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: March 31, 2021

or

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

Commission File Number 001-35280

VERICEL CORPORATION

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of April 30, 2021, 46,355,625 shares of Common Stock, no par value per share, were outstanding.

VERICEL CORPORATION
QUARTERLY REPORT ON FORM 10-Q
TABLE OF CONTENTS

		Page
	PART I - FINANCIAL INFORMATION	
Item 1.	Financial Statements (Unaudited):	3
	Condensed Consolidated Balance Sheets as of March 31, 2021 and December 31, 2020	3
	Condensed Consolidated Statements of Operations for the three months ended March 31, 2021 and 2020	4
	Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2021 and 2020	5
	Condensed Consolidated Statements of Shareholders' Equity from December 31, 2020 to March 31, 2021 and from December 31, 2019 to March 31, 2020	6
	Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2021 and 2020	7
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	28
Item 4.	Controls and Procedures	28
	PART II — OTHER INFORMATION	
Item 1.	Legal Proceedings	29
Item 1A.	Risk Factors	29
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	32
Item 3.	Defaults Upon Senior Securities	33
Item 4.	Mine Safety Disclosures	33
Item 5.	Other Information	33
Item 6.	Exhibits	34
Exhibit Index		34
Signatures		35

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,154	$ 33,620
Short-term investments	25,402	42,187
Accounts receivable (net of allowance for doubtful accounts of $121 and $143, respectively)	29,122	34,504
Inventory	10,322	9,356
Other current assets	4,213	3,893
Total current assets	127,213	123,560
Property and equipment, net	9,076	7,633
Restricted cash	211	211
Right-of-use assets	48,943	50,105
Long-term investments	26,021	24,099
Total assets	$ 211,464	$ 205,608
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,826	$ 6,755
Accrued expenses	9,965	11,293
Current portion of operating lease liabilities	4,398	4,394
Other liabilities	41	41
Total current liabilities	23,230	22,483
Operating lease liabilities	47,968	48,789
Other long-term liabilities	57	76
Total liabilities	$ 71,255	$ 71,348
COMMITMENTS AND CONTINGENCIES		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding 46,225 and 45,804, respectively	519,360	510,061
Accumulated other comprehensive income (loss)	(47)	14
Accumulated deficit	(379,104)	(375,815)
Total shareholders' equity	140,209	134,260
Total liabilities and shareholders' equity	$ 211,464	$ 205,608

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 March 31,	
	2021	2020
Product sales, net	$ 33,627	$ 26,678
Other revenue	941	—
Total revenue	34,568	26,678
Cost of product sales	11,583	9,922
Gross profit	22,985	16,756
Research and development	3,630	3,763
Selling, general and administrative	22,660	18,069
Total operating expenses	26,290	21,832
Loss from operations	(3,305)	(5,076)
Other income (expense):		
Interest income	76	306
Interest expense	(1)	(2)
Other income	84	67
Total other income	159	371
Net loss before tax provision	(3,146)	(4,705)
Tax provision	(143)	—
Net loss	$ (3,289)	$ (4,705)
Net loss per share attributable to common shareholders (Basic and diluted)	$ (0.07)	$ (0.10)
Weighted average number of common shares outstanding (Basic and diluted)	45,984	44,924

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

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

	Three Months Ended March 31,	
	2021	**2020**
Net loss	$ (3,289)	$ (4,705)
Other comprehensive loss:		
Unrealized gain (loss) on investments	(61)	41
Comprehensive loss	$ (3,350)	$ (4,664)

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

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

	Common Stock		Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
BALANCE, DECEMBER 31, 2020	45,804	$ 510,061	$ 14	$ (375,815)	$ 134,260
Net loss	—	—	—	(3,289)	(3,289)
Compensation expense related to stock options and restricted stock units granted, net of forfeitures	—	7,019	—	—	7,019
Stock option exercises	359	3,532	—	—	3,532
Shares issued under the Employee Stock Purchase Plan	14	249	—	—	249
Issuance of stock upon restricted stock unit vesting	76	—	—	—	—
Restricted stock withheld for employee tax remittance	(28)	(1,501)	—	—	(1,501)
Unrealized loss on investments	—	—	(61)	—	(61)
BALANCE, MARCH 31, 2021	46,225	$ 519,360	$ (47)	$ (379,104)	$ 140,209

	Common Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	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

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

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

	Three Months Ended March 31,	
	2021	2020
Operating activities:		
Net loss	$ (3,289)	$ (4,705)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization expense	811	533
Stock compensation expense	7,019	3,768
Foreign currency translation loss	2	7
Gain on sale of fixed assets	(22)	—
Amortization of premiums and discounts on marketable securities	273	(20)
Non-cash lease cost	1,171	794
Changes in operating assets and liabilities:		
Inventory	(966)	(466)
Accounts receivable	5,382	7,997
Other current assets	(320)	(549)
Accounts payable	2,174	(59)
Accrued expenses	(1,328)	(1,864)
Operating lease liabilities	(821)	(750)
Net cash provided by operating activities	10,086	4,686
Investing activities:		
Purchases of investments	(10,426)	(5,676)
Sales and maturities of investments	24,955	20,135
Expenditures for property, plant and equipment	(2,343)	(717)
Net cash provided by investing activities	12,186	13,742
Financing activities:		
Net proceeds from common stock issuance due to stock option exercises	3,781	420
Payments on employee's behalf for taxes related to vesting of restricted stock units	(1,501)	(97)
Other	(18)	(17)
Net cash provided by financing activities	2,262	306
Net increase in cash, cash equivalents, and restricted cash	24,534	18,734
Cash, cash equivalents, and restricted cash at beginning of period	33,831	26,978
Cash, cash equivalents, and restricted cash at end of period	$ 58,365	$ 45,712

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, or Vericel), 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® (autologous cultured chondrocytes on porcine collagen membrane) and Epicel® (cultured epidermal autografts).

MACI 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 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® (concentrate of proteolytic enzymes enriched in bromelain), a registration-stage biological orphan product for the 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 cellular therapies 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 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 many state, local and national governments – including those in Massachusetts and Michigan, where the Company's operations are located – have responded at times by issuing, extending and supplementing orders requiring quarantines, restrictions on travel, and the mandatory closure of certain non-essential businesses, among other actions. In the U.S., the status and application of these orders have varied on a state-by-state basis since the early days of the pandemic. Many of the restrictions have been periodically updated as infection rates in the U.S. have risen and fallen, as new virus “variants” have emerged, and as world health leaders learn more about the virus, its transmission pathway and who is most at risk. Because Vericel is deemed an essential business, the Company has been exempted from government orders requiring the closure of workplaces and the cessation of business operations.

Notwithstanding being an essential business, the Company’s business and operations were, at times, adversely impacted by the effects of COVID-19 during 2020. At the urging of the American College of Surgeons and the United States Surgeon General, hospitals, health systems and surgeons minimized, postponed, or canceled electively scheduled surgeries during the initial wave of the pandemic in the spring of 2020. 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 the Company experienced a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders during March and April of 2020. The widespread suspension of surgical procedures impacted the Company’s business and operations during the first and second quarters of 2020. The level and degree of restriction on elective surgeries, on the ability of patients to seek treatment and on U.S. business operations generally fluctuated throughout 2020 as COVID-19 infection rates rose and fell during the summer months and into the autumn. By the first quarter of 2021, the pandemic’s effects on the Company’s MACI business had largely dissipated. Although hospitals are now better prepared for a subsequent surge in COVID-19 patients and COVID-19 vaccines have been approved and are being widely distributed in the United States, 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 were to rise again, or if new COVID-19 variants emerge which render current vaccine treatments ineffective. 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.

At the outset of the pandemic, 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 the Company’s 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. Depending on the pandemic's trajectory in the coming months, it may take additional actions to the extent required, or it may ease certain protective measures to the extent available data and state and local rules permit.

Going Concern

The accompanying Condensed Consolidated Financial Statements have been prepared on a basis which assumes that the Company will continue as a going concern and contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. As of March 31, 2021, the Company had an accumulated deficit of $379.1 million, and had a net loss of $3.3 million during the three months ended March 31, 2021. The Company had cash and cash equivalents of $58.2 million and investments of $51.4 million as of March 31, 2021. The Company expects that cash from the sales of our products and 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 Condensed Consolidated Financial Statements. 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 March 31, 2021 and for the three months ended March 31, 2021 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, revenue and expenses. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The Company bases its estimates on historical experience and on various other assumptions that it believes 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 revenue 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. The Company has 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 March 31, 2021, 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.

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, 2020, as filed with the SEC on February 24, 2021 (Annual Report).

Consolidated Statement of Cash Flows

The following table presents certain supplementary cash flows information for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
(In thousands)	**2021**	**2020**
Supplementary Cash Flows information:		
Non-cash information:		
Right-of-use asset and lease liability recognized	$ —	$ 326
Additions to property and equipment included in accounts payable	530	105
Restricted shares held for employee tax remittance included in accounts payable	65	66
Cash information:		
Interest paid (net of interest capitalized)	$ 1	$ 2

	Three Months Ended March 31,	
(In thousands)	**2021**	**2020**
Reconciliation of cash, cash equivalents, and restricted cash reported in the statement of financial position:		
Cash and cash equivalents	$ 58,154	$ 45,623
Restricted cash, included in other long-term assets	211	89
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 58,365	$ 45,712

3. Recent Accounting Pronouncements

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 became effective for the Company on January 1, 2021 and had no material impact on its Condensed Consolidated Financial Statements.

4. Revenue

Revenue Recognition and Net Product Sales

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

MACI Biopsy Kits

MACI biopsy kits are sold directly to hospitals and ambulatory surgical centers 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 engages 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 revenue 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, fee schedules or based on a percentage of published rates. 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. The total allowance for uncollectible consideration as of March 31, 2021 and December 31, 2020 was $6.1 million and $5.3 million, respectively. Changes to the estimate of the amount of consideration that will not be collected could have a material impact to the revenue recognized. A 0.5% change to the estimated uncollectible percentage could result in approximately a $0.2 million increase or decrease in the revenue recognized for the three months ended March 31, 2021.

Changes in estimates of the transaction price are recorded through revenue in the period in which such change occurs. During the three months ended March 31, 2021 and March 31, 2020, changes in estimates related to prior period sales resulted in an increase to revenue of $0.5 million and $1.2 million, respectively. The changes in estimates recorded during the three months ended March 31, 2021 and March 31, 2020, were primarily due to completion of the billing claims process for implants that occurred in 2020 or prior. 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.

Additionally, potential credit risk exposure has been evaluated for the Company's accounts receivable in accordance with *ASC 326, Financial Instruments - Credit Losses.* The loss percentage is calculated by pooling account receivables containing similar risk characteristics and applying collectability forecasts which are derived from current and historical economic and financial information. The loss percentage calculated was applied to accounts receivables as of March 31, 2021 and December 31, 2020. The allowance related to the potential impacts of COVID-19 on accounts receivable from third-party insurers, government payers, hospitals and patients as of December 31, 2020 included less than $0.1 million, and no additional allowance was recorded during the three months ended March 31, 2021.

Epicel

The Company sells Epicel directly to hospitals and burn centers 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 revenue 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.

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) committed to procure NexoBrid directly from MediWound, under an emergency use authorization. As a result, during 2020, BARDA accepted the first shipments of NexoBrid, per the agreement between BARDA and MediWound. The Company recognizes revenue based on a percentage of gross profits for sales of NexoBrid to BARDA upon delivery, at which time BARDA is in control of the product. As of March 31, 2021, the Company did not take title to the product or hold a direct contract or distribution agreement with BARDA. During the three months ended March 31, 2021, the Company recognized $0.9 million of revenue. No revenue related to the procurement by BARDA was recognized for the three months ended March 31, 2020. See note 11 for further information.

Revenue by Product and Customer

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

	Three Months Ended March 31,	
Revenue by product (in thousands)	**2021**	**2020**
MACI implants and kits		
Implants based on contracted rate sold through a specialty pharmacy (a)	$ 13,206	$ 11,338
Implants subject to third party reimbursement sold through a specialty pharmacy (b)	4,280	3,730
Implants sold direct based on contracted rates (c)	4,466	3,109
Implants sold direct subject to third party reimbursement (d)	849	436
Biopsy kits - direct bill	519	466
Change in estimates related to prior periods (e)	477	1,207
Epicel		
Direct bill (hospital)	9,830	6,392
Total product revenue	$ 33,627	$ 26,678
NexoBrid revenue (f)	941	—
Total net revenue	$ 34,568	$ 26,678

(a) Represents implants sold through Orsini and AllCare 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 revenue based on a percentage of gross profits for 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 March 31, 2021 was 14% and 12% for the same period in 2020. For the Company's total MACI revenue, and MACI and Epicel accounts receivable balances there were no customers for the three months ended March 31, 2021 or March 31, 2020, with a concentration greater than 10%.

5. Selected Balance Sheet Components

Inventory

Inventory as of March 31, 2021 and December 31, 2020:

(In thousands)	March 31, 2021	December 31, 2020
Raw materials	$ 9,409	$ 8,775
Work-in-process	884	537
Finished goods	29	44
Inventory	$ 10,322	$ 9,356

Property and Equipment

Property and Equipment, net as of March 31, 2021 and December 31, 2020:

(In thousands)	March 31, 2021	December 31, 2020
Machinery and equipment	$ 3,701	$ 3,672
Furniture, fixtures and office equipment	810	809
Computer equipment and software	6,967	6,846
Leasehold improvements	5,594	5,560
Construction in process	4,071	2,021
Financing right-of-use lease	102	111
Total property and equipment, gross	21,245	19,019
Less accumulated depreciation	(12,169)	(11,386)
Property and equipment, net	$ 9,076	$ 7,633

Depreciation expense for the three months ended March 31, 2021 was $0.8 million and $0.5 million for the same period in 2020.

Accrued Expenses

Accrued Expenses as of March 31, 2021 and December 31, 2020 are as follows:

(In thousands)	March 31, 2021	December 31, 2020
Bonus related compensation	$ 2,605	$ 5,721
Employee related accruals	4,300	3,482
Other accrued expenses	3,060	2,090
Accrued expenses	$ 9,965	$ 11,293

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 present value of 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-of-use assets and liabilities, on a discounted basis on the balance sheet. Effective October 21, 2020 the Company entered into an agreement with one of its Cambridge, Massachusetts facility leases. The 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. The agreement also provides a tenant improvement allowance of approximately $4.3 million, available through December 31, 2023.

Leases with an initial term of 12 months or less are not recorded on the balance sheet. During the three months ended March 31, 2021 and 2020, lease expense of less than $0.1 million was recorded related to short-term leases. During the three months ended March 31, 2021, the Company recorded $0.2 million of leasehold improvements funded by tenant improvement allowances available under the lease agreements. The contribution toward the cost of tenant improvements is recorded as a reduction of the operating lease assets. For the three months ended March 31, 2021, the Company recognized $1.9 million of operating lease expense and $1.4 million for the same period in 2020. During the three months ended March 31, 2021 and 2020, 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 March 31, 2021 and December 31, 2020 are as follows:

(In thousands)	Classification	March 31, 2021	December 31, 2020
Assets			
Operating	Right-of-use assets	$ 48,943	$ 50,105
Finance	Property and equipment, net	102	111
		$ 49,045	$ 50,216
Liabilities			
Current			
Operating	Current portion of operating lease liabilities	$ 4,398	$ 4,394
Finance	Other liabilities	41	41
		$ 4,439	$ 4,435
Non-current			
Operating	Operating lease liabilities	$ 47,968	$ 48,789
Finance	Other long-term liabilities	57	76
		$ 48,025	$ 48,865

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 Amended and Restated 2019 Omnibus Incentive Plan (2019 Plan) was approved on April 29, 2020 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 of the 2019 Plan. 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.

As of March 31, 2021, there were 2,942,648 shares available for future grant under the 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 720,228 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 April 2021, employees purchased 11,776 shares resulting in proceeds from the sale of common stock of $0.3 million under the ESPP for the first quarter of 2021.

Service-Based Stock Options

During the three months ended March 31, 2021 and 2020, the Company granted service-based options to purchase common stock of 1,337,955 and 1,186,140, respectively. 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 months ended March 31, 2021 and 2020 was $32.02 and $8.64, respectively.

Restricted Stock Units

During the three months ended March 31, 2021 and 2020, the Company granted 214,113 and 186,136 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 units are recorded at fair value at the date of grant, which is based on the closing share price on the grant date. Compensation expense is recorded for restricted stock units that are expected to vest based on their fair value at grant date and is amortized over the expected vesting period. The weighted average grant-date fair value of restricted stock units granted during the three months ended March 31, 2021 was $50.81, and $11.24 for the same period in 2020. The aggregate fair value of restricted stock units granted in the three months ended March 31, 2021 and 2020 was $10.9 million and $2.1 million, respectively.

During the three months ended March 31, 2021 and 2020, 47,857 and 22,340 shares, respectively of common stock were issued upon the vesting of restricted stock units. These amounts are net of 28,240 and 13,872 shares, respectively that were withheld for payment of taxes on the behalf of employees. For the three months ended March 31, 2021 and 2020 the total fair value of restricted stock awards vested was $4.1 million and $0.4 million, respectively. The total fair value of restricted stock units withheld for payment of taxes during the three months ended March 31, 2021 and 2020 was $1.5 million and $0.2 million, respectively.

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 product sales, research and development expenses and selling, general and administrative expenses is summarized in the following table:

(in thousands)	Three Months Ended March 31, 2021	2020
Cost of product sales	$ 911	$ 493
Research and development	863	513
Selling, general and administrative	5,245	2,762
Total non-cash stock-based compensation expense	$ 7,019	$ 3,768

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 March 31, 2021 and December 31, 2020:

	March 31, 2021				
		Gross Unrealized			
	Amortized Cost	Gains	Losses	Credit Losses	Estimated Fair Value
Money market funds	$ 15,598	$ —	$ —	$ —	$ 15,598
Commercial paper	9,998	—	—	—	9,998
Corporate notes	40,082	—	(47)	—	40,035
U.S. government securities	1,500	—	—	—	1,500
U.S. government agency bonds	1,074	—	—	—	1,074
U.S. asset-backed securities	1,815	—	—	—	1,815
	$ 70,067	$ —	$ (47)	$ —	$ 70,020
Classified as:					
Cash equivalents					$ 18,597
Short-term investments					25,402
Long-term investments					26,021
					$ 70,020

	December 31, 2020				
		Gross Unrealized			
(In thousands)	Amortized Cost	Gains	Losses	Credit Losses	Estimated Fair Value
Money market funds	$ 3,698	$ —	$ —	$ —	$ 3,698
Commercial paper	8,993	1	—	—	8,994
Corporate notes	35,917	—	—	(6)	35,911
U.S. government securities	12,828	14	—	—	12,842
U.S. government agency bonds	5,000	1	—	—	5,001
U.S. asset-backed securities	3,534	4	—	—	3,538
	$ 69,970	$ 20	$ —	$ (6)	$ 69,984
Classified as:					
Cash equivalents					$ 3,698
Short-term investments					42,187
Long-term investments					24,099
					$ 69,984

Investments classified as short-term have maturities of less than one year. Investments classified as long-term are those which: (i) have a maturity of greater than one year, and (ii) the Company does 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 March 31, 2021 and December 31, 2020, all marketable securities held by the Company had remaining contractual maturities of three years or less.

Unrealized gains are included as a component of accumulated other comprehensive income in the condensed consolidated balance sheets and statements of stockholders' equity and a component of total comprehensive income (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 (loss), net of taxes. There were no material realized losses on marketable securities during the three months ended March 31, 2021. There have been no impairments of the Company's assets measured and carried at fair value during the three months ended March 31, 2021 or March 31, 2020, respectively.

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, 2020 to March 31, 2021. 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:

	March 31, 2021				December 31, 2020			
		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	$ 15,598	$ 15,598	$ —	$ —	$ 3,698	$ 3,698	$ —	$ —
Commercial paper	9,998	—	9,998	—	8,994	—	8,994	—
Corporate notes	40,035	—	40,035	—	35,911		35,911	—
U.S. government securities	1,500	—	1,500	—	12,842		12,842	—
U.S. government agency bonds	1,074	—	1,074	—	5,001		5,001	—
U.S. asset-backed securities	1,815	—	1,815	—	3,538		3,538	—
	$ 70,020	$ 15,598	$ 54,422	$ —	$ 69,984	$ 3,698	$ 66,286	$ —

The fair values of the cash equivalents and marketable securities are based on observable market prices.

10. Net Loss Per Common Share

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

(Amounts in thousands, except per share amounts)	Three Months Ended March 31, 2021	2020
Numerator:		
Net loss	$ (3,289)	$ (4,705)
Denominator:		
Weighted-average common shares outstanding (basic and diluted)	45,984	44,924
Net loss per share attributable to common shareholders (basic and diluted)	$ (0.07)	$ (0.10)
Anti-dilutive shares excluded from the calculation of diluted earnings per share[(a)] (amounts in millions):		
Stock options	6.2	6.2
Restricted stock units	0.4	0.3

(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. On June 30, 2020, the Company announced MediWound's submission of a biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) seeking the approval of NexoBrid. Subsequently, 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) target date of June 29, 2021. Pursuant to the terms of the license agreement, if the BLA is approved, MediWound will transfer the BLA to the Company and the Company will market NexoBrid in the U.S. Both MediWound and the Company, under the supervision of a Central Steering Committee comprised of members of both companies will continue to guide the development of NexoBrid in North America. 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, subsequent to approval. 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 March 31, 2021, the milestone payments were 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, following approval. 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 the Company, 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 March 31, 2021, the Company did not hold a direct contract or distribution agreement with BARDA. During 2020, BARDA accepted the first shipments of NexoBrid for emergency use preparedness per the agreement between BARDA and

MediWound. During the three months ended March 31, 2021, the Company recognized $0.9 million of revenue. No revenue related to the procurement by BARDA was recognized for three months ended March 31, 2020.

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. In addition, the Company also pays for usage of an offsite warehouse space. In February 2021, the terms of the operating agreement were extended through March 31, 2027. The Company records rent expense related to this agreement on a straight-line basis over the remaining term.

Future minimum payments related to the Company's contractual obligations are as follows:

		Payments Due by Period					
Contractual Obligations (in thousands)	**Total**	**April 1, 2021 to December 31, 2021**	**2022**	**2023**	**2024**	**2025**	**More than 5 Years**
Purchase commitments	$ 9,504	$ 8,853	$ 651	$ —	$ —	$ —	$ —
Warehouse Operating Agreement	4,302	677	896	642	642	642	803
Total	$ 13,806	$ 9,530	$ 1,547	$ 642	$ 642	$ 642	$ 803

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® 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® 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. In 2020, MediWound submitted to the FDA a BLA seeking the approval of NexoBrid for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. The FDA subsequently accepted the BLA for filing and has assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021. See "Risk Factors - NexoBrid's approval in the United States for the treatment of severe burns may be delayed, and it may not be approved for use in the United States and other North American markets."

COVID-19

The pandemic caused by the spread of a novel strain of coronavirus (COVID-19) has created 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 many state, local and national governments – including those in Massachusetts and Michigan, where our operations are located – have responded at times by issuing, extending and supplementing orders requiring quarantines, restrictions on travel, and the mandatory closure of certain non-essential businesses, among other actions. In the U.S., the status and application of these orders have varied on a state-by-state basis since the early days of the pandemic. Many of the restrictions have been periodically updated as infection rates in the U.S. have risen and fallen, as new virus "variants" have emerged, and as world health leaders learn more about the virus, its transmission pathway and who is most at risk. Because Vericel is deemed an essential business, the Company has been exempted from government orders requiring the closure of workplaces and the cessation of business operations.

Notwithstanding being an essential business, the Company's business and operations were, at times, adversely impacted by the effects of COVID-19 during 2020. At the urging of the American College of Surgeons and the United States Surgeon General, hospitals, health systems and surgeons minimized, postponed, or canceled electively scheduled surgeries during the initial wave of the pandemic in the spring of 2020. 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 the Company experienced a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders during March and April of 2020. The widespread suspension of surgical procedures impacted the Company's business and operations during the first and second quarters of 2020. The level and degree of restriction on elective surgeries, on the ability of patients to seek treatment and on U.S. business operations generally fluctuated throughout 2020 as COVID-19 infection rates rose and fell during the summer months and into the autumn. By the first quarter of 2021, the pandemic's effects on the Company's MACI business had largely dissipated. Although hospitals are now better prepared for a subsequent surge in COVID-19 patients and COVID-19 vaccines have been approved and are being widely distributed in the United States, 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 were to rise again, or if new COVID-19 variants emerge which render current vaccine treatments ineffective.

Because Epicel is used almost exclusively in an emergent setting by burn centers and surgeons throughout the country, Epicel revenue and procedure volumes have been less affected by the pandemic. Nevertheless, large burns and burn admissions can be affected by restrictions on human activity resulting from more severe government lockdown orders. Epicel procedure volumes did experience a slow-down during the second quarter of 2020, however, the reduction was less pronounced than that observed with MACI. Further reductions could be observed in the future, based on the degree of restrictions imposed.

At the outset of the pandemic, 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 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 pandemic evolves and may take additional actions to the extent required. Depending on the pandemic's trajectory in the coming months, we may take additional actions to the extent required, or we may ease certain protective measures to the extent available data and state and local rules permit.

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 six (6) days and established shipping shelf life of three (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 48 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.

We believe it is possible that we could experience variable impacts on our business, should there be a 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 levels, including the availability of COVID-19 vaccines, shelter-in-place orders, social distancing measures, travel bans and restrictions, and business and government shutdowns, may again 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 revenue of our products in 2021 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, following regulatory approval. As previously mentioned, MediWound has submitted a BLA to the FDA seeking commercial approval of NexoBrid. On September 16, 2020, we announced that the FDA accepted the BLA for review and has assigned a PDUFA target date of June 29, 2021.

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 the date of this report, we currently have 76 MACI sales representatives to enable the sales force to reach our target audience. 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 that 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 months ended March 31, 2021 and 2020, net revenue for MACI was $23.8 million and $20.3 million, respectively.

Epicel

Epicel is a permanent skin replacement for deep dermal or full-thickness burns greater than or equal to 30% of TBSA. Epicel is regulated by the Center for Biologics Evaluation and Research, or CBER of the U.S. Food and Drug Administration 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 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 seven (7) account managers and four (4) burn clinical specialists, overseen by a senior sales director. During the three months ended March 31, 2021 and 2020, net revenue for Epicel was $9.8 million and $6.4 million, respectively.

NexoBrid

Our portfolio also includes NexoBrid, a registration-stage, topically-administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns. On June 30, 2020, we announced MediWound's submission of a BLA to the FDA seeking the approval of NexoBrid. Subsequently, on September 16, 2020, we announced that the FDA accepted the BLA for review and assigned a PDUFA target date of June 29, 2021. See "Risk Factors - NexoBrid’s approval in the United States for the treatment of severe burns may be delayed, and it may not be approved for use in the United States and other North American markets." 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, if the BLA is approved, MediWound will transfer the BLA to Vericel and Vericel will market NexoBrid in the U.S. Both MediWound and Vericel, under the supervision of a Central Steering Committee comprised of members of both companies will continue to guide development of NexoBrid in North America. Under our license agreement with MediWound, NexoBrid is being manufactured for BARDA prior to approval by the FDA under an emergency use authorization. During the three months ended March 31, 2021, net revenue of $0.9 million associated with delivery of NexoBrid to BARDA was recorded. No revenue related to the procurement of BARDA was recognized for three months ended March 31, 2020.

Results of Operations

Net Loss

Our net loss for the three months ended March 31, 2021 and 2020 totaled $3.3 million and $4.7 million, respectively.

(In thousands)	Three Months Ended March 31, 2021	2020
Net revenue	$ 34,568	$ 26,678
Cost of product sales	11,583	9,922
Gross profit	22,985	16,756
Total operating expenses	26,290	21,832
Loss from operations	(3,305)	(5,076)
Other income	159	371
Tax provision	(143)	—
Net loss	$ (3,289)	$ (4,705)

Net Revenue

Net revenue increased for the three months ended March 31, 2021 compared to the same period in 2020, driven by strong volume growth for both MACI and Epicel. Additionally, during the three months ended March 31, 2021, we recorded $0.9 million of revenue associated with delivery of NexoBrid to BARDA for emergency response preparedness.

Net revenue for the three months ended March 31, 2021 and 2020 are shown below.

Revenue by product (In thousands)	Three Months Ended March 31, 2021	2020
MACI	$ 23,797	$ 20,286
Epicel	9,830	6,392
NexoBrid	941	—
Total Revenue	$ 34,568	$ 26,678

Seasonality. During the past year, the effects of the COVID-19 pandemic disrupted the normal seasonality of our MACI business. These effects included, among others, the temporary limitation of elective surgical procedures throughout the country, the inability of our Clinical Account Specialists to call on surgeon customers and, we believe, a reduction in the number of patients seeking treatment for cartilage damage. In the four years preceding 2020, ACI sales volumes from the first through the fourth quarter 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 COVID-19, the seasonality in 2020 did not follow our historical patterns, and seasonality in 2021 could be impacted by COVID-19 related factors, as well. 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 38% to as low as 18% of annual revenue.

Gross Profit and Gross Profit Ratio

(In thousands)	Three Months Ended March 31, 2021	2020
Gross profit	$ 22,985	$ 16,756
Gross profit %	66 %	63 %

Gross profit increased for the three months ended March 31, 2021 compared to the same period in 2020 primarily due to the increase in MACI and Epicel volume and other revenue related to NexoBrid.

Research and Development Costs

	Three Months Ended March 31,	
(In thousands)	**2021**	**2020**
Research and development costs	$ 3,630	$ 3,763

The following table summarizes research and development expenses which includes license fees, materials, professional fees and the approximate allocation of employee-related salary and fringe benefit costs for our research and development projects:

	Three Months Ended March 31,	
(In thousands)	**2021**	**2020**
ACI	$ 1,888	$ 2,105
Epicel	934	1,027
NexoBrid	808	631
Total research and development costs	$ 3,630	$ 3,763

Research and development expenses for the three months ended March 31, 2021 were $3.6 million compared to $3.8 million for the same period in 2020. R&D costs continue to be centered around process development, regulatory, and medical affairs for MACI and Epicel.

Selling, General and Administrative Costs

	Three Months Ended March 31,	
(In thousands)	**2021**	**2020**
Selling, general and administrative costs	$ 22,660	$ 18,069

Selling, general and administrative expenses for the three months ended March 31, 2021 were $22.7 million compared to $18.1 million for the same period in 2020. The increase in selling, general and administrative expenses during the three months ended March 31, 2021, compared to the same period in 2020, is due primarily to an incremental $2.5 million increase in stock-based compensation expense and a $1.1 million increase in MACI sales force expenses as a result of the sales team expansion in 2020.

Other Income (Expense)

	Three Months Ended March 31,	
(In thousands)	**2021**	**2020**
Net interest income	$ 75	$ 304
Other income	84	67
Total other income	$ 159	$ 371

The decrease in other income for the three months ended March 31, 2021, compared to the same period in 2020 is due primarily to the 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 product sales, research and development expenses and selling, general and administrative expenses is summarized in the following table:

(In thousands)	Three Months Ended March 31, 2021	2020
Cost of product sales	$ 911	$ 493
Research and development	863	513
Selling, general and administrative	5,245	2,762
Total non-cash stock-based compensation expense	$ 7,019	$ 3,768

The increase in stock-based compensation expense for the three months ended March 31, 2021 compared to the same period in 2020 is due primarily to increases in stock prices which impacts the fair value of the options and restricted stock units awarded and the expense recognized in the period.

As of March 31, 2021, there was approximately $50.1 million of total unrecognized compensation cost related to non-vested service-based stock options granted under the 2019 Plan and the Prior Plans, compared to $13.1 million as of December 31, 2020. That cost is expected to be recognized over a weighted-average period of 3.6 years. As of March 31, 2021, there was approximately $11.7 million of total unrecognized compensation cost related to non-vested restricted stock awards granted under the 2019 Plan and Prior Plans, compared to $2.1 million as of December 31, 2020. That cost is also expected to be recognized over a weighted-average period of 3.6 years. The estimated unrecognized compensation cost is not reduced by expected forfeitures.

Liquidity and Capital Resources

Since our acquisition in 2014 of MACI and Epicel, 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, and product candidates. To date, we have financed our operations primarily through cash received through Epicel and MACI sales, debt and public and private sales of our equity securities. We generated $10.1 million in operating cash flows during the three months ended March 31, 2021, and we may continue to finance our operations through the sales of equity securities.

(In thousands)	Three Months Ended March 31, 2021	2020
Cash provided by operating activities	$ 10,086	$ 4,686
Cash provided by investment activities	12,186	13,742
Cash provided by financing activities	2,262	306
Net increase in cash, cash equivalents and restricted cash	$ 24,534	$ 18,734

Our cash and cash equivalents totaled $58.2 million, short-term investments totaled $25.4 million and long-term investments totaled $26.0 million as of March 31, 2021. The $10.1 million of cash provided by operations during the three months ended March 31, 2021 was the result of cash collections from a decrease in accounts receivable of $5.4 million from the prior quarter, an increase in accounts payable of $2.2 million, including noncash charges of $7.0 million related to stock compensation expense, $1.2 million of operating lease amortization and $0.8 million in depreciation and amortization expense and a $3.3 million net loss.

Our cash and cash equivalents totaled $45.7 million and short-term investments totaled $36.0 million and long-term investments of $1.7 million as of March 31, 2020. The $4.7 million of cash provided operations during the three months ended March 31, 2020 was the result of cash collections from a decrease in accounts receivable of $8.0 million from the prior quarter, including noncash charges of $3.8 million related to stock compensation expense, offset by a $1.9 million decrease in accrued expenses and a $4.7 million net loss.

The change in cash provided by investing activities during the three months ended March 31, 2021 was the result of $25.0 million of investment sales and maturities offset by $10.4 million in investment purchases and property plant and equipment purchases of $2.3 million primarily for manufacturing upgrades through March 31, 2021. The cash provided by investing activities for the three months ended March 31, 2020 was the result of $20.1 million of investment sales and maturities offset by $5.7 million in investment purchases, and property plant and equipment purchases of $0.7 million primarily for manufacturing upgrades and leasehold improvements.

The change in cash provided from financing activities was the result of net proceeds from the exercise of stock options of $3.8 million, partially offset by the payment of employee withholding taxes related to the vesting of restricted stock units of $1.5 million during the three months ended March 31, 2021. The change in cash provided from financing activities during the three months ended March 31, 2020 was the result of proceeds from the exercise of stock options of $0.4 million, slightly offset by the payment of employee withholding taxes related to the vesting of restricted stock units of $0.1 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 Condensed Consolidated Financial Statements. However, the continuing effects of the COVID-19 pandemic continue to evolve and may result in irrecoverable losses from customers.

If revenue declines 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 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 any future impacts 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 March 31, 2021, 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. 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 Annual Report are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. There have been no material changes to that information disclosed in our Annual Report during the three months ended March 31, 2021.

Cautionary Note Regarding Forward-Looking Statements

This report, including the documents incorporated by reference herein, contains certain statements that describe our management's beliefs concerning future business conditions, plans and prospects, growth opportunities and the outlook for our business based upon information currently available. Such statements are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Wherever possible, we have identified these forward-looking statements by words such as "will," "may," "anticipates," "believes," "intends," "estimates," "expects," "plans," "projects," "trends," "opportunity," "current," "intention," "position," "assume," "potential," "outlook," "remain," "continue," "maintain," "sustain," "seek," "target," "achieve," "continuing," "ongoing," and similar words or phrases, or future or conditional verbs such as "would," "should," "could," "may," or similar expressions. These forward-looking statements are based upon assumptions our management believes are reasonable. Such forward-looking statements are subject to risks and uncertainties which could cause our actual results, performance and achievements to differ materially from those expressed in, or implied by, these statements, including, among others, the risks and uncertainties listed in our Annual Report under "Part I, Item 1A Risk Factors."

Because our forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different and any or all of our forward-looking statements may turn out to be wrong. Forward-looking statements speak only as of the date made and can be affected by assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in our discussion in our Annual Report will be important in determining future results. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. Consequently, we cannot assure you that our expectations or forecasts expressed in such forward-looking statements will be achieved. Except as required

by law, we undertake no obligation to publicly update any of our forward-looking or other statements, whether as a result of new information, future events, or otherwise. 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 March 31, 2021, 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 $0.4 million and $0.5 million decrease in the fair value of our investment portfolio as of March 31, 2021 and December 31, 2020, 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 Chief Executive Officer and Chief Financial Officer (its Certifying Officers), evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation as of March 31, 2021, 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 Certifying Officers, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the three months ended March 31, 2021, 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).

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 Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and expound upon and amend the specific risks resulting from the COVID-19 pandemic, as well as the specific risks related to the U.S. Food & Drug Administration's (FDA) review of MediWound's submitted BLA for approval of NexoBrid in the United States. 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, the COVID-19 pandemic has created 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 many state, local and national governments – including those in Massachusetts and Michigan, where the Company's operations are located – have responded at times by issuing, extending and supplementing orders requiring quarantines, restrictions on travel, and the mandatory closure of certain non-essential businesses, among other actions. In the U.S., the status and application of these orders have varied on a state-by-state basis since the early days of the pandemic. Many of the restrictions have been periodically updated as infection rates in the U.S. have risen and fallen, as new virus "variants" have emerged, and as world health leaders learn more about the virus, its transmission pathway and who is most at risk. As a biopharmaceutical company, Vericel is deemed an essential business and has been exempted from government orders requiring the closure of workplaces and the cessation of business operations, as they have existed from time-to-time during the pandemic. Even though widespread distribution of vaccines designed to protect against COVID-19 infection began in the United States and other countries throughout the world in early 2021, the pandemic remains highly fluid and the number of COVID-19 infections has fluctuated significantly in various geographies during 2020 and early 2021 and could continue to do so. As such, many state and local governments have re-instituted restrictions on businesses, travel, and personal activities from time-to-time and 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 pandemic evolves. Depending on the pandemic's trajectory in the coming months, we may take additional actions to the extent required, or we may ease certain protective measures to the extent available data and state and local rules permit. Both these existing measures and any future actions we take may result in 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 has and could

continue to 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.

- Hospitals, health systems and surgeons minimized, postponed, or canceled electively scheduled surgeries during the initial wave of the pandemic in the spring of 2020. These actions 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 the Company experienced a significant increase in cancellations of scheduled MACI procedures as well as a slowdown in new MACI orders during March and April of 2020, which negatively impacted the Company's business and results of operations during the first and second quarters of 2020. The level and degree of restriction on elective surgeries, on the ability of patients to seek treatment and on U.S. business operations generally fluctuated throughout 2020 as COVID-19 infection rates rose and fell during the summer months and into the autumn. By the first quarter of 2021, the pandemic's effects on the Company's MACI business had largely dissipated. Although hospitals are now better prepared for a subsequent surge in COVID-19 patients and COVID-19 vaccines have been made available and are being widely distributed in the United States, 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 were to rise again, or if new COVID-19 variants emerge which render current vaccine treatments ineffective. We believe our MACI business will 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 and could lead to potential impairments to inventory and accounts receivable. While trauma injury admissions have been reported to have declined due to various COVID-19 related restrictions and although Epicel has been less directly impacted by the pandemic given the critical nature of severe burn injuries, it is difficult to ascertain the continued impact of COVID-19 on the treatment of 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. Three (3) such sites have currently paused enrollment of new PEAK patients as a result of the effects of the pandemic, and the PEAK Study experienced a slow-down in its traditional rate of patient enrollment during 2020 and into 2021. Furthermore, 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. A future 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 both domestic and international 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 or executive orders resulting from the COVID-19 pandemic for an extended period of time, including staffing shortages, production slowdowns, disruptions in delivery systems, or federal, state or foreign orders requiring the diversion of key supplies for use in the production or manufacturing of vaccines designed to inoculate individuals against COVID-19, 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 six (6) days and established shipping shelf life of three (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 in the future 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.

- During the pandemic we have generally 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 resurgence of COVID-19, COVID-19 variants, 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 certain 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 directors contract an illness related to COVID-19 and are unable to perform their duties. For example, COVID-19 illness could impact members of management or our board of directors resulting in absenteeism from management meetings or meetings of the directors or committees of directors, and making it more difficult for management to effectively oversee our daily operations, or to convene the quorums of the full board of directors or its committees needed to conduct meetings for the management of our affairs.

- A resurgence of COVID-19 or any new COVID-19 variants 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. 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 and has assigned a PDUFA target date for the product of June 29, 2021. However, health regulatory agencies globally, including the FDA, have experienced, and may continue to 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 and its ability to monitor our clinical trials. Additionally, in many instances across the industry, the FDA has postponed, or has been unable to conduct certain inspections of domestic and international manufacturing facilities in connection with its regulatory review of product applications as a result of travel and other restrictions caused by the pandemic. As part of its ongoing review of the BLA submission, the FDA has communicated to MediWound that physical Current Good Manufacturing Practice (cGMP) inspections of manufacturing facilities in Israel and Taiwan are required before the BLA can be approved, as the FDA must assess the ability of those facilities to conduct certain manufacturing operations in compliance with cGMP. The FDA has indicated further that because of restrictions on travel caused by the COVID-19 pandemic, the agency may be unable to conduct the required inspections of those facilities during the current review cycle in order to meet the PDUFA target date of June 29, 2021. Should restrictions prevent or delay the FDA in conducting necessary reviews or physical inspections of the manufacturing facilities involved in the production of NexoBrid, or should other events impact FDA's response times, the timeline for approval of NexoBrid could be materially delayed, which could materially affect the development, study and ultimate commercialization of the product.

- The trading prices of our common stock and that of other biopharmaceutical companies have been highly volatile during 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 a resurgence of the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

- The negative economic effects of the pandemic have, at times, caused increased unemployment in the U.S. resulting in many individuals losing their employer-based insurance coverage. Although the economy has begun to recover from the pandemic's initial effects, the continued or future unemployment of our potential patients may adversely affect our ability to commercialize our products. In addition, market disruption or rising unemployment caused by a resurgence of 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 continued outbreak or a worsening of COVID-19 may also negatively impact our commercialization strategy for our products and product candidates, if approved. At times during the pandemic, 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 has included our sales personnel. Hospitals may continue or increase these and similar measures in the future should the COVID-19 virus continue to spread or surge in certain areas. In addition, COVID-19 levels 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. Although many face-to-face interactions are again resuming, we have, at times, 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.

NexoBrid's approval in the United States for the treatment of severe burns may be delayed, and it may not be approved for use in the United States and other North American markets.

On September 16, 2020, we announced that the FDA has accepted for review MediWound's BLA seeking marketing approval for NexoBrid in the United States for the treatment of severe burns, and has assigned a PDUFA target date for the product of June 29, 2021. The BLA submission is based in large part on data derived from a U.S. Phase 3 pivotal study. MediWound is conducting twelve and twenty-four month safety follow-ups for cosmesis, function, quality of life and other safety measurements. Data from MediWound's twelve-month follow-up has been compiled and is being evaluated by the FDA, while data from the twenty-four month follow-up, which is ongoing, will be submitted as a safety update as part of a post-approval commitment, if the BLA is approved. While this and previous studies evaluating NexoBrid have met their primary endpoints, we cannot predict the outcome of the planned safety follow-ups or whether the FDA will approve the BLA based on the available preclinical and clinical data and the submitted manufacturing processes and cGMP data.

As part of its ongoing review of the BLA submission, the FDA has communicated to MediWound that physical cGMP inspections of manufacturing facilities in Israel and Taiwan are required before the BLA can be approved, as the FDA must assess the ability of those facilities to conduct certain manufacturing operations in compliance with cGMP. The FDA has indicated further that because of restrictions on travel caused by the COVID-19 pandemic, the agency may be unable to conduct the required inspections of those facilities during the current review cycle in order to meet the PDUFA target date of June 29, 2021.

Additionally, as part of its ongoing review of the BLA submission, the FDA has communicated to MediWound that it has identified certain issues related to the Chemistry, Manufacturing and Controls (CMC) section of the BLA and has requested that MediWound provide additional information. Although MediWound is providing the requested information to the FDA, the FDA has indicated that it is unlikely that the additional information will be reviewed during the current review cycle. Moreover, we cannot predict whether MediWound's responses to the CMC-related information requests from the FDA will be considered sufficient by the agency.

We cannot predict how long the FDA may take to review and approve NexoBrid during this or a subsequent review cycle, or whether any such approval in the United States will ultimately be granted. In addition, if approval to market NexoBrid is sought in Mexico or Canada, we cannot predict how long regulatory authorities in those countries will take to provide NexoBrid with marketing authorization in their jurisdictions or whether such authorizations will be granted at all. A significant delay or a failure to receive regulatory approval for NexoBrid in the United States may have a material adverse impact on our business prospects.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
31.1**	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	Inline XBRL Instance Document
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

** Filed herewith.

SIGNATURES

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

Date: May 5, 2021

VERICEL CORPORATION

/s/ DOMINICK C. COLANGELO

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

/s/ JOSEPH A. MARA

Joseph A. Mara
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 31.1

CERTIFICATION

I, Dominick C. Colangelo, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2021

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

EXHIBIT 31.2

CERTIFICATION

I, Joseph A. Mara, 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: May 5, 2021

/s/ JOSEPH A. MARA

Joseph A. Mara

Chief Financial Officer

(Principal Financial 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 March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

(1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 5, 2021

/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 March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

(1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 5, 2021

/s/ JOSEPH A. MARA
Joseph A. Mara
Chief Financial Officer
(Principal Financial Officer)

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