

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2025

or

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

For the transition period from _____ to _____

Commission File Number: 001-39059



AVITA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

85-1021707
(IRS Employer
Identification No.)

28159 Avenue Stanford
Suite 220
Valencia, CA 91355

(Address of principal executive offices and Zip Code)

Registrant's telephone number, including area code: (661) 367-9170

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	RCEL	The Nasdaq Stock Market LLC

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

If an emerging growth company, indicate by check mark if the registrant has selected 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 ☒

The number of shares of the registrant's common stock, par value \$0.0001, outstanding as of May 5, 2025 was 26,434,658.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including uncertainties associated with our expectations regarding future revenue, or future growth in revenue, profit, or gross and/or operating margins; the ability to achieve or sustain profitability; industry market conditions; increased competition; changes in our production capacity; failure to obtain, maintain and enforce our intellectual property rights, including our expectations regarding the future scope of such rights; failure to obtain and/or maintain regulatory approvals and comply with applicable regulations; the conduct or outcome of pre-clinical or clinical (human) studies; operational and management restructuring activities; our ability to find and maintain partnerships relating to collaborations, strategic arrangements, and licensing arrangements; mergers and acquisitions (and related integration activities); if third parties fail to uphold their contractual duties or meet expected deadlines; our ability to obtain and maintain favorable coverage and reimbursement determinations from third party payors; market reaction to growth or product initiatives; our ability to expand our sales and marketing organizations to address existing and new markets that we intend to target; market penetration of our products; the ability to continue to scale our manufacturing operations to meet the demand for our products; our ability to attract and retain qualified personnel, including management; solvency; non-compliance with debt covenants, which may result in the acceleration of our debt obligations or the need for renegotiations with our lenders, tax and interest rates; inflationary pressures on the U.S. and global economies, respectively; changes in the legal or regulatory environments; the impact of a cybersecurity breach, terrorist attack or other geopolitical instability, pandemic or epidemic, or natural disaster; and future working capital, costs, productivity, business process, rationalization, investment (including rates), consulting, operational, financial, and capital projects and/or initiatives. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these terms or other similar expressions.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the sections in this Quarterly Report on Form 10-Q titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for our management to predict all risk factors and uncertainties.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

PART I – Financial Information

Item 1. FINANCIAL STATEMENTS

AVITA MEDICAL, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	As of	
	March 31, 2025	December 31, 2024
ASSETS		
Cash and cash equivalents	\$ 14,870	\$ 14,050
Marketable securities	10,948	21,835
Accounts receivable, net	12,045	11,786
Prepays and other current assets	1,709	2,060
Inventory	8,395	7,269
Total current assets	47,967	57,000
Plant and equipment, net	9,894	10,018
Operating lease right-of-use assets	3,356	3,571
Corporate-owned life insurance (“COLI”) asset	2,605	3,006
Intangible assets, net	5,447	5,570
Other long-term assets	287	546
Total assets	<u>\$ 69,556</u>	<u>\$ 79,711</u>
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS’ EQUITY (DEFICIT)		
Accounts payable and accrued liabilities	\$ 8,677	\$ 6,294
Accrued wages and fringe benefits	8,346	10,451
Current non-qualified deferred compensation (“NQDC”) liability	495	2,094
Contingent liability	3,000	-
Other current liabilities	2,438	1,319
Total current liabilities	22,956	20,158
Long-term debt	41,464	42,245
Non-qualified deferred compensation liability	3,665	2,969
Contract liabilities	315	324
Operating lease liabilities, long-term	2,609	2,840
Contingent liability, long-term	-	3,000
Warrant liabilities	3,054	3,432
Total liabilities	<u>74,063</u>	<u>74,968</u>
Non-qualified deferred compensation plan share awards	64	244
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 26,434,658 and 26,354,042, shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	3	3
Preferred stock, \$0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at March 31, 2025 and December 31, 2024	-	-
Company common stock held by the non-qualified deferred compensation plan	(1,308)	(1,319)
Additional paid-in capital	370,820	367,568
Accumulated other comprehensive loss	(413)	(1,939)
Accumulated deficit	(373,673)	(359,814)
Total stockholders’ equity (deficit)	<u>(4,571)</u>	<u>4,499</u>
Total liabilities, non-qualified deferred compensation plan share awards and stockholders’ equity (deficit)	<u>\$ 69,556</u>	<u>\$ 79,711</u>

The accompanying notes form part of the unaudited Consolidated Financial Statements.

AVITA MEDICAL, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Sales revenue	\$ 18,325	\$ 11,104
Lease revenue	189	-
Total revenues	18,514	11,104
Cost of sales	(2,833)	(1,513)
Gross profit	15,681	9,591
Operating expenses:		
Sales and marketing	(14,834)	(12,640)
General and administrative	(6,390)	(8,963)
Research and development	(6,284)	(5,194)
Total operating expenses	(27,508)	(26,797)
Operating loss	(11,827)	(17,206)
Interest expense	(1,233)	(1,356)
Other expense, net	(791)	(66)
Loss before income taxes	(13,851)	(18,628)
Income tax expense	(8)	(30)
Net loss	<u>\$ (13,859)</u>	<u>\$ (18,658)</u>
Net loss per common share:		
Basic and diluted	\$ (0.53)	\$ (0.73)
Weighted-average common shares:		
Basic and diluted	26,253,565	25,637,783

The accompanying notes form part of the unaudited Consolidated Financial Statements.

AVITA MEDICAL, INC.
Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Net loss	\$ (13,859)	\$ (18,658)
Change in fair value due to credit risk on long-term debt	1,541	(1,092)
Net unrealized loss on marketable securities	(15)	(89)
Comprehensive loss	<u>\$ (12,333)</u>	<u>\$ (19,839)</u>

The accompanying notes form part of the unaudited Consolidated Financial Statements.

AVITA MEDICAL, INC.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except shares)
(Unaudited)

	<u>Common Stock</u>							
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)	
Balance at December 31, 2024	26,354,042	\$ 3	\$ (1,319)	\$ 367,568	\$ (1,939)	\$ (359,814)	\$ 4,499	
Net loss	-	-	-	-	-	(13,859)	(13,859)	
Stock-based compensation	-	-	-	2,675	-	-	2,675	
Exercise of stock options	66,008	-	-	363	-	-	363	
Distribution of Company common stock held by the NQDC Plan	-	-	147	15	-	-	162	
Vesting of Company common stock held by the NQDC Plan	14,608	-	(136)	136	-	-	-	
Change in redemption value of share awards in NQDC Plan	-	-	-	63	-	-	63	
Net unrealized loss on marketable securities	-	-	-	-	(15)	-	(15)	
Change in fair value due to credit risk on long-term debt	-	-	-	-	1,541	-	1,541	
Balance at March 31, 2025	26,434,658	\$ 3	\$ (1,308)	\$ 370,820	\$ (413)	\$ (373,673)	\$ (4,571)	

	<u>Common Stock</u>						
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2023	25,682,078	\$ 3	\$ (1,130)	\$ 350,039	\$ (1,887)	\$ (297,969)	\$ 49,056
Net loss	-	-	-	-	-	(18,658)	(18,658)
Stock-based compensation	-	-	-	2,585	-	-	2,585
Exercise of stock options	106,973	-	-	631	-	-	631
Distribution/diversification of Company common stock held by the NQDC Plan	-	-	186	78	-	-	264
Change in redemption value of share awards in NQDC Plan	-	-	-	(128)	-	-	(128)
Net unrealized loss on marketable securities	-	-	-	-	(89)	-	(89)
Change in fair value due to credit risk on long-term debt	-	-	-	-	(1,092)	-	(1,092)
Balance at March 31, 2024	<u>25,789,051</u>	<u>\$ 3</u>	<u>\$ (944)</u>	<u>\$ 353,205</u>	<u>\$ (3,068)</u>	<u>\$ (316,627)</u>	<u>\$ 32,569</u>

The accompanying notes form part of the unaudited Consolidated Financial Statements.

AVITA Medical, Inc.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Cash flow from operating activities:		
Net loss	\$ (13,859)	\$ (18,658)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of long-term debt	760	397
Change in fair value of warrant liability	(378)	870
Depreciation and amortization	521	203
Stock-based compensation	2,694	2,591
Non-cash lease expense	215	214
Loss on fixed asset disposal	14	-
Excess and obsolete inventory related charges	313	83
Provision for credit losses	(7)	80
Amortization of premium of marketable securities	(128)	(677)
Non-cash changes in the fair value of NQDC plan	(695)	278
Changes in operating assets and liabilities:		
Trade and other receivables	(253)	503
Prepays and other current assets	350	(1,862)
Inventory	(1,439)	(1,659)
Operating lease liability	(231)	(224)
Corporate-owned life insurance ("COLI") asset	492	(215)
Other long-term assets	259	(46)
Accounts payable and accrued expenses	2,330	(763)
Accrued wages and fringe benefits	(2,105)	(2,170)
Current non-qualified deferred compensation liability	(1,567)	473
Other current liabilities	1,119	(109)
Non-qualified deferred compensation plan liability	1,294	(165)
Contract liabilities	(8)	(8)
Net cash used in operating activities	(10,309)	(20,864)
Cash flows from investing activities:		
Purchase of marketable securities	-	(2,904)
Maturities of marketable securities	11,000	19,200
Purchase of plant and equipment	(221)	(1,147)
Patent filing fees	(13)	(83)
Net cash provided by investing activities	10,766	15,066
Cash flow from financing activities:		
Proceeds from exercise of stock options	363	631
Net cash provided by financing activities	363	631
Net increase/(decrease) in cash and cash equivalents	820	(5,167)
Cash and cash equivalents beginning of the period	14,050	22,118
Cash and cash equivalents end of the period	<u>\$ 14,870</u>	<u>\$ 16,951</u>
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid during the period	\$ -	\$ 17
Interest paid during the period	\$ 1,232	\$ 1,355
Non-cash investing activities:		
Plant and equipment purchases not yet paid	\$ 168	\$ 74
Right-of-use-asset obtained in exchange for lease liabilities	\$ -	\$ 1,053

The accompanying notes form part of the unaudited Consolidated Financial Statements.

AVITA MEDICAL, INC.
Notes to Consolidated Financial Statements
(Unaudited)

1. The Company

Nature of the Business

AVITA Medical, Inc. and its subsidiaries (collectively, “AVITA Medical” or the “Company”) is a leading therapeutic acute wound care company delivering transformative solutions. The Company’s technologies are designed to optimize wound healing, effectively accelerating the time to patient recovery. The Company’s solutions improve the healing outcomes for patients with traumatic injuries and surgical repairs, addressing critical healing needs that arise from unpredictable and life-changing events. At the forefront of the Company’s portfolio is the patented and proprietary RECELL® System (“RECELL System” or “RECELL”), approved by the U.S. Food and Drug Administration (the “FDA”) for the treatment of thermal burn wounds and full-thickness skin defects. RECELL harnesses the healing properties of a patient’s own skin to create an autologous skin cell suspension, Spray-On Skin™ Cells, offering an innovative solution for improved clinical outcomes at the point-of-care.

The single-use RECELL Autologous Cell Harvesting Device (“RECELL Ease-of-Use” or “RECELL EOU”) is approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects. The Company’s next-generation device, RECELL GO™ Autologous Cell Harvesting Device (“RECELL GO”), was approved by the FDA in May of 2024 to treat thermal burn wounds and full-thickness skin defects. RECELL GO introduces enhanced features that support greater consistency and standardization across clinical settings. It consists of two components: a multi-use, AC-powered RECELL GO Processing Device (the “RPD”) and a RECELL GO Preparation Kit (the “RPK”). The RPK contains the single-use RECELL GO Cartridge, disaggregation head, RECELL Enzyme™, and other components. The RPD provides the control for the RPK, manages the pressure applied to disaggregate the donor skin cells, and precisely regulates the incubation times of the RECELL Enzyme and solutions to optimize cell yield and promote cell viability.

RECELL GO mini™ Autologous Cell Harvesting Device (“RECELL GO mini”), which was approved by the FDA in December of 2024, is a line extension of the RECELL GO system, designed specifically to treat smaller wounds up to 480 cm². It utilizes the same RPD but features a RECELL GO mini Preparation Kit (the “mini RPK”), which includes a single-use RECELL GO mini Cartridge optimized for smaller skin samples. These modifications are intended to align with the needs of clinicians treating smaller wounds. This design aims to support broaden adoption of the RECELL GO platform in trauma centers.

The Company holds the right to manufacture, market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, in the United States under the terms of an exclusive multi-year distribution agreement (the “Distribution Agreement”) and a contract manufacturing agreement (the “Manufacturing Agreement”) with Stedical Scientific, Inc. (“Stedical”). The Company also holds the right to market, sell, and distribute Cohealyx™, a unique collagen-based dermal matrix, under the terms of an exclusive multi-year development and distribution agreement (the “Regenity Agreement”) with Collagen Matrix, Inc. dba Regenity Biosciences (“Regenity”). Under the terms of the Regenity Agreement, Regenity manufactures and supplies Cohealyx and the Company holds the exclusive marketing, sales, and distribution rights to this product under its private label in the U.S., and potentially in countries in the European Union, as well as in Australia and Japan. See Note 11 of the Consolidated Financial Statements for additional information regarding the Company’s commitments with Stedical and Regenity.

Liquidity and Capital Resources

The Company has incurred operating losses and negative cash flows from operations since its inception and has an accumulated deficit of \$373.7 million as of March 31, 2025. For the three months ended March 31, 2025 and 2024, the Company used \$10.3 million and \$20.9 million of cash, respectively in its operating activities. For the years ended December 31, 2024 and 2023, the Company used \$48.9 million and \$38.0 million of cash, respectively, in its operating activities. As of March 31, 2025, the Company had cash, cash equivalents, and marketable securities of \$25.8 million. Historically, the Company has funded its operations principally through the sales of its products, issuance of equity securities, and debt financing.

The Company’s Consolidated Financial Statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Management believes that the Company’s cash, cash equivalents, and marketable securities will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these Consolidated Financial Statements.

In connection with the Long-term debt described in Note 6 of the Consolidated Financial Statements, the Company will need to be in compliance with a minimum trailing 12-month net revenue at the end of each quarter and maintain a minimum quarterly cash and cash equivalents balance. If the Company cannot generate sufficient revenue in the future or maintain the cash balance, the Company may not be in compliance with the covenants and additional repayments may be necessary or the lender may call the debt. The Company was not in compliance with the trailing 12-month net revenue covenant for the first quarter of 2025. On March 31, 2025, the Company received a waiver related to the trailing 12-month net revenue covenant for the first quarter of 2025, which was set at \$73.0 million. As of March 31, 2025, the Company was in compliance with all other financial covenants in the Credit Agreement (as defined in Note 6 of the Consolidated Financial Statements).

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Consolidated Financial Statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the “SEC”). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the Consolidated Financial Statements reflect all adjustments of a normal and recurring nature that are considered necessary for a fair presentation of the results for the interim periods presented. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited Consolidated Financial Statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year-ended December 31, 2024 filed with the SEC on February 13, 2025 and lodged with the Australian Securities Exchange (“ASX”) on February 14, 2025 (the “2024 Annual Report”).

There have been no changes to the Company’s significant accounting policies as described in the 2024 Annual Report that have had a material impact on the Company’s Consolidated Financial Statements. See the summary of the Company’s significant accounting policies set forth in the notes to its Consolidated Financial Statements included in the 2024 Annual Report.

Principles of Consolidation

The accompanying Consolidated Financial Statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The amendments affected by this ASU require (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. These amendments are effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact of adopting this ASU on its Consolidated Financial Statements and disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income (Topic 220): Expense Disaggregation Disclosures*, which requires disaggregated disclosures of certain costs and expenses in the notes to financial statements. This guidance will be effective for annual reporting periods beginning after December 15, 2026, and for interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting this ASU on its Consolidated Financial Statements and disclosures.

Use of Estimates

The preparation of the accompanying Consolidated Financial Statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts (including the stand-alone selling price (“SSP”) for the RPD, allowance for credit losses, reserves for inventory excess and obsolescence, carrying value of long-lived assets, the useful lives of long-lived assets, accounting for marketable securities, income taxes, fair value of debt, fair value of warrants and stock-based compensation) and related disclosures. Estimates have been prepared based on the current and available information. However, actual results could differ from estimated amounts.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash held at deposit institutions and cash equivalents. Cash equivalents consist primarily of money market funds. Cash equivalents also include short-term highly liquid investments with original maturities of three months or less from the date of purchase. The Company holds cash at deposit institutions in the amount of \$2.0 million and \$2.3 million as of March 31, 2025 and December 31, 2024, respectively. The Company does not have cash on deposit denominated in foreign currency in foreign institutions as of March 31, 2025 and December 31, 2024. As of March 31, 2025 and December 31, 2024, the Company held cash equivalents in the amounts of \$12.9 million and \$11.7 million, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, trade receivables, and debt and other liabilities. As of March 31, 2025 and December 31, 2024, substantially all the Company's cash and cash equivalents were deposited in accounts at financial institutions, and those deposited amounts exceed federally insured limits and are subject to the risk of bank failure.

As of March 31, 2025, one commercial customer accounted for more than 10% of net accounts receivable and represented 11% of accounts receivable. For the three-months ended March 31, 2025 and 2024, no single customer accounted for more than 10% of revenues. As of December 31, 2024, two commercial customers accounted for more than 10% of accounts receivable. Customer A constituted 21% of the accounts receivable, while Customer B represented 11%.

Revenue Recognition

The Company generates revenues primarily from:

- The sale of RECELL EOU, RPK and mini RPK (collectively, the "RPKs"), PermeaDerm and Cohealyx products to hospitals, other treatment centers, and distributors.
- Lease revenue for the RPD.

The Company's sale of the RECELL EOU, PermeaDerm and Cohealyx products are accounted for under ASC 606, *Revenue from contracts with customers* ("ASC 606"). Revenue for the RECELL GO system is disaggregated between two accounting standards: (1) ASC 606 for the RPK and (2) ASC 842, *Leases* ("ASC 842") for the RPD.

To determine revenue recognition for contracts that are within the scope of ASC 606, the Company performs the following five steps:

1. Identify the contract with a customer
2. Identify the performance obligations
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations
5. Recognize revenue when/as a performance obligation(s) is(are) satisfied

In order for an arrangement to be considered a contract, it must be probable that the Company will collect the consideration to which it is entitled for goods or services to be transferred. The Company then assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for providing the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

When accounting for a contract that contains multiple performance obligations, the Company must develop judgmental assumptions to determine the estimated SSP for each performance obligation identified in the contract. We utilize the observable SSP when available, which represents the price charged for the promised product or service when sold separately. When the SSP for our products or services are not directly observable, we determine the SSP using relevant information available and apply suitable estimation methods including, but not limited to, the cost-plus margin approach. The Company then allocates the transaction price to each performance obligation based on the relative SSP and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied.

Most of the Company's contracts have a single performance obligation. As such, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. Revenue is recognized net of volume discounts (variable consideration). For the Company's contracts that have an original duration of one year or less, since contract inception and customer payment occur within the same period the Company does not consider the time value of money. Further, because of the short duration of these contracts, the Company has not disclosed the transaction price for the remaining performance obligations as of each reporting period or when the Company expects to recognize this revenue. The Company has further applied the practical expedient to exclude sales tax in the transaction price and expense contract acquisition costs such as commissions and shipping and handling expenses as incurred.

Revenue recognition for contracts that are within the scope of ASC 606 and ASC 842

The Company enters into contracts with customers where it receives consideration for the RPKs and does not receive additional consideration for the RPD. As a result, judgment and analysis are required to determine the appropriate accounting, including: (i) whether the arrangement contains an embedded lease, and if so, whether such embedded lease is a sales-type lease or an operating lease, (ii) the amount of the total consideration, as well as variable consideration, (iii) the identification of the distinct performance obligations contained within the arrangement, (iv) how the arrangement consideration should be allocated to each performance obligation when multiple performance obligations exist, including the determination of standalone selling price, and (v) when to recognize revenue on the performance obligations.

In determining whether the lease components are related to a sales-type lease or an operating lease, the Company evaluates if the lease transfers ownership at the end of the lease term, the existence of purchase options, the lease term in relation to the economic life of the asset, if the lease payments exceed the fair value of the asset, and if the asset is of a specialized nature. The Company also evaluates if the lease results in a loss at the lease commencement date. As the lease term is for a major part of the economic life, the lease meets the classification criteria for sales-type lease. However, to determine if the contract results in a loss at the lease commencement date the Company evaluated the consideration in the contract. The consideration at lease commencement does not contain fixed payments, purchase options, penalty payments or residual value guarantees. The variable consideration is related to the sale of the RPKs. As the variable lease payments are not dependent on an index or rate, the variable consideration is excluded from consideration at contract inception resulting in a loss at lease commencement. As such, the Company classifies the lease as an operating lease.

The contracts contain an operating lease component, the RPD, and non-lease components, the RPKs. The lease component will be accounted for under the ASC 842 and the non-lease component will be accounted for under ASC 606, as described above. In accordance with ASC 842, the consideration in the contract will be allocated to each separate lease component and non-lease component of the contract. The consideration is allocated to these lease and non-lease components based on the SSP (as described above for contracts within the scope of ASC 606). In accordance with ASC 842, variable lease payments will be recognized once the sale of the RPKs occurs and control has transferred to the customer. Consideration will be allocated to the RPD and the RPKs based on the SSP. Consideration related to the RPD will be recognized as Lease revenue and consideration related to the RPKs will be recognized as Sales revenues in accordance with guidance in ASC 606, as described above, upon transfer of control of the RPKs, which generally occurs at the time the product is shipped or delivered depending on the customer's shipping terms.

Assets in the Company's lease program are reported in Plant and equipment, net on the Consolidated Balance Sheets and are depreciated over the useful life of the RPD device's 200 uses, as indicated in the Instructions for Use that were approved by the FDA, and expensed as Costs of goods sold in the Consolidated Statements of Operations. The RPD depreciation has a direct relationship to the number of RPKs sold. Based on customer usage, each purchase of a RPKs results in a 1/200 depreciation to the RPD.

3. Marketable Securities

The following table summarizes the amortized cost and estimated fair values of securities available-for-sale:

	As of March 31, 2025			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 12,884	\$ -	\$ -	\$ 12,884
Total cash equivalents	<u>\$ 12,884</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 12,884</u>
Current marketable securities:				
U.S. Treasury securities	\$ 10,949	\$ -	\$ (1)	\$ 10,948
Total current marketable securities	<u>\$ 10,949</u>	<u>\$ -</u>	<u>\$ (1)</u>	<u>\$ 10,948</u>

	As of December 31, 2024			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 11,720	\$ -	\$ -	\$ 11,720
Total cash equivalents	<u>\$ 11,720</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 11,720</u>
Current marketable securities:				
U.S. Treasury securities	\$ 21,821	\$ 14	\$ -	\$ 21,835
Total current marketable securities	<u>\$ 21,821</u>	<u>\$ 14</u>	<u>\$ -</u>	<u>\$ 21,835</u>

The maturities of our available-for-sale securities are summarized in the following table using contractual maturities. Actual maturities may differ from contractual maturities due to obligations that are called or prepaid.

	As of March 31, 2025		As of December 31, 2024	
	Amortized Cost	Carrying Value	Amortized Cost	Carrying Value
(in thousands)				
Due in one year or less	\$ 10,949	\$ 10,948	\$ 21,821	\$ 21,835

Unrealized gains and losses, net of any related tax effects for available-for-sale securities are excluded from earnings and are included in other comprehensive loss and reported as a separate component of stockholders' equity until realized. Realized gains and losses on marketable securities are included in Other expense, net, in the accompanying Consolidated Statements of Operations. The Company had a net unrealized loss of \$1,000 and net unrealized gain of \$14,000 as of March 31, 2025 and December 31, 2024, respectively. The Company did not have sales of investments during the three-months ended March 31, 2025 and 2024 that resulted in realized gains or losses. As of March 31, 2025 and December 31, 2024, the Company did not recognize credit losses. The Company has accrued interest income receivable of \$103,000 and \$121,000 as of March 31, 2025 and December 31, 2024, respectively, recorded in Prepaids and other current assets in the Consolidated Balance Sheets.

4. Fair Value Measurements

ASC 820, *Fair Value Measurement*, the authoritative guidance on fair value measurements establishes a framework with respect to measuring assets and liabilities at fair value on a recurring basis and non-recurring basis. Under the framework, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as of the measurement date. The framework also establishes a three-tier hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability and are developed based on the best information available in the circumstances. The hierarchy consists of the following three levels:

Level 1: Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.

Level 2: Inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Inputs are unobservable inputs for the asset or liability.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis, based on the three-tier fair value hierarchy:

(in thousands)	As of March 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 12,884	\$ -	\$ -	\$ 12,884
Total cash equivalents	\$ 12,884	\$ -	\$ -	\$ 12,884
Current marketable securities:				
U.S. Treasury securities	\$ -	\$ 10,948	\$ -	\$ 10,948
Total current marketable securities	\$ -	\$ 10,948	\$ -	\$ 10,948
Total marketable securities and cash equivalents	\$ 12,884	\$ 10,948	\$ -	\$ 23,832
Financial liabilities:				
Long-term debt	\$ -	\$ -	\$ 41,464	\$ 41,464
Warrant liabilities	1,182	-	1,872	3,054
Non-qualified deferred compensation plan liability	-	4,160	-	4,160
Total financial liabilities	\$ 1,182	\$ 4,160	\$ 43,336	\$ 48,678
Financial assets:				
Corporate-owned life insurance policies	\$ -	\$ 2,605	\$ -	\$ 2,605
Total financial assets	\$ -	\$ 2,605	\$ -	\$ 2,605

(in thousands)	As of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 11,720	\$ -	\$ -	\$ 11,720
Total cash equivalents	\$ 11,720	\$ -	\$ -	\$ 11,720
Current marketable securities:				
U.S. Treasury securities	\$ -	\$ 21,835	\$ -	\$ 21,835
Total current marketable securities	\$ -	\$ 21,835	\$ -	\$ 21,835
Total marketable securities and cash equivalents	\$ 11,720	\$ 21,835	\$ -	\$ 33,555
Financial liabilities:				
Long-term debt	\$ -	\$ -	\$ 42,245	\$ 42,245
Warrant liability	-	-	3,432	3,432
Non-qualified deferred compensation plan liability	-	5,063	-	5,063
Total financial liabilities	\$ -	\$ 5,063	\$ 45,677	\$ 50,740
Financial assets:				
Corporate-owned life insurance policies	\$ -	\$ 3,006	\$ -	\$ 3,006
Total financial assets	\$ -	\$ 3,006	\$ -	\$ 3,006

The following table presents the summary of changes in the fair value of our Level 3 financial instruments:

(in thousands)	As of March 31, 2025		As of December 31, 2024	
	Long-term debt	Warrant liability	Long-term debt	Warrant liability
Balance beginning of period	\$ 42,245	\$ 3,432	\$ 39,812	\$ 3,158
Change in fair value in earnings	760	(1,560)	2,463	274
Change in fair value in other comprehensive loss	(1,541)	-	(30)	-
Balance end of period, at fair value	\$ 41,464	\$ 1,872	\$ 42,245	\$ 3,432

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. The Company's Level 1 liabilities include the Penny Warrants (as defined below) and are valued based upon observable market prices. Level 2 assets consist of U.S Treasury securities and U.S. Government Agency obligations. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. The corporate-owned life insurance contracts are recorded at cash surrender value, which approximates the fair value and is categorized as Level 2. Non-qualified deferred compensation plan liability is measured at fair value based on quoted prices of identical instruments to the investment vehicles selected by the participants and it is recorded as Level 2. There were no transfers between fair value measurement levels during the periods ended March 31, 2025 and December 31, 2024.

Long-term Debt

The fair value of the debt was determined using a Monte Carlo Simulation ("MCS") in order to predict the probability of different outcomes. The valuation was performed based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the debt is recorded in the Consolidated Balance Sheets. The fair value is estimated by the Company each reporting period and the change in the fair value is recorded in both earnings and other comprehensive income depending on the instrument's inherent credit risk and market risk related to the debt valuation.

As the debt is subject to net revenue requirements, the valuation of the debt was determined using MCS. The underlying metric to be simulated is the projected Trailing Twelve Month ("TTM") revenues at each quarter end through the maturity date of October 18, 2028. Based on the simulated metric, the different levels of simulated TTM revenues may trigger different discounted cash flow scenarios in which the TTM revenues are lower than the targeted revenues per the Credit Agreement or the TTM revenues are equal to or higher than the targeted revenues per the Credit Agreement, as discussed in Note 6 of the Consolidated Financial Statements. MCS performs 100,000 iterations of various simulated revenues to determine the fair value of the debt.

The below assumptions were used in the MCS:

	March 31, 2025	December 31, 2024
Risk-free interest rate	3.86%	4.25%
Revenue volatility	63.00%	63.00%
Revenue discount rate	18.35%	14.11%

Warrant Liabilities

On February 13, 2025, the Company issued 145,180 warrants with an exercise price of \$0.01 per share (the “Penny Warrants”). The Penny Warrants were issued in connection with the Credit Agreement (as defined in Note 6 of the Consolidated Financial Statements). The fair value of the Penny Warrants liability was determined based on quoted prices in active markets, which represents a Level 1 measurement within the fair value hierarchy. The fair value of the Penny Warrants liability, which is reported within Warrant liabilities on the Consolidated Balance Sheets, is estimated by the Company based on the closing price of the Company’s Common Stock as quoted on the Nasdaq Capital Market (“Nasdaq”) under the ticker code, “RCEL”.

On the Closing Date of the Credit Agreement (as defined in Note 6 of the Consolidated Financial Statements), the Company issued 409,661 warrants with an exercise price of \$10.9847 per share (the “\$10.9847 Warrants”). The fair value of the \$10.9847 Warrants liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the \$10.9847 Warrants liability, which is reported within Warrant liabilities on the Consolidated Balance Sheets, is estimated by the Company based on the Black-Scholes option pricing model with the following key inputs:

	March 31, 2025	December 31, 2024
Price of common stock	\$ 8.14	\$ 12.80
Expected term	8.56 years	8.80 years
Expected volatility	51.59%	48.89%
Exercise price	\$ 10.9847	\$ 10.9847
Risk-free interest rate	4.13%	4.49%
Expected dividends	0.00%	0.00%

5. Revenues

The Company generates revenues primarily from:

- The sale of EOU, RECELL GO RPK, RECELL GO mini RPK, PermeaDerm, and Cohealyx products to hospitals, other treatment centers, and distributors.
- Lease revenue for the RECELL GO RPD.

EOU, PermeaDerm, and Cohealyx Sales

The Company’s sale of the EOU, PermeaDerm and Cohealyx products are accounted for under ASC 606, as discussed in Note 2 of the Consolidated Financial Statements. See Note 11 of the Consolidated Financial Statements for additional information regarding the Company’s commitments with Stedical and Regenity.

RECELL GO and RECELL GO mini Sales

Revenue for the RECELL GO device is disaggregated between two accounting standards: (1) ASC 606 for the RPK and (2) ASC 842 for the RPD. The RECELL GO and RECELL GO mini devices consist of single-use RPKs and a durable AC powered device, RPD. The Company enters into contracts with customers where it receives consideration for the single-use RPKs and does not receive additional consideration for the RPD. The consideration in the contract is allocated based on the SSP. Upon sale of the RPKs, the consideration is allocated to the lease and non-lease components. Consideration received for the RPK is recorded in Sales revenues in the Consolidated Statement of Operations and consideration for the lease is recorded in Lease revenue in the Consolidated Statement of Operations. During the three-months ended March 31, 2025, the Company recorded approximately \$9.5 million in Sales revenue related to the RPKs and \$189,000 in Lease revenue related to the RPD in the Consolidated Statement of Operations.

Distributor Transactions

For international markets, the Company exclusively partners with third-party distributors (currently, COSMOTEC in Japan, PolyMedics Innovation GmbH, in Germany, and Revolution Surgical Pty Ltd in Australia and New Zealand). Revenue recognition occurs when the distributors obtain control of the product. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers and do not contain return rights. These transactions are accounted for in accordance with the Company's revenue recognition policy described in Note 2 of the Consolidated Financial Statements.

Variable Consideration

The Company evaluates its contracts with customers for forms of variable consideration, which may require an adjustment to the transaction price based on their estimated impact. For commercial customers, revenue from the sale of goods is recognized net of volume discounts. The Company uses the expected value method when estimating variable consideration. Revenue is only recognized to the extent that it is probable that a significant reversal will not occur.

Volume Discounts — The Company generally provides contracted customers with volume discounts that are explicitly stated in the Company's customer contracts. The RECELL system is sold with respective volume discounts based on aggregated sales over a 12-month period on a customer-by-customer basis. Revenue from these sales is recognized based on the price specified in the contract, net of estimated volume discounts, and net of any sales tax charged. Goods sold are not eligible for return. The Company has determined such discounts are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue and as a reduction to accounts receivable, net.

Contract Assets and Contract Liabilities

Contract assets include amounts related to the Company's contractual right to consideration for both completed and partially completed performance for which the Company does not have the right to payment. As of March 31, 2025 and December 31, 2024, the Company does not have any contract assets.

Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer. The Company had unsatisfied performance obligations of \$348,000 and \$357,000 as of March 31, 2025 and December 31, 2024, respectively. These balances are classified between current and long-term. As of March 31, 2025 and December 31, 2024, a total of \$33,000 was included in Other current liabilities and \$315,000 and \$324,000, respectively, in Contract liabilities in the Consolidated Balance Sheets. As of December 31, 2023, the Company had an unsatisfied performance obligation of \$390,000.

For the three-months ended March 31, 2025 and 2024, the Company recognized revenue of approximately \$64,000 and \$36,000, respectively, for amounts included in the beginning balance of Contract liabilities.

Remaining Performance Obligations

The Company's remaining performance obligations are calculated as the dollar value of the remaining unsatisfied performance obligations on executed contracts. The estimated revenue expected to be recognized in the future once the performance obligations are satisfied under the Company's existing customer agreements was \$348,000 and \$357,000 as of March 31, 2025 and December 31, 2024, respectively. These amounts are classified between current and long-term in Other current liabilities and Contract liabilities in the Consolidated Balance Sheets. The Company expects to recognize approximately \$33,000 as revenue in the next twelve months.

Cost to Obtain and Fulfill a Contract

Contract fulfillment costs include commissions and shipping expenses. The Company has opted to immediately expense the incremental cost of obtaining a contract when the underlying related asset would have been amortized over one year or less. The Company generally does not incur costs to obtain new contracts.

Disaggregated Revenue

The Company disaggregates revenue from contracts with customers into geographical regions, by customer type and by product. As noted in the segment footnote, the Company's business consists of one reporting segment. A reconciliation of revenue by geographical region, customer type and product is provided in Note 10 of the Consolidated Financial Statements.

6. Long-term debt

On October 18, 2023 (the "Closing Date") the Company entered into a credit agreement, by and between the Company, as borrower, and an affiliate of OrbiMed Advisors, LLC (the "Lender") as the lender and administrative agent (the "Credit Agreement"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to \$90.0 million, of which (i) \$40.0 million was made available on the Closing Date (the "Initial Commitment Amount"), (ii) \$25.0 million will be made available, at the Company's discretion, on or prior to December 31, 2024, subject to certain net revenue requirements, and (iii) \$25.0 million will be made available, at the Company's discretion, on or prior to June 30, 2025, subject to certain net revenue covenants (the "Loan Facility"). The maturity date of the Credit Agreement is October 18, 2028 ("Maturity Date"). On the Closing date, the Company closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Lender. The Company received net proceeds of \$38.8 million upon closing after deducting the Lender's transaction costs in connection with the Loan Facility.

On November 7, 2024, the Lender and the Company mutually agreed to a third amendment (the "Third Amendment") to the Credit Agreement. Under the terms of the Third Amendment and subject to the payment by the Company of a consent fee to the Lender, the Company and the Lender mutually agreed to (1) terminate the two additional tranches of available debt in the aggregate amount of \$50.0 million and (2) remove the trailing 12-month revenue covenant for the fourth quarter of 2024, which was set at \$67.5 million.

On February 13, 2025, the Lender and the Company mutually agreed to a fourth amendment (the "Fourth Amendment") to the Credit Agreement. Under the terms of the Fourth Amendment, the Company and the Lender mutually agreed to amend the trailing 12-month revenue covenant to \$73.0 million for the quarter ending March 31, 2025, to \$78.0 million for the quarter ending June 30, 2025, to \$84.0 million for the quarter ending September 30, 2025, to \$92.0 million for the quarter ending December 31, 2025 and to \$103.0 million for the quarter ending March 31, 2026, and Lender received the Penny Warrants. The \$115.0 million revenue covenant for all subsequent quarters through the date of debt maturity remains in effect. On March 31, 2025, the Company received a waiver related to the trailing 12-month revenue covenant for the first quarter of 2025, and paid the Lender a fee. All revenue covenants for subsequent quarters remain in effect.

All obligations under the Credit Agreement are guaranteed by all of the Company's wholly owned subsidiaries (subject to certain exceptions) and secured by substantially all of the Company's and each guarantor's assets. The loan will be due in full on the Maturity Date unless the Company elects to repay the principal amount at any time prior to the Maturity Date. Upon prepayment, the Company will owe an exit fee of 3% on the principal amount of the loans as well as the applicable repayment premium. The repayment premium varies between 0.0% - 3.0% of the principal amount of the loan, depending on certain conditions that are defined in the Credit Agreement. The repayment premium may also incorporate the make-whole amount. The make-whole amount represents the remaining scheduled interest payments on the Loan Facility during the period commencing on the prepayment date through the 24-month anniversary of the Closing Date. The Credit Agreement further states that the Company will be required to repay portions of the principal amount of the Loan Facility if the Company does not achieve certain net revenue thresholds. If, for any quarter until the Maturity Date, the Company's net revenue does not equal or exceed the applicable trailing 12-month amount as set forth in the Credit Agreement, then the Company shall repay, in equal quarterly installments of 5.0% of the outstanding principal amount of the Loan Facility on the date the net revenue amount was not satisfied, together with the exit fee and repayment premium, if applicable. The Company shall repay amounts outstanding in full immediately upon an acceleration as a result of an event of default as set forth in the Credit Agreement, together with a repayment premium and other fees. As of March 31, 2025, the Company has not made any repayments on the outstanding debt balance.

During the term of the Credit Agreement, interest payable in cash by the Company shall accrue on any outstanding debt at a rate per annum equal to the greater of (x) the SOFR rate for such period and (y) 4.00% plus, in either case, 8.00%. As of March 31, 2025, the interest rate was 12.32%. During an event of default, any outstanding amount will bear interest at a rate of 4.00% in excess of the otherwise applicable rate of interest. The Company paid certain fees with respect to the Credit Agreement, including an upfront fee, an unused fee on the undrawn portion of the Loan Facility, continues to pay an administration fee, and may have to pay a repayment premium and an exit fee, as well as certain other fees and expenses of the Lender.

The Credit Agreement contains certain customary events of default, including with respect to nonpayment of principal, interest, fees or other amounts; material inaccuracy of a representation or warranty; failure to perform or observe covenants; material defaults on other indebtedness; bankruptcy and insolvency events; material monetary judgments; loss of certain key permits, persons and contracts; material adverse effects; certain regulatory matters; and any change of control. On March 31, 2025, the Company received a waiver related to the trailing 12-month revenue covenant for the first quarter of 2025, which was set at \$73.0 million. As of March 31, 2025, the Company was in compliance with all other financial covenants in the Credit Agreement.

Each of the Credit Agreement and the Pledge and Security Agreement entered into by the Company, the guarantors and the Lender on October 18, 2023 (the “Pledge and Security Agreement”) contains a number of customary representations, warranties and covenants that, among other things, will limit or restrict the ability of the Company and its subsidiaries to (subject to certain qualifications and exceptions): create liens and encumbrances; incur additional indebtedness; merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of their capital stock; amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with affiliates; and enter into certain restrictive agreements. In addition, the Company and the guarantors will be required to maintain at least \$10.0 million of unrestricted cash and cash equivalents.

On the Closing Date, the Company issued to an affiliate of the Lender the \$10.9847 Warrants, with a term of 10 years from the issuance date. The \$10.9847 Warrants contain customary share adjustment provisions, as well as weighted average price protection in certain circumstances.

On February 13, 2025, as a condition to the execution of the Fourth Amendment, the Company issued to the Lender the Penny Warrants, with a term of 10 years from the issuance date. The Penny Warrants contain customary share adjustment provisions, as well as weighted average price protection in certain circumstances.

As permitted under ASC 825, *Financial Instruments*, the Company elected the fair value option to record the long-term debt and warrants with changes in fair value recorded in the Consolidated Statements of Operations in Other expense, net. Changes related to instrument-specific credit risk are revalued by comparing the amount of the total change in fair value of the long-term debt to the amount of change in fair value that would have occurred if the Company’s credit spread had not changed between the reporting periods, and is recorded in Accumulated other comprehensive loss in the Consolidated Balance Sheets. The difference between the fair value of the long-term debt and the unpaid principal balance of \$40.0 million is an additional liability of \$1.5 million and an additional liability of \$2.2 million as of March 31, 2025 and December 31, 2024, respectively. For changes in fair value, refer to Note 4 of the Consolidated Financial Statements.

7. Inventory

The composition of the inventory is as follows (in thousands):

	As of	
	March 31, 2025	December 31, 2024
Raw materials	\$ 2,468	\$ 2,449
Work in process	337	389
Finished goods	5,590	4,431
Total inventory	<u>\$ 8,395</u>	<u>\$ 7,269</u>

The Company values its inventories to reflect the lower of cost or net realizable value. Charges for estimated excess and obsolescence are recorded in Cost of sales in the Consolidated Statements of Operations and were \$313,000 and \$83,000 for the three-months ended March 31, 2025 and 2024, respectively.

8. Intangible Assets

The composition of intangible assets, net is as follows (in thousands):

	Weighted Average Useful Life	As of March 31, 2025			As of December 31, 2024		
		Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount
Patent 1	12	136	(48)	88	136	(46)	90
Patent 2	13	238	(73)	165	238	(61)	177
Patent 3	18	108	(19)	89	108	(25)	83
Patent 4	19	67	(10)	57	67	(9)	58
Patent 5	17	52	(4)	48	46	(3)	43
Patent 6	2	127	(56)	71	121	(42)	79
Regenity License	10	5,000	(125)	4,875	5,000	(14)	4,986
Trademarks	Indefinite	54	-	54	54	-	54
Total intangible assets		<u>\$ 5,782</u>	<u>\$ (335)</u>	<u>\$ 5,447</u>	<u>\$ 5,770</u>	<u>\$ (200)</u>	<u>\$ 5,570</u>

For the three-months ended March 31, 2025 and 2024, the Company did not identify any events or changes in circumstances that indicated that the carrying value of its intangibles may not be recoverable. As such, there was no impairment of intangible assets recognized for the three-months ended March 31, 2025 and 2024. Amortization expense of intangibles included in the Consolidated Statements of Operations was \$135,000 and \$17,000 for the three-months ended March 31, 2025 and 2024, respectively. Due to Regenity receiving 510(k) clearance for Cohealyx in December 2024, the Company recorded a license (the “Regenity License”) of \$5.0 million. For further details refer to Note 11 of the Consolidated Financial Statements.

The Company expects the future amortization of amortizable intangible assets held at March 31, 2025 to be as follows (in thousands):

	Estimated Amortization Expense
Remainder of 2025	\$ 452
2026	567
2027	542
2028	542
2029	542
Thereafter	2,748
Total	<u>\$ 5,393</u>

9. Plant and Equipment

The composition of plant and equipment, net is as follows (in thousands):

	Useful Lives	As of	
		March 31, 2025	December 31, 2024
Computer equipment	3 - 5 years	\$ 1,859	\$ 1,645
Computer software	3 years	836	836
Construction in progress ("CIP")		99	442
Furniture and fixtures	7 years	1,221	1,177
Laboratory and other equipment	3 - 5 years	1,183	954
Leasehold improvements	Lesser of life or lease term	4,658	4,607
RECELL molds	5 years	514	503
RECELL GO RPD CIP		1,371	1,464
RECELL GO RPD		403	453
Operating lease assets - RPD	200 uses	1,602	1,384
Less: accumulated amortization and depreciation		(3,852)	(3,447)
Total plant and equipment, net		<u>\$ 9,894</u>	<u>\$ 10,018</u>

Construction in progress consists primarily of leasehold improvements for the renovations to the Ventura production facility, and RECELL GO RPD CIP consists of materials for the manufacture of the RPDs. RPDs have a useful life of 200 uses and are being amortized based on customer usage as determined by orders placed for the sales of the RPKs. RECELL GO RPD represents assets available to be leased by customers and are not depreciated until leased.

Depreciation expense related to plant and equipment was \$385,000 and \$186,000 for the three-months ended March 31, 2025 and 2024, respectively. No impairment was recorded for the three-months ended March 31, 2025 and 2024.

Lesser Arrangements

As discussed in Note 5 of the Consolidated Financial Statements, the contracts for the RECELL GO device include an operating lease for the customer's right to use the RPD. The lease arrangement does not contain fixed consideration. Variable lease payments are not included in consideration at lease inception. The variable consideration related to the lease is allocated based on the SSP and is recognized when control of the RPKs is transferred to the customer.

The table below summarizes the Company's Lease revenue as presented in the Consolidated Statement of Operations for the three-months ended March 31, 2025 and 2024.

(in thousands)	Three-Months Ended	
	March 31, 2025	March 31, 2024
Variable lease revenue	\$ 189	-

Assets held for lease and included in Plant and equipment consisted of the following (in thousands):

	As of	
	March 31, 2025	December 31, 2024
Rental RPD assets	\$ 1,602	\$ 1,384
Accumulated depreciation	(70)	(47)
Net rental RPD assets	<u>\$ 1,532</u>	<u>\$ 1,337</u>

10. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets are primarily located in the United States as of March 31, 2025 and December 31, 2024.

Revenue by region for the three-months ended March 31, 2025 and 2024 were as follows (in thousands):

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Revenue by region:		
United States	\$ 17,756	\$ 10,532
Japan	634	461
European Union	49	51
Australia	40	17
United Kingdom	35	43
Total	<u>\$ 18,514</u>	<u>\$ 11,104</u>

Revenue by customer type for the three-months ended March 31, 2025 and 2024 were as follows (in thousands):

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Revenue by customer type:		
Commercial sales	\$ 18,450	\$ 11,068
Deferred commercial revenue recognized	8	8
BARDA revenue for right of first access	56	28
Total	<u>\$ 18,514</u>	<u>\$ 11,104</u>

Commercial revenue by product for the three-months ended March 31, 2025 and 2024 were as follows (in thousands):

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Commercial revenue by product:		
RECELL	\$ 17,675	\$ 10,962
Other wound care products	586	106
Lease revenue	189	-
Total commercial sales	<u>\$ 18,450</u>	<u>\$ 11,068</u>

Consolidated net loss by segment for the three-months ended March 31, 2025 and 2024 were as follows (in thousands):

	Three Months Ended	
	March 31, 2025	March 31, 2024
Total revenues	\$ 18,514	\$ 11,104
Purchases of inventory	(2,497)	(1,237)
Other cost of sales	(336)	(276)
Gross profit	15,681	9,591
Operating expenses:		
Sales and marketing	(14,834)	(12,640)
General and administrative	(6,390)	(8,963)
Research and development	(6,284)	(5,194)
Total operating expenses	(27,508)	(26,797)
Operating loss	(11,827)	(17,206)
Interest expense	(1,233)	(1,356)
Other expense, net	(791)	(66)
Loss before income taxes	(13,851)	(18,628)
Income tax expense	(8)	(30)
Net loss	<u>\$ (13,859)</u>	<u>\$ (18,658)</u>

11. Commitments and Contingencies

The Company is subject to certain contingencies arising in the ordinary course of business. The Company records accruals for these contingencies to the extent that a loss is both probable and reasonably estimable. If some amount within a range of loss appears more likely than any other amount within the range, that amount is accrued. Alternatively, when no amount within a range of loss appears to be a better estimate than any other amount, the lowest amount in the range is accrued. The Company expenses legal costs associated with loss contingencies as incurred. As of March 31, 2025 and December 31, 2024, the Company did not have any outstanding or threatened litigation that would have a material impact on the Consolidated Financial Statements.

Commitments with Stedical

On January 26, 2024, the Company entered into the Distribution Agreement with Stedical. Under the terms of the Distribution Agreement, the Company held the exclusive rights to market, sell, and distribute PermeaDerm products, including any future enhancements or modifications, within the United States. The initial term is for five years, with the option to renew for an additional five years, contingent upon meeting certain minimum requirements.

On March 17, 2025, the Company and Stedical entered into an Amendment Two (the “Amendment”) of the Distribution Agreement. Under the terms of the Amendment, the Company’s share of revenue from PermeaDerm sales increased from 50% to 60% and Stedical becomes eligible for certain milestone payments conditioned upon AVITA Medical’s achievement of specified sales targets. For 2025, the Company is required to reach \$6.0 million in gross sales of PermeaDerm. For every year thereafter, the Company must achieve a minimum 20% increase in revenue from sale of PermeaDerm. In the event the Company fails to achieve the specified growth rate for two subsequent years, the Company will be required to make a cash payment to Stedical equal to the difference between what Stedical would have received if that growth target was met for that second year and the amount of payments that were made to Stedical during that second year. In addition, under the terms of the Amendment, Stedical’s share from the sale of PermeaDerm is reduced by the Company’s actual cost to manufacture PermeaDerm. The Amendment revises the initial term of the Distribution Agreement to ten years from the date of the Amendment.

On March 17, 2025, the Company entered into the Manufacturing Agreement with Stedical to manufacture PermeaDerm in the United States for the purposes of (i) sale in the United States under the terms of the Distribution Agreement and (ii) sale to Stedical for sale or distribution outside of the United States. The initial term is for ten years.

Development and Distribution Agreement with Regenity

On July 31, 2024, the Company entered into the Regenity Agreement to market, sell, and distribute Cohealyx, a unique collagen-based dermal matrix under the Company's private label in the U.S., with the potential to commercialize the product in countries in the European Union, as well as in Japan and Australia. The initial term of the Regenity Agreement is five years, with an automatic extension of an additional five years, contingent upon meeting certain criteria. The Regenity Agreement also requires the Company to meet certain revenue targets in order to maintain its exclusive distribution rights. In the event the Company fails to meet those revenue targets, the Company will be required to make a cash payment to Regenity equal to the difference between what Regenity would have received if the revenue target was met and the amount of payments that were made to Regenity during the year.

Under the terms of the Regenity Agreement, the Company made a \$2.0 million payment upon receipt of 510(k) clearance by Regenity in December 2024. The Company has a further obligation to make up to an additional \$3.0 million payment on or before January 4, 2026 to guarantee development and manufacturing capacity (and related resources), contingent on positive results of certain clinical studies related to Cohealyx. As such, upon Regenity receiving 501(k) clearance in December 2024, the Company recorded \$5.0 million in Intangible assets, net on the Consolidated Balance Sheets. As of March 31, 2025 and December 31, 2024, the Company recorded \$3.0 million in Contingent liability and \$3.0 million in Contingent liability, long-term, respectively, on the Consolidated Balance Sheets.

12. Common and Preferred Stock

The Company’s CHES Depositary Interests (“CDIs”) are quoted on the ASX under the ticker code, “AVH.” The Company’s shares of Common stock are quoted on Nasdaq under the ticker code, “RCEL.” One share of Common Stock on Nasdaq is equivalent to five CDIs on the ASX.

The Company is authorized to issue 200,000,000 shares of Common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share, issuable in one or more series as designated by the Company’s board of

directors. No other class of capital stock is authorized. As of March 31, 2025 and December 31, 2024, 26,434,658 and 26,354,042 shares of Common stock, respectively, were issued and outstanding and no shares of Preferred stock were outstanding during any period.

Common stock held in the rabbi trust is classified in a manner similar to treasury stock and presented separately on the Consolidated Balance Sheets as Common stock held by the NQDC Plan. As of March 31, 2025 and December 31, 2024, a total of 126,506 and 244,218 shares awards have been deferred, respectively. Vested shares are converted to Common stock and are reclassified to permanent equity.

13. Stock-Based Payment Plans

Stock-Based Payment Expenses

Stock-based payment transactions are recognized as compensation expense based on the fair value of the instrument on the date of grant. The Company uses the graded-vesting method to recognize compensation expense. Compensation cost is reduced for forfeitures as they occur in accordance with ASU 2016-09, *Simplifying the Accounting for Share-Based Payment*. No income tax benefit was recognized in the Consolidated Statements of Operations for stock-based payment arrangements for the three-months ended March 31, 2025 and 2024.

In June 2023, the stockholders approved the Company's Employee Stock Purchase Plan (the "ESPP"), which became effective on July 1, 2023. On June 30, 2023, the Company filed a Registration Statement on Form S-8 to register 1,000,000 shares of Common stock under the ESPP, as a result of the Company's stockholders approving the ESPP at the 2023 Annual Meeting. The ESPP features two six-month offering periods per year, running from June 1 to November 30 and December 1 to May 31.

The Company has included stock-based compensation expense for all equity awards and the ESPP as part of operating expenses in the accompanying Consolidated Statements of Operations as follows:

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Sales and marketing expenses	\$ 504	\$ 527
General and administrative expenses	1,579	1,661
Research and development expenses	611	403
Total	<u>\$ 2,694</u>	<u>\$ 2,591</u>

A summary of share option activity as of March 31, 2025, and changes during the period ended, is presented below:

	Service Only Share Options	Performance-Based Share Options	Total Share Options
Outstanding shares at December 31, 2024	3,349,037	191,171	3,540,208
Granted	1,207,000	-	1,207,000
Exercised	(52,550)	(13,458)	(66,008)
Expired	(98,250)	(4,062)	(102,312)
Forfeited	(59,678)	(588)	(60,266)
Outstanding shares at March 31, 2025	<u>4,345,559</u>	<u>173,063</u>	<u>4,518,622</u>
Exercisable at March 31, 2025	<u>1,404,308</u>	<u>157,661</u>	<u>1,561,969</u>
Vested and expected to vest - March 31, 2025	<u>4,345,559</u>	<u>173,063</u>	<u>4,518,622</u>

A summary of the status of the Company's unvested RSUs as of March 31, 2025, and changes that occurred during the period, is presented below:

	Tenure-Based RSUs	Performance Condition RSUs	Total RSUs
Unvested RSUs outstanding at December 31, 2024	109,315	7,881	117,196
Granted	-	-	-
Vested	(11,983)	(2,625)	(14,608)
Forfeited	(600)	-	(600)
Unvested RSUs outstanding at March 31, 2025	<u>96,732</u>	<u>5,256</u>	<u>101,988</u>

14. Income Taxes

Tax expense for the three-months ended March 31, 2025 and 2024 was \$8,000 and \$30,000, respectively. These amounts are related to state minimum taxes.

15. Net Loss per Share

The following is a reconciliation of the basic and diluted loss per share computations:

	Three-Months Ended	
	March 31, 2025	March 31, 2024
(in thousands, except per share amounts)		
Net loss	\$ (13,859)	\$ (18,658)
Weighted-average common shares—outstanding, basic and diluted	26,254	25,638
Net loss per common share, basic and diluted	\$ (0.53)	\$ (0.73)

	Three-Months Ended	
	March 31, 2025	March 31, 2024
Anti-dilutive shares excluded from diluted net loss per common share:		
Stock options	4,518,622	3,541,384
Restricted stock units	101,988	214,228
ESPP	79,735	83,545
Warrants	554,841	409,661

The Company's basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the relevant period. In accordance with ASC 710-10, *Compensation - General*, 126,506 shares of Common stock held by the rabbi trust are excluded from the denominator in the basic and diluted net loss per common share calculations. For the purposes of the calculation of diluted net loss per share, options to purchase common stock, restricted stock units and unvested shares of Common Stock issued upon the early exercise of stock options have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive. Because the Company has reported a net loss for the three-months ended March 31, 2025 and 2024, diluted net loss per common share is the same as the basic net loss per share for those periods.

16. Subsequent Events

The Company has evaluated subsequent events through the filing of this Quarterly Report on Form 10-Q and determined that except as disclosed below, no events have occurred that would require adjustment to, or disclosures in, the Consolidated Financial Statements.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited Consolidated Financial Statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results, conditions, or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks referenced under Part II, Item 1A, "Risk Factors."

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules regulations of the Securities and Exchange Commission (the "SEC") and the Australian Securities and Investments Commission (the "ASIC"), to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances under which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Please see "Note Regarding Forward-Looking Statements" on page 3.

Overview

AVITA Medical, Inc. ("we", "our", "us") is a leading therapeutic acute wound care company delivering transformative solutions. Our technologies are designed to optimize wound healing, effectively accelerating the time to patient recovery. Our solutions improve the healing outcomes for patients with traumatic injuries and surgical repairs, addressing critical healing needs that arise from unpredictable and life-changing events. At the forefront of our portfolio is our patented and proprietary RECELL[®] System ("RECELL System" or "RECELL"), approved by the U.S. Food & Drug Administration (the "FDA") for the treatment of thermal burn wounds and full-thickness skin defects. RECELL harnesses the healing properties of a patient's own skin to create an autologous skin cell suspension, Spray-On Skin[™] Cells, offering an innovative solution for improved clinical outcomes at the point of care. In the United States, we also hold the rights to market, sell, manufacture, and distribute PermeaDerm[®], a biosynthetic wound matrix, under the terms of exclusive multi-year distribution and contract manufacturing agreements with Stedical Scientific, Inc. ("Stedical"). We also entered into an exclusive multi-year development and distribution agreement with Collagen Matrix, Inc. dba Regenity Biosciences ("Regenity"). Regenity will manufacture and supply Cohealyx[™], an AVITA Medical-branded, FDA-cleared, collagen-based dermal matrix. Under the agreement, we will hold the exclusive rights to market, sell, and distribute Cohealyx in the U.S., with potential expansion into the European Union, Australia, and Japan.

The single-use RECELL Autologous Cell Harvesting Device ("RECELL Ease-of-Use" or "RECELL EOU") is approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects. Our next-generation device, RECELL GO[®] Autologous Cell Harvesting Device ("RECELL GO"), is FDA-approved to treat thermal burn wounds and full-thickness skin defects. RECELL GO introduces enhanced features that support greater consistency and standardization across clinical settings. It consists of two components: the RECELL GO Processing Device (the "RPD") and the RECELL GO Preparation Kit (the "RPK"). The RPD is a multi-use, AC-powered device that controls the RPK. The RPK is a single-use cartridge that contains the RECELL Enzyme[™]. The RPD regulates the pressure applied to disaggregate the cells and precisely controls the incubation time of the RECELL Enzyme to optimize cell yield and promote cell viability. RECELL GO mini[™] Autologous Cell Harvesting Device ("RECELL GO mini"), which was approved by the FDA in December 2024, is a line extension of the RECELL GO system, designed specifically to treat smaller wounds up to 480 cm². It utilizes the same RPD but features a RECELL GO mini Preparation Kit, which includes a single-use RECELL GO mini cartridge optimized for smaller skin samples. These modifications are intended to align with the needs of clinicians treating smaller wounds. This design aims to support broaden adoption of the RECELL GO platform in trauma centers.

To further our mission of improving clinical outcomes and establishing new standards of acute wound care, we have outlined the following strategic objectives:

- Increase market penetration in U.S. burn centers, positioning RECELL GO as the standard of care in burn management
- Expand adoption of RECELL GO for the treatment of full-thickness skin defects throughout the U.S.
- Expand adoption of RECELL GO mini in trauma and burn centers treating smaller wounds
- Expand adoption of Cohealyx after full commercial launch on April 1, 2025
- Conduct a post-market study of Cohealyx in 2025 to develop clinical data to further support continuing commercialization
- Conduct a post-market study of PermeaDerm in 2025 to develop clinical data to further support commercialization
- Seek additional business development opportunities complementary to our target markets
- Obtain CE mark for RECELL GO, allowing us to market RECELL GO in the European Union, the U.K., and Australia under existing distribution agreements
- Drive commercial revenue growth, generate positive cash flow, and achieve operating profitability

Business Environment and Current Trends

The macroeconomic environment may have unexpected adverse effects on businesses and healthcare institutions globally that may negatively impact our consolidated operating results. There remains significant uncertainty in the current macroeconomic environment due to factors including supply chain shortages, increased cost of healthcare, changes to inflation rates, a competitive labor market, tariffs, and other related global economic conditions and geopolitical conditions. If these conditions continue or worsen, they could adversely impact our future operating results.

Changes in reimbursement rates and coverage policy by third party payors may place additional financial pressure on hospitals and the broader healthcare system. Healthcare institutions may take actions to mitigate any persistent pressures on their budgets and such actions could impact the future demand for our products. Geopolitical conditions may also impact our operations. Although we do not have operations in Russia, Ukraine or the Middle East, the continuation of the military conflicts in these regions and/or an escalation of the conflicts beyond their current scope may further weaken the global economy that could result in additional inflationary pressures or supply chain constraints.

Recent Developments

On April 1, 2025, we initiated a full commercial launch of Cohealyx, a collagen-based dermal matrix branded by AVITA Medical and co-developed with Regenity. Cohealyx is designed to support cellular migration and revascularization, advancing readiness for wound bed closure. In pre-clinical and initial clinical utilization, Cohealyx is integrated into the wound bed as early as seven days.

Cohealyx expands our therapeutic wound care portfolio, complementing our flagship product, the RECELL System, which is FDA-approved for the treatment of thermal burns and full-thickness skin defects, and PermeaDerm, a temporary biosynthetic dressing used to support healing before and after grafting. These products support the two-stage standard of care for full-thickness wounds. Cohealyx is used as a dermal matrix to manage the wound bed. RECELL Spray-On Skin Cells and wound protection with PermeaDerm provide solutions for definitive closure. This integrated approach may improve clinical outcomes and expands our market opportunity.

The post-market study, TONE, and the health care economics study, both related to our vitiligo initiative were published during the first quarter of 2025. However, the reimbursement environment for vitiligo remains challenging and uncertain. As a consequence, we are pausing from further commercial investment in vitiligo at this time.

Results of Operations for the three-months ended March 31, 2025 compared to the three-months ended March 31, 2024.

The table below summarizes the results of our operations for each of the periods presented (in thousands).

Statement of Operations Data:	Three-Months Ended		\$ Change	% Change
	March 31, 2025	March 31, 2024		
Sales revenue	\$ 18,325	\$ 11,104	7,221	65%
Lease revenue	189	-	189	100%
Total revenues	18,514	11,104	7,410	67%
Cost of sales	(2,833)	(1,513)	(1,320)	(87)%
Gross profit	15,681	9,591	6,090	63%
Operating expenses:				
Sales and marketing	(14,834)	(12,640)	(2,194)	17%
General and administrative	(6,390)	(8,963)	2,573	(29)%
Research and development	(6,284)	(5,194)	(1,090)	21%
Total operating expenses	(27,508)	(26,797)	(711)	3%
Operating loss	(11,827)	(17,206)	5,379	(31)%
Interest expense	(1,233)	(1,356)	123	(9)%
Other expense, net	(791)	(66)	(725)	nm
Loss before income taxes	(13,851)	(18,628)	4,777	(26)%
Income tax expense	(8)	(30)	22	nm
Net loss	\$ (13,859)	\$ (18,658)	4,799	(26)%

*nm = not meaningful

Total revenues increased by 67%, or \$7.4 million, to \$18.5 million, compared to \$11.1 million in the same period in the prior year. Our commercial revenue was \$18.5 million in the three-months ended March 31, 2025, an increase of \$7.4 million, or 67%, compared to \$11.1 million in the corresponding period in the prior year. The growth in commercial revenues was largely driven by deeper penetration within customer accounts, new accounts for full-thickness skin defect and, to a lesser extent, new product launches.

Gross profit margin was 84.7% compared to 86.4% in the corresponding period in the prior year. Note that the gross margin for RECELL products only was 86.4% for the quarter, which we believe will remain in this range for future quarters. The decrease in the overall gross margin percentage from the prior year was primarily caused by volume discounts, a higher inventory reserve, and product mix. The Company shares the average sales price for Cohealyx at 50% and for PermeaDerm at 60%. Although these arrangements are highly beneficial, they inevitably result in an overall decrease in gross margin percentage. Therefore, the product mix is expected to continue to impact the overall gross margin percentage while increasing the gross profit, and given that expenses associated with this revenue do not increase significantly, operating profit on a quarterly basis.

Total operating expenses increased by 3% or \$0.7 million to \$27.5 million, compared with \$26.8 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 17%, or \$2.2 million, to \$14.8 million, compared to \$12.6 million in the corresponding period in the prior year. Higher costs in the current year are due to increases in salaries and benefits of approximately \$1.4 million, and commissions expense of \$1.4 million, offset by decreases in professional fees of \$0.2 million, deferred compensation expenses of \$0.2 million, and \$0.2 million in other selling expenses. The increase in salaries and benefits is due to the expansion of the sales force to support our growing commercial capabilities. Higher commissions were directly associated with the increase in revenues. The increase in stock-based compensation is due to additional grants related to the expansion of the sales force. The decrease in professional fees is due to higher expenses in the prior year related to pricing studies for future product development. The decrease in deferred compensation expense is driven by lower stock price used to calculate the deferred compensation liability for the deferred restricted stock awards.

General and administrative expenses decreased by 29%, or \$2.6 million, to \$6.4 million, compared to \$9.0 million in the same period in the prior year. Lower costs in the current year are due to decreases in salaries and benefits of approximately \$0.8 million, deferred compensation expense of \$0.8 million, professional fees of \$0.6 million, and \$0.4 million in other corporate expenses. The decrease in salaries and benefits is primarily attributable to decreased headcount and lower severance payments. The decrease in deferred compensation expense is driven by lower stock price used to calculate the deferred compensation liability for the deferred restricted stock awards. The decrease in professional fees is due to lower consulting costs and lower legal fees.

Research and development expenses increased by 21%, or \$1.1 million, to \$6.3 million, compared to \$5.2 million in the same period in the prior year. Higher costs in the current year are due to increases in salaries and benefits of approximately \$1.3 million, stock-based compensation expense of \$0.2 million, offset by a decrease in professional fees of \$0.2 million, and \$0.2 million in lower other development expenses. The increase in salaries and benefits and stock-based compensation expenses is due to the increase in headcount resulting from the deployment of a team of Medical Science Liaisons. The decrease in professional fees is due to the completion of the vitiligo TONE study partially offset by clinical trial costs associated with PermeaDerm and Cohealyx.

Other expense, net increased by \$0.7 million to expense of \$0.8 million from expense of \$0.1 million in the prior period. In the current period, other expense, net consists of a non-cash charge of \$0.8 million related to the change in fair value of debt and \$0.8 million in debt issuance costs, offset by a non-cash gain of \$0.4 million related to the change in fair value of warrants and \$0.3 million in income related to our investments and \$0.1 million in other gains, net. The prior period expense consisted of non-cash charges of \$0.9 million and \$0.4 million related to the changes in fair value of warrant liability and debt, respectively, offset by \$0.9 million related to our investments and \$0.3 million in other gains, net.

Liquidity and Capital Resources

Overview

We expect to utilize cash reserves until U.S. sales of our products reach a level sufficient to fund ongoing operations. We have funded our research and development activities, and more recently our substantial investment in sales and marketing activities, through the issuance of debt. We had approximately \$14.9 million in cash and cash equivalents and \$10.9 million in marketable securities as of March 31, 2025. As of the date of these financial statements, we believe we have sufficient cash reserves to fund operations for the next 12 months.

On October 18, 2023 (the “Closing Date”), the Company entered into a Credit Agreement (the “Credit Agreement”), by and between the Company, as borrower, and an affiliate of OrbiMed Advisors, LLC, as the lender and administrative agent (the “Lender”). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to \$90.0 million (the “Loan Facility”), of which \$40.0 million was borrowed on the Closing Date, less certain fees and expenses payable to or on behalf of the Lender. On November 7, 2024, the Lender and the Company mutually agreed to a third amendment (the “Third Amendment”) to the Credit Agreement. Under the terms of the Third Amendment and subject to the payment by the Company of a consent fee to the Lender, the Company and the Lender mutually agreed to (1) terminate two additional tranches of available debt in the aggregate amount of \$50.0 million and (2) remove the trailing 12-month revenue covenant for the fourth quarter of 2024, which was set at \$67.5 million. All revenue covenants for subsequent quarters remained in effect. The indebtedness under the Credit Agreement is secured by substantially all of our assets and will accrue interest at a rate equal to the greater of (a) forward-looking one-month term SOFR rate and (b) four percent (4%) per annum, plus eight percent (8%). In the event that the Company does not meet certain 12-month trailing revenue targets at the end of future fiscal quarters, the outstanding balance of the loan must be repaid in equal quarterly installments of 5% of the funded amount through the maturity date. In addition, if we don’t maintain a minimum cash and cash equivalents balance at the end of each reporting period, we may have to repay amounts outstanding in full as a result of an event of default. The Credit Agreement contains representations, warranties and covenants that are customary for this type of agreement.

On February 13, 2025, we entered into a fourth amendment to the Credit Agreement (the “Fourth Amendment”), which amended the trailing 12-month revenue covenant to \$73.0 million for the quarter ending March 31, 2025, to \$78.0 million for the quarter ending June 30, 2025, to \$84.0 million for the quarter ending September 30, 2025, to \$92.0 million for the quarter ending December 31, 2025 and to \$103.0 million for the quarter ending March 31, 2026. The \$115.0 million revenue covenant for all subsequent quarters through the date of debt maturity remains in effect. We were not in compliance with the trailing 12-month net revenue covenant for the first quarter of 2025. On March 31, 2025, we received a waiver related to the trailing 12-month net revenue covenant for the first quarter of 2025, which was set at \$73.0 million.

On February 13, 2025, as a condition to the execution of the Fourth Amendment, we issued to the Lender warrants to purchase up to 145,180 shares of our common stock, at an exercise price of \$0.01 per share, with a term of 10 years from the issuance date.

The following table summarizes our cash flows for the periods presented (in thousands):

(in thousands)	Three-Months Ended	
	March 31, 2025	March 31, 2024
Net cash used in operating activities	\$ (10,309)	\$ (20,864)
Net cash provided by investing activities	10,766	15,066
Net cash provided by financing activities	363	631
Net increase/(decrease) in cash and cash equivalents	820	(5,167)
Cash and cash equivalents at beginning of the period	14,050	22,118
Cash and cash equivalents at end of the period	14,870	16,951

Net cash used in operating activities was \$10.3 million and \$20.9 million during the three-months ended March 31, 2025 and 2024, respectively. The decrease in net cash used in operations was primarily due to higher gross profit as a result of increased revenues.

Net cash provided by investing activities was \$10.8 million and \$15.1 million during the three-months ended March 31, 2025 and 2024, respectively. The decrease in cash provided by investing activities is primarily attributable to lower cash inflows from maturities of marketable securities and lower cash outflows from purchases of marketable securities in the current year, as well as a decrease in cash outflow for capital expenditures compared to the prior year. The decrease in capital expenditures in the current year is primarily related to higher leasehold improvement costs in the Ventura production facility to enhance manufacturing output in the prior year.

Net cash provided by financing activities was \$0.4 million and \$0.6 million during the three-months ended March 31, 2025 and 2024, respectively. The decrease in cash provided by financing activities is related to proceeds from the exercises of stock options.

Capital Management and Material Cash Requirements

We aim to manage capital so that the Company continues as a going concern while also maintaining optimal returns to stockholders and benefits for other stakeholders. We also aim to maintain a capital structure that ensures the lowest cost of capital available to us. We regularly review our capital structure and seek to take advantage of available opportunities to improve outcomes for us and our stockholders.

For the three-months ended March 31, 2025, there were no dividends paid and we have no plans to commence the payment of dividends. Under the terms of the Regenity Agreement, we made a \$2.0 million payment during the three-months ended March 31, 2025. We have a further obligation to make up to an additional \$3.0 million payment on or before January 4, 2026 to guarantee development and manufacturing capacity (and related resources), contingent on positive results of certain clinical studies and have recorded \$3.0 million in Contingent liability in the Consolidated Balance Sheets.

With the exception of the milestone payment under the Regenity Agreement, we do not have any other purchase commitments or long-term contractual obligations except for lease obligations as of March 31, 2025. In addition, we have no material off-balance sheet arrangements (as defined in the applicable rules and regulations established by the SEC) that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. While we have no committed plans to issue further shares on the market, we will continue to assess market conditions.

Critical Accounting Estimates

Except as disclosed in Note 2 of our Consolidated Financial Statements, there have been no material changes to our critical accounting policies and estimates from the information provided in Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in the 2024 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Financial Officer evaluated, with the participation of our management, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. As of March 31, 2025, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Securities Exchange Act”), were effective.

Our disclosure controls and procedures have been formulated to ensure that (i) information that we are required to disclose in reports that we file or submit under the Securities Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (ii) information required to be disclosed by us is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Part II - Other Information

Item 1. LEGAL PROCEEDINGS

We are not currently a party to any legal proceedings that we believe will have a material adverse effect on our business or financial condition. We may, however, be subject to various claims or legal actions arising in the ordinary course of business from time to time.

Item 1A. RISK FACTORS

In addition to the other information set forth in this report, you should carefully consider the factors discussed under Part I, Item 1A, “Risk Factors,” in the 2024 Annual Report and as updated from time to time in the Company’s subsequent Quarterly Reports on Form 10-Q. These factors could materially adversely affect our business, financial condition, liquidity, results of operations and capital position, and could cause our actual results to differ materially from our historical results or the results contemplated by the forward-looking statements contained in this report. Other than the addition of the risk factor set forth below, there have been no material changes to the risk factors described in Part I, Item 1A, “Risk Factors,” included in the 2024 Annual Report.

Tariffs and Changes in Trade Policy Could Adversely Affect Our Business, Financial Condition, and Results of Operations

We currently derive less than 5% of our net sales from international operations and a *de minimus* portion of our raw materials and components are sourced internationally. The sale and shipment of our products across international borders, as well as the purchase of materials and components from international sources, subject us to U.S. and foreign governmental trade regulations, including those related to duties, and tariffs. Recent shifts in U.S. trade policy and the imposition of tariffs on imports from certain countries, as well as retaliatory tariffs imposed by those countries on U.S. goods, may negatively impact our business, results of operations, and financial condition. We cannot predict the future direction of trade policy or the impact of any future trade restrictions or retaliatory measures that may further impact our business.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

(a) The following exhibits are filed as part of the Quarterly Report on Form 10-Q:

Exhibit No.	Description
3.1	<u>Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K12B filed on June 30, 2020)</u>
3.2	<u>Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.2 of the registrant's Form 10-KT filed on February 28, 2022)</u>
3.3	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 of the registrant's Form 10-KT filed on February 28, 2022)</u>
4.1	<u>Form of Warrants (included as Annex A to the Fourth Amendment incorporated by reference to Exhibit 10.1 hereto)</u>
10.1	<u>Fourth Amendment to the Credit Agreement between the Lender and the Company, dated February 13, 2025 (incorporated by reference to Exhibit 10.1 of the registrant's Form 8-K filed on February 13, 2025)</u>
10.2	<u>Contract Manufacturing Agreement between the Company and Stedical Scientific, Inc. dated March 17, 2025 (incorporated by reference to Exhibit 10.1 of the registrant's Form 8-K filed on March 17, 2025)</u>
10.3	<u>Amendment Two to the Exclusive Distribution Agreement between the Company and Stedical Scientific, Inc. dated March 17, 2025 (incorporated by reference to Exhibit 10.2 of the registrant's Form 8-K filed on March 17, 2025)</u>
10.4*	<u>Waiver to the Credit Agreement between the Lender and the Company, dated March 31, 2025</u>
31.1*	<u>Rule 13a-14(a) Certification of Chief Executive Officer</u>
31.2*	<u>Rule 13a-14(a) Certification of Chief Financial Officer</u>
32**	<u>18 U.S.C. Section 1350 Certifications</u>
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Management contract or compensation plan or arrangement

* Filed herewith

** Furnished herewith

Signatures

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

Date: May 8, 2025

AVITA MEDICAL, INC.

By: /s/ James Corbett

James Corbett
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ David O'Toole

David O'Toole
Chief Financial Officer
(Principal Financial and Accounting Officer)