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: September 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 ☐

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 ☐

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. ☐

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 October 30, 2020, 45,428,794 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)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,507	$ 26,889
Short-term investments	42,035	42,829
Accounts receivable (net of allowance for doubtful accounts of $187 and $306, respectively)	26,174	32,168
Inventory	10,080	6,816
Other current assets	3,586	2,953
Total current assets	125,382	111,655
Property and equipment, net	7,115	7,144
Restricted cash	211	89
Right-of-use leased assets	24,796	25,103
Long-term investments	—	9,247
Total assets	$ 157,504	$ 153,238
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,475	$ 6,345
Accrued expenses	8,695	7,948
Current portion of operating lease liabilities	6,102	5,461
Other liabilities	41	41
Total current liabilities	21,313	19,795
Operating lease liabilities	21,487	22,242
Other long-term liabilities	74	110
Total liabilities	$ 42,874	$ 42,147
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 45,315 and 44,864, respectively	$ 502,587	$ 489,749
Other comprehensive gain	78	21
Accumulated deficit	(388,035)	(378,679)
Total shareholders' equity	114,630	111,091
Total liabilities and shareholders' equity	$ 157,504	$ 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Product sales, net	$ 31,020	$ 30,499	$ 77,712	$ 78,460
Other revenue	1,238	—	1,238	—
Total revenue	32,258	30,499	78,950	78,460
Cost of product sales	9,787	9,324	28,369	26,986
Gross profit	22,471	21,175	50,581	51,474
Research and development	2,913	3,096	9,902	27,174
Selling, general and administrative	16,041	14,982	50,596	44,761
Total operating expenses	18,954	18,078	60,498	71,935
Income (loss) from operations	3,517	3,097	(9,917)	(20,461)
Other income (expense):				
Interest income	121	385	574	1,293
Interest expense	(2)	(2)	(5)	(6)
Other income (expense)	(18)	(10)	(8)	8
Total other income	101	373	561	1,295
Net income (loss)	$ 3,618	$ 3,470	$ (9,356)	$ (19,166)
Net income (loss) per share attributable to common shareholders (Basic)	$ 0.08	$ 0.08	$ (0.21)	$ (0.44)
Weighted average number of common shares outstanding (Basic)	45,272	44,251	45,112	43,979
Net income (loss) per share attributable to common shareholders (Diluted)	$ 0.08	$ 0.07	$ (0.21)	$ (0.44)
Weighted average number of common shares outstanding (Diluted)	47,314	46,667	45,112	43,979

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ 3,618	$ 3,470	$ (9,356)	$ (19,166)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	(68)	(9)	57	29
Comprehensive income (loss)	$ 3,550	$ 3,461	$ (9,299)	$ (19,137)

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
Net income	—	—	—	—	3,618	3,618
Compensation expense related to stock options and restricted stock units granted, net of forfeitures	—	2,675	—	—	—	2,675
Stock option exercises	77	500	—	—	—	500
Shares issued under the Employee Stock Purchase Plan	44	309	—	—	—	309
Unrealized loss on investments	—	—	—	(68)	—	(68)
BALANCE, SEPTEMBER 30, 2020	45,315	$ 502,587	$ —	$ 78	$ (388,035)	$ 114,630

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

	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
Net income	—	—	—	—	3,470	3,470
Compensation expense related to stock options and restricted stock units granted, net of forfeitures	—	3,285	—	—	—	3,285
Stock option exercises	416	1,427	—	—	—	1,427
Shares issued under the Employee Stock Purchase Plan	18	275	—	—	—	275
Unrealized loss on investments	—	—	—	(9)	—	(9)
Exercise of warrants resulting in issuance of common stock	20	104	(104)	—	—	—
BALANCE, SEPTEMBER 30, 2019	44,520	$ 485,141	$ —	$ 29	$ (388,180)	$ 96,990

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

	Nine Months Ended September 30,	
	2020	2019
Operating activities:		
Net loss	$ (9,356)	$ (19,166)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation and amortization expense	1,649	1,174
Stock compensation expense	10,819	10,095
Foreign currency translation loss	59	21
Loss on sale of fixed assets	30	—
Amortization of premiums and discounts on marketable securities	24	(529)
Amortization and interest accretion related to operating leases	3,312	2,011
Changes in operating assets and liabilities:		
Inventory	(3,264)	(3,265)
Accounts receivable	5,994	3,496
Other current assets	(633)	(425)
Accounts payable	(52)	(1,895)
Accrued expenses	747	30
Operating lease liabilities	(3,110)	(1,804)
Other non-current assets and liabilities, net	16	(76)
Net cash provided by (used for) operating activities	6,235	(10,333)
Investing activities:		
Purchases of short-term investments	(29,049)	(46,303)
Maturities of short-term investments	39,123	73,777
Expenditures for property, plant and equipment	(1,556)	(2,255)
Net cash provided by investing activities	8,518	25,219
Financing activities:		
Net proceeds from common stock issuance due to stock option exercises	2,182	3,762
Payments on employee's behalf for taxes related to vesting of restricted stock unit awards	(163)	—
Other	(32)	(29)
Net cash provided by financing activities	1,987	3,733
Net increase in cash, cash equivalents, and restricted cash	16,740	18,619
Cash, cash equivalents, and restricted cash at beginning of period	26,978	18,286
Cash, cash equivalents, and restricted cash at end of period	$ 43,718	$ 36,905

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 therapies for the sports medicine and severe burn care markets. Vericel currently markets two cell therapy products in the United States, MACI® and Epicel®. Vericel obtained both products in May 2014, as part of the acquisition of certain assets and the assumption of certain liabilities of 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. Epicel® (cultured epidermal autografts) is a permanent skin replacement 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 also holds an exclusive license from MediWound Ltd. (MediWound) for North American rights to NexoBrid®, a registration-stage biological orphan product for debridement of severe thermal burns. 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 pandemic caused by the spread of a novel strain of coronavirus (COVID-19) has created significant volatility, uncertainty, and economic disruption in both domestic and international markets. The virus was first reported in China 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 immediately thereafter. Following the President's declaration, state governments, including those in Massachusetts and Michigan where the Company's operations are located, began issuing orders requiring businesses that do not conduct essential services to temporarily close their physical workplaces to employees and customers. The status and application of those orders have varied on a state-by-state basis. Because Vericel is deemed an essential business, the Company continues to be exempt from such state orders in their current forms.

Notwithstanding being an essential business, the Company's business and operations have been adversely impacted by the effects of COVID-19. In mid-March, the American College of Surgeons and United States Surgeon General recommended that each hospital, health system, and surgeon minimize, postpone, or cancel electively scheduled surgeries. These recommendations were followed by numerous state level executive orders either restricting or partially restricting elective surgeries. Because MACI is an elective surgical procedure, as a result of these restrictions, beginning in mid-March 2020, the Company began 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. The widespread suspension of elective procedures impacted the Company's business and operations during the first and second quarters of 2020. These restrictions began to ease in May and, by the end of September 2020, there were no state orders in place that directly impacted a surgeon's or patient's ability to move forward with a MACI surgery. Because Epicel is used almost exclusively in the emergent setting by burn centers and surgeons throughout the country, Epicel revenue and procedure volumes have been less affected by the pandemic. Although hospitals are now better prepared for a subsequent surge in COVID-19 patients, the risk remains that regional or local restrictions could again be placed on the performance of elective surgical procedures if the number of COVID-19 infections in the United States continues to rise.

In March 2020, the Company put in place a comprehensive workplace protection plan, which institutes protective measures in response to COVID-19. 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 all international business travel, limiting domestic business travel to essential purposes, 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. The Company is reviewing these measures regularly as the pandemic evolves and may take additional actions to the extent required.

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. For the three and nine months ended September 30, 2020, the Company had net income of $3.6 million and a net loss of $9.4 million, respectively, and had an accumulated deficit of $388.0 million as of September 30, 2020. The Company had cash and cash equivalents of $43.5 million and investments of $42.0 million as of September 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 effects of the COVID-19 pandemic continue to evolve and may result in irrecoverable losses of customers and significantly impact long-term liquidity requiring the Company to engage in layoffs, furloughs and/or reductions in salaries. To the extent the United States experiences a resurgence in COVID-19 infections and elective surgery restrictions are reinstated on a widespread basis and significantly impact 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 September 30, 2020 and for the three and nine months ended September 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 U.S. generally accepted accounting principles (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 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 September 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 nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,	
(In thousands)	**2020**	**2019**
Supplementary Cash Flows information:		
Non-cash information:		
Right-of-use asset and lease liability recognized	$ 3,140	$ 2,338
Additions to property, plant and equipment included in accounts payable	340	46
Warrants exercised for common stock	—	104
Cash information:		
Interest paid (net of interest capitalized)	$ 5	$ 6

Total cash, cash equivalents, and restricted cash of $43.7 million as of September 30, 2020, shown in the statement of cash flows is comprised of cash and cash equivalents of $43.5 million and restricted cash of $0.2 million which is included in other long-term assets on the consolidated balance sheet. As of September 30, 2019, cash and cash equivalents were $36.9 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 were recognized when it was probable that the loss had 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 created a more consistent disclosure framework that increased clarity and removed, modified and added 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 on 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 on its condensed consolidated financial statements.

4. Revenue

Revenue Recognition of Net Product Sales and Other Revenue

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

Product Sales

MACI Biopsy Kits

MACI biopsy kits are sold directly to hospitals based on contracted rates in an 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 is used by the doctor to provide a sample of cartilage tissue to the Company, which can later be used to manufacture a MACI implant. The ordering of the kit does not obligate the Company to manufacture an implant nor does the receipt of the cartilage tissue. The customer's order of an implant is separate from the process of ordering the biopsy kit. Therefore, the sale of the biopsy 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 MACI in a manner in which 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 collect 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 patients. The sales directly to DMS are made 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 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 estimated 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 estimates expected collections for these transactions using the portfolio approach. 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 September 30, 2020. The total allowance for uncollectible consideration as of September 30, 2020 and December 31, 2019 was $4.6 million and $3.9 million, respectively. The allowance includes less than $0.1 million 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% increase to the estimated uncollectible percentage could result in approximately a $0.2 million decrease in the revenue recognized for the nine months ended September 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 nine months ended September 30, 2020 resulted in an increase to revenue of less than $0.01 million and $0.7 million, respectively. During the same periods in 2019, the changes in estimates related to prior period sales resulted in an increase to revenue of $0.7 million and $0.4 million, respectively. The changes in estimates recorded during the three and nine months ended September 30, 2020, were primarily due to completion of the billing claims process for implants that occurred in 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 an approved contract or purchase order. Similar to MACI, there is no obligation to manufacture Epicel 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 Epicel grafts and the claim is billable to the hospital.

Other Revenue

NexoBrid

The Company entered into exclusive license and supply agreements with MediWound, under which MediWound will manufacture and supply NexoBrid on a unit price basis, which may be increased pursuant to the terms of the agreement. The U.S. Biomedical Advanced Research and Development Authority (BARDA) has committed to procure NexoBrid. As of September 30, 2020, the Company does not hold a direct contract or distribution agreement with BARDA, or take title to the product. The Company recognizes income from sales of NexoBrid to BARDA upon delivery, at which time BARDA is in control of the product. During the three months ended September 30, 2020, the first order of NexoBrid was delivered and the Company recognized $1.2 million of revenue. See note 11 for further discussion of the NexoBrid license and supply agreements.

Revenue by Product and Customer

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

Revenue by product (in thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
MACI implants and kits				
Implants based on contracted rate sold through a specialty pharmacy (a)	$ 14,897	$ 11,779	$ 36,084	$ 34,555
Implants subject to third party reimbursement sold through a specialty pharmacy (b)	3,529	4,030	10,299	10,584
Implants sold direct based on contracted rates (c)	4,602	3,039	9,528	9,715
Implants sold direct subject to third party reimbursement (d)	782	573	1,793	1,176
Biopsy kits - direct bill	539	533	1,348	1,632
Change in estimates related to prior periods (e)	8	656	695	353
Epicel				
Direct bill (hospital)	6,663	9,889	17,965	20,445
Total product revenue	$ 31,020	$ 30,499	$ 77,712	$ 78,460
Other revenue (f)	1,238	—	1,238	—
Total net revenue	$ 32,258	$ 30,499	$ 78,950	$ 78,460

(a) Represents implants sold through Orsini and AllCare in both 2020 and 2019 whereby such specialty pharmacies have 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.

(b) Represents implants sold through Orsini or AllCare whereby 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. Also represents direct sales under a contract to the specialty distributor DMS.

(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.

(f) Represents income from sales of NexoBrid to BARDA, pursuant to the license agreement between the Company and MediWound.

Concentration of Credit Risk

The Company's total Epicel revenue concentration from a customer for the three months ended September 30, 2019 was 10%. For the Company's total Epicel and MACI revenue and accounts receivable balances there were no other customers for the three and nine months ended September 30, 2020, and for the nine months ended September 30, 2019, with a concentration greater than 10%.

5. Selected Balance Sheet Components

Inventory

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

(In thousands)	September 30, 2020	December 31, 2019
Raw materials	$ 9,265	$ 6,085
Work-in-process	771	541
Finished goods	44	190
Inventory	$ 10,080	$ 6,816

Property and Equipment

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

(In thousands)	September 30, 2020	December 31, 2019
Machinery and equipment	$ 3,683	$ 3,152
Furniture, fixtures and office equipment	810	775
Computer equipment and software	6,585	6,174
Leasehold improvements	5,436	5,256
Construction in process	1,190	859
Financing right-of-use lease	120	148
Total property and equipment, gross	17,824	16,364
Less accumulated depreciation	(10,709)	(9,220)
Property and equipment, net	$ 7,115	$ 7,144

Depreciation expense for the three and nine months ended September 30, 2020 was $0.6 million and $1.6 million, respectively, and $0.4 million and $1.2 million for the same periods in 2019.

Accrued Expenses

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

(In thousands)	September 30, 2020	December 31, 2019
Bonus related compensation	$ 4,291	$ 5,116
Employee related accruals	2,674	1,785
Other accrued expenses	1,730	1,047
Accrued expenses	$ 8,695	$ 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 facilities include 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. Effective October 21, 2020 the Company entered into an agreement for one of its Cambridge, Massachusetts facility leases. This agreement extended the terms of the lease to expire on February 29, 2032, with monthly contractual lease payments ranging from $0.4 million to $0.6 million.

Leases with an initial term of 12 months or less are not recorded on the balance sheet and for both the three and nine months ended September 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 nine months ended September 30, 2020, the Company recognized $1.6 million and $4.5 million of operating lease expense and $1.4 million and $4.0 million for the same periods in 2019.

For both the three and nine months ended September 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 classified on the balance sheet, as of September 30, 2020 and December 31, 2019 are as follows:

(In thousands)	Classification	September 30, 2020	December 31, 2019
Assets			
Operating	Right-of-use assets	$ 24,796	$ 25,103
Finance	Property and equipment, net	120	148
		$ 24,916	$ 25,251
Liabilities			
Current			
Operating	Current portion of operating lease liabilities	$ 6,102	$ 5,461
Finance	Other liabilities	41	41
		$ 6,143	$ 5,502
Non-current			
Operating	Operating lease liabilities	$ 21,487	$ 22,242
Finance	Other long-term liabilities	74	110
		$ 21,561	$ 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 granted to employees and non-employees under these plans expire no later than ten years from the date of grant. Options and restricted stock units generally become exercisable or vest 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. The Amended and Restated 2019 Plan increased the total number of shares of the Company's common stock reserved for issuance under the 2019 Plan by 2,400,000 shares, revised the ratio at which "full-value" awards are counted against the share reserve from 1.25 to 1.4, and extended the term of the plan to April 29, 2030.

As of September 30, 2020, there were 4,553,487 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 693,498 shares have been issued since the inception of the plan in 2015. Participation in this plan is available to substantially all employees. The ESPP is a compensatory plan accounted for under the expense recognition provisions of the share-based payment accounting standards. Compensation expense is recorded based on the fair market value of the options at the grant date, which corresponds to the first day of each purchase period and is amortized over the purchase period. In October 2020, employees purchased 20,591 shares resulting in proceeds from the sale of common stock of $0.3 million under the ESPP for the third quarter of 2020.

Service-Based Stock Options

During the three and nine months ended September 30, 2020, the Company granted service-based options to purchase common stock of 28,000 and 1,324,890, respectively, and 111,600 and 1,750,110, 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, and the options 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 nine months ended September 30, 2020 was $10.81 and $8.70, respectively and $13.28 and $12.77, respectively, for the same periods in 2019.

Restricted Stock Units

During the nine months ended September 30, 2020 and September 30, 2019, the Company granted 196,836 and 186,922 service-based restricted stock units, respectively. 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 nine months ended

September 30, 2020 was $11.41, and $17.71 for the same period in 2019. The aggregate fair value of restricted stock units granted in the nine months ended September 30, 2020 was $2.2 million, and $3.3 million for the same period in 2019.

During the nine months ended September 30, 2020, 32,840 shares of common stock were issued upon the vesting of restricted stock units. These amounts are net of 13,872 shares, that were withheld for payment of taxes on the behalf of employees, during the nine months ended September 30, 2020.

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 September 30,		Nine Months Ended September 30,	
(in thousands)	2020	2019	2020	2019
Cost of goods sold	$ 481	$ 543	$ 1,541	$ 1,519
Research and development	458	583	1,455	1,993
Selling, general and administrative	1,736	2,159	7,823	6,583
Total non-cash stock-based compensation expense	$ 2,675	$ 3,285	$ 10,819	$ 10,095

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 condensed 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 September 30, 2020 and December 31, 2019:

	September 30, 2020				
		Gross Unrealized			
	Amortized Cost	Gains	Losses	Credit Losses	Estimated Fair Value
Money market funds	$ 28,059	$ —	$ —	$ —	$ 28,059
Commercial paper	9,984	—	—	—	9,984
Corporate notes	11,161	25	—	—	11,186
U.S. government securities	13,764	40	—	—	13,804
U.S. government agency bonds	3,498	1	—	—	3,499
U.S. asset-backed securities	3,550	12	—	—	3,562
	$ 70,016	$ 78	$ —	$ —	$ 70,094
Classified as:					
Cash equivalents					$ 28,059
Short-term investments					42,035
					$ 70,094

	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 September 30, 2020 we held short-term investments and as of 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 September 30, 2020 and December 31, 2019, 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 nine months ended September 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 September 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 September 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 September 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, U.S. government agency bonds and U.S. 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:

	September 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	$ 28,059	$ 28,059	$ —	$ —	$ 5,381	$ 5,381	$ —	$ —
Commercial paper	9,984	—	9,984	—	11,892	—	11,892	—
Corporate notes	11,186	—	11,186	—	18,380	—	18,380	—
U.S. government securities	13,804	—	13,804	—	11,295	—	11,295	—
U.S. government agency bonds	3,499	—	3,499	—	—	—	—	—
U.S. asset-backed securities	3,562	—	3,562	—	10,509	—	10,509	—
	$ 70,094	$ 28,059	$ 42,035	$ —	$ 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 Income (Loss) Per Common Share

The following reflects the net income (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 September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Numerator:				
Net income (loss)	$ 3,618	$ 3,470	$ (9,356)	$ (19,166)
Denominator:				
Weighted-average common shares outstanding (basic)	45,272	44,251	45,112	43,979
Weighted-average common shares outstanding (diluted)	47,314	46,667	45,112	43,979
Net income (loss) per share attributable to common shareholders (basic)	$ 0.08	$ 0.08	$ (0.21)	$ (0.44)
Net income (loss) per share attributable to common shareholders (diluted)	$ 0.08	$ 0.07	$ (0.21)	$ (0.44)
Anti-dilutive shares excluded from the calculation of diluted earnings per share[(a)] (amounts in millions):				
Stock options	2.4	1.6	5.7	5.1
Restricted stock unit awards	—	—	0.3	0.2

(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 to commercialize NexoBrid and any improvements to NexoBrid in 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 Biologics License Application (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. On September 16, 2020, the Company announced that the FDA has accepted the BLA for review and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 29, 2021. 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 for 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, which is contingent 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. As of September 30, 2020, the milestone payments are not yet probable and therefore, not considered a liability. 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 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.

BARDA has committed to procure NexoBrid directly from MediWound under an emergency use authorization, and under such commitment the Company will receive a percentage of gross profit for sales directly to BARDA. If BARDA procures NexoBrid directly from Vericel, 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. As of September 30, 2020, the Company does not hold a direct contract or distribution agreement with BARDA. On August 25, 2020, BARDA accepted the first shipment of NexoBrid for emergency use preparedness per the agreement between BARDA and MediWound. As a result, the Company recognized $1.2 million of revenue during the three months ended September 30, 2020; see note 4 for further information.

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. 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. Epicel® (cultured epidermal autografts) is 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 also hold an exclusive license from MediWound Ltd. for North American rights to NexoBrid, a registration-stage biological orphan product for debridement of severe thermal burns.

COVID-19

The pandemic caused by the spread of a novel strain of coronavirus (COVID-19) has created volatility, uncertainty and economic disruption in both domestic and international markets. After the virus was first reported in China 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 immediately thereafter. Following the President's declaration, state governments, including those in Massachusetts and Michigan where our operations are located, began issuing orders requiring businesses that do not conduct essential services to temporarily close their physical workplaces to employees and customers. The status and application of those orders have varied on a state-by-state basis since the early days of the pandemic. Because Vericel is deemed an essential business, we continue to be exempt from such state orders in their current forms.

Notwithstanding being an essential business, Vericel's business and operations have been adversely impacted by the effects of COVID-19. In mid-March, the American College of Surgeons and United States Surgeon General recommended that each hospital, health system, and surgeon minimize, postpone, or cancel electively scheduled surgeries. These recommendations were followed by numerous state level executive orders either restricting or partially restricting elective surgeries. Because MACI is an elective surgical procedure, as a result of these restrictions, beginning in mid-March 2020, we began 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. The widespread suspension of elective procedures impacted our business and operations during the first and second quarters of 2020. These restrictions began to ease in May and, by the end of September 2020, there were no state orders in place that directly impacted a surgeon's or patient's ability to move forward with a MACI surgery. Consequently, MACI procedure and order volumes have recovered in recent months. In late September and October 2020, the number of COVID-19 infections began to increase markedly in various geographies, and on November 1, 2020, the rolling seven-day average of new daily coronavirus cases in the United States reached the highest level at any point during the pandemic. Although hospitals are now better prepared for a subsequent surge in COVID-19 patients, the risk remains that regional or local restrictions could again be placed on the performance of elective surgical procedures if the number of COVID-19 infections in the United States continues to rise. Because Epicel is used almost exclusively in the emergent setting by burn centers and surgeons throughout the country, Epicel revenue and procedure volumes have been less effected by the pandemic.

In March 2020, Vericel put in place a comprehensive workplace protection plan, which institutes protective measures in response to COVID-19. 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 all international business travel, limiting domestic business travel to essential purpose travel only, 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. In addition, we put certain expense reduction measures in place including a reduction of discretionary spending. We are reviewing these measures regularly as the pandemic evolves and may take additional actions to the extent required.

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 our 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 customer surgical sites. Epicel final product has an established shelf life of 24 hours and is hand carried to customer hospitals by courier. Transportation is primarily by commercial or charter airline. Although we have not experienced material shipping delays or materially 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 our distributors, operations or third-party service providers' ability to manage patient cases.

The COVID-19 pandemic remains fluid and continues to evolve differently across various geographies. Although state, local and hospital facility restrictions were largely lifted by the end of September 2020, the location, extent, and timing of those restrictions varied greatly as the virus spread across the United States, beginning in March. In some specific areas of the country, restrictions on elective surgical procedures were lifted and re-imposed multiple times. We believe it is likely that we will continue to experience variable impacts on our business, based on the resurgence of COVID-19 in various areas of the United States. Measures taken to limit the impact of COVID-19 at the international, national and local level, including shelter-in-place orders, social distancing measures, travel bans and restrictions, and business and government shutdowns, may continue to create significant negative economic impacts on a global basis. Given that uncertainty, we cannot reliably estimate the extent to which the COVID-19 pandemic may continue to impact utilization and revenues of our products in the fourth quarter of 2020 and beyond.

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 North America. NexoBrid is currently in clinical development in North America and on September 16, 2020 we announced that the FDA accepted the BLA for review and has assigned a PDUFA goal date of June 29, 2021. Until 2017, our active product candidate portfolio included ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to dilated cardiomyopathy, or DCM. We have no current plans to continue the development of ixmyelocel-T.

MACI

MACI is a third-generation autologous chondrocyte implantation (ACI) product for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults.

Our target audience of U.S. physicians is approximately 5,000 orthopedic surgeons and is divided into two segments - a group of orthopedic surgeons who self-identify and/or have a formal specialty as sports medicine physicians, and a sub-population of general orthopedic surgeons who perform a high volume of cartilage repair procedures. As of September 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. 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 nine months ended, September 30, 2020, net revenues for MACI were $24.4 million and $59.7 million, respectively, and $20.6 million and $58.0 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 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 for Epicel 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 2019. We currently have an eleven-person field force comprised of 7 sales representatives and 4 clinical support specialists. For the three and nine months ended September 30, 2020, net revenues for Epicel were $6.7 million and $18.0 million, respectively and $9.9 million and $20.4 million, respectively, for the same periods in 2019.

NexoBrid

Our portfolio also 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. On September 16, 2020, Vericel announced that the FDA has accepted the BLA for review and has assigned a PDUFA goal date of June 29, 2021. 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. Under our license agreement with MediWound, NexoBrid is being manufactured for BARDA prior to approval by the FDA under an emergency use authorization. Vericel recorded revenue of $1.2 million associated with the first delivery of NexoBrid to BARDA during the three and nine months ended September 30, 2020.

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 Income

Our net income and loss for the three and nine months ended September 30, 2020 totaled $3.6 million and $9.4 million, respectively, and $3.5 million and $19.2 million, respectively, for the same periods in 2019.

(In thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Net revenues	$ 32,258	$ 30,499	$ 78,950	$ 78,460
Cost of product sales	9,787	9,324	28,369	26,986
Gross profit	22,471	21,175	50,581	51,474
Total operating expenses	18,954	18,078	60,498	71,935
Income (loss) from operations	3,517	3,097	(9,917)	(20,461)
Other income	101	373	561	1,295
Net income (loss)	$ 3,618	$ 3,470	$ (9,356)	$ (19,166)

Net Revenues

Net revenues increased for the three and nine months ended September 30, 2020 compared to the same periods in 2019, primarily driven by a recovery in MACI volume growth as a result of the lifting of state and local restrictions on elective surgeries in the second quarter, which impacted surgical capacity. The increase in MACI net revenue was partially offset by a decrease of $2.5 million related to Epicel due to the variable occurrence of severe burns. Additionally, we recorded revenue associated with the first delivery of NexoBrid to BARDA for emergency response preparedness.

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

Revenue by product (In thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
MACI	$ 24,357	$ 20,610	$ 59,747	$ 58,015
Epicel	6,663	9,889	17,965	20,445
NexoBrid	1,238	—	1,238	—
Total Revenue	$ 32,258	$ 30,499	$ 78,950	$ 78,460

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. Due to the low incidence and variable occurrence 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 September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Gross profit	$ 22,471	$ 21,175	$ 50,581	$ 51,474
Gross profit %	70 %	69 %	64 %	66 %

Gross profit increased for the three months ended September 30, 2020 compared to the same period in 2019 primarily due to the increase in MACI volume and other revenue related to NexoBrid.

Gross profit decreased for the nine months ended September 30, 2020 compared to the same period in 2019 due to the revenue impact from COVID-19 earlier in the year.

Research and Development Costs

(In thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Research and development costs	$ 2,913	$ 3,096	$ 9,902	$ 27,174

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

(In thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
ACI	$ 1,655	$ 1,804	$ 5,409	6,165
Epicel	685	875	2,397	2,813
NexoBrid	573	415	2,080	18,164
Other	—	2	16	32
Total research and development costs	$ 2,913	$ 3,096	$ 9,902	$ 27,174

Research and development expenses for the three months ended September 30, 2020 were $2.9 million compared to $3.1 million for the same period in 2019.

Research and development expenses for the nine months ended September 30, 2020 were $9.9 million compared to $27.2 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 September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Selling, general and administrative costs	$ 16,041	$ 14,982	$ 50,596	$ 44,761

Selling, general and administrative expenses for the three months ended September 30, 2020 were $16.0 million compared to $15.0 million for the same period in 2019. The increase in selling, general and administrative expenses during the three months ended September 30, 2020 is due primarily to an incremental $1.5 million in MACI sales force expenses due to the sales force expansion in the second quarter of 2020 and $0.3 million of patient reimbursement support services, which were partially offset by a reduction in discretionary spend as a result of the COVID-19 pandemic.

Selling, general and administrative expenses for the nine months ended September 30, 2020 increased to $50.6 million from $44.8 million for the same period in 2019. The increase in selling, general and administrative expenses during the nine months ended September 30, 2020 is due primarily to an incremental $3.2 million in MACI sales force expenses driven by the sales force expansion in the second quarter of 2020, a $1.2 million increase in stock compensation expense, $1.0 million of patient reimbursement support services, and $0.7 million in Epicel sales force expenses due to the team's growth over the past several quarters. Other areas of fixed expense growth such as facilities, depreciation, and insurance were offset by reductions to discretionary marketing programs as a result of the COVID-19 pandemic.

Other Income (Expense)

(In thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Net interest income	$ 119	$ 383	$ 569	$ 1,287
Other income (expense)	(18)	(10)	(8)	8
Total other income	$ 101	$ 373	$ 561	$ 1,295

The decrease in interest income for the three and nine months ended September 30, 2020 compared to the same period in 2019 is due primarily to the lowering of 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 selling, general and administrative expenses is summarized in the following table:

(In thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Cost of goods sold	$ 481	$ 543	$ 1,541	$ 1,519
Research and development	458	583	1,455	1,993
Selling, general and administrative	1,736	2,159	7,823	6,583
Total non-cash stock-based compensation expense	$ 2,675	$ 3,285	$ 10,819	$ 10,095

The decrease in stock-based compensation expense for the three months ended September 30, 2020, and the increase in the nine months ended September 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 $43.5 million and short-term investments totaled $42.0 million as of September 30, 2020. The $6.2 million of cash provided by operations during the nine months ended September 30, 2020 was the result of cash collections and a decrease in accounts receivable of $6.0 million from the prior quarter, including noncash charges of $10.8 million in stock compensation expense, $3.3 million of operating lease amortization and $1.6 million in depreciation and amortization expense offset by a $9.4 million net loss.

Our cash and cash equivalents totaled $36.9 million and short-term investments totaled $37.8 million at September 30, 2019. The $10.3 million of cash used by operations during the nine months ended September 30, 2019 was largely the result of our net loss of $19.2 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 $10.1 million in stock compensation expense, and $1.2 million in depreciation and amortization expense.

The change in cash provided by investing activities during the nine months ended September 30, 2020 is the result of $39.1 million of investment maturities offset by $29.0 million in short-term investment purchases and property plant and equipment purchases of $1.6 million primarily for manufacturing upgrades through September 30, 2020. The cash provided by investing activities for the nine months ended September 30, 2019 is the result of $46.3 million in short-term investments purchases offset by $73.8 million of maturities and property plant and equipment purchases of $2.3 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 $2.2 million, slightly offset by the payment of employee withholding taxes related to the vesting of restricted stock units of $0.2 million during the nine months ended September 30, 2020. The change in cash provided from financing activities during the nine months ended September 30, 2019 is the result of proceeds from the exercise of stock options of $3.8 million.

We believe that 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 continue to evolve and may result in irrecoverable losses from customers and significantly impact long-term liquidity requiring us to engage in layoffs, furloughs, and/or reductions in salaries. 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 revenues decline for a sustained period, 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 September 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. 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 nine months ended September 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;
- the timing of the FDA’s review of the BLA for NexoBrid;
- expectations regarding approval by the FDA of the BLA for NexoBrid;
- 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 September 30, 2020, we held marketable debt securities, which are classified as available-for-sale and carried at fair value in the accompanying condensed 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 $0.2 million and $0.3 million decrease in the fair value of our investment portfolio as of September 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 September 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 Principal 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 September 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 in our Form 8-K filed on April 2, 2020, and which were updated in our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2020 and June 30, 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. Companies and organizations conducting biopharmaceutical research and development have been largely exempted from closure orders as the sector has been deemed essential to maintaining continuity of operations of the critical infrastructure as determined by the federal government. Since March, the steps taken by many state and local officials, which have included requiring businesses to implement mandatory training and protection measures for their workforce, 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 eased restrictions on workplaces and individuals in an effort to reopen the economies of those regions. The pandemic remains highly fluid throughout the country and around the world, however, and the number of COVID-19 infections has fluctuated significantly in various geographies over the course of the past seven months. As such, many state and local governments have re-instituted restrictions on businesses, travel, and personal activities from time-to-time and it is expected that additional such measures may occur in the future as the pandemic evolves.

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 all international business travel, limiting domestic business travel to essential purposes, 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 during the first and second quarters of 2020. 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, we 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 our results of operations for the first and second quarters of 2020. These restrictions began to ease in May and, by the end of September 2020, there were no state orders in place that directly impacted a surgeon's or patient's ability to move forward with a MACI surgery. However, the COVID-19 pandemic remains unpredictable and many areas of the United States, and the world, have experienced a resurgence of COVID-19 infections in recent weeks. Indeed, on November 1, 2020, the rolling seven-day average of new daily coronavirus cases in the United States reached the highest level at any point during the pandemic. Although hospitals are now better prepared for a subsequent surge in COVID-19 patients, the risk remains that regional or local restrictions could again be placed on the performance of elective surgical procedures if the number of COVID-19 infections in the United States continues to rise. We believe our MACI business may be negatively impacted if elective surgical procedures are again restricted. Further, continued, and prolonged material disruption to the operations of our employees, distributors, suppliers or customers will impact our sales and operating results that could lead to potential impairments to inventory and accounts receivable. We believe Epicel has been less directly impacted by the pandemic given the critical nature of severe burn injuries; however, trauma injury admissions have been reported to have declined due to various COVID-19 related restrictions. Given the variable occurrence of the severe burns Epicel is used to treat, 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 two (2) such sites have currently paused enrollment of new PEAK patients as a result of the effects of the pandemic, the Study has not experienced a slow-down in its traditional rate of patient enrollment. However, the PEAK Study or another of our clinical trials may in the future 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 that current supply chain interruptions will impact our 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 commercially launch 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 by 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 largely restricted on-site staff in our facilities to only those personnel and contractors who must perform essential activities related to the manufacture, production and delivery of our products. We have encouraged the majority of our remaining employees to work remotely. Our continued reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. Additionally, 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.

- Continued 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 September 16, 2020, we announced that the FDA has accepted for review a BLA 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. For instance, the COVID-19 pandemic may impact the FDA's response times to regulatory submissions, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections any or all of which may result in timelines being materially delayed, which could materially affect the development, study and ultimate commercialization of our product candidates. It is unknown how long these disruptions could continue, were they to occur.

- The trading prices for our common stock and that of 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 from 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, a resurgence of COVID-19 in the United States, may cause customers or patients to postpone or cancel previously scheduled surgeries or to decline to schedule surgeries utilizing our products, which would negatively impact our operations and financial results. 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

Purchases of Equity Securities by the Issuer

We repurchased the following shares of our common stock in the periods set forth in the table below:

Period	Total Number of Shares Repurchased	Average Price Paid per Share
July 1 - 31, 2020 (a)	661	$ 15.11
August 1 - 31, 2020	—	—
September 1 - 30, 2020	—	—
Total	661	$ 15.11

(a) Participants in our stock-based incentive plans are permitted to use the fair market value of our common stock they own to pay for the exercise of stock options, otherwise known as the "stock swap method". During the three months ended September 30, 2020, in connection with the exercise of a stock option, an optionee tendered 661 shares of our common stock held by the optionee in consideration of the full aggregate exercise price.

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 Principal 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 Principal 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: November 5, 2020

VERICEL CORPORATION

/s/ DOMINICK C. COLANGELO

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

/s/ SANDRA L. PENNELL

Sandra L. Pennell
Vice President and Corporate Controller
(Principal Financial and Accounting 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: November 5, 2020

/s/ DOMINICK C. COLANGELO
Dominick C. Colangelo
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Sandra L. Pennell, 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: November 5, 2020

/s/ SANDRA L. PENNELL

Sandra L. Pennell

Vice President and Corporate Controller

(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 September 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: November 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 September 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: November 5, 2020

/s/ SANDRA L. PENNELL
Sandra L. Pennell
Vice President and Corporate Controller
(Principal Financial and Accounting 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.