
UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

FOR THE QUARTERLY PERIOD ENDED: September 30, 2024

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 October 31, 2024, 49,358,408 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)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 53,681	\$ 69,088
Restricted cash	16,669	17,778
Short-term investments	48,053	40,469
Accounts receivable (net of allowance for doubtful accounts of \$12 and \$43, respectively)	48,479	58,356
Inventory	15,756	13,087
Other current assets	7,882	6,853
Total current assets	<u>190,520</u>	<u>205,631</u>
Property and equipment, net	88,413	41,635
Intangible assets, net	6,406	6,875
Right-of-use assets	71,561	73,462
Long-term investments	32,895	25,283
Other long-term assets	610	771
Total assets	<u>\$ 390,405</u>	<u>\$ 353,657</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 20,884	\$ 22,347
Accrued expenses	14,343	17,215
Current portion of operating lease liabilities	6,119	6,187
Total current liabilities	<u>41,346</u>	<u>45,749</u>
Operating lease liabilities	91,344	81,856
Other long-term liabilities	243	100
Total liabilities	<u>132,933</u>	<u>127,705</u>
COMMITMENTS AND CONTINGENCIES (Note 12)		
Shareholders' equity:		
Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 49,265 and 47,829, respectively	669,735	629,229
Accumulated other comprehensive gain (loss)	359	(100)
Accumulated deficit	<u>(412,622)</u>	<u>(403,177)</u>
Total shareholders' equity	<u>257,472</u>	<u>225,952</u>
Total liabilities and shareholders' equity	<u>\$ 390,405</u>	<u>\$ 353,657</u>

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product sales, net	\$ 57,905	\$ 45,581	\$ 161,848	\$ 132,520
Total revenue	57,905	45,581	161,848	132,520
Cost of product sales	16,252	14,973	48,240	45,451
Gross profit	41,653	30,608	113,608	87,069
Research and development	6,093	5,676	19,874	16,141
Selling, general and administrative	38,025	29,989	107,694	90,123
Total operating expenses	44,118	35,665	127,568	106,264
Loss from operations	(2,465)	(5,057)	(13,960)	(19,195)
Other income (expense):				
Interest income	1,578	1,262	4,850	3,196
Interest expense	(154)	(150)	(460)	(444)
Other income (expense)	140	(1)	125	(18)
Total other income	1,564	1,111	4,515	2,734
Loss before income taxes	(901)	(3,946)	(9,445)	(16,461)
Income tax benefit	—	(286)	—	(286)
Net loss	\$ (901)	\$ (3,660)	\$ (9,445)	\$ (16,175)
Net loss per common share:				
Basic and diluted	\$ (0.02)	\$ (0.08)	\$ (0.19)	\$ (0.34)
Weighted-average common shares outstanding:				
Basic and diluted	49,085	47,649	48,639	47,537

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	\$ (901)	\$ (3,660)	\$ (9,445)	\$ (16,175)
Other comprehensive income (loss):				
Unrealized gain on investments	632	158	459	515
Comprehensive loss	<u>\$ (269)</u>	<u>\$ (3,502)</u>	<u>\$ (8,986)</u>	<u>\$ (15,660)</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, 2023	47,829	\$ 629,229	\$ (100)	\$ (403,177)	\$ 225,952
Net loss	—	—	—	(3,862)	(3,862)
Stock-based compensation expense	—	9,834	—	—	9,834
Stock option exercises	487	6,779	—	—	6,779
Shares issued under the Employee Stock Purchase Plan	9	247	—	—	247
Issuance of stock for restricted stock unit vesting	265	—	—	—	—
Restricted stock withheld for employee tax remittance	(101)	(4,909)	—	—	(4,909)
Unrealized loss on investments	—	—	(145)	—	(145)
BALANCE, MARCH 31, 2024	48,489	\$ 641,180	\$ (245)	\$ (407,039)	\$ 233,896
Net loss	—	—	—	(4,682)	(4,682)
Stock-based compensation expense	—	9,520	—	—	9,520
Stock option exercises	329	4,020	—	—	4,020
Shares issued under the Employee Stock Purchase Plan	14	414	—	—	414
Issuance of stock for restricted stock unit vesting	34	—	—	—	—
Restricted stock withheld for employee tax remittance	(4)	(163)	—	—	(163)
Unrealized loss on investments	—	—	(28)	—	(28)
BALANCE, JUNE 30, 2024	48,862	\$ 654,971	\$ (273)	\$ (411,721)	\$ 242,977
Net loss	—	—	—	(901)	(901)
Stock-based compensation expense	—	9,224	—	—	9,224
Stock option exercises	382	5,442	—	—	5,442
Shares issued under the Employee Stock Purchase Plan	9	353	—	—	353
Issuance of stock for restricted stock unit vesting	16	—	—	—	—
Restricted stock withheld for employee tax remittance	(4)	(255)	—	—	(255)
Unrealized gain on investments	—	—	632	—	632
BALANCE, SEPTEMBER 30, 2024	49,265	\$ 669,735	\$ 359	\$ (412,622)	\$ 257,472

	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
Net loss	—	—	—	(5,020)	(5,020)
Stock-based compensation expense	—	8,761	—	—	8,761
Stock option exercises	68	889	—	—	889
Shares issued under the Employee Stock Purchase Plan	18	384	—	—	384
Issuance of stock for restricted stock unit vesting	26	—	—	—	—
Restricted stock withheld for employee tax remittance	(3)	(79)	—	—	(79)
Unrealized gain on investments	—	—	15	—	15
BALANCE, JUNE 30, 2023	47,616	\$ 612,059	\$ (621)	\$ (412,510)	\$ 198,928
Net loss	—	—	—	(3,660)	(3,660)
Stock-based compensation expense	—	7,924	—	—	7,924
Stock option exercises	50	787	—	—	787
Shares issued under the Employee Stock Purchase Plan	13	329	—	—	329
Issuance of stock for restricted stock unit vesting	8	—	—	—	—
Restricted stock withheld for employee tax remittance	(3)	(86)	—	—	(86)
Unrealized gain on investments	—	\$ —	\$ 158	\$ —	\$ 158
BALANCE, SEPTEMBER 30, 2023	47,684	\$ 621,013	\$ (463)	\$ (416,170)	\$ 204,380

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)

	Nine Months Ended September 30,	
	2024	2023
Operating activities:		
Net loss	\$ (9,445)	\$ (16,175)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization expense	4,027	3,483
Stock-based compensation expense	28,578	25,416
Amortization of premiums and discounts on marketable securities	(542)	(788)
Amortization of debt issuance costs	161	161
Non-cash lease costs	5,139	4,291
Other	25	18
Changes in operating assets and liabilities:		
Inventory	(2,669)	3,365
Accounts receivable	9,877	6,810
Other current assets	(1,029)	(627)
Accounts payable	(1,639)	360
Accrued expenses	(2,887)	(2,562)
Operating lease liabilities	6,182	1,408
Other non-current assets and liabilities, net	143	65
Net cash provided by operating activities	35,921	25,225
Investing activities:		
Purchases of investments	(52,612)	(36,254)
Sales and maturities of investments	38,416	60,890
Expenditures for property and equipment	(50,187)	(12,178)
Purchases of intangible assets	—	(7,500)
Net cash (used in) provided by investing activities	(64,383)	4,958
Financing activities:		
Net proceeds from common stock issuance	17,255	4,614
Payments on employee's behalf for taxes related to vesting of restricted stock unit awards	(5,309)	(2,262)
Other	—	(41)
Net cash provided by financing activities	11,946	2,311
Net (decrease) increase in cash, cash equivalents, and restricted cash	(16,516)	32,494
Cash, cash equivalents, and restricted cash at beginning of period	86,866	51,067
Cash, cash equivalents, and restricted cash at end of period	\$ 70,350	\$ 83,561

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

	Nine Months Ended September 30,	
	2024	2023
Supplemental disclosure of cash flow information:		
Non-cash information:		
Right-of-use asset and lease liability recognized	\$ 3,238	\$ 36,022
Additions to property and equipment included in accounts payable	10,301	5,568
	Nine Months Ended September 30,	
	2024	2023
Reconciliation to amounts within the condensed consolidated balance sheets:		
Cash and cash equivalents	\$ 53,681	\$ 60,473
Restricted cash	16,669	23,088
Total cash, cash equivalents, and restricted cash at end of period	\$ 70,350	\$ 83,561

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 leading provider of 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 that is indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. Since MACI's commercial launch, a treating surgeon has been able to use MACI to treat a patient through an open surgical procedure. In August 2024, however, the U.S. Food & Drug Administration ("FDA") approved a supplemental Biologics License Application ("sBLA") expanding the MACI indication to add instructions for the arthroscopic delivery of MACI to the product's approved labeling. MACI Arthro[™] allows surgeons to evaluate and prepare the cartilage defect site as well as deliver the MACI implant through small incisions using custom-designed arthroscopic instruments developed by the Company ("MACI Arthro instruments"). MACI Arthro became commercially available in the United States during the third quarter of 2024 and the Company began selling the MACI Arthro instruments at that time.

Epicel (cultured epidermal autografts) is a permanent skin replacement for the treatment of adult and pediatric patients with deep-dermal or full-thickness burns comprising greater than or equal to 30 percent of total body surface area ("TBSA"). The Company also holds an exclusive license from MediWound Ltd. ("MediWound") for North American rights to NexoBrid (anacaulase-bcdb), a topically administered biological orphan product containing proteolytic enzymes, which is indicated for the removal of eschar in adult and pediatric patients with deep partial-thickness and/or full thickness thermal burns. Following the FDA's approval of a Biologics License Application for NexoBrid in December 2022, the Company began commercial sales of NexoBrid in the U.S. during the third quarter of 2023.

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 conditions. 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.

The Ongoing Military Conflicts in the Middle East

In May 2019, the Company entered into exclusive license and supply agreements with MediWound, under which MediWound manufactures and supplies NexoBrid to the U.S. market on a unit price basis. MediWound develops and manufactures NexoBrid, in part, at its facilities in Yavne, Israel.

The Company continues to monitor the ongoing military conflicts in the Middle East region involving Israel, and the Company is in close communication with MediWound leadership. MediWound's NexoBrid manufacturing operations are continuing and, as of the date of this disclosure, MediWound does not anticipate a material disruption to its ongoing supply of commercial NexoBrid to the United States. To the extent the conflicts in the Middle East region intensify or expand to include additional countries or militant groups and MediWound's facilities in Israel are damaged or destroyed, travel to and from Israel is halted or inhibited, or significant key MediWound operational personnel are called to military service, MediWound's ability to continue to supply NexoBrid to the U.S. market could be disrupted. As of the date of this report, the Company maintains an ample supply of NexoBrid at its U.S.-based third-party logistics provider.

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 September 30, 2024, the Company had an accumulated deficit of \$412.6 million and had a net loss of \$9.4 million during the nine months ended September 30, 2024. The Company had cash and cash equivalents of \$53.7 million and investments of \$80.9 million as of September 30, 2024. 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, the loss of which could have a negative effect on its operations and liquidity. 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, 2023 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, 2023, as filed with the SEC on February 29, 2024 ("Annual Report").

Recent Accounting Pronouncements

No new accounting standards were adopted during the nine months ended September 30, 2024. The Company considers the applicability and impact of any recent Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB"), as noted below:

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The disclosure requirements must be applied retrospectively to all prior periods presented in the financial statements. The effective date for the standard is for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, to provide more detailed income tax disclosure requirements. The guidance requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as information on income taxes paid. The disclosure requirements will be applied on a prospective basis, with the option to apply it retrospectively. The effective date for the standard is for fiscal years beginning after *December 15, 2024*, with early adoption permitted. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

3. Revenue

Revenue Recognition and Product Sales, Net

The Company recognizes product revenue from sales of MACI biopsy kits, MACI implants, MACI Arthro instruments, 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 set forth 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 treating surgeon 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 Arthro Instruments

MACI Arthro instruments are sold directly to hospitals and ambulatory surgical centers based upon rates set forth in price lists. The Company recognizes revenue from the sale of MACI Arthro instruments upon delivery of the instruments, at which time the customer (the facility) is in control of the instruments. MACI Arthro instruments can be used by an orthopedic surgeon to deliver MACI to a treated patient using an arthroscopic approach. The customer's order of a MACI implant is separate from the process of ordering the MACI Arthro instruments. Therefore, the sale of the MACI Arthro instruments and any sale of implants are distinct 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 each specialty pharmacy a fee in each instance when it dispenses MACI for use in treating a patient. Both Orsini and AllCare perform collection activities to collect payment from customers. In addition, the Company sells MACI directly to hospitals pursuant to an agreed upon purchase order and to a distributor, DMS Pharmaceutical Group, Inc. ("DMS") at a contracted rate for the treatment of patients at military facilities throughout the U.S. The Company engages a third party to provide services in connection with a patient support program to manage patient cases and to ensure that complete and correct billing information is provided to the insurers and hospitals.

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 a MACI implant 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 through its specialty pharmacies, 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 September 30, 2024. The total allowance for uncollectible consideration as of September 30, 2024 and December 31, 2023 was \$4.8 million and \$5.6 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 \$0.4 million decrease or increase in the revenue recognized for the nine months ended September 30, 2024.

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 period.

Epistel

The Company sells Epistel 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 Epistel 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 Epistel upon delivery to the hospital, at which time the customer is in control of the Epistel 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 September 30, 2024, the Company did not hold a direct contract or distribution agreement with BARDA, or take title to the product procured by BARDA.

In December 2022, the FDA approved a BLA for NexoBrid, granting a license for its commercial use in the U.S. NexoBrid is a topically-administered biological orphan product containing proteolytic enzymes, which is indicated for the removal of eschar in adults with deep partial-thickness and/or full thickness thermal burns. In August 2024, the FDA additionally approved NexoBrid for pediatric use.

The Company sells NexoBrid to specialty distributors. These customers subsequently resell NexoBrid to hospitals and burn centers. Product revenue is recorded net of reserves for specialty distributor fees, prompt payment or other discounts and allowances for returns, as applicable. The Company recognizes product revenue from sales of NexoBrid when the specialty distributors take control of the product, which typically occurs upon delivery to the specialty distributors.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<i>MACI implants, kits, and instruments</i>				
Implants based on contracted rate sold through a specialty pharmacy ^(a)	\$ 31,637	\$ 22,598	\$ 90,246	\$ 68,220
Implants subject to third party reimbursement sold through a specialty pharmacy ^(b)	3,473	5,030	10,160	13,526
Implants sold direct based on contracted rates ^(c)	6,968	5,797	21,465	19,932
Implants sold direct subject to third-party reimbursement ^(d)	1,083	1,432	3,227	2,974
Biopsy kits and instruments - direct bill	469	457	1,530	1,517
Change in estimates related to prior periods ^(e)	1,026	2,275	2,345	1,945
<i>Total MACI implants, kits, and instruments</i>	<u>44,656</u>	<u>37,589</u>	<u>128,973</u>	<u>108,114</u>
<i>Epicel</i>				
Direct bill (hospital)	12,184	7,394	30,606	23,808
<i>NexoBrid ^(f)</i>				
	1,065	598	2,269	598
Total revenue	<u>\$ 57,905</u>	<u>\$ 45,581</u>	<u>\$ 161,848</u>	<u>\$ 132,520</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 U.S. commercial revenue of NexoBrid.

4. Selected Balance Sheet Components

Inventory

Inventory consisted of the following:

(In thousands)	September 30, 2024	December 31, 2023
Raw materials	\$ 11,854	\$ 11,348
Work-in-process	1,850	1,210
Finished goods	2,052	529
Total inventory	<u>\$ 15,756</u>	<u>\$ 13,087</u>

Property and Equipment

Property and Equipment, net consisted of the following:

(In thousands)	September 30, 2024	December 31, 2023
Machinery and equipment	\$ 5,901	\$ 5,562
Furniture, fixtures and office equipment	1,647	1,731
Computer equipment and software	9,972	9,116
Leasehold improvements	15,927	14,901
Construction in process	80,544	32,531
Total property and equipment, gross	113,991	63,841
Less accumulated depreciation	(25,578)	(22,206)
Total property and equipment, net	<u>\$ 88,413</u>	<u>\$ 41,635</u>

Depreciation expense for the three and nine months ended September 30, 2024 was \$1.2 million and \$3.5 million, respectively, and \$1.0 million and \$3.0 million, respectively, for the same periods in 2023.

Intangible Assets

Intangible assets, net consisted of the following:

(In thousands)	Useful Life (in years)	Amortization Method	September 30, 2024			December 31, 2023		
			Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
NexoBrid license	12	Straight-line	\$ 7,500	\$ (1,094)	\$ 6,406	\$ 7,500	\$ (625)	\$ 6,875

Amortization expense for the three and nine months ended September 30, 2024 was \$0.2 million and \$0.5 million, respectively, and \$0.2 million and \$0.5 million, respectively, for the same periods in 2023.

Future amortization expense of intangible assets as of September 30, 2024 is estimated to be as follows:

(In thousands)	Amount
Remainder of 2024	\$ 156
2025	625
2026	625
2027	625
2028	625
Thereafter	3,750
Total	<u>\$ 6,406</u>

Accrued Expenses

Accrued Expenses consisted of the following:

(In thousands)	September 30, 2024	December 31, 2023
Bonus-related compensation	\$ 7,580	\$ 9,757
Employee-related accruals	3,087	3,503
Insurance reimbursement-related liabilities	3,336	3,591
Other accrued expenses	340	364
Total accrued expenses	<u>\$ 14,343</u>	<u>\$ 17,215</u>

5. Leases

The Company leases facilities in Ann Arbor, Michigan, Cambridge, Massachusetts and Burlington, Massachusetts. The Ann Arbor facility includes office space, and the Cambridge facilities include clean rooms, laboratories for MACI and Epical manufacturing and office space. The Company also leases offsite warehouse space and other computer-related equipment.

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

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 are 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. The Company funded the remaining 50% of its required cost amount, or approximately \$28.3 million, with cash on hand, pursuant to the Construction Escrow Agreement in April 2024.

The term of the Burlington Lease began on June 1, 2023 (the “Commencement Date”), when the Company gained control of and commenced tenant improvement work at the Premises. The Company’s obligation to pay rent for the Premises began on July 1, 2024 (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. The tenant improvement allowance is being used towards the design and construction of the tenant improvements made to the Premises, subject to the terms set forth in the Burlington Lease.

The Company was not involved in the initial construction of the core and shell of the building. On June 1, 2023, the Company gained control of the Premises to begin construction of its tenant improvements. As such, the corresponding right-of-use asset and lease liability of \$35.5 million was recorded on the Company’s condensed consolidated balance sheet. As there was not an implicit rate within the lease available, the Company estimated the incremental borrowing rate of 7.7%, based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term. The lease term of 13.1 years does not include the lease extension option, as the Company is not reasonably certain to exercise that option. The Company has determined that certain improvements to the Premises are landlord-owned improvements and costs incurred for these improvements are accounted for as a variable lease payment. In the nine months ended September 30, 2024, the Company recorded a right-of-use asset related to landlord-owned improvements incurred of approximately \$3.6 million.

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 and nine months ended September 30, 2024 and 2023, lease expense of less than \$0.1 million was recorded related to short-term leases. For the three and nine months ended September 30, 2024, the Company recognized \$3.2 million and \$9.6 million, respectively, of operating lease expense and \$3.2 million and \$7.1 million, respectively, for the same period in 2023. For the three and nine months ended September 30, 2023, 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	September 30, 2024	December 31, 2023
Assets			
Operating	Right-of-use assets	\$ 71,561	\$ 73,462
Liabilities			
<i>Current</i>			
Operating	Current portion of operating lease liabilities	\$ 6,119	\$ 6,187
<i>Non-current</i>			
Operating	Operating lease liabilities	\$ 91,344	\$ 81,856
Total leased liabilities		<u>\$ 97,463</u>	<u>\$ 88,043</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:

(In thousands)	September 30, 2024				
	Amortized Cost	Gross Unrealized		Credit Losses	Estimated Fair Value
		Gains	Losses		
Commercial paper	\$ 5,543	\$ 3	\$ —	\$ —	\$ 5,546
Corporate notes	68,255	365	(15)	—	68,605
U.S. government agency bonds	6,791	7	(1)	—	6,797
	<u>\$ 80,589</u>	<u>\$ 375</u>	<u>\$ (16)</u>	<u>\$ —</u>	<u>\$ 80,948</u>
Classified as:					
Short-term investments					\$ 48,053
Long-term investments					32,895
					<u>\$ 80,948</u>

(In thousands)	December 31, 2023				
	Amortized Cost	Gross Unrealized		Credit Losses	Estimated Fair Value
		Gains	Losses		
Commercial paper	\$ 3,638	\$ 1	\$ —	\$ —	\$ 3,639
Corporate notes	47,228	—	(69)	—	47,159
U.S. government securities	983	—	—	—	983
U.S. government agency bonds	14,003	—	(32)	—	13,971
	<u>\$ 65,852</u>	<u>\$ 1</u>	<u>\$ (101)</u>	<u>\$ —</u>	<u>\$ 65,752</u>
Classified as:					
Short-term investments					\$ 40,469
Long-term investments					25,283
					<u>\$ 65,752</u>

As of September 30, 2024 and December 31, 2023, 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 and nine months ended September 30, 2024 and 2023.

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, 2023 to September 30, 2024.

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

(In thousands)	September 30, 2024				December 31, 2023			
	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	\$ 29,333	\$ 29,333	\$ —	\$ —	\$ 34,672	\$ 34,672	\$ —	\$ —
Commercial paper ^(a)	5,546	—	5,546	—	4,876	—	4,876	—
Corporate notes	68,605	—	68,605	—	47,159	—	47,159	—
U.S. government agency bonds	6,797	—	6,797	—	13,971	—	13,971	—
U.S. government securities ^(a)	15,904	—	15,904	—	24,874	—	24,874	—
	<u>\$ 126,185</u>	<u>\$ 29,333</u>	<u>\$ 96,852</u>	<u>\$ —</u>	<u>\$ 125,552</u>	<u>\$ 34,672</u>	<u>\$ 90,880</u>	<u>\$ —</u>

^(a) Approximately \$15.9 million of U.S. government securities as of September 30, 2024, and approximately \$23.9 million of U.S. government securities and \$1.2 million of commercial paper as of December 31, 2023, had an original maturity of 90 days or less and is recorded as a cash equivalent.

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 September 30, 2024, 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 (collectively the “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 the employee stock purchase plan) is summarized in the following table:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of product sales	\$ 762	\$ 660	\$ 2,914	\$ 2,341
Research and development	1,095	892	3,281	2,862
Selling, general and administrative	7,367	6,372	22,383	20,213
Total non-cash stock-based compensation expense	\$ 9,224	\$ 7,924	\$ 28,578	\$ 25,416

Service-Based Stock Options

During the three and nine months ended September 30, 2024, the Company granted service-based options to purchase common stock of 105,025 and 745,412, respectively, and 58,500 and 594,217, respectively, for the same periods in 2023. The weighted-average grant-date fair value of service-based options granted during the three and nine months ended September 30, 2024 was \$27.73 and \$28.08 per option, respectively, and \$22.36 and \$18.80, respectively, for the same periods in 2023.

Restricted Stock Units

During the three and nine months ended September 30, 2024, the Company granted 35,610 and 622,535 restricted stock units, respectively, and 23,520 and 552,841, respectively, for the same periods in 2023. The weighted-average grant-date fair value of restricted stock units granted during the three and nine months ended September 30, 2024 was \$47.59 and \$48.19 per unit, respectively, and \$36.51 and \$30.24, respectively, for the same periods in 2023.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	\$ (901)	\$ (3,660)	\$ (9,445)	\$ (16,175)
Basic weighted-average common shares outstanding	49,085	47,649	48,639	47,537
Effect of dilutive stock options and restricted stock units	—	—	—	—
Diluted weighted-average common shares outstanding	49,085	47,649	48,639	47,537
Basic loss per common share	\$ (0.02)	\$ (0.08)	\$ (0.19)	\$ (0.34)
Diluted loss per common share	\$ (0.02)	\$ (0.08)	\$ (0.19)	\$ (0.34)
Anti-dilutive shares excluded from diluted net loss per common share:				
Stock options	6,115	6,859	6,115	6,859
Restricted stock units	1,142	943	1,142	943

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 orphan product containing proteolytic enzymes, for which the FDA approved a BLA in December 2022 permitting the product's use for the removal of eschar in adults with deep partial-thickness and/or full thickness thermal burns. Subsequently, in August 2024, the FDA approved a supplemental BLA expanding NexoBrid's indication to include pediatric patients.

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. The FDA's December 2022 approval of NexoBrid resulted in the achievement of a \$7.5 million regulatory milestone payment pursuant to the terms of the license agreement. The Company recorded the \$7.5 million milestone for the licensing rights to commercially sell NexoBrid in the U.S. as an intangible asset as of December 31, 2022. The \$7.5 million milestone payment was paid to MediWound in February of 2023.

Additionally, the Company is 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 NexoBrid in North America exceed \$75.0 million. As of September 30, 2024, the sales milestone payments are not yet probable and therefore, not recorded as a liability. The Company also pays 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 is manufacturing, and will continue to 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 initial term, the Company may extend the supply agreement on an annual basis for up to 10 additional years, at its sole discretion. Under the supply agreement, the Company is permitted to establish an alternate source of supply in certain circumstances, including the event of a supply failure.

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 was completed during the third quarter of 2022. As a part of BARDA's commitment to procure NexoBrid, the Company received a percentage of gross profit for sales directly to

BARDA. As of September 30, 2024, the Company did not hold a direct contract or distribution agreement with BARDA, or take title to the product procured by BARDA.

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 September 30, 2024, the Company had 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.

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 leading provider of advanced therapies for the sports medicine and severe burn care markets. Whether we are treating damaged cartilage or severe burns, we provide advanced therapies to repair serious injuries and restore lives. Our highly differentiated portfolio of cell therapy and specialty biologic products combines innovations in biology with medical technologies. We were among the first companies to achieve commercial success in the complex field of cell therapies with treatments that use tissue engineering to regenerate skin and healthy knee cartilage. 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), a topically-administered biological orphan product containing proteolytic enzymes, which is indicated for the removal of eschar in adult and pediatric patients with deep partial-thickness and/or full-thickness thermal burns.

The Ongoing Military Conflicts in the Middle East

In May 2019, we entered into exclusive license and supply agreements with MediWound, under which MediWound manufactures and supplies NexoBrid to the U.S. market on a unit price basis. MediWound develops and manufactures NexoBrid, in part, at its facilities in Yavne, Israel.

We continue to monitor the ongoing military conflicts in the Middle East region involving Israel, and we are in close communication with MediWound leadership. MediWound's NexoBrid manufacturing operations are continuing and, as of the date of this disclosure, MediWound does not anticipate a material disruption to its ongoing supply of commercial NexoBrid to the United States. To the extent the conflicts in the Middle East region intensify or expand to include additional countries or militant groups and MediWound's facilities in Israel are damaged or destroyed, travel to and from Israel is halted or inhibited, or significant key MediWound operational personnel are called to military service, MediWound's ability to continue to supply NexoBrid to the U.S. market could be disrupted. As of the date of this report, we maintain an ample supply of NexoBrid at our U.S.-based third-party logistics provider.

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 sourced from Taiwan.

Product Portfolio

Our marketed products include two FDA-approved autologous cell therapies and one FDA-approved specialty biologic product. MACI is 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 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 TBSA. Both autologous cell therapy products are currently manufactured and marketed in the U.S. NexoBrid is a topically-administered biological orphan product containing proteolytic enzymes that is indicated for eschar removal in adult and pediatric patients with deep partial-thickness and/or full-thickness burns. We hold exclusive license and supply agreements with MediWound to commercialize NexoBrid in North America. 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 conditions.

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 formal specialty training in sports medicine, and a subpopulation of general orthopedic surgeons who perform a high volume of cartilage repair procedures involving the knee. Our MACI commercial team consists of individual sales representatives that regularly engage with our target audience. The team is divided into geographic regions, each managed by a Regional Sales Director and led by a Senior Vice President of 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 consists of autologous cultured chondrocytes, which are human-derived cells that are obtained from the patient’s own cartilage, and which are seeded onto resorbable Type I/III collagen membrane. Since MACI’s commercial launch, a treating surgeon has been able to use MACI to treat a patient through an open surgical procedure. In August 2024, however, the FDA approved a supplemental Biologics License Application (“sBLA”) expanding the MACI indication to add instructions for the arthroscopic delivery of MACI to the product’s approved labeling, permitting the repair of single or multiple full-thickness cartilage defects of the knee up to 4 cm² in size via that approach. MACI Arthro™ provides a less invasive technique compared to the current approach and allows surgeons to evaluate, prepare and treat the cartilage defect, and deliver the MACI implant, under direct arthroscopic visualization using specialized and custom-designed instruments (the “MACI Arthro instruments”) through small incisions or portals. The arthroscopic delivery of MACI could increase the ease of MACI’s use for physicians and may reduce both the length of the procedure as well as procedure-induced trauma, ultimately resulting in a reduction of a patient’s post-operative pain and accelerating a patient’s recovery. MACI Arthro became commercially available in the United States during the third quarter of 2024 and we began selling the MACI Arthro instruments at that time. In conjunction with the launch of MACI Arthro, we have expanded our target surgeon base from 5,000 to 7,000 to include orthopedic surgeons that perform high volumes of knee cartilage repair surgeries, predominantly through arthroscopic procedures.

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 and we are on track to initiate a MACI Ankle clinical trial beginning in 2025. If approved, we believe MACI’s expansion into the ankle will be a significant long-term growth driver for the product, beginning in the latter half of the decade.

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., and certain HUDs are restricted by the amount which a manufacturer may charge for its use.

Epicel is not price-restricted in this manner because on February 18, 2016, the FDA approved our HDE supplement to revise the labeled indications of use for Epicel to specifically include pediatric patients, thus allowing Epicel to be sold for profit. 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.

NexoBrid

Our portfolio of commercial-stage products also includes NexoBrid (anacaulase-bcdb), a topically-administered biological orphan product containing proteolytic enzymes, for which the FDA approved a BLA in December 2022 permitting the product’s use for the removal of eschar in adults with deep partial-thickness and/or full thickness thermal burns. Subsequently, in August 2024, the FDA approved a sBLA expanding NexoBrid’s indication to include pediatric patients.

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 people that are hospitalized in the U.S. each year for burn-related injuries, 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. Both our Epicel and NexoBrid products are serviced by our burn care field force, which consists of individual sales and clinical representatives that regularly engage with our target audience. The team is divided into geographical regions, each managed by a Regional Sales Director and led by a Vice President of National Burn Care Sales.

In May 2019, we entered into exclusive license and supply agreements with MediWound to commercialize NexoBrid in North America. 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 sourced from Taiwan.

Results of Operations

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

(In thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024	2023	Change \$	Change %	2024	2023	Change \$	Change %
Total revenue	\$ 57,905	\$ 45,581	\$ 12,324	27.0 %	\$ 161,848	\$ 132,520	\$ 29,328	22.1 %
Cost of product sales	16,252	14,973	1,279	8.5 %	48,240	45,451	2,789	6.1 %
Gross profit	41,653	30,608	11,045	36.1 %	113,608	87,069	26,539	30.5 %
Research and development	6,093	5,676	417	7.3 %	19,874	16,141	3,733	23.1 %
Selling, general and administrative	38,025	29,989	8,036	26.8 %	107,694	90,123	17,571	19.5 %
Total operating expenses	44,118	35,665	8,453	23.7 %	127,568	106,264	21,304	20.0 %
Loss from operations	(2,465)	(5,057)	2,592	(51.3)%	(13,960)	(19,195)	5,235	(27.3)%
Total other income	1,564	1,111	453	40.8 %	4,515	2,734	1,781	65.1 %
Income tax benefit	—	(286)	286	(100.0)%	—	(286)	286	(100.0)%
Net loss	\$ (901)	\$ (3,660)	\$ 2,759	(75.4)%	\$ (9,445)	\$ (16,175)	\$ 6,730	(41.6)%

Comparison of the Periods Ended September 30, 2024 and 2023

Total Revenue

Revenue by product is as follows:

(In thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024	2023	Change \$	Change %	2024	2023	Change \$	Change %
MACI	\$ 44,656	\$ 37,589	\$ 7,067	18.8 %	\$ 128,973	\$ 108,114	\$ 20,859	19.3 %
Epicel	12,184	7,394	4,790	64.8 %	30,606	23,808	6,798	28.6 %
NexoBrid	1,065	598	467	78.1 %	2,269	598	1,671	279.4 %
Total revenue	\$ 57,905	\$ 45,581	\$ 12,324	27.0 %	\$ 161,848	\$ 132,520	\$ 29,328	22.1 %

Total revenue increase for the three and nine months ended September 30, 2024, compared to the same periods in 2023, was driven primarily by MACI volume and price growth, in addition to burn care revenue from higher Epicel and NexoBrid volume.

Seasonality

Sales of MACI implants have historically experienced a level of seasonality throughout the year. In the last five years through 2023, MACI sales volumes from the first through the fourth quarter on average represented 20% (18%-22% range), 22% (16%-24% range), 23% (21%-26% range) and 35% (33%-38% range) respectively, of total annual volumes. Historically, 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 encompassing a large total body surface area, Epicel revenue has inherent variability from quarter-to-quarter and does not exhibit significant seasonality. Although U.S. sales of NexoBrid only began in September 2023, and we are still relatively early in its commercial launch, we do not expect NexoBrid revenue to experience significant seasonality given its emergent use in treating severe burns.

Gross Profit

Gross profit increase for the three and nine months ended September 30, 2024, compared to the same periods in 2023, was driven by revenue growth across all products, combined with our primarily fixed manufacturing cost structure which consists mainly of labor and 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 September 30,				Nine Months Ended September 30,			
	2024	2023	Change \$	Change %	2024	2023	Change \$	Change %
MACI	\$ 4,345	\$ 4,020	\$ 325	8.1 %	\$ 14,635	\$ 10,412	\$ 4,223	40.6 %
Epicel	1,138	890	248	27.9 %	3,463	2,975	488	16.4 %
NexoBrid	610	766	(156)	(20.4)%	1,776	2,754	(978)	(35.5)%
Total research and development expenses	\$ 6,093	\$ 5,676	\$ 417	7.3 %	\$ 19,874	\$ 16,141	\$ 3,733	23.1 %

Research and development expenses increased for the three months ended September 30, 2024, compared to the same period in 2023. The increase is primarily due to higher headcount and employee expenses.

Research and development expenses increased for the nine months ended September 30, 2024, compared to the same period in 2023. The increase is primarily due to higher headcount and employee expenses, as well as increased MACI arthroscopic development program costs in 2024.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2024 were \$38.0 million, compared to \$30.0 million for the same period in 2023. The increase in selling, general and administrative expenses was primarily due to higher headcount and employee expenses, including stock compensation and sales incentive compensation, and an increase in marketing programs and events, including to support the MACI arthroscopic launch.

Selling, general and administrative expenses for the nine months ended September 30, 2024 were \$107.7 million, compared to \$90.1 million for the same period in 2023. The increase in selling, general and administrative expenses was primarily due to higher headcount and employee expenses, including stock compensation and sales incentive compensation, an increase in marketing programs and events, including to support the MACI arthroscopic launch, and the lease expense associated with the Burlington Lease.

Total Other Income

The increase in other income for the three and nine months ended September 30, 2024, compared to the same periods in 2023 was due to an increase in interest income primarily due to fluctuations in the rates of return on our investments in various marketable debt securities and money market funds.

Stock-based Compensation Expense

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

(In thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024	2023	Change \$	Change %	2024	2023	Change \$	Change %
Cost of product sales	\$ 762	\$ 660	\$ 102	15.5 %	\$ 2,914	\$ 2,341	\$ 573	24.5 %
Research and development	1,095	892	203	22.8 %	3,281	2,862	419	14.6 %
Selling, general and administrative	7,367	6,372	995	15.6 %	22,383	20,213	2,170	10.7 %
Total non-cash stock-based compensation expense	<u>\$ 9,224</u>	<u>\$ 7,924</u>	<u>\$ 1,300</u>	<u>16.4 %</u>	<u>\$ 28,578</u>	<u>\$ 25,416</u>	<u>\$ 3,162</u>	<u>12.4 %</u>

The increase in stock-based compensation expense for the three and nine months ended September 30, 2024, compared to the same periods in 2023, 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)	Nine Months Ended September 30,	
	2024	2023
Net cash provided by operating activities	\$ 35,921	\$ 25,225
Net cash (used in) provided by investing activities	(64,383)	4,958
Net cash provided by financing activities	11,946	2,311
Net (decrease) increase in cash, cash equivalents, and restricted cash	<u>\$ (16,516)</u>	<u>\$ 32,494</u>

Net Cash Provided by Operating Activities

Our cash, cash equivalents and restricted cash totaled \$70.4 million, short-term investments totaled \$48.1 million and long-term investments totaled \$32.9 million as of September 30, 2024. The \$35.9 million of cash provided by operations during the nine months ended September 30, 2024 was primarily the result of non-cash charges of \$28.6 million related to stock-based compensation expense, \$5.1 million of operating lease amortization and \$4.0 million in depreciation and amortization expense, offset by a net loss of \$9.4 million and a net increase of \$7.8 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 and receipts of tenant improvement allowances which exceeded payments on operating leases amortization, offset by a decrease in accounts payable and accrued expenses due to timing of payments and an increase in inventory primarily related to supporting NexxBrid commercial availability.

Our cash, cash equivalents and restricted cash totaled \$83.6 million, short-term investments totaled \$44.9 million and long-term investments totaled \$20.2 million as of September 30, 2023. The \$25.2 million of cash provided by operations during the nine months ended September 30, 2023 was primarily the result of non-cash charges of \$25.4 million related to stock-based compensation expense, \$4.3 million of operating lease amortization and \$3.5 million in depreciation and amortization expense, offset by a net loss of \$16.2 million and a net increase of \$8.8 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 and receipts of tenant improvement allowances, offset by a decrease in accrued expenses due to timing of payments.

Net Cash (Used In) Provided By Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2024 was the result of \$52.6 million in investment purchases and \$50.2 million of property and equipment purchases primarily for construction in process related to the Burlington Lease, offset by \$38.4 million of investment sales and maturities.

Net cash provided by investing activities during the nine months ended September 30, 2023 was the result of \$60.9 million of investment sales and maturities, offset by \$36.3 million in investment purchases, a \$7.5 million regulatory milestone payment to MediWound resulting from the FDA's approval of the NexoBrid BLA, and \$12.2 million of property and equipment purchases primarily for manufacturing upgrades and construction in process related to the Burlington Lease.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2024 was the result of net proceeds from the exercise of stock options and the employee stock purchase plan of \$17.3 million, partially offset by the payment of employee withholding taxes related to the vesting of restricted stock units of \$5.3 million.

Net cash provided by financing activities during the nine months ended September 30, 2023 was the result of net proceeds from the exercise of stock options and purchases under the employee stock purchase plan of \$4.6 million, partially offset by the payment of employee withholding taxes related to the vesting of restricted stock units of \$2.3 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, Epicel and NexoBrid sales, debt, and public and private sales of our equity securities. In the future, 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. Our actual cash requirements may differ from projections and will depend on many factors, including 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, global macroeconomic conditions, costs associated with possible acquisitions or development of complementary business activities, and the cost to market our products.

As of September 30, 2024, we were not party to any off-balance sheet arrangements.

Sources of Capital

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 September 30, 2024, 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, 2023. In connection with the Burlington Lease, the Company funded the remaining 50% of its required cost amount, or approximately \$28.3 million, with cash on hand, pursuant to the Construction Escrow Agreement in

April 2024. There have been no other material changes, outside of the ordinary course of business, to our contractual obligations and commitments since December 31, 2023.

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 nine months ended September 30, 2024. 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, 2023.

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®, MACI Arthro™, 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, contributions to adjusted EBITDA, 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 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, surgeon adoption of MACI Arthro, physician and burn center adoption of NexoBrid, labor strikes, changes in surgeon and hospital treatment prioritizations caused by the temporary shortage of essential medical supplies, supply chain disruptions or other events or factors that might affect our ability to manufacture MACI or Epicel or affect MediWound's ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, including but not limited to the ongoing military conflicts in the Middle East region involving Israel, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine and the Middle East conflicts, adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, global geopolitical tensions or record inflation and potential future impacts on our business or the economy generally stemming from a public health emergency. 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 on Form 10-K 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, 2023. Our exposures to market risk have not changed materially since December 31, 2023.

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 September 30, 2024, 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 Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange 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 September 30, 2024, 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, 2023, filed with the SEC on February 29, 2024. 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, 2023.

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

Rule 10b5-1 Trading Plans

During the three months ended September 30, 2024, none of the Company's Section 16 officers or directors adopted, modified or terminated a "Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K of the Exchange Act).

Additionally, there were no "non-Rule 10b5-1 trading arrangements" (as defined in Item 408 of Regulation S-K of the Exchange Act) adopted, modified or terminated during the three months ended September 30, 2024 by our Section 16 officers or directors.

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.				
10.1†*	Eleventh Amendment to the Distribution Agreement between Orsini Pharmaceutical Services, Inc. and the Company, dated July 31, 2024.				
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.

† Certain immaterial and confidential portions of this exhibit have been omitted in accordance with Item 601 (a)(5) of Regulation S-K.

SIGNATURES

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

Date: November 7, 2024

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)

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH IMMATERIAL AND THE TYPE OF INFORMATION THAT VERICEL TREATS AS CONFIDENTIAL. ACCORDINGLY, SUCH INFORMATION HAS BEEN OMITTED AND REPLACED WITH “[***]”.

ELEVENTH AMENDMENT TO DISTRIBUTION AGREEMENT

This Eleventh Amendment to the Distribution Agreement (“Eleventh Amendment”) is between Vericel Corporation (“Vericel”) and Orsini Pharmaceutical Services, Inc. (“Orsini”). This Eleventh Amendment is effective as of July 31, 2024 (“Effective Date”).

Whereas, Vericel and Orsini are parties to a Distribution Agreement dated May 15, 2017 (as amended, the “Agreement”), under which Vericel appointed Orsini as a specialty pharmacy distributor for MACI®;

Whereas, the Parties entered into the First Amendment to the Agreement effective August 10, 2017;

Whereas, the Parties entered into the Second Amendment to the Agreement effective October 13, 2017;

Whereas, the Parties entered into the Third Amendment to the Agreement effective November 14, 2017;

Whereas, the Parties entered into the Fourth Amendment to the Agreement effective July 25, 2018;

Whereas, the Parties entered into the Fifth Amendment to the Agreement effective August 10, 2018;

Whereas, the Parties entered into the Sixth Amendment to the Agreement effective April 18, 2019;

Whereas, the Parties entered into the Seventh Amendment to the Agreement effective October 1, 2021;

Whereas, the Parties entered into the Eighth Amendment to the Agreement effective May 15, 2022;

Whereas, the Parties entered into the Ninth Amendment to the Agreement effective May 15, 2024;

Whereas, the Parties entered into the Tenth Amendment to the Agreement effective June 30, 2024;

Now therefore, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to further amend the Agreement as follows:

1. Section 7.1 Term. Section 7.1 shall be deleted and replaced with the following:

The Term of this Agreement shall continue until **May 15, 2027** (“Term”). The Parties may renew the Agreement for two (2) additional two-year terms, upon mutual agreement. Orsini shall not enter into any agreement with a Payor covering the Product unless Vericel has approved the reimbursement amount for the Product in writing. Unless otherwise agreed to in writing by Vericel, the minimum reimbursement amount for the Product shall be [***]. For the avoidance of doubt, if Vericel does not approve a reimbursement amount for MACI, Orsini shall have the ability to enter into a separate agreement for the other products they support. Any proposed material modifications to the conditions for reimbursement for the Product relating to Payors on Exhibit B and/or for the proposed addition of Payors to Exhibit B - Contracted Payors shall require Vericel’s prior written approval, which approval shall not be unreasonably withheld or delayed as long as target reimbursement rates are met. Orsini shall provide to Vericel the allowable reimbursement amount for the Payors listed on Exhibit B per the payment terms

provided in Exhibit A. Should a Payor request extended payment terms in excess of sixty (60) days, Orsini will secure advance written approval from Vericel. Exhibit B will be modified from time to time in writing by the Parties as additional Payors are contracted with Orsini and approved by Vericel.

2. **Exhibits A and B.** The Parties agree that Exhibits A and B to the Agreement shall be deleted and replaced with the attached revised and restated Exhibits A and B.
3. **No Other Changes.** To the extent terms in this Eleventh Amendment conflict with the Agreement and/or any of the amendments to the Agreement, the terms of this Eleventh Amendment shall prevail. Except as provided in this Eleventh Amendment, the terms and conditions of the Agreement will continue in full force and effect.
4. **Counterparts/Signatures.** This Eleventh Amendment may be executed in multiple counterparts, each of which constitutes an original, and all of which, collectively, constitute only one agreement. The signatures of the parties need not appear on the same counterpart, and delivery of an executed counterpart signature page by facsimile or other form of electronic transmission shall be as effective as executing and delivering this Eleventh Amendment in the presence of the other parties to this Eleventh Amendment.

IN WITNESS WHEREOF, the parties executed this Eleventh Amendment as of its Effective Date.

Vericel Corporation

By: /s/ Roland DeAngelis
Name: Roland P. DeAngelis, Jr.
Title: Chief Commercial Officer

Date: 31-Jul-2024

Orsini Pharmaceutical Services, Inc.

By: /s/ Eyad Farah
Name: Eyad Farah
Title: Chief Operating Officer

Date: 31-Jul-2024

EXHIBIT A -- PAYMENT TERMS AND PRICING**1. Product.**

Product, under this Agreement is defined as:

Product	NDC Number
MACI 1	69866-1030-05
MACI 2	69866-1030-08

2. Orsini Counseling and Dispensing.

A. Orsini, when acting as the dispensing specialty pharmacy for Product, shall review Case Materials related to a patient's clinical history, diagnosis and approval for MACI and may contact the patient regarding the patient's financial responsibility. [***].

B. Vericel shall, at its expense and using its account with carriers, arrange for Product to be shipped to Orsini so that Orsini may label and dispense the Product to the patient by the surgery date. Vericel shall also be responsible for the shipping cost for the Product from Orsini's facility to the treating facility.

C. In order to perform its specialty pharmacy services, Orsini shall take title to the Product upon receipt of the Product at its facility. Vericel, however, shall retain the risk of loss related to the Product throughout its shipment from Vericel's manufacturing facility to Orsini and from Orsini's facility to the treating facility, including any damages relating to delay in shipment by the delivery company. Notwithstanding the preceding sentence, Orsini shall be responsible for damages that occur to the Product while in its possession, unless the cause of the damage is Force Majeure as defined in Section 8(a) of the Agreement.

3. Claim Submittal, In Network & Rate Confirmation, Contracting and Payment Coordination between Parties.

A. [***]. Orsini, working with Vericel's contractor, shall submit claims for Products [***] of Product implantation. Orsini shall provide a claim submission to Vericel's contractor prior to submission and provide Vericel's contractor [***] to review and comment on the claim, which comments Orsini shall address in good faith. Orsini shall appeal or resubmit for payment all denied and otherwise rejected claims for which a good faith basis exists to do so, within five (5) business days from Orsini's receipt of such notice of denial or rejection. [***]. Orsini shall notify Vericel daily of denials or claims otherwise rejected and the reason for the denial or rejection. [***].

B. [***].

C. When reasonably determined by Vericel representatives and Orsini, Orsini will consult with Vericel and its designated representatives with regard to MACI contracting and claims submission.

D. [***].

4. Service Level Agreements (SLA).

Service level agreements (credits and incentives to dispensing fee)

[***]

5. Payment Terms.

A. Vericel shall pay Orsini for each Product dispensed by Orsini, regardless of the Product NDC, a Fixed fees (“Dispensing Fee”) per the following fee schedule:

[***]

B. Within [***] of receipt of payment from a Payor related to the Product, Orsini shall remit to Vericel all reimbursements related to Products dispensed by Orsini except as provided above. The payments shall be deposited into a bank account maintained by and in the name and sole control of Vericel (the “Vericel Account”). In conjunction with each deposit, Orsini shall remit to Vericel a schedule detailing the cases for which a payment was deposited into the account including the case number and the amount deposited for each case.

C. On a weekly basis, Orsini shall remit to Vericel a schedule which includes the gross reimbursements received from the Payor and patient related to Products dispensed by Orsini, including whether the payments were deposited into the Vericel Account and the date of payment into the Vericel Account. Such schedule of payments shall include the case number and other identifiers agreed to by the Parties. [***].

D. In addition to the remitting of payment to Vericel as set forth above, Orsini shall update, on a daily basis, the payment status of submitted cases to Vericel and its contractors through Vericel Central or other mutually agreed upon method.

E. Subject to the terms of the Agreement, as amended, Vericel acknowledges that it retains the risk of payment for all cases received by Orsini on June 16, 2018, or thereafter.

F. Except as provided herein, all payments (including interest payments, if any) for the Product received by Orsini during the Term and after the expiration or termination of the Agreement shall be the sole property of Vericel and shall be remitted to Vericel in accordance with the Agreement. In the event of a termination or expiration of the Agreement, Orsini shall continue to collect on claims covered by the Agreement, consistent with the terms of the Agreement, for a period of twelve months following the expiration or termination of the Agreement.

G. Orsini represents and warrants that each of Orsini’s Payor agreements set forth on Exhibit B are in full force and effect and apply to the Product.

H. If a Payor recoups any payment on a case for which Orsini has made payment to Vericel, Orsini shall notify Vericel in writing and shall be entitled to deduct from Vericel funds a sum equal to the amount of the recoupment. If there are insufficient Vericel Funds, Orsini shall invoice Vericel for the amount of the recoupment and Vericel shall pay Orsini within thirty (30) days of receipt of the invoice. Vericel’s obligation under this Paragraph H shall survive the termination of the Agreement. The Parties shall discuss appealing and/or disputing the proposed recoupment with the Payor. If an appeal is successful, Orsini shall treat the payment in accordance with the terms of this Eleventh Amendment.

I. The Parties agree that fees paid hereunder are not designed nor constitute inducements for Orsini to utilize or recommend the utilization of Vericel Products under federal and/or similar state laws. Orsini shall properly disclose and otherwise comply with applicable law.

EXHIBIT B –Contracted Payors – Update payer list to be reviewed and accepted by Orsini and Vericel on quarterly basis.

Consistent with Section 1.1 and Section 7.1 of the Agreement, the Payors listed on this Exhibit shall only apply to [***].

[***]

EXHIBIT C –RACI

[***]

CERTIFICATION

I, Dominick C. Colangelo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vericel Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 7, 2024

/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: November 7, 2024

/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 September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

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

Date: November 7, 2024

/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.