
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, 2023

or

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

Commission File Number 001-35280

VERICEL CORPORATION

(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction of incorporation or organization)

94-3096597

(I.R.S. Employer Identification No.)

64 Sidney Street

Cambridge, MA 02139

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(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 No

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

As of April 30, 2023, 47,564,919 shares of Common Stock, no par value per share, were outstanding.

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

Item 1. Financial Statements (Unaudited)

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 61,834	\$ 51,067
Short-term investments	57,442	68,471
Accounts receivable (net of allowance for doubtful accounts of \$47 and \$47, respectively)	38,359	46,539
Inventory	15,370	15,986
Other current assets	4,540	4,803
Total current assets	177,545	186,866
Property and equipment, net	18,197	15,837
Intangible assets, net	7,344	7,500
Right-of-use assets	40,851	41,535
Long-term investments	19,910	19,962
Other long-term assets	1,249	1,303
Total assets	\$ 265,096	\$ 273,003
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 11,125	\$ 16,930
Accrued expenses	13,111	16,190
Current portion of operating lease liabilities	4,497	4,302
Other current liabilities	20	41
Total current liabilities	28,753	37,463
Operating lease liabilities	42,365	43,268
Total liabilities	71,118	80,731
COMMITMENTS AND CONTINGENCIES (Note 12)		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding 47,507 and 47,253, respectively	602,104	593,245
Accumulated other comprehensive loss	(636)	(978)
Accumulated deficit	(407,490)	(399,995)
Total shareholders' equity	193,978	192,272
Total liabilities and shareholders' equity	\$ 265,096	\$ 273,003

The accompanying notes to condensed consolidated financial statements are an integral part of these statements.

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

	Three Months Ended March 31,	
	2023	2022
Product sales, net	\$ 41,017	\$ 35,852
Other revenue	—	222
Total revenue	41,017	36,074
Cost of product sales	14,497	12,622
Gross profit	26,520	23,452
Research and development	5,212	4,860
Selling, general and administrative	29,485	25,865
Total operating expenses	34,697	30,725
Loss from operations	(8,177)	(7,273)
Other income (expense):		
Interest income	839	88
Interest expense	(145)	(18)
Other (expense) income	(12)	112
Total other income	682	182
Net loss	\$ (7,495)	\$ (7,091)
Net loss per common share:		
Basic and diluted	\$ (0.16)	\$ (0.15)
Weighted-average common shares outstanding:		
Basic and diluted	47,387	46,985

The accompanying notes to condensed consolidated financial statements are an integral part of these statements.

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

	<u>Three Months Ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
Net loss	\$ (7,495)	\$ (7,091)
Other comprehensive loss:		
Unrealized gain (loss) on investments	342	(459)
Comprehensive loss	<u>\$ (7,153)</u>	<u>\$ (7,550)</u>

The accompanying notes to 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 Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
BALANCE, DECEMBER 31, 2022	47,253	\$ 593,245	\$ (978)	\$ (399,995)	\$ 192,272
Net loss	—	—	—	(7,495)	(7,495)
Stock-based compensation expense	—	8,731	—	—	8,731
Stock option exercises	132	2,009	—	—	2,009
Shares issued under the Employee Stock Purchase Plan	11	216	—	—	216
Issuance of stock for restricted stock unit vesting	183	—	—	—	—
Restricted stock withheld for employee tax remittance	(72)	(2,097)	—	—	(2,097)
Unrealized gain on investments	—	—	342	—	342
BALANCE, MARCH 31, 2023	47,507	\$ 602,104	\$ (636)	\$ (407,490)	\$ 193,978

	Common Stock		Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
BALANCE, DECEMBER 31, 2021	46,880	\$ 553,902	\$ (154)	\$ (383,286)	\$ 170,462
Net loss	—	—	—	(7,091)	(7,091)
Stock-based compensation expense	—	9,531	—	—	9,531
Stock option exercises	125	1,155	—	—	1,155
Shares issued under the Employee Stock Purchase Plan	9	310	—	—	310
Issuance of stock for restricted stock unit vesting	108	—	—	—	—
Restricted stock withheld for employee tax remittance	(41)	(1,423)	—	—	(1,423)
Unrealized loss on investments	—	—	(459)	—	(459)
BALANCE, MARCH 31, 2022	47,081	\$ 563,475	\$ (613)	\$ (390,377)	\$ 172,485

The accompanying notes to condensed consolidated financial statements are an integral part of these statements.

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

	Three months ended March 31,	
	2023	2022
Operating activities:		
Net loss	\$ (7,495)	\$ (7,091)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization expense	1,158	873
Stock-based compensation expense	8,731	9,531
Amortization of premiums and discounts on marketable securities	(290)	194
Amortization of debt issuance costs	54	—
Non-cash lease costs	1,112	1,076
Other	12	4
Changes in operating assets and liabilities:		
Inventory	616	(1,004)
Accounts receivable	8,180	5,582
Other current assets	263	(847)
Accounts payable	(274)	(219)
Accrued expenses	(3,079)	(3,734)
Operating lease liabilities	(1,128)	(897)
Net cash provided by operating activities	7,860	3,468
Investing activities:		
Purchases of investments	(9,787)	(12,629)
Sales and maturities of investments	21,500	5,041
Expenditures for property and equipment	(1,413)	(3,081)
Purchases of intangible assets	(7,500)	—
Net cash provided by (used in) investing activities	2,800	(10,669)
Financing activities:		
Net proceeds from common stock issuance	2,225	1,465
Payments on employee's behalf for taxes related to vesting of restricted stock unit awards	(2,097)	(943)
Other	(21)	(19)
Net cash provided by financing activities	107	503
Net increase (decrease) in cash, cash equivalents, and restricted cash	10,767	(6,698)
Cash, cash equivalents, and restricted cash at beginning of period	51,067	68,541
Cash, cash equivalents, and restricted cash at end of period	\$ 61,834	\$ 61,843

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

	<u>Three months ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
Supplemental disclosure of cash flow information:		
Non-cash information:		
Right-of-use asset and lease liability recognized	\$ 419	\$ —
Additions to property and equipment included in accounts payable	2,282	317
Restricted stock held for employee tax remittance included in accounts payable	—	480
	<u>Three months ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
Reconciliation of amounts within the condensed consolidated balance sheets:		
Cash and cash equivalents	\$ 61,834	\$ 55,659
Restricted cash	—	6,184
Total cash, cash equivalents, and restricted cash at end of period	<u>\$ 61,834</u>	<u>\$ 61,843</u>

The accompanying notes to 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 three commercial-stage products in the U.S., MACI[®], Epicel[®] and NexoBrid[®].

MACI (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. Epicel (cultured epidermal autografts) is a permanent skin replacement for the treatment of adult and pediatric patients with deep-dermal or full-thickness burns comprising greater than or equal to 30 percent of total body surface area (“TBSA”). The Company also holds an exclusive license from MediWound Ltd. (“MediWound”) to commercialize NexoBrid (anacaulase-bcdb) in North America. On December 28, 2022, the U.S. Food and Drug Administration (“FDA”) approved a Biologics License Application (“BLA”) for NexoBrid, granting a license for commercial use in the U.S. NexoBrid is a topically-administered biological product containing proteolytic enzymes and is indicated for the removal of eschar in adults with deep partial-thickness and/or full thickness 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 and specialty biologics for use in the treatment of specific diseases.

The Company is subject to risks common to companies in the life sciences industry including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with FDA regulations and approval requirements, as well as the ability to grow the Company’s business through appropriate commercial strategies.

COVID-19

In March 2020, the World Health Organization declared the spread of a novel strain of coronavirus (“COVID-19”) to be a pandemic, which contributed to an economic downturn on a global scale, as well as significant volatility in the financial markets. At the time of the pandemic’s inception, and at times throughout its duration, there was significant volatility in the Company’s results of operations on a quarterly basis due to the widespread and periodic cancellation or delay of elective MACI surgical procedures throughout the U.S., staffing shortages and the Company’s ability to access customers. Based on declining COVID-related statistics, the U.S. Department of Health and Human Services has announced that the federal Public Health Emergency for COVID-19 is set to expire at the end of the day on May 11, 2023. Although at this juncture the pandemic’s effects on the Company’s business and results of operations have moderated, should a resurgence of COVID-19 occur it could result in additional disruptions that could impact the Company’s business and operations in the future, including intermittent restrictions on the ability of Company personnel to travel and access customers for selling, marketing, training, case support and product development feedback, delays in approvals by regulatory bodies, delays in product development efforts, and additional government requirements or other incremental mitigation efforts that may further impact its capacity to manufacture, sell and support the use of its products.

The War in Ukraine

The ongoing war between Russia and Ukraine and the related sanctions and other penalties imposed by countries across the globe against Russia are continuing to create substantial uncertainty in the global economy and have contributed to heightened inflation and supply chain disruptions. While the Company does not have operations in Russia or Ukraine and does not have exposure to distributors, or third-party service providers in Russia or Ukraine, it is unable to predict the ultimate impact that these actions will have on the global economy or on its financial condition, results of operations, and cash flows as of the date of these condensed consolidated financial statements.

Liquidity

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, 2023, the Company had an accumulated deficit of \$407.5 million and had a net loss of \$7.5 million during the three months ended March 31, 2023. The Company had cash and cash equivalents of \$61.8 million and investments of \$77.4 million as of March 31, 2023. The Company expects that cash from the sales of its products and existing cash, cash equivalents, investments, and available borrowing capacity will be sufficient to support the Company's current operations through at least 12 months from the issuance of these condensed consolidated financial statements. If revenues decline for a sustained period, the Company may need to access additional capital; however, the Company may not be able to obtain additional financing on acceptable terms or at all. The terms of any additional financing may adversely affect the holdings or the rights of the Company's shareholders.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and investments in marketable debt securities. The Company may maintain deposits in financial institutions in excess of the insurance coverage offered by the Federal Deposit Insurance Corporation ("FDIC"), the loss of which could have a negative effect on our operations and liquidity. The Company is closely monitoring ongoing events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally. The Company believes that it is not exposed to significant credit risk as its deposits, including cash and cash equivalents, are held at multiple high credit quality financial institutions. The Company has not experienced any losses on these deposits; however no assurances can be provided that there will not be losses experienced in the future. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated based on the fact that many of these securities are either government-backed or of high credit rating.

2. Basis of Presentation

The accompanying condensed consolidated financial statements of Vericel 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 ("U.S. 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 condensed consolidated balance sheet as of December 31, 2022 has been derived from the audited consolidated financial statements at that date, but does not include all the information and notes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on February 23, 2023 ("Annual Report").

Recent Accounting Pronouncements

No new accounting standards were adopted during the three months ended March 31, 2023. The Company considers the applicability and impact of any recent Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB"). Based on the assessment, the ASUs were determined to be either not applicable or are expected to have minimal impact on the Company's condensed consolidated financial statements.

3. Revenue

Revenue Recognition and Product Sales, Net

The Company recognizes product revenue from sales of MACI biopsy kits, MACI implants, Epicel grafts and NexoBrid 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 by the Company from the customer following biopsy. 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 Group, Inc. ("DMS") for patients treated at military treatment facilities. 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 that 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 past payer precedents. Net product revenue is recognized net of estimated contractual allowances, which considers historical collection experience from both the payer and patient, denial rates and the terms of the Company's contractual arrangements. The Company estimates expected collections for these transactions using the portfolio approach. The Company records a reduction to revenue at the time of sale for its estimate of the amount of consideration that will not be collected. In addition, potential credit risk exposure has been evaluated for the Company's accounts receivable in accordance with *ASC 326, Financial Instruments - Credit Losses*. The Company assesses risk and determines a loss percentage by pooling accounts receivable based on similar risk characteristics. The loss percentage is calculated through the use of forecasts that are based on current and historical economic and financial information. This loss percentage was applied to the accounts receivables as of March 31, 2023. The total allowance for uncollectible consideration as of March 31, 2023 and December 31, 2022 was \$7.1 million and \$6.1 million, respectively. Changes to the estimate of the amount of consideration that will not be collected could have a material impact on the revenue recognized. A 50 basis points change to the estimated uncollectible percentage could result in an approximately \$0.3 million decrease or increase in the revenue recognized for the three months ended March 31, 2023.

Changes in estimates of the Transaction Price are recorded through revenue in the period in which such change occurs. Changes in estimates related to prior periods are shown in the Revenue by Product and Customer table below and relate primarily to changes in the initial expected reimbursement or collection expectation upon completion of the billing claims process for MACI implants that occurred in a prior year.

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 in May 2019, pursuant to which MediWound will manufacture and supply NexoBrid on a unit price basis, which may be increased pursuant to the terms of the agreements. Additionally, beginning in 2020 the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) procured quantities of NexoBrid from MediWound, for use as a medical countermeasure in the event of a mass casualty emergency in the U.S. involving thermal burns. The initial, quarterly, procurement of NexoBrid by BARDA under its agreement with MediWound completed during the third quarter of 2022. The Company recognized revenue based on a percentage of gross profits for sales of NexoBrid to BARDA upon delivery, at which time BARDA was in control of the product. As of March 31, 2023, the Company did not hold a direct contract or distribution agreement with BARDA, or take title to the product procured by BARDA.

On May 9, 2023, MediWound announced BARDA’s award of additional funding under the parties’ existing agreement, \$3 million of which will support the replacement of NexoBrid, previously procured for emergency response preparedness, which has since expired. Pursuant to the terms of the Company’s license agreement with MediWound, the Company would recognize revenue based on a percentage of gross profits, minus a percentage of net sales, on any sales of NexoBrid directly to BARDA upon delivery, pursuant to this additional award.

Additionally, on December 28, 2022, the FDA approved a BLA for NexoBrid, granting a license for commercial use in the U.S. NexoBrid is a topically-administered biological product containing proteolytic enzymes and is indicated for the removal of eschar in adults with deep partial-thickness and/or full thickness thermal burns.

Revenue by Product and Customer

The following table and descriptions below show the products from which the Company generated its revenue for the periods indicated:

Revenue by product (in thousands)	Three Months Ended March 31,	
	2023	2022
<i>MACI implants and kits</i>		
Implants based on contracted rate sold through a specialty pharmacy ^(a)	\$ 22,698	\$ 15,190
Implants subject to third party reimbursement sold through a specialty pharmacy ^(b)	3,485	3,369
Implants sold direct based on contracted rates ^(c)	6,919	5,634
Implants sold direct subject to third-party reimbursement ^(d)	501	861
Biopsy kits - direct bill	535	522
Change in estimates related to prior periods ^(e)	52	419
<i>Total MACI implants and kits</i>	<u>34,190</u>	<u>25,995</u>
<i>Epicel</i>		
Direct bill (hospital)	6,827	9,857
<i>NexoBrid revenue ^(f)</i>		
	—	222
Total revenue	<u>\$ 41,017</u>	<u>\$ 36,074</u>

(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 and AllCare whereby such specialty pharmacy does not have a direct contract with the underlying payer, and are subject to third-party reimbursement. The amount of reimbursement is established based on publicly available rates, fee schedules or past payer precedents.

(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 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 and relate to changes to the initial expected reimbursement or collection expectations upon completion of the billing claims process. The change in estimates is a result of additional information, changes in collection expectations 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 (see Note 11).

4. Selected Balance Sheet Components

Inventory

Inventory consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
Raw materials	\$ 14,264	\$ 15,101
Work-in-process	1,043	832
Finished goods	63	53
Total inventory	<u>\$ 15,370</u>	<u>\$ 15,986</u>

Property and Equipment

Property and Equipment, net consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
Machinery and equipment	\$ 5,212	\$ 5,041
Furniture, fixtures and office equipment	1,710	1,710
Computer equipment and software	8,208	8,224
Leasehold improvements	14,120	13,689
Construction in process	8,121	5,438
Financing right-of-use lease	28	37
Total property and equipment, gross	37,399	34,139
Less accumulated depreciation	(19,202)	(18,302)
Total property and equipment, net	<u>\$ 18,197</u>	<u>\$ 15,837</u>

Depreciation expense for the three months ended March 31, 2023 and 2022 was \$1.0 million and \$0.9 million, respectively.

Intangible Assets

Intangible assets, net consisted of the following:

(In thousands)	Useful Live (in years)	Amortization Method	March 31, 2023			December 31, 2022		
			Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
NexoBrid license	12	Straight-line	\$ 7,500	\$ (156)	\$ 7,344	\$ 7,500	\$ —	\$ 7,500

Amortization expense for the three months ended March 31, 2023 was \$0.2 million.

Future amortization expense of intangible assets as of March 31, 2023 is estimated to be as follows:

(In thousands)	Amount
Remainder of 2023	\$ 469
2024	625
2025	625
2026	625
2027	625
Thereafter	4,375
Total	\$ 7,344

Accrued Expenses

Accrued Expenses consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
Bonus related compensation	\$ 3,588	\$ 7,132
Employee related accruals	2,739	3,101
Insurance reimbursement-related liabilities	5,769	5,030
Other accrued expenses	1,015	927
Total accrued expenses	\$ 13,111	\$ 16,190

5. 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, and other computer-related equipment.

With respect to the Ann Arbor facility, in March 2023, the Company entered into an amendment to that lease extending its term until April 30, 2025. Monthly contractual payments are expected to range from \$17,000 to \$18,000.

On January 28, 2022, the Company entered into a lease agreement (the “Burlington Lease”) to lease approximately 126,000 square feet of to-be-constructed manufacturing, laboratory and office space in Burlington, Massachusetts (the “Premises”). Once constructed, the Premises will serve as the Company’s new corporate headquarters and primary manufacturing facility.

The term of the Burlington Lease is currently expected to begin mid-year 2023 (the “Commencement Date”). The Company’s obligation to pay rent for the Premises will begin on the earlier of: 13 months from the Commencement Date; or the date on which the Company first occupies the Premises to conduct operations (the “Rent Commencement Date”). The initial term of the Lease is 144 months following the Rent Commencement Date. The Company has a one-time option to extend the term of the Lease for an additional 10 years, exercisable under certain conditions and at a market rate determined in accordance with the Burlington Lease.

The annual base rent of the Burlington Lease is initially \$57 per square foot per year, subject to annual increases of 2.5%. Monthly contractual payments are expected to range from \$0.6 million to \$0.8 million. Additionally, the Company is responsible for reimbursing the landlord for the Company’s share of the Premises’ property taxes and certain other operating expenses. The Burlington Lease also provides for a tenant improvement allowance from the landlord in an amount equal to \$200 per square foot of the Premises, or approximately \$24.4 million in total, following certain reductions to the tenant improvement allowance to account for the costs associated with changes to the landlord’s work on the Premises, as requested by the Company. The tenant improvement allowance will be used towards the design and construction of certain tenant improvements made to the Premises, subject to the terms set forth in the Burlington Lease.

The Company is not involved in the initial construction of the core and shell of the building and will record the lease liability and right-of-use asset on its condensed consolidated balance sheet when the construction is substantially completed and it obtains control of the Premises, which is currently expected to be on or around the Commencement Date.

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In January 2022, in connection with the execution of the Burlington Lease, the Company issued a letter of credit collateralized by cash deposits of approximately \$6.0 million. Subsequent to the execution of the Revolving Credit Agreement on July 29, 2022 (see Note 8, "Revolving Credit Agreement" for further details), the letter of credit is issued under the sub-facility limit of the Revolving Credit Agreement. Such letter of credit shall be reduced to approximately \$4.2 million and \$1.8 million at the conclusion of the third and sixth lease years, respectively, provided certain conditions set forth in the Burlington Lease are satisfied.

For the three months ended March 31, 2023 and 2022, lease expense of less than \$0.1 million was recorded related to short-term leases. For the three months ended March 31, 2023 and 2022, the Company recognized \$1.7 million of operating lease expense. For the three months ended March 31, 2023 and 2022, the Company recognized less than \$0.1 million of financing lease expense.

Operating and finance lease assets and liabilities are as follows:

(In thousands)	Classification	March 31, 2023	December 31, 2022
Assets			
Operating	Right-of-use assets	\$ 40,851	\$ 41,535
Finance	Property and equipment, net	28	37
Total leased assets		<u>\$ 40,879</u>	<u>\$ 41,572</u>
Liabilities			
<i>Current</i>			
Operating	Current portion of operating lease liabilities	\$ 4,497	\$ 4,302
Finance	Other current liabilities	20	41
<i>Non-current</i>			
Operating	Operating lease liabilities	\$ 42,365	\$ 43,268
Total leased liabilities		<u>\$ 46,882</u>	<u>\$ 47,611</u>

6. 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:

March 31, 2023						
(In thousands)	Amortized Cost	Gross Unrealized		Credit Losses		Estimated Fair Value
		Gains	Losses			
Commercial paper	\$ 14,306	\$ —	\$ (48)	\$ —		\$ 14,258
Corporate notes	43,157	—	(559)	—		42,598
U.S. government securities	4,920	5	—	—		4,925
U.S. government agency bonds	15,600	—	(29)	—		15,571
	<u>\$ 77,983</u>	<u>\$ 5</u>	<u>\$ (636)</u>	<u>\$ —</u>		<u>\$ 77,352</u>
Classified as:						
Short-term investments						\$ 57,442
Long-term investments						19,910
						<u>\$ 77,352</u>
December 31, 2022						
(In thousands)	Amortized Cost	Gross Unrealized		Credit Losses		Estimated Fair Value
		Gains	Losses			
Commercial paper	\$ 15,707	\$ —	\$ (101)	\$ —		\$ 15,606
Corporate notes	52,159	—	(831)	—		51,328
U.S. government agency bonds	21,545	—	(46)	—		21,499
	<u>\$ 89,411</u>	<u>\$ —</u>	<u>\$ (978)</u>	<u>\$ —</u>		<u>\$ 88,433</u>
Classified as:						
Short-term investments						\$ 68,471
Long-term investments						19,962
						<u>\$ 88,433</u>

As of March 31, 2023 and December 31, 2022, all marketable securities held by the Company had remaining contractual maturities of three years or less. There have been no impairments of the Company’s assets measured and carried at fair value during the three months ended March 31, 2023 and 2022.

7. 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).

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The commercial paper, corporate notes, U.S. government securities, and U.S. government agency bonds 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. There were no transfers into or out of Level 3 from December 31, 2022 to March 31, 2023.

The following table summarizes the valuation of the Company's financial instruments that are measured at fair value on a recurring basis:

(In thousands)	March 31, 2023				December 31, 2022			
	Total	Fair value measurement category			Total	Fair value measurement category		
		Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
Assets:								
Money market funds	\$ 39,906	\$ 39,906	\$ —	\$ —	\$ 1,262	\$ 1,262	\$ —	\$ —
Commercial paper	14,258	—	14,258	—	15,606	—	15,606	—
Corporate notes	42,598	—	42,598	—	51,328	—	51,328	—
U.S. government securities	4,925	—	4,925	—	—	—	—	—
U.S. government agency bonds ^(a)	15,571	—	15,571	—	27,976	—	27,976	—
	<u>\$ 117,258</u>	<u>\$ 39,906</u>	<u>\$ 77,352</u>	<u>\$ —</u>	<u>\$ 96,172</u>	<u>\$ 1,262</u>	<u>\$ 94,910</u>	<u>\$ —</u>

^(a) Approximately \$6.5 million of U.S. government agency bonds had an original maturity of 90 days or less and were recorded as a cash equivalent as of December 31, 2022.

The fair values of the cash equivalents and marketable securities are based on observable market prices. The Company's accounts receivables, accounts payable and accrued expenses are valued at cost which approximates fair value.

8. Revolving Credit Agreement

On July 29, 2022, the Company, as borrower, entered into a \$150.0 million five-year senior secured revolving credit agreement by and among the Company, the other loan parties thereto, the lenders party thereto, and JPMorgan Chase Bank, N.A., as the administrative agent (the "Revolving Credit Agreement"). The Revolving Credit Agreement includes a \$15.0 million sub-facility for the issuance of letters of credit, of which the Company is utilizing approximately \$6.2 million. Amounts available under the Revolving Credit Agreement are for the working capital needs and other general corporate purposes of the Company. The Company incurred and capitalized approximately \$1.1 million of debt issuance costs related to the Revolving Credit Agreement.

Outstanding borrowings under the Revolving Credit Agreement bear interest, with pricing based from time to time at the Company's election at (i) the Secured Overnight Financing Rate ("SOFR") plus 0.10% plus a spread ranging from 1.25% to 2.50% as determined by the Company's Total Net Leverage Ratio (as defined in the Revolving Credit Agreement) or (ii) the alternative base rate (as defined in the Revolving Credit Agreement) plus a spread ranging from 0.25% to 1.50% as determined by the Company's Total Net Leverage Ratio. The Revolving Credit Agreement also includes a commitment fee, which ranges from 0.20% to 0.25% as determined by the Company's Total Net Leverage Ratio.

The Company is permitted to voluntarily prepay borrowings under the Revolving Credit Agreement, in whole or in part, without premium or penalty. On any business day on which the total amount of outstanding Revolving Loans (as defined in the Revolving Credit Agreement) and letters of credit exceeds the total Revolving Commitments (as defined in the Revolving Credit Agreement).

Agreement), the Company must prepay the Revolving Loans in an amount equal to such excess. As of March 31, 2023, there are no outstanding borrowings under the Revolving Credit Agreement.

The Revolving Credit Agreement contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The Revolving Credit Agreement requires the Company to be in quarterly compliance, measured on a trailing four quarter basis, with a financial covenant. The maximum Total Net Leverage Ratio (as defined in the Revolving Credit Agreement) is 3.50 to 1.00. The Company may elect to increase the maximum Total Net Leverage Ratio to 4.00 to 1.00 for a period of four consecutive quarters in connection with a Permitted Acquisition (as defined in the Revolving Credit Agreement).

The Revolving Credit Agreement contains usual and customary restrictions on the ability of the Company and its subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all, or substantially all, of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

Obligations under the Revolving Credit Agreement are secured by first priority liens over substantially all of the assets of Vericel Corporation, excluding certain subsidiaries (subject to customary exclusions set forth in the Revolving Credit Agreement and the other transaction documents).

9. Stock-Based Compensation

The Vericel Corporation 2022 Omnibus Incentive Plan ("2022 Plan") was approved on April 27, 2022, 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 2022 Plan shall not be less than the fair market value of the Company's common stock on the date of grant. The 2022 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, the 2017 Omnibus Incentive Plan, and the Amended and Restated 2019 Omnibus Incentive Plan ("Prior Plans"), and no new grants have been granted under the Prior Plans after approval of the 2022 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 2022 Plan.

Stock Compensation Expense

Non-cash stock-based compensation expense (service-based stock options, restricted stock units and employee stock purchase plan) is summarized in the following table:

(in thousands)	Three Months Ended March 31,	
	2023	2022
Cost of product sales	\$ 885	\$ 1,118
Research and development	977	1,350
Selling, general and administrative	6,869	7,063
Total non-cash stock-based compensation expense	\$ 8,731	\$ 9,531

Service-Based Stock Options

During the three months ended March 31, 2023 and 2022, the Company granted service-based options to purchase common stock of 467,957 and 993,589, respectively. The weighted-average grant-date fair value of service-based options granted during the three months ended March 31, 2023 and 2022 was \$18.00 and \$20.99 per option, respectively.

Restricted Stock Units

During the three months ended March 31, 2023 and 2022, the Company granted 496,505 and 343,022 restricted stock units, respectively. The weighted-average grant-date fair value of restricted stock units granted during the three months ended March 31, 2023 and 2022 was \$29.82 and \$34.97 per unit, respectively.

10. Net Loss Per Common Share

A summary of net loss per common share is presented below:

(Amounts in thousands, except per share amounts)	Three Months Ended March 31,	
	2023	2022
Net loss	\$ (7,495)	\$ (7,091)
Basic weighted-average common shares outstanding	47,387	46,985
Effect of dilutive stock options and restricted stock units	—	—
Diluted weighted-average common shares outstanding	47,387	46,985
Basic loss per common share	\$ (0.16)	\$ (0.15)
Diluted loss per common share	\$ (0.16)	\$ (0.15)
Anti-dilutive shares excluded from diluted net loss per common share:		
Stock options	6,918	6,479
Restricted stock units	954	625

11. NexoBrid License and Supply Agreements

On May 6, 2019, the Company entered into exclusive license and supply agreements with MediWound to commercialize NexoBrid in North America. NexoBrid is a topically-administered biological product, which was approved by the FDA on December 28, 2022 for commercial use in the U.S. NexoBrid contains proteolytic enzymes and is indicated for the removal of eschar in adults with deep partial-thickness and/or full thickness thermal burns.

Pursuant to the terms of the license agreement, following the FDA approval of NexoBrid, MediWound transferred the BLA to Vericel effective February 20, 2023. Both MediWound and Vericel, 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 (the “Central Steering Committee”). NexoBrid is approved in the European Union (“EU”) and other international markets and has been designated as an orphan biologic in the U.S., EU and other international markets.

In May 2019, the Company paid MediWound \$17.5 million in consideration for the license, which was recorded as research and development expense during 2019. Pursuant to the terms of the license agreement, in February 2023, the Company tendered to MediWound a \$7.5 million regulatory milestone payment following the FDA’s BLA approval of NexoBrid on December 28, 2022. The Company recorded the \$7.5 million milestone payment for the licensing rights to commercially sell NexoBrid in the U.S., as an intangible asset (see Note 4, “Selected Balance Sheet Components” for further details).

The Company is additionally obligated to pay MediWound up to \$125.0 million, which is contingent upon meeting certain sales milestones. The first sales milestone payment of \$7.5 million would be triggered when annual net sales of NexoBrid or improvements to it in North America exceed \$75.0 million. As of March 31, 2023, the sales milestone payments are not yet probable and therefore, not recorded as 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. Pursuant to the terms of the Company’s supply agreement with MediWound, MediWound will manufacture NexoBrid for the Company on a unit price basis, which may be increased pursuant to the terms of the supply agreement. 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. Under the supply agreement, the Company possesses the option to extend the initial term of the agreement by an additional 24 months, which it did in May 2022. After the exclusivity period or upon supply failure, the Company will be permitted to establish an alternate source of supply.

Additionally, beginning in 2020 BARDA procured quantities of NexoBrid from MediWound for use as a medical countermeasure in the event of a mass casualty emergency in the U.S. involving thermal burns. The initial, quarterly, procurement of NexoBrid by BARDA under its agreement with MediWound completed during the third quarter of 2022. As a part of BARDA's commitment to procure NexoBrid, the Company has received a percentage of gross profit for sales directly to BARDA. As of March 31, 2023, the Company did not hold a direct contract or distribution agreement with BARDA, or take title to the product procured by BARDA.

On May 9, 2023, MediWound announced BARDA's award of additional funding under the parties' existing agreement, \$3 million of which will support the replacement of NexoBrid, previously procured for emergency response preparedness, which has since expired. Pursuant to the terms of the Company's license agreement with MediWound, the Company would recognize revenue based on a percentage of gross profits, minus a percentage of net sales, on any sales of NexoBrid directly to BARDA, upon delivery, pursuant to this additional award.

12. Commitments and Contingencies

From time to time, the Company could be a party to various legal proceedings arising in the ordinary course of business. The costs and outcome of litigation, regulatory, investigatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to the Company and could have a material adverse effect on the Company's results of operations or financial condition. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against the Company, could materially and adversely affect its financial condition or results of operations. If a matter is both probable to result in material liability and the amount of loss can be reasonably estimated, the Company estimates and discloses the possible material loss or range of loss. If such loss is not probable or cannot be reasonably estimated, a liability is not recorded in its condensed consolidated financial statements.

As of March 31, 2023, the Company has no material ongoing litigation in which the Company was a party or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

13. Subsequent Events

In April 2023, in connection with the Burlington Lease, the Company entered into a construction escrow agreement (the "Construction Escrow Agreement") with the facility's landlord and an escrow agent. Pursuant to the terms of the Construction Escrow Agreement, in April 2023, the Company began funding into an escrow account maintained by the escrow agent a portion of its share of tenant improvement construction costs at the facility, which will be designated as restricted cash. At the same time, the facility's landlord began funding a portion of its tenant improvement allowance through a separate escrow account. To date, the Company has transferred into its escrow account 50% of its required cost amount, or approximately \$28.3 million. The Company anticipates funding the remaining 50% of its required cost amount in late 2023 or early 2024. Additionally, and in order to support the expansion of the Company's autologous cell manufacturing operations at the new facility in Burlington, the Company plans to invest in the acquisition and installation of certain specialized manufacturing and laboratory equipment.

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

Overview

Vericel Corporation is a fully-integrated, commercial-stage biopharmaceutical company and a leader in advanced therapies for the sports medicine and severe burn care markets. We currently market two U.S. Food and Drug Administration ("FDA") approved autologous cell therapy products and one FDA-approved specialty biologic product in the U.S. 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. ("MediWound") for North American rights to NexoBrid (anacaulase-bcdb). On December 28, 2022, the FDA approved a Biologics License Application ("BLA") for NexoBrid, granting a license for commercial use in the U.S. NexoBrid is a topically-administered biological product containing proteolytic enzymes and is indicated for the removal of eschar in adults with deep partial-thickness and/or full thickness thermal burns. Following NexoBrid's approval, we have begun cross-functional commercial launch activities for the product, including education, training and engagement activities and the deployment of additional NexoBrid account managers. The ultimate timing of the availability of commercial NexoBrid in the United States is dependent, in part, on MediWound's completion of certain manufacturing updates required by the FDA in connection with the NexoBrid BLA approval. Based on MediWound's current timeline to complete these activities, we now expect to receive U.S. commercial NexoBrid from MediWound and begin commercial sales during the third quarter of 2023.

COVID-19

In March 2020, the World Health Organization declared the spread of a novel strain of coronavirus ("COVID-19") to be a pandemic, which contributed to an economic downturn on a global scale, as well as significant volatility in the financial markets. At the time of the pandemic's inception, and at times throughout its duration, there was significant volatility in our results of operations on a quarterly basis due to the widespread and periodic cancellation or delay of elective MACI surgical procedures throughout the U.S., staffing shortages and our ability to access customers. Based on declining COVID-related statistics, the U.S. Department of Health and Human Services has announced that the federal Public Health Emergency for COVID-19 is set to expire at the end of the day on May 11, 2023. Although at this juncture the pandemic's effects on our business and results of operations have moderated, should a resurgence of COVID-19 occur it could result in additional disruptions that could impact our business and operations in the future, including intermittent restrictions on the ability of our personnel to travel and access customers for selling, marketing, training, case support and product development feedback, delays in approvals by regulatory bodies, delays in product development efforts, and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our products.

The War in Ukraine

The ongoing war between Russia and Ukraine and the related sanctions and other penalties imposed by countries across the globe against Russia are continuing to create substantial uncertainty in the global economy and have contributed to heightened inflation and supply chain disruptions. While we do not have operations in Russia or Ukraine and do not have exposure to distributors, or third-party service providers in Russia or Ukraine, we are unable to predict the ultimate impact that these actions will have on the global economy or on our financial condition, results of operations, and cash flows as of the date of these condensed consolidated financial statements.

Manufacturing

We have a cell manufacturing facility in Cambridge, Massachusetts, which is used for U.S. manufacturing and distribution of MACI and Epicel. The manufacturing process for NexoBrid is conducted by MediWound, primarily at manufacturing locations in Israel. Certain raw materials utilized in NexoBrid's manufacture, including the supply of the active ingredient bromelain, are obtained from Taiwan.

Product Portfolio

Our marketed products include two FDA-approved autologous cell therapies: MACI, a third-generation 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; and Epicel, 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 TBSA. Both autologous cell therapy products are currently manufactured and marketed in the U.S. Our product portfolio also includes a FDA-approved specialty biologic, NexoBrid, which is a topically-administered biological orphan product containing proteolytic enzymes that is indicated for eschar removal in adults with deep partial-thickness and/or full-thickness burns. We have entered into exclusive license and supply agreements with MediWound to commercialize NexoBrid in North America. On December 28, 2022, the FDA approved a BLA for NexoBrid, granting a license for commercial use in the U.S. Following NexoBrid's approval, we have begun cross-functional commercial launch activities for the product, including education, training and engagement activities and the deployment of additional NexoBrid account managers. The ultimate timing of the availability of commercial NexoBrid in the United States is dependent, in part, on MediWound's completion of certain manufacturing updates required by the FDA in connection with the NexoBrid BLA approval. Based on MediWound's current timeline to complete these activities, we now expect to receive U.S. commercial NexoBrid from MediWound and begin commercial sales during the third quarter of 2023.

MACI

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

Our target audiences are orthopedic surgeons who self-identify and/or have a formal specialty as sports medicine physicians, and a subpopulation of general orthopedic surgeons who perform a high volume of cartilage repair procedures. As of the date of this report, we employ approximately 75 MACI sales representatives to enable the sales force to reach our target audience. The team is divided into geographic regions, each managed by a Regional Manager and led by a Vice President of National MACI Sales. 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. With respect to private commercial payers that have not yet approved a medical policy for MACI, we often obtain approval on a case-by-case basis.

MACI is currently implanted into the patient's cartilage defect through an open surgical procedure. We are currently evaluating the potential for the arthroscopic delivery of MACI to the cartilage defect – a procedure in which a surgeon can evaluate, prepare and treat the cartilage defect under direct vision using specialized instruments delivered through a number of smaller incisions or portals. The arthroscopic delivery of MACI could increase the ease of MACI's use for physicians and reduce both the length of the procedure and a patient's post-operative pain and recovery. We have designed and are currently developing novel and specialized instruments to be used in and help facilitate such a procedure. We have recently discussed with the FDA a non-clinical regulatory strategy to support the potential inclusion of arthroscopic delivery in MACI's approved labeling. Specifically, following a Type C meeting with the FDA, we submitted a protocol for a MACI arthroscopic delivery human factors validation study and plan to initiate the study in the third quarter of 2023.

We also are evaluating the feasibility and potential market opportunity involved in delivering MACI treatment to patients suffering from cartilage damage in the ankle. We believe that this potential lifecycle enhancement and indication expansion for MACI will require conducting an additional randomized clinical trial concerning the product's use in the ankle. Earlier this year, we conducted pre-IND interactions with the FDA concerning our clinical development program for MACI to treat cartilage injuries in the ankle, and based on feedback from the FDA, our team is actively working to finalize our non-clinical testing and propose a clinical development plan/protocol to FDA for review.

Epicel

Epicel is a permanent skin replacement for deep-dermal or full-thickness burns comprising greater than or equal to 30 percent TBSA. Epicel is regulated by the Center for Biologics Evaluation and Research ("CBER") of the FDA under medical device authorities, and is the only FDA-approved cultured epidermal autograft product available for large total surface area burns in both adult and pediatric patients. Epicel was designated as a HUD in 1998 and a Humanitarian Device Exemption ("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 large 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 to be 360,400 which is approximately 40 times larger than the volume of grafts sold in 2022. As of March 31, 2023, our burn care field force was recently expanded to approximately 20 individuals to prepare for the launch of NexoBrid. The team is divided into geographic regions, each managed by a Regional Manager and led by a Vice President of National Burn Care Sales.

NexoBrid

Our portfolio of commercial-stage products now includes NexoBrid (anacaulase-bcdb), a topically-administered biological product containing proteolytic enzymes. The FDA approved NexoBrid on December 28, 2022, and the product is indicated for the removal of eschar in adults with deep partial-thickness and/or full thickness thermal burns. We have entered into exclusive license and supply agreements with MediWound to commercialize NexoBrid in North America.

NexoBrid is approved in the European Union (“EU”) and other international markets and has been designated as an orphan biologic in the U.S., EU and other international markets. NexoBrid has the potential to change the standard of care for eschar removal with respect to hospitalized burn patients and treat a significant addressable market in the U.S. With respect to NexoBrid, of the approximately 40,000 burn patients that are hospitalized in the U.S. each year, the majority, over 30,000, have thermal burns and will likely require some level of eschar removal. NexoBrid’s FDA approval expands our burn care franchise’s total addressable market, which will permit us to treat a significantly larger segment of hospitalized burn patients than with Epicel alone. The expansion of our target addressable market supports a broader commercial footprint, and we believe that this may help drive both increased NexoBrid use as well as increased Epicel awareness throughout the burn care space. With NexoBrid’s approval, our cross-functional commercial launch activities for the product are underway, including education, training and engagement activities and the deployment of additional NexoBrid account managers.

The manufacturing process for NexoBrid is conducted by MediWound, primarily at manufacturing locations in Israel. Certain raw materials utilized in NexoBrid’s manufacture, including the supply of the active ingredient bromelain are obtained from Taiwan. We expect to receive U.S. commercial product from MediWound and begin commercial sales of NexoBrid in the U.S. during the third quarter of 2023.

Results of Operations

The following is a summary of our condensed consolidated results of operations:

(In thousands)	Three Months Ended March 31,			
	2023	2022	Change \$	Change %
Total revenue	\$ 41,017	\$ 36,074	\$ 4,943	13.7 %
Cost of product sales	14,497	12,622	1,875	14.9 %
Gross profit	26,520	23,452	3,068	13.1 %
Research and development	5,212	4,860	352	7.2 %
Selling, general and administrative	29,485	25,865	3,620	14.0 %
Total operating expenses	34,697	30,725	3,972	12.9 %
Loss from operations	(8,177)	(7,273)	(904)	12.4 %
Total other income	682	182	500	274.7 %
Net loss	\$ (7,495)	\$ (7,091)	\$ (404)	5.7 %

Comparison of the Periods Ended March 31, 2023 and 2022

Total Revenue

Revenue by product is as follows:

(In thousands)	Three Months Ended March 31,			
	2023	2022	Change \$	Change %
MACI	\$ 34,190	\$ 25,995	\$ 8,195	31.5 %
Epicel	6,827	9,857	(3,030)	(30.7)%
NexoBrid	—	222	(222)	(100.0)%
Total revenue	\$ 41,017	\$ 36,074	\$ 4,943	13.7 %

Total revenue increase for the three months ended March 31, 2023 compared to the same period in 2022, was driven primarily by MACI volume and price growth, which more than offset lower Epicel volume and lower revenue associated with the delivery of NexoBrid to BARDA for emergency response preparedness.

Seasonality. Since March 2020, the effects of the COVID-19 pandemic have, at times, disrupted the normal seasonality of our MACI business. These previous effects have included periodic restrictions on the performance of elective surgical procedures throughout the country, the unavailability of physicians and/or changes to their treatment prioritizations, reductions in the levels of healthcare facility staffing and, in certain instances, the willingness or ability of patients to seek treatment and the inability of our sales representatives to call on surgeon customers. As a result of these effects, the MACI business seasonality in 2021 and 2020 did not follow our historic patterns. At this juncture the pandemic's effects on our business and results of operations have moderated, although there continues to be a level of uncertainty whether MACI seasonality will return to pre-pandemic patterns. In the last five years through 2022, MACI sales volumes from the first through the fourth quarter on average represented 20% (18%-21% range), 21% (16%-24% range), 24% (21%-26% range) and 35% (33%-38% range) respectively, of total annual volumes. MACI orders are normally stronger in the fourth quarter due to several factors including the satisfaction by patients of insurance deductible limits and the time of year patients prefer to start rehabilitation. Due to the low incidence and variable occurrence of severe burns, Epicel revenue has inherent variability from quarter-to-quarter and does not exhibit significant seasonality.

Gross Profit

Gross profit increase for the three months ended March 31, 2023 compared to the same period in 2022, was driven by higher MACI volume and price growth, which more than offset higher employee costs, raw material price increases and higher external storage and manufacturing facility costs.

Research and Development Expenses

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

(In thousands)	Three Months Ended March 31,			
	2023	2022	Change \$	Change %
MACI	\$ 3,073	\$ 2,989	\$ 84	2.8 %
Epicel	1,171	1,220	(49)	(4.0)%
NexoBrid	968	651	317	48.7 %
Total research and development expenses	\$ 5,212	\$ 4,860	\$ 352	7.2 %

Research and development expenses for the three months ended March 31, 2023 were \$5.2 million, compared to \$4.9 million for the same period in 2022. The increase is primarily due to lower reimbursement of expenses from MediWound related to NexoBrid BLA resubmission.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended March 31, 2023 were \$29.5 million compared to \$25.9 million for the same period in 2022. The increase in selling, general and administrative expenses was primarily due to higher headcount and employee expenses, additional travel and in-person events across the commercial organization, and an increase in marketing expenses.

Total Other Income

The change in other income for the three months ended March 31, 2023, compared to the same period in 2022 was due primarily to fluctuations in the rates of return on our investments in various marketable debt securities slightly offset by interest expense related to our Revolving Credit Agreement.

Stock-based Compensation Expense

Non-cash stock-based compensation expense is summarized in the following table:

(In thousands)	Three Months Ended March 31,			
	2023	2022	Change \$	Change %
Cost of product sales	\$ 885	\$ 1,118	\$ (233)	(20.8)%
Research and development	977	1,350	(373)	(27.6)%
Selling, general and administrative	6,869	7,063	(194)	(2.7)%
Total non-cash stock-based compensation expense	\$ 8,731	\$ 9,531	\$ (800)	(8.4)%

The decrease in stock-based compensation expense for the three months ended March 31, 2023 compared to the same period in 2022, was due primarily to fluctuations in stock prices and the mix of service-based options and restricted stock units, which impacts the fair value of the options and restricted stock units awarded and the expense recognized in the period.

Liquidity and Capital Resources*Cash Flows*

The following table summarizes our sources and uses of cash for each of the periods presented:

(In thousands)	Three months ended March 31,	
	2023	2022
Net cash provided by operating activities	\$ 7,860	\$ 3,468
Net cash provided by (used in) investing activities	2,800	(10,669)
Net cash provided by financing activities	107	503
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ 10,767	\$ (6,698)

Net Cash Provided by Operating Activities

Our cash and cash equivalents totaled \$61.8 million, short-term investments totaled \$57.4 million and long-term investments totaled \$19.9 million as of March 31, 2023. The \$7.9 million of cash provided by operations during the three months ended March 31, 2023 was primarily the result of non-cash charges of \$8.7 million related to stock-based compensation expense, \$1.1 million of operating lease amortization and \$1.2 million in depreciation and amortization expense, offset by a net loss of \$7.5 million and a net increase of \$4.6 million related to movements in our working capital accounts. The overall increase in cash from our working capital accounts was primarily driven by a decrease in accounts receivable due to cash collections on the revenue from the seasonally-high previous sequential quarter, offset by a decrease in accounts payable and accrued expenses due to timing of payments.

Our cash, cash equivalents and restricted cash totaled \$61.8 million, short-term investments totaled \$44.9 million and long-term investments totaled \$22.8 million as of March 31, 2022. The \$3.5 million of cash provided by operations during the three months ended March 31, 2022 was primarily the result of non-cash charges of \$9.5 million related to stock-based compensation expense, \$1.1 million of operating lease amortization, \$0.9 million in depreciation and amortization expense, offset by a net loss of \$7.1 million and a net decrease of \$1.1 million related to movements in our working capital accounts. The overall decrease in cash from our working capital accounts was primarily driven by a decrease in accounts payable and accrued expenses due to timing of payments, an increase in inventory due to increased production needs, offset by a decrease in accounts receivable due to a decrease in sales volume compared to the previous sequential quarter.

Net Cash Provided By (Used In) Investing Activities

Net cash provided by investing activities during the three months ended March 31, 2023 was the result of \$21.5 million of investment sales and maturities, offset by \$9.8 million in investment purchases, a \$7.5 million regulatory milestone payment to MediWound resulting from the FDA's approval of the NexoBrid BLA, and \$1.4 million of property and equipment purchases primarily for manufacturing upgrades and construction in process related to the Burlington Lease.

Net cash used in investing activities during the three months ended March 31, 2022 was the result of \$12.6 million in investments purchases and \$3.1 million of property and equipment purchases primarily for manufacturing upgrades and leasehold improvements, offset by \$5.0 million of investment sales and maturities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2023 was the result of net proceeds from the exercise of stock options and the employee stock purchase plan of \$2.2 million, partially offset by the payment of employee withholding taxes related to the vesting of restricted stock units of \$2.1 million.

Net cash provided by financing activities during the three months ended March 31, 2022 was primarily the result of net proceeds from the exercise of stock options and the employee stock purchase plan of \$1.5 million partially offset by payments of employee withholding taxes related to the vesting of restricted stock units of \$0.9 million.

Liquidity

Since our acquisition of MACI and Epicel in 2014, 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 advance and complete our product development and product life-cycle management programs and to market and commercialize our products, including NexoBrid. To date, we have financed our operations primarily through cash received through MACI and Epicel sales, debt, and public and private sales of our equity securities. We may finance our operations through the sales of equity securities, revolver borrowings or other debt financings, in addition to cash generated from operations.

We believe that our current cash on hand, cash equivalents, investments, and available borrowing capacity will be sufficient to support our current operations through at least 12 months from the issuance of the condensed consolidated financial statements included in this report. Although the effects of the ongoing COVID-19 pandemic have moderated in recent months, our business and operations may be adversely affected in the future if conditions were to worsen. Our actual cash requirements may differ from projections and will depend on many factors, including any future impacts of the COVID-19 pandemic, the level and pace of future research and development efforts, 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 associated with possible acquisitions or development of complementary business activities, and the cost to market our products.

As of March 31, 2023, we were not party to any off-balance sheet arrangements.

Sources of Capital

On August 27, 2021, we entered into a Sales Agreement with SVB Securities, LLC (f/k/a SVB Leerink LLC), as sales agent ("SVB Securities"), pursuant to which we may offer and sell up to \$200.0 million of shares of our common stock, no par value per share ("ATM Shares"). The ATM Shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to an automatically effective shelf registration statement on Form S-3ASR (File No. 333-259119) filed by us on August 27, 2021, which expires three years from the filing date. We also filed a prospectus supplement relating to the offering and sale of the ATM Shares on August 27, 2021. We are not obligated to make any sales of ATM Shares, and SVB Securities is not required to sell any specific number or dollar amount of the ATM Shares under the Sales Agreement. As of March 31, 2023, we have sold no shares pursuant to the Sales Agreement.

On July 29, 2022, we entered into a \$150.0 million five-year senior secured revolving credit agreement by and among the Company, the other loan parties thereto, the lenders party thereto, and JPMorgan Chase Bank, N.A., as the administrative agent (the "Revolving Credit Agreement"). We have no immediate plans to borrow under the Revolving Credit Agreement, but we may use the facility for working capital needs and other general corporate purposes. As of March 31, 2023, there are no outstanding borrowings under the Revolving Credit Agreement, and we are in compliance with all applicable covenant

requirements. See Note 8, “Revolving Credit Agreement” in the accompanying condensed consolidated financial statements for further details.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth in the heading “Management’s Discussion and Analysis of Financial Conditions and Results of Operations - Contractual Obligations” in our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes, outside of the ordinary course of business, to our contractual obligations and commitments since December 31, 2022, except as noted below.

In April 2023, in connection with the Burlington Lease, we entered into a construction escrow agreement (the “Construction Escrow Agreement”) with the facility’s landlord and an escrow agent. Pursuant to the terms of the Construction Escrow Agreement, in April 2023 we began funding into an escrow account maintained by the escrow agent a portion of our share of tenant improvement construction costs at the facility, which will be designated as restricted cash. At the same time, the facility’s landlord began funding a portion of its tenant improvement allowance through a separate escrow account. To date, we have transferred into our escrow account 50% of our required cost amount, or approximately \$28.3 million. We anticipate funding the remaining 50% of our required cost amount in late 2023 or early 2024. Additionally, and in order to support the expansion of our autologous cell manufacturing operations at the new facility in Burlington, we plan to invest in the acquisition and installation of certain specialized manufacturing and laboratory equipment.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect our reported assets, liabilities, revenues, expenses, and related disclosures. Actual results may differ materially from these estimates under different assumptions and conditions.

There have been no material changes to our critical accounting policies and estimates in the three months ended March 31, 2023. For further information, refer to our summary of significant accounting policies and estimates in our Annual Report on Form 10-K filed for the year ended December 31, 2022.

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. Among the factors that could cause actual results to differ materially from those set forth in the forward-looking statements include, but are not limited to, uncertainties associated with our expectations regarding future revenue, growth in revenue, market penetration for MACI[®], Epicel[®], and NexoBrid[®], growth in profit, gross margins and operating margins, the ability to continue to scale our manufacturing operations to meet the demand for our cell therapy products, including the timely completion of a new headquarters and manufacturing facility in Burlington, Massachusetts, the ability to achieve or sustain profitability, the expected target surgeon audience, potential fluctuations in sales and volumes and our results of operations over the course of the year, timing and conduct of clinical trial and product development activities, timing and likelihood of the FDA’s potential approval of the arthroscopic delivery of MACI to the knee or the use of MACI to treat cartilage defects in the ankle, the estimate of the commercial growth potential of our products and product candidates, competitive developments, changes in third-party coverage and reimbursement, the ultimate timing of the commercial launch of NexoBrid in the United States, physician and burn center adoption of NexoBrid, supply chain disruptions or other events affecting MediWound Ltd.’s ability to manufacture and supply NexoBrid to meet customer demand, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine, adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, global geopolitical tensions or record inflation and the ongoing or future impacts of the COVID-19 pandemic on our business or the economy generally. 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” and the risk listed in this Quarterly 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 on Form 10-K 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

For quantitative and qualitative disclosures about market risk, see Part II, Item 7A. “Quantitative and Qualitative Disclosures About Market Risk,” of our Annual Report on Form 10-K for the year ended December 31, 2022. Our exposures to market risk have not changed materially since December 31, 2022.

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, 2023, 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, 2023, 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

Factors that could cause the Company’s actual results to differ materially from those in this Quarterly Report are any of the risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. As of the date of this Quarterly Report on Form 10-Q, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, except as follows.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems.

We maintain cash and investments that are held in a number of investment and deposit accounts at leading financial institutions. The amounts held in the deposit accounts are in excess of the insurance coverage offered by the FDIC, and we may in the future, continue to have assets held at financial institutions that exceed the insurance coverage offered by the FDIC, the loss of which would have a severe negative effect on our operations and liquidity.

Uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, Federal Deposit Insurance Corporation (“FDIC”) and Federal Reserve Board have announced a program to provide up to \$25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of banks or financial institutions in a timely fashion or at all.

Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements directly face liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity. Furthermore, should our customers have relationships with financial institutions that fail, this may result in a delay of collecting outstanding receivables, which could have a material adverse effect on our business.

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 Number	Description of Exhibits	Incorporated by Reference			Filing Date
		Form	File Number	Exhibit	
3.1	Restated Articles of Incorporation of the Company.	8-K	000-22025	4.1	December 17, 2009
3.2	Certificate of Amendment to Restated Articles of Incorporation of the Company dated February 9, 2010.	S-1	333-160044	3.2	March 31, 2010
3.3	Certificate of Amendment to Restated Articles of Incorporation of the Company dated March 22, 2011.	8-K	000-22025	3.1	March 25, 2011
3.4	Certificate of Amendment to the Restated Articles of Incorporation of the Company, dated November 21, 2014.	8-K	001-35280	3.1	November 24, 2014
3.5	Amended and restated bylaws.	8-K	000-22025	3.1	November 12, 2010
4.1	Description of Capital Stock.	10-K	001-35280	4.5	February 25, 2020
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 and 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 10, 2023

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)

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 10, 2023

/s/ DOMINICK C. COLANGELO

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

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 10, 2023

/s/ JOSEPH A. MARA

Joseph A. Mara

Chief Financial Officer

(Principal Financial Officer)

**18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Vericel Corporation (the "Company") on Form 10-Q for the quarter ended March 31, 2023, 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 10, 2023

/s/ DOMINICK C. COLANGELO

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

/s/ JOSEPH MARA

Joseph 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.