may result in continued disruption to our business.

The extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious disease, impacts our preclinical studies, clinical trial operations and current or future commercialization efforts will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The rapid development and fluidity of this situation precludes any prediction as to the full adverse impact of the COVID-19 pandemic. Nevertheless, the COVID-19 pandemic may adversely affect our business, financial condition and results of operations, and it may have the effect of heightening many of the risks described herein, including the below.

- The implantation of MACI is an elective surgical procedure. On March 13, 2020 and March 14, 2020, the American College of Surgeons and United States Surgeon General, respectively, recommended that each hospital, health system, and surgeon minimize, postpone, or cancel electively scheduled surgeries, which resulted in a reduction in MACI sales. The stated purpose for these recommendations was that every elective surgery could spread COVID-19 within a facility, use up personal protective equipment (PPE) which may be needed by healthcare workers treating COVID-19 patients, and burden hospital workforce who may be needed to respond to COVID-19. These recommendations were followed by numerous state-level executive orders either banning or partially banning elective surgeries. By April 3, 2020, 31 U.S. states had issued executive mandates calling for the suspension of elective or non-essential surgeries.

- As a result of these restrictions, beginning in mid-March 2020, the Company started to experience a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders. Those cancellations negatively impacted the Company's results of operations for the first and second quarters of 2020. Continued and prolonged material disruption of the Company's employees, distributors, suppliers or customers will impact its sales and operating results that could lead to potential impairments to inventory and accounts receivable. As the number of COVID-19 cases began to decrease in certain parts of the United States, many states began easing their respective moratoriums on elective surgeries, however, the recent resurgence of the virus in certain parts of the country have led to the re-imposition of elective surgical procedure restrictions including Florida, California, Mississippi, Tennessee, Arizona and Texas. The Company's MACI business will continue to be negatively impacted as long as multiple state orders remain in effect restricting elective surgical procedures. We believe Epicel may be less directly impacted by the pandemic given the critical nature of severe burn injuries, however trauma injury admissions have been reported to be reduced due to the various COVID-19 related restrictions. Given the rare nature of the severe burns Epicel treats, it is difficult to ascertain whether a similar decline is occurring with severe burns.

- We are currently conducting the PEAK (A Study of MACI in Patients Aged 10 to 17 Years with Symptomatic Chondral or Osteochondral Defects of the Knee) Study at ten (10) sites throughout the United States. Although it is premature to draw any conclusions at this time, given the reduction of elective surgical procedures as a result of COVID-19, the Company anticipates a decreased rate of patient enrollment to the PEAK Study. Additionally, the PEAK Study or another of our clinical trials may experience difficulties associated with patient visits and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including closure of site access to outside medical monitors, quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials, interruption or delays in the operations of the FDA, heightened exposure of patients, principal investigators and site staff to COVID-19 if an outbreak occurs in their geography, or other reasons related to the COVID-19 pandemic. Further, patients who are already recruited into our clinical trials may be unable or unwilling to attend follow-up visits within the timelines specified in our trial protocols, potentially impacting our ability to meet our clinical trial endpoints. An outbreak may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out our clinical trials.

- We continue to manufacture MACI and Epicel and we maintain a significant safety back-up of all key raw materials. We do not expect current supply chain interruptions will impact the Company's ongoing manufacturing operations. However, we currently rely on third parties to, among other things, manufacture and supply raw materials, which are used to produce our products, and supply other goods and services to run our business. If any such third parties in our supply chain are adversely impacted by current or future restrictions resulting from the COVID-19 pandemic for an extended period of time, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture our products and product candidates and conduct our research and development operations, or for potential commercial launch of any of our product candidates, if approved. With respect to customer delivery, MACI final product has an established shelf life of 6 days and established shipping shelf life of 3 days. Currently, MACI is picked-up by courier and shipped by commercial air or

ground transportation to our customers' locations. Epicel final product has an established shelf life of 24 hours and is hand carried to customer hospital sites by courier. Transportation is primarily commercial or charter airline. Although we have not experienced material shipping delays or increased costs to date, significant disruption of air travel could result in the inability to deliver MACI or Epicel final products to customer sites within appropriate timeframes, which would have a material adverse effect on our business and results of operations.

- We have closed much of our office space and requested that most of our personnel, including the majority of our administrative employees, work remotely. Our continued reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. We continue to manufacture MACI and Epicel but have largely restricted on-site staff to only those personnel and contractors who must perform essential activities related to the manufacture, production and delivery of our products. However, the continued spread or resurgence of COVID-19 or similar infectious diseases in the U.S. may lead to further government-imposed quarantines and restrictions, which may result in the closure of our administrative offices, with our employees working outside of our offices for an extended period of time. These actions may also result in the disruption of our manufacturing operations, which are currently accomplished within our administrative offices. Additionally, such quarantines and restrictions may adversely affect our ability to conduct certain product enhancement and business development activities.

- Our continued reliance on personnel working from home may also increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, institutional review boards and ethics committees, third party contractors and suppliers, clinical trial sites and other important agencies and contractors. Our business operations may be further disrupted if any of our employees, officers or board of directors contract an illness related to COVID-19 and are unable to perform their duties. For example, COVID-19 illness could impact members of management or our board of directors resulting in absenteeism from management meetings or meetings of the directors or committees of directors, and making it more difficult for management to effectively oversee our daily operations, or to convene the quorums of the full board of directors or its committees needed to conduct meetings for the management of our affairs.

- A spread or resurgence of the COVID-19 virus, may cause our employees, and employees of third-party contractors and licensees, including MediWound, responsible for conducting research and development activities to be unable to access laboratories and places of business for an extended period of time as a result of the temporary closure of such workspaces and the possibility that governmental authorities further modify current restrictions. As a result, this could delay timely completion of ongoing clinical trials or preclinical activities, and our ability to select future development candidates.

- NexoBrid is currently a pre-commercial product in North America. On June 30, 2020, the Company announced that it submitted a BLA to the FDA seeking marketing approval for Nexobrid in the United States. However, health regulatory agencies globally, including the FDA, may experience disruptions in their operations as a result of the continued spread of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials or consider our regulatory submissions and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development, study and ultimate commercialization of our product candidates.

- The trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the continued spread or resurgence of the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

- Given the economic downturn and increased unemployment in the U.S. related to COVID-19, millions of individuals have lost and may lose their employer-based insurance coverage, which may adversely affect our ability to commercialize our products. In addition, market disruption and rising unemployment caused by the COVID-19 pandemic may lead to delays in obtaining insurance coverage and reimbursement of newly approved products as well as an increase in the numbers of uninsured patients and patients who may no longer be able to afford their co-insurance or co-pay obligations. These factors may lead to decreased utilization of our products, which could reduce revenue. The outbreak of COVID-19 may also negatively impact our commercialization strategy for our products and product

candidates, if approved. Hospitals and other medical institutions have reduced and diverted staffing, diverted resources to patients suffering COVID-19 and limited hospital access for non-patients, which may include our sales personnel. Hospitals may continue and increase these and similar measures in the future should the COVID-19 virus continue to spread or surge in certain areas. In addition, continued travel restrictions due to COVID-19 could impact the ability of our sales personnel to travel to customers. We have encouraged our sales personnel to conduct many of their interactions with physicians and patients through the use of webinars, telemedicine, direct-to-consumer advertising and social media. These circumstances may adversely affect the ability of our sales professionals to effectively market our products to physicians in the future, which may have a negative impact on our potential sales and our market penetration.

If any of these risks related to the impact of the COVID-19 pandemic were to occur, our preclinical activities, clinical development progress, data and timelines, commercialization efforts including any potential revenue from sales, supply chain continuity, and general business operations, could be delayed and/or materially harmed and our business, prospects, financial condition, and results of operations would suffer as a result. The extent to which the current pandemic, or a future pandemic, impacts our business and operations will depend on future developments, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and governmental actions to contain the outbreak or treat its impact, which are highly uncertain and cannot be predicted with confidence.

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

Not applicable.

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

Exhibit No.	Description
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**	Inline XBRL Instance Document
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

** 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: August 5, 2020

VERICEL CORPORATION

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo

President and Chief Executive Officer

(Principal Executive Officer)

/s/ GERARD MICHEL

Gerard Michel

Chief Financial Officer and Vice President, Corporate Development

(Principal Financial Officer)

EXHIBIT 31.1

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: August 5, 2020

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo

President and Chief Executive Officer

(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Gerard J. 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(s) 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(s) 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 5, 2020

/s/ GERARD J. MICHEL

Gerard J. Michel

Chief Financial Officer and Vice President

of Corporate Development

(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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, 2020, 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 5, 2020

/s/ DOMINICK C. COLANGELO

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

A signed original of this written statement required by Section 906 has been provided to Vericel Corporation and will be retained by Vericel Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

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, 2020, 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 5, 2020

/s/ GERARD MICHEL

Gerard Michel

Chief Financial Officer and Vice President, Corporate Development

(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Vericel Corporation and will be retained by Vericel Corporation and furnished to the Securities and Exchange Commission or its staff upon request.