

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2023

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

85-1021707

(State or other jurisdiction of incorporation or organization)

(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
The

Common Stock, par value \$0.0001 per share

RCEL

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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 November 6, 2023 was

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SPECIAL 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 statements regarding our future revenues; solvency; future industry market conditions; future changes in our capacity and operations; future operating and overhead costs; intellectual property; regulatory and related approvals; the conduct or outcome of pre-clinical or clinical (human) studies; operational and management restructuring activities (including implementation of methodologies and changes in the board of directors); our ability to expand our sales organization to address effectively existing and new markets that we intend to target; future employment and contributions of personnel; tax and rising interest rates; productivity, business process, rationalization, investment, acquisition and acquisition integrations, consulting, operational, tax, financial and capital projects and initiatives; inflationary pressures on the U.S. and global economy; changes in the legal or regulatory environment; and future working capital, costs, revenues, business opportunities, cash flows, margins, earnings and growth. 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 "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential", or "continue" 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	
	September 30, 2023	December 31, 2022
ASSETS		
Cash and cash equivalents	\$ 50,854	\$ 18,164
Marketable securities	\$ 9,264	\$ 61,178
Accounts receivable, net	5,875	3,515
BARDA receivables	201	898
Prepays and other current assets	3,356	1,578
Inventory	4,377	2,125
Total current assets	73,927	87,458
Marketable securities long-term	6,930	-
Plant and equipment, net	1,862	1,200
Operating lease right-of-use assets	2,607	851
Corporate-owned life insurance ("COLI") asset	1,923	1,238
Intangible assets, net	459	465
Other long-term assets	236	122
Total assets	\$ 81,014	\$ 98,264
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	3,019	3,002
Accrued wages and fringe benefits	7,143	6,623
Current non-qualified deferred compensation liability	333	78

Other current liabilities	1,341	990
Total current liabilities	11,836	10,693
Non-qualified deferred compensation liability	3,361	1,270
Contract liabilities	365	698
Operating lease liabilities, long term	1,845	306
Total liabilities	17,407	12,967
Non-qualified deferred compensation plan share awards	629	557
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.0001 par value per share,		
200,000,000 shares authorized,		
25,550,694 and		
25,208,436 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	3	3
Preferred stock, \$0.0001 par value per share,		
10,000,000 shares authorized,		
no shares issued or outstanding at September 30, 2023 and December 31, 2022.		
Company common stock held by the non-qualified deferred compensation plan ("NQDC Plan")	(1,290)	(127)
Additional paid-in capital	347,192	339,825
Accumulated other comprehensive income	7,977	7,627

Accumulated deficit	((
	290,904	262,588
))
Total stockholders' equity		
	62,978	84,740
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity		
	81,014	98,264
	<u>\$</u>	<u>\$</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		Nine-Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenues				
	\$ 13,645	\$ 9,092	\$ 35,948	\$ 24,966
Cost of sales	(2,113)	(1,530)	(5,984)	(4,694)
Gross profit				
	11,532	7,562	29,964	20,272
BARDA income				
	212	904	1,369	2,189
Operating expenses:				
Sales and marketing expenses	(10,532)	(5,411)	(27,075)	(15,571)
General and administrative expenses	(6,124)	(5,004)	(20,584)	(18,009)
Research and development expenses	(4,394)	(3,799)	(14,056)	(10,478)
Total operating expenses				
	(21,050)	(14,214)	(61,715)	(44,058)
Operating loss				
	(9,306)	(5,748)	(30,382)	(21,597)
Interest expense				
	(10)	(6)	(21)	(10)
Other income				
	615	170	2,141	307
Loss before income taxes				
	(8,701)	(5,584)	(28,262)	(21,300)
Income tax expense				
	(11)	(4)	(54)	(12)
Net loss				
	(8,712)	(5,588)	(28,316)	(21,312)
Net loss per common share:				
Basic and Diluted	(0.34)	(0.22)	(1.12)	(0.85)
Weighted-average common shares:				
Basic and Diluted	25,401,754	25,006,995	25,281,920	24,972,331

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		Nine-Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Net loss	((((
	\$ 8,712	\$ 5,588	\$ 28,316	\$ 21,312
Foreign currency translation loss	((((
	47	96	57	188
Net unrealized gain/(loss) on marketable securities, net of tax	((((
	65	90	407	522
Comprehensive loss	((((
	<u>\$ 8,694</u>	<u>\$ 5,774</u>	<u>\$ 27,966</u>	<u>\$ 22,022</u>

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

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

	Three-Months Ended September 30, 2023						
	Common Stock	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulate d Deficit	Total Stockholder s' Equity	
	Shares	Ammoun t	\$	\$	\$	\$	
Balance at June 30, 2023							
			(
	25,447,615	3	\$ 892	\$ 343,769	\$ 7,959	\$ 282,192	\$ 68,647
Net loss							
							()
							8,712) 8,712)
Stock-based compensation							
					2,367		2,367
Exercise of stock options					110		110
	17,221						
Vesting of restricted stock units							
			45,336				
Company common stock held by the NQDC Plan					()		
					636)	636	
Distribution of Company common stock held by the NQDC Plan					238	284	522
Change in redemption value of share awards in NQDC plan					26		26
Other comprehensive gain						18	18
Balance at September 30, 2023							
			()				
	25,550,694	3	\$ 1,290)	\$ 347,192	\$ 7,977	\$ 290,904)	\$ 62,978

	Three-Months Ended September 30, 2022						
	Common Stock	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulate d Deficit	Total Stockholder s' Equity	
	Shares	Ammoun t	\$	\$	\$	\$	
Balance at June 30, 2022							
	()						
	25,003,088	3	\$ -	\$ 336,668	\$ 7,536	\$ 251,647)	\$ 92,560
Net loss							
							()
							5,588) 5,588)
Stock-based compensation							
					1,229		1,229
Vesting of restricted stock units							
				9,887			
Company common stock held by the NQDC					()		
					127)	127	

Change in redemption value of share awards in NQDC plan	(29	29
	-	-)
Other comprehensive loss	(()
	186	-	186
Balance at September 30, 2022	(()
	25,030,902	\$ 3	\$ 127
))	\$ 337,995
			\$ 7,350
			\$ 257,235
			\$ 87,986

Company common stock held by the NQDC Plan	(
	17,927		127		127			
)						
Change in classification of deferred compensation share awards		((
		192					192	
Change in redemption value of share awards in NQDC plan))
		80					80	
Other comprehensive loss		(((
							710	710
))
Balance at September 30, 2022		(
	25,030,902	\$ 3	\$ 127	\$ 337,995	\$ 7,350	\$ 257,235	\$ 87,986	
	=====	=====	=====	=====	=====	=====	=====	

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

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

	Nine-Months Ended	
	September 30, 2023	September 30, 2022
Cash flow from operating activities:		
Net loss	\$ 28,316	\$ 21,312
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	445	438
Stock-based compensation	6,213	5,782
Non-cash lease expense	531	515
Loss on fixed asset disposal	83	3
Investment losses	17	-
Patent impairment loss	4	-
Remeasurement and foreign currency transaction gain	23	121
Excess and obsolete inventory related charges	149	284
BARDA deferred costs	147	12
Contract cost amortization	255	253
Provision for doubtful accounts	113	10
Amortization of premium of marketable securities	794	12
Non-cash changes in the fair value of NQDC plan	899	5
Changes in operating assets and liabilities:		
Trade and other receivables	2,473	449
BARDA receivables	697	484
Prepays and other current assets	2,057	168
Inventory	2,405	119

	((
Operating lease liability	571	531
))
	((
Corporate-owned life insurance asset	643	840
))
	((
Other long-term assets	114	163
))
	((
Accounts payable and accrued expenses	70	433
)	(
Accrued wages and fringe benefits	524	570
	()
	((
Current non-qualified deferred compensation liability	651	-
)	-
Other current liabilities	345	511
Non-qualified deferred compensation plan liability	1,174	829
	((
	((
Contract liabilities	333	212
))
	((
Other long-term liabilities	-	50
	((
	((
Net cash used in operations	27,148	15,654
Cash flows from investing activities:	((
	((
Purchase of marketable securities	7,633	59,408
))
Sale of marketable securities	2,372	-
Maturities of marketable securities	65,289	43,669
	((
	((
Purchase of plant and equipment	1,085	382
))
	((
Patent filing fees	32	53
))
	((
Net cash provided by/(used in) investing activities	58,911	16,174
Cash flow from financing activities:	((
Proceeds from exercise of stock options	942	1
Net cash provided by financing activities	942	1
	((
Effect of foreign exchange rate on cash and cash equivalents	15	70
))

			(
	32,690	31,897	
Net increase/(decrease) in cash and cash equivalents)
Cash and cash equivalents beginning of the period	18,164	55,712	
Cash and cash equivalents end of the period	<u>\$ 50,854</u>	<u>\$ 23,815</u>	
Supplemental Disclosure of Cash Flow Information			
Income taxes paid during the period	\$ 44	\$	17
Interest paid during the period	\$ 21	\$	10
Plant and equipment purchases not yet paid	\$ 114	\$	7

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 "Company"), is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. The Company's RECELL® System technology platform harnesses the regenerative properties of a patient's own skin to create Spray-On Skin™ cells. In September 2018, the United States Food & Drug Administration ("FDA") granted premarket approval ("PMA") to the RECELL System for use in the treatment of acute thermal burns in patients eighteen years and older. Following receipt of the original PMA, the Company commenced commercialization of the RECELL System in January 2019 in the United States. In June 2021, the FDA approved expanded use of the RECELL System in combination of meshed autografting for acute full-thickness thermal wounds in pediatric and adult patients. In February 2022, the FDA approved a PMA supplement for the RECELL Autologous Cell Harvesting Device, an enhanced ease-of-use device aimed at providing clinicians a more efficient user experience and simplified workflow. On June 7, 2023, the FDA approved a PMA supplement for full-thickness skin defects ("FTSD") based on results of the Company's pivotal trial for soft tissue repair and reconstruction. Following this approval, the Company commenced a commercial launch on June 8, 2023.

On June 16, 2023, the FDA approved a PMA application for the repigmentation of stable depigmented vitiligo lesions. Following FDA approval, the Company established a framework, which consists of three steps, to secure reimbursement for vitiligo. The first step is to conduct the 100-patient post market study called TONE. TONE will evaluate repigmentation using the RECELL device and will also seek to measure the improvement in the quality-of-life following treatment of stable vitiligo with RECELL. TONE, including publication, is expected to be complete by the end of 2024. The second step is to initiate a health economics study to capture the longitudinal healthcare costs for a vitiligo patient, which is expected to be completed by the end of 2024. The purpose of these studies is to demonstrate how treating vitiligo with RECELL can significantly reduce the lifetime healthcare cost of patients. As a result, commercial payors will stand to benefit economically by providing coverage of RECELL for the repigmentation of stable depigmented vitiligo lesions. Conversations with commercial payors will begin during the first quarter of 2025. Commercial coverage will be rolled out on a tiered basis based on state and geographic factors. The Company anticipates that the initial phase of reimbursement coverage will likely begin in the third quarter of 2025 with appropriately sized commercial support as coverage is established.

Additionally, on June 29, 2023, the Company submitted a PMA supplement to the FDA for RECELL GO™. RECELL GO maintains the FDA Breakthrough Device designation from predecessor devices. On September 29, 2023, the Company received notice from the FDA that additional information regarding the PMA is required for the continuation of a substantive review for RECELL GO. This request, which is not unique to the Breakthrough Device Program, placed the application file on hold while the Company addresses the FDA's questions. A category of questions posed by the FDA will require additional in-house testing. The Company has already made significant progress in developing the data plan for testing with some testing underway. Consequently, the Company expects to submit the complete response to the FDA no later than February 28, 2024. Upon the submission to the FDA, the application will reenter the 180-day cycle, with 90 days remaining in the review period. This timing would imply a product launch on May 31, 2024.

In February 2019, the Company entered into a collaboration with COSMOTEC Company Ltd ("COSMOTEC"), an M3 Group company, to market and distribute the RECELL System in Japan. Under the terms of the agreement, AVITA Medical will supply the RECELL product, and COSMOTEC will be the sole distributor of the product in Japan. The Company worked with COSMOTEC to advance its application for approval of the RECELL System in Japan pursuant to Japan's Pharmaceuticals and Medical Devices Act ("PMDA"). In February 2022, COSMOTEC's application for regulatory approval was approved by the PMDA with labeling for burns only. In September 2022, COSMOTEC commercially launched RECELL in Japan following Japan's Ministry of Health, Labor, and Welfare approval of reimbursement pricing.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("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 Condensed 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, 2022 filed with the SEC on February 23, 2023 and the Australian Securities Exchange ("ASX") on February 24, 2023 (the "Annual Report").

There have been no changes to the Company's significant accounting policies as described in the Annual Report on Form 10-K 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 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.

Reclassification of prior year presentation

Certain prior year amounts within Other current liabilities have been reclassified to Current non-qualified deferred compensation liability, in the Consolidated Balance Sheets for consistency with current period presentation. These reclassifications had no effect on the reported results of operations or financial position.

Certain prior-year amounts included in Note 11 - Reporting Segment and Geographic Information have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the total Revenues. An adjustment was made to reclassify COSMOTEC sales from the United States to Japan.

Recent Accounting Pronouncements

In October 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-06 which amends the disclosure or presentation requirements related to various subtopics in the FASB ASC. The amendments in ASU 2023-06 modify the disclosure or presentation requirements of a variety of Topics in the ASC. Certain of the amendments represent clarifications to or technical corrections of the current requirements. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. The Company is currently evaluating the provisions of the amendments and the impact on its future consolidated statements.

In July 2023, the SEC adopted the final rule under SEC Release No. 33-11216, "Cybersecurity Risk Management, Strategy, Governance and Incident Disclosure." The final rule establishes new requirements related to material cybersecurity incidents, which would need to be disclosed on Form 8-K within four business days of their being deemed material, and annual disclosures in Form 10-K pertaining to (1) cybersecurity risk management and strategy, (2) management's role in assessing and managing material risks from cybersecurity threats, and (3) the board of directors' oversight of cybersecurity risks. The Form 10-K disclosures will be due beginning with annual reports for fiscal years ending on or after December 15, 2023, and the Form 8-K disclosures will be due beginning December 18, 2023. The Company will comply with the disclosure requirements set forth in the final rule as each becomes effective.

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 doubtful accounts, carrying value of long-lived assets, the useful lives of long-lived assets, accounting for marketable securities, income taxes, stock-based compensation, estimated credit losses, and the stand-alone selling price for the Biomedical Advanced Research and Development Authority ("BARDA") contract) and related disclosures. Estimates have been prepared on the basis of the current and available information. However, actual results could differ from estimated amounts.

Foreign Currency Translation and Foreign Currency Transactions

The financial position and results of operations of the Company's operating non-U.S. subsidiaries are generally determined using the respective local currency as the functional currency of that subsidiary. Assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each period end. Income statement accounts are translated at the average rate of exchange prevailing during the period. Adjustments arising from the use of differing exchange rates from period to period are included in Other

comprehensive gain (loss) in Stockholders' Equity. Gains and losses resulting from foreign currency transactions are included in General and administrative expenses in the Consolidated Statement of Operations. Gains and losses resulting from foreign currency transactions were a gain of \$

27,000
and \$

76,000
for the three-months ended September 30, 2023 and 2022, respectively. Gains and losses resulting from foreign currency transactions were a gain of \$

39,000
and \$

123,000
for the nine-months ended September 30, 2023 and 2022, respectively.

The Company's non-operating subsidiaries that use the U.S. dollar as their functional currency remeasure monetary assets and liabilities at exchange rates in effect at the end of each period and nonmonetary assets and liabilities at historical rates. Gains and losses resulting from these remeasurements, and foreign currency transactions are included in General and administrative expenses in the Consolidated Statement of Operations. During the three-months ended September 30, 2023 and 2022, the Company recorded a loss of \$

1,000
and a gain of \$

6,000
, respectively. During the nine-months ended September 30, 2023 and 2022, the Company recorded a loss of \$

16,000
and a loss of \$

2,000
, respectively

Cash and Cash Equivalents

Cash and cash equivalents consist of cash held at deposit institutions and cash equivalents. Cash equivalents consist of short-term highly liquid investments with original maturities of three months or less from the date of purchase and consist primarily of money market funds. The Company holds cash at deposit institutions in the amount of \$

4.4
million and \$

4.1
million, of which \$

660,000
and \$

737,000
is denominated in foreign currencies in foreign institutions as of September 30, 2023 and December 31, 2022, respectively. As of September 30, 2023 and December 31, 2022, the Company held cash equivalents in the amount of \$

46.4
million and \$

14.1
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 other receivables. As of September 30, 2023 and December 31, 2022, substantially all of the Company's cash was deposited in accounts at financial institutions, and amounts may exceed federally insured limits and subject to the risk of bank failure.

As of September 30, 2023, no single commercial customer accounted for more than

10
% of net accounts receivable. As of December 31, 2022, one commercial customer accounted for more than

10
% of total net accounts receivable. For the three-months and nine-months ended September 30, 2023 and 2022, no single customer accounted for more than

10

% of revenues.

Employee Stock Purchase Plan ("ESPP")

The Company's Employee Stock Purchase Plan (the "ESPP"), features two six-month offering periods per year, running from June 1 to November 30 and December 1 to May 31. The ESPP provides eligible employees with an opportunity to purchase shares of the Company's common

stock through payroll deductions of up to

15

% of their eligible compensation. Under the ESPP, employees can purchase the Company's Common Stock at the lower of

85

% of the fair value of shares on either the first or last day of the offering period. Amounts deducted and accumulated by the participant are recorded as ESPP liability and included in Accrued wages and fringe benefits in the Consolidated Balance Sheets. This amount is used to purchase shares of common stock at the end of each six-month purchase period. Once the shares are purchased, the ESPP liability is reclassified to stockholders' equity on the purchase date. The ESPP is a compensatory plan accounted for under the expense recognition provision of share-based payment accounting standards. Compensation expense is recorded based on the fair market value at the grant date, which corresponds to the first day of each purchase period. The Black-Scholes option pricing model is used to estimate the grant date fair value.

3. Marketable Securities

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

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	As of September 30, 2023	Carrying Value
(in thousands)					
Cash equivalents:					
Money market funds	\$ 46,431	\$ -	\$ -	\$ 46,431	
Total cash equivalents	<u>\$ 46,431</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 46,431</u>	
Current marketable securities:					
U.S. Treasury securities	\$ 5,451	\$ 3	\$ 14	\$ 5,440	
Commercial paper	1,593	-	5	1,588	
Corporate debt securities	550	-	-	550	
U.S. Government agency obligations	1,690	-	4	1,686	
Total current marketable securities	<u>\$ 9,284</u>	<u>\$ 3</u>	<u>\$ 23</u>	<u>\$ 9,264</u>	
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	As of December 31, 2022	
(in thousands)					
Cash equivalents:					
Money market funds	\$ 14,089	\$ -	\$ -	\$ 14,089	
Total cash equivalents	<u>\$ 14,089</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 14,089</u>	
Current marketable securities:					
U.S. Treasury securities	\$ 43,092	\$ 1	\$ 393	\$ 42,700	
Commercial paper	12,743	-	-	12,743	

				(
Corporate debt securities	3,865		23)	3,842
				(
U.S. Government agency obligations	1,901		8)	1,893
				(
Total current marketable securities	\$ 61,601	\$ 1	\$ 424)	\$ 61,178
Long-term marketable securities:					
				(
Asset backed securities	\$ 3,568	\$ 7	\$ 3)	\$ 3,572
				(
U.S. Treasury securities	2,416		6)	2,410
				(
U.S. Government agency obligations	949		1)	948
				(
Total long-term marketable securities	\$ 6,933	\$ 7	\$ 10)	\$ 6,930

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

(in thousands)	As of September 30, 2023		As of December 31, 2022	
	Amortized Cost	Carrying Value	Amortized Cost	Carrying Value
Due in one year or less	\$ 9,284	\$ 9,264	\$ 61,601	\$ 61,178
Due after one year through three years	\$ -	\$ -	\$ 6,933	\$ 6,930

Gross unrealized gains and losses on the Company's marketable securities were an unrealized gain of \$

3,000
and an unrealized loss of \$

23,000
as of September 30, 2023, which resulted in a net unrealized loss of \$

20,000
. Gross unrealized gains and losses on the Company's marketable securities were an unrealized gain of \$

8,000
and an unrealized loss of \$

434,000
as of December 31, 2022, which resulted in a net unrealized loss of \$

426,000
. As of September 30, 2023, and December 31, 2022, the Company did

no

t recognize credit losses. Proceeds from sales of investments available-for-sale during the three-months and nine-months ended September 30, 2023 were \$

2.4

million. Gross realized losses during the three-months and nine-months ended September 30, 2023 were \$

17,000

. The Company did

no

t have sales of investments during the three-months and nine-months ended September 30, 2022. The Company has accrued interest income of \$

228,000
and \$

168,000
as of September 30, 2023, and December 31, 2022, respectively, in Prepaid and other current assets.

4. Fair Value Measurements

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 September 30, 2023				Total
	Level 1	Level 2	Level 3		
Cash equivalents:					
Money market funds	\$ 46,431	\$ -	\$ -	\$ -	\$ 46,431
Total cash equivalents	\$ 46,431	\$ -	\$ -	\$ -	\$ 46,431
Current marketable securities:					

U.S. Treasury securities	\$	-	\$	5,440	\$	-	\$	5,440
Commercial paper				1,588				1,588
Corporate debt securities				550				550
U.S. Government agency obligations				1,686				1,686
Total current marketable securities	\$	-	\$	9,264	\$	-	\$	9,264
Total marketable securities and cash equivalents	\$	46,431	\$	9,264	\$	-	\$	55,695

(in thousands)	As of December 31, 2022				Total
	Level 1	Level 2	Level 3		
Cash equivalents:					
Money market funds	\$ 14,089	\$ -	\$ -	\$ -	\$ 14,089
Total cash equivalents	\$ 14,089	\$ -	\$ -	\$ -	\$ 14,089
Current marketable securities:					
U.S. Treasury securities	-	42,700	-	-	42,700
Commercial paper	-	12,743	-	-	12,743
Corporate debt securities	-	3,842	-	-	3,842
U.S. Government agency obligations	-	1,893	-	-	1,893
Total current marketable securities	\$ -	\$ 61,178	\$ -	\$ -	\$ 61,178
Long-term marketable securities:					
Asset backed securities	\$ -	\$ 3,572	\$ -	\$ -	\$ 3,572
U.S. Treasury securities	-	2,410	-	-	2,410
U.S. Government agency obligations	-	948	-	-	948
Total long-term marketable securities	\$ -	\$ 6,930	\$ -	\$ -	\$ 6,930
Total marketable securities and cash equivalents	\$ 14,089	\$ 68,108	\$ -	\$ -	\$ 82,197

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. Level 2 assets consist of commercial paper, U.S. Government agency obligations, corporate debt securities, asset backed securities and U.S Treasury securities. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. As of September 30, 2023 and December 31, 2022, the Company had no investments that were measured using unobservable (Level 3) inputs. There were no transfers between fair value measurement levels as of September 30, 2023 or December 31, 2022.

5. Revenues

The Company's revenue consists of sale of the RECELL System to hospitals, treatment centers and COSMOTEC ("commercial customers") and to BARDA (collectively "customers"), predominately in the United States. In addition, the Company records service revenue for the emergency preparedness services provided to BARDA. Services are included in Revenues within the Consolidated Statements of Operations.

Remaining Performance Obligations

Revenues from remaining performance obligations are calculated as the dollar value of the remaining performance obligations on executed contracts. The estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) pursuant to the Company's existing customer agreements is \$

469,000
and \$

698,000
as of September 30, 2023 and December 31, 2022, respectively. Approximately \$

70,000
as of September 30, 2023 and \$

274,000
as of December 31, 2022, of the total balance relates to our July 2020 contract with BARDA for the purchase, delivery and storage of RECELL Systems for emergency response preparedness for a period of three years. The Company expects to recognize these amounts as services are provided to BARDA. We are contracted to manage this inventory of product until the federal government requests shipment or at contract termination on December 31, 2023. The remaining balance of \$

399,000
and \$

424,000
as of September 30, 2023 and December 31, 2022, respectively, relate to our contract with COSMOTEC. The Company expects to recognize these amounts as revenue on a straight-line basis over the term of the contract with COSMOTEC.

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 the period ended September 30, 2023 and December 31, 2022, the Company does

no

to 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 \$

469,000
and \$

698,000
of contract liabilities as of September 30, 2023 and December 31, 2022, respectively. As of September 30, 2023 and December 31, 2022, a total of \$

104,000
and \$

0
, respectively, was included in Other current liabilities and \$

365,000
and \$

698,000
, respectively, in Contract liabilities in the Consolidated Balance Sheets. The balance relates to the unsatisfied performance obligation for emergency preparedness under the BARDA and amounts received from

COSMOTEC. The Company recognized \$ 90,000 and \$ 93,000 of revenue from BARDA for amounts included in the beginning balance of contract liabilities for the three-months ended September 30, 2023 and 2022, respectively, and \$ 250,000 and \$ 279,000 for the nine-months ended September 30, 2023 and 2022, respectively. The Company recognized \$ 8,000 and \$ 25,000 of revenue from COSMOTEC for amounts included in the beginning balance of contract liabilities for the three-months and nine-months ended September 30, 2023, respectively. The Company recognized \$ 3,000 of revenue included in the beginning balance of contract liabilities for the three-months and nine-months ended September 30, 2022.

Disaggregated Revenue

The Company disaggregates revenue from contracts with customers into geographical regions and by customer type. As noted in the segment footnote, the Company's business consists of one reporting segment. A reconciliation of disaggregated revenue by geographical region and customer type is provided in Segment Note 11.

6. Leases

During February 2023, the Company remeasured the lease liability for an office lease due to an increase in the lease term. As a result of the remeasurement of the lease liability, there was an increase of approximately \$ 1.1 million to the operating lease ROU assets and operating lease liabilities. There was no impact on earnings as a result of the lease modification.

During May 2023, the Company entered into a new office lease in Irvine, California. The lease commenced during July 2023 and resulted in an increase of \$ 1.1 million in the operating lease ROU asset and operating lease liabilities.

The following table sets forth the Company's operating lease expenses which are included in operating expenses in the Consolidated Statements of Operations (in thousands):

	Three-Months Ended	Nine-Months Ended	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Operating lease cost						
	\$ 260	\$ 194	\$ 655	\$ 582		
Variable lease cost	\$ 28	\$ 13	\$ 43	\$ 38		
Total lease cost	<u>\$ 288</u>	<u>\$ 207</u>	<u>\$ 698</u>	<u>\$ 620</u>		

Supplemental cash flow information related to operating leases for the three-months and nine-months ended September 30, 2023 and 2022 was as follows (in thousands):

	Three-Months Ended	Nine-Months Ended	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Cash paid for amounts included in the measurement of lease liabilities:						
Operating cash outflows from operating leases	\$ 146	\$ 201	\$ 556	\$ 598		

Supplemental balance sheet information, as of September 30, 2023 and December 31, 2022, related to operating leases was as follows (in thousands, except for operating lease weighted average remaining lease term and operating lease weighted average discount rate):

	As of	
	September 30, 2023	December 31, 2022
Reported as:		
Operating lease right-of-use assets		
	\$ 2,607	\$ 851
Total right-of-use assets		
	<u>\$ 2,607</u>	<u>\$ 851</u>
Other current liabilities:		
Operating lease liabilities, short-term		
	\$ 904	\$ 612
Operating lease liabilities, long term		
	1,845	306
Total operating lease liabilities		
	<u>\$ 2,749</u>	<u>\$ 918</u>
Operating lease weighted average remaining lease term (years)		
	3.51	1.44
Operating lease weighted average discount rate		
	8.68 %	6.71 %

As of September 30, 2023, maturities of the Company's operating lease liabilities are as follows (in thousands):

	Operating Leases
Remainder of 2023	\$ 257
2024	1,028
2025	738
2026	684
2027	318
2028	190
Total lease payments	3,215
Less imputed interest	(466)
Total operating lease liabilities	<u>\$ 2,749</u>

As of September 30, 2023, there were no leases entered into that had not yet commenced.

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

	As of	
	September 30, 2023	December 31, 2022
Raw materials		
	\$ 2,875	\$ 1,131
Work in process	661	384
Finished goods	841	610
Total inventory	<hr/> \$ 4,377	<hr/> \$ 2,125

The Company has reduced the carrying value of 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 \$

81,000
and \$

125,000
for the three-months ended September 30, 2023 and 2022, respectively, and \$

149,000
and \$

284,000
for the nine-months ended September 30, 2023 and 2022, respectively.

8. Intangible Assets

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

	Weighted Average Useful Life	As of September 30, 2023			As of December 31, 2022			Net Carry Amount
		Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization		
Patent 1	3	\$ 17	\$ 17	\$ -	\$ 17	\$ 16	\$ 1	
Patent 2	13	140	35	105	137	28	109	
Patent 3	14	204	50	154	194	39	155	
Patent 5	19	98	10	88	89	6	83	
Patent 6	20	44	5	39	43	4	39	
Patent 7	13	2	-	2	2	-	2	
Patent 8	19	10	1	9	13	-	13	
Patent 10	19	3	-	3	3	-	3	
Patent 11	19	6	1	5	6	-	6	
Trademarks	Indefinite	54	-	54	54	-	54	
Total intangible assets		\$ 578	\$ 119)	\$ 459	\$ 558	\$ 93)	\$ 465	

During the three-months ended September 30, 2023, 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 intangibles assets recognized for the three-months ended September 30, 2023. For the nine-months ended September 30, 2022, the Company recorded an impairment charge of approximately \$

4,000 in General and administrative expenses in the Consolidated Statement of Operations. During the three-months and nine-months ended September 30, 2022, 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 intangibles assets recognized for the three-months and nine-months ended September 30, 2022. Amortization expense of intangibles included in the Consolidated Statements of Operations were \$

9,000
and \$

8,000
for the three-months ended September 30, 2023 and 2022, respectively, and \$

26,000
and \$

50,000
for the nine-months ended September 30, 2023 and 2022, respectively.

The Company expects the future amortization of amortizable intangible assets held at September 30, 2023 to be as follows (in thousands):

	Estimated Amortization Expense
Remainder of 2023	\$ 9
2024	35
2025	35
2026	35
2027	35
2028	34
Thereafter	222
Total	\$ 405

9. Plant and Equipment

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

	Useful Lives	As of September 30, 2023	As of December 31, 2022
Computer equipment	3 years	951 \$	755 \$
Computer software	3 years	840	871
Construction in progress		370	258
Furniture and fixtures	7 years	765	439
Laboratory equipment	5 years	713	643
Leasehold improvements	Lesser of life or lease term	352	257
RECELL moulds	5 years	128	129
Less: accumulated amortization and depreciation		(2,257)	(2,152)
Total plant and equipment, net		1,862 \$	1,200 \$

Depreciation expense related to plant and equipment was \$

156,000
and \$

130,000
for the three-months ended September 30, 2023 and 2022 respectively, and \$

419,000
and \$

388,000
for the nine-months ended September 30, 2023 and 2022, respectively. The Company recorded an impairment charge of approximately \$

80,000
and \$

83,000
, for the three-months and nine-months ended September 30, 2023, respectively. Amounts are recorded in General and administrative expenses in the Consolidated Statement of Operations. During the three-months and nine-months ended September 30, 2022, the Company did not identify any events or changes in circumstances that indicated that the carrying value of its plant and equipment may not be recoverable. As such, there was no impairment of plant and equipment recognized for the three-months and nine-months ended September 30, 2022.

10. Other Current and Long-Term Assets and Liabilities

Prepays and other current assets consisted of the following (in thousands):

	As of September 30, 2023	As of December 31, 2022
Prepaid expenses	\$ 1,509	\$ 921
Investment receivable	1,500	-

Lease deposits	37	110
Accrued investment income	228	168
BARDA contract costs	56	252
Other receivables	26	127
Total prepaids and other current assets	\$ 3,356	\$ 1,578

Prepaid expenses primarily consist of prepaid benefits and insurance.

Other long-term assets consisted of the following (in thousands):

	As of	
	September 30, 2023	December 31, 2022
Long-term lease deposits	\$ 151	\$ 25
Long-term prepaids	85	97
Total other long-term assets	\$ 236	\$ 122

Other current liabilities consisted of the following (in thousands):

	As of	As of
	September 30, 2023	December 31, 2022
Operating lease liability	\$ 904	\$ 612
BARDA deferred costs	47	194
BARDA deferred revenue	104	-
Other current liabilities	286	184
Total other current liabilities	\$ 1,341	\$ 990

11. 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 September 30, 2023, and December 31, 2022, with an insignificant amount located in Australia and the United Kingdom.

Revenue by region for the three-months and nine-months ended September 30, 2023 and 2022 were as follows (in thousands):

	Three-Months Ended		Nine-Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenue:				
United States				
	\$ 12,961	\$ 8,441	\$ 33,379	\$ 24,117
Foreign:				
Japan	581	555	2,309	555
Australia				
	61	57	156	173
United Kingdom				
	42	39	104	121
Total	\$ 13,645	\$ 9,092	\$ 35,948	\$ 24,966

Revenue and cost of sales by customer type for the three-months and nine-months ended September 30, 2023 and 2022 were as follows (in thousands):

	Three-Months Ended		Nine-Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenue:				
Commercial sales				
	\$ 13,547	\$ 8,999	\$ 35,673	\$ 24,687
Deferred commercial revenue				
	8	-	25	-
BARDA:				

Services for emergency preparedness	90	93	250	279
Total				
	\$ 13,645	\$ 9,092	\$ 35,948	\$ 24,966
Three-Months Ended				
	September 30, 2023	September 30, 2022	Nine-Months Ended	
Cost of sales:			September 30, 2023	September 30, 2022
Commercial cost				
	\$ 2,110	\$ 1,446	\$ 5,835	\$ 4,453
BARDA:				
Product cost	(((
	83	-	106	12
Emergency preparedness service cost				
	86	84	255	253
Total				
	\$ 2,113	\$ 1,530	\$ 5,984	\$ 4,694

12. 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 to be a better estimate 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 September 30, 2023 and December 31, 2022, the Company did

no

t have any outstanding or threatened litigation that would have a material impact on the financial statements.

13. Common and Preferred Stock

The Company's CHESS Depositary Interests ("CDIs") are quoted on the ASX under the ticker code, "AVH". The Company's shares of common stock are quoted on the Nasdaq Capital Market ("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 September 30, 2023, and December 31, 2022,

25,550,694

and

25,208,436

shares of common stock, respectively, were issued and outstanding and

no

shares of preferred stock were outstanding during any period.

14. 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*. The Company recorded stock-based compensation expense of \$

2.4
million and \$

1.4
million for the three-months ended September 30, 2023 and 2022, respectively, and \$

6.2
million and \$

5.8
million for the nine-months ended September 30, 2023 and 2022, respectively.

No

income tax benefit was recognized in the Consolidated Statements of Operations for stock-based payment arrangements for the three-months and nine-months ended September 30, 2023, and 2022.

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

Nine-Months Ended

	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Sales and marketing expenses				
	\$ 513	\$ 408	\$ 915	\$ 1,022
General and administrative expenses	1,534	761	4,442	4,071
Research and development expenses	383	267	856	689
Total operating expenses	\$ 2,430	\$ 1,436	\$ 6,213	\$ 5,782

A summary of share option activity as of September 30, 2023, 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, 2022	1,724,252	511,194	2,235,446
Granted	919,193	-	919,193
Exercised	(133,750)	(30,000)	(163,750)
Expired	(59,812)	(180,473)	(240,285)
Forfeited	(58,963)	(6,958)	(65,921)
Outstanding shares at September 30, 2023	2,390,920	293,763	2,684,683
Exercisable at September 30, 2023	875,323	255,629	1,130,952

A summary of the status of the Company's unvested RSUs as of September 30, 2023, and changes that occurred during the period is presented below:

Unvested Shares	Tenure-Based RSUs	Performance Condition RSUs	Total RSUs
Unvested RSUs outstanding at December 31, 2022	394,872	65,646	460,518
Granted	57,798	-	57,798
Vested	(149,168)	(29,340)	(178,508)
Forfeited	(39,250)	(8,286)	(47,536)
Unvested RSUs outstanding at September 30, 2023	264,252	28,020	292,272

Employee Stock Purchase Plan

In June 2023, the stockholders approved the AVITA Medical, Inc. Employee Stock Purchase Plan (the "ESPP"). The ESPP became effective on July 1, 2023. On June 30, 2023, the Company filed 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 first offering period for the ESPP is July 1 – November 30, 2023. Subsequent offering periods will begin the first trading day of December and June each year.

As of September 30, 2023, the Company had \$

410,000 in accrued payroll contributions. As of December 31, 2022, the Company did

no t have any accrued payroll contributions. There have been

no shares issued under the ESPP plan as of September 30, 2023.

15. Income Taxes

Tax expense for the three-months ended September 30, 2023 and 2022 was \$

11,000 and \$

4,000 , respectively, and \$

54,000 and \$

12,000 for the nine-months ended September 30, 2023 and 2022, respectively. These amounts are related to state minimum taxes.

16. Net Loss per Share

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

(in thousands, except per share amounts)	Three-Months Ended		Nine-Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Net loss	\$ 8,712	\$ 5,588	\$ 28,316	\$ 21,312
Weighted-average common shares—outstanding, basic and diluted	25,402	25,007	25,282	24,972

Net loss per common share, basic and diluted

	0.34	0.22	1.12	0.85
	\$	\$	\$	\$

	Three-Months Ended September 30, 2023	September 30, 2022	Nine-Months Ended September 30, 2023	Nine-Months Ended September 30, 2022
--	--	--------------------	---	---

Anti-dilutive shares excluded from diluted net loss per common share:

Stock options	2,684,683	1,774,070	2,684,683	1,774,070
Restricted stock units	292,272	220,920	292,272	220,920

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*,

117,909

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 details on shares of common stock held by the rabbi trust refer to Note 17. 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 and nine-months ended September 30, 2023, and 2022, diluted net loss per common share is the same as the basic net loss per share for those periods.

17. Retirement Plans

The Company offers a 401(k) retirement savings plan (the "**401(k) Plan**") for its employees, including its executive officers, who satisfy certain eligibility requirements. The Internal Revenue Code of 1986, as amended, allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) Plan. The Company matches contributions to the 401(k) Plan based on the amount of salary deferral contributions the participant makes to the 401(k) Plan. The Company will match up to

6

% of an employee's compensation that the employee contributes to his or her 401(k) Plan account up to the maximum allowable. Total Company's matching contributions to the 401(k) Plan were \$

263,000
and \$

312,000
for the three-months ended September 30, 2023 and 2022, respectively, and \$

934,000
and \$

783,000
for the nine-months ended September 30, 2023 and 2022, respectively.

Non-Qualified Deferred Compensation Plan

The Company's NQDC plan, which became effective on October 2021, allows for eligible management and highly compensated key employees to elect to defer a portion of their salary, bonus and RSU awards to later years. Cash deferrals are immediately vested and are subject to investment risk, and a risk of forfeiture under certain circumstances. RSU deferrals are subject to the vesting conditions of the award. Once RSUs vest, subject to a six-month and one day holding period, employees are allowed to diversify the common stock into other investment options offered by the plan. For cash deferrals, the Company matches

4
% to

6
% (depending on level) of employee contributions. These matching employer contributions are vested over a two-year period with

25
% vesting on year one and

75
% vesting on year two for employees under 55 years of age. Employer contributions for employees over 55 years of age are immediately vested. Employer contributions to the NQDC plan were \$

80,000
and \$

75,000
for the three-months ended September 30, 2023 and 2022, respectively, and \$

161,000
and \$

197,000
for the nine-months ended September 30, 2023 and 2022, respectively. The Company's deferred compensation plan liability was \$

3.7
million and \$

1.3
million as of September 30, 2023 and December 31, 2022, respectively. These amounts are split between current and long term on the Consolidated Balance Sheets. As of September 30, 2023, \$

0.3
million is included in Current non-qualified deferred compensation liability and \$

3.4
million in Non-qualified deferred compensation liability. As of December 31, 2022, \$

78,000
is included in Current non-qualified deferred compensation liability and \$

1.3
million in Non-qualified deferred compensation liability. During the third quarter of 2023, the Company had a payout of approximately \$

753,000

in the deferred compensation liability for terminated employees.

The fair values of the Company's deferred compensation plan assets and liability are included in the table below. For additional information on the fair value hierarchy and the inputs used to measure fair value, see Note 4, Fair Value Measurements.

(in thousands)	Fair Value as of September, 2023				Fair Value as of December 31, 2022			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Corporate-owned life insurance policies (1)	\$ -	\$ 2,091	\$ -	\$ 2,091	\$ -	\$ 1,238	\$ -	\$ 1,238
Non-qualified deferred compensation plan liability (2)	- -	3,694	- -	3,694	- -	1,348	- -	1,348

(1) The corporate-owned life insurance contracts are recorded at cash surrender value, which is provided by a third party and reflects the net asset value of the underlying publicly traded mutual funds and are categorized as Level 2.

(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.

Rabbi Trust

During April 2022, the Company established a rabbi trust to hold the assets of the NQDC plan. The rabbi trust holds the COLI asset and the common stock from deferred RSU awards that have vested. The NQDC permits diversification of fully vested shares into other equity securities subject to a six-month and one day holding period. In accordance with ASR 268, *Redeemable Preferred Stock*, and ASC 718, *Compensation — Stock Compensation*, prior to vesting, the deferred share awards are classified as an equity instrument and changes in fair value of the amount owed to the participant are not recognized. The redemption amounts of the deferred awards are based on the vested percentage and are recorded outside of permanent equity as Non-qualified deferred

compensation share awards on the Consolidated Balance Sheets. As of September 30, 2023, a total of

81,052 shares awards have been deferred, and a total of

117,909 shares were vested at the redemption value of \$

1.3 million. As of December 31, 2022, a total of

253,048 share awards have been deferred, and a total of

17,927 awards vested with a redemption value of \$

127,000

. Vested shares are converted to common stock and are reclassified to permanent equity. 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.

The following table summarizes the eligible share award activity as of September 30, 2023 and December 31, 2022 (in thousands):

	As of	
	September 30, 2023	December 31, 2022
(in thousands)		
Non-qualified deferred compensation share awards:		
Balance at inception/beginning of period	\$ 557	\$ -
Change in classification of deferred compensation share awards	- 192	- 192
Stock-based compensation expense	475	471
Change in redemption value	998 21	()
Vesting of share awards held by NDQC	1,401 127	()
Ending Balance	\$ 629	\$ 557

18. Subsequent Events

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

Credit Agreement

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 (the “**Initial Commitment Amount**”). In addition, an aggregate of \$

50.0 million will be made available in two separate \$

25.0 million tranches, at the Company’s discretion, subject to certain net revenue requirements. The first tranche of \$

25.0 million will be made available on or before December 31, 2024. The second tranche of \$

25.0 million will be made available on or prior to June 30, 2025, only if the first tranche was drawn upon. 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 indebtedness under the Credit Agreement will be 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 twelve-month trailing revenue targets at the end of certain 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. The Credit Agreement contains representations, warranties and covenants that are customary for this type of agreement.

On the Closing Date, the Company issued to an affiliate of the Lender a warrant (the "**Warrant**") to purchase up to

409,661
shares of the Company's common stock, at an exercise price of \$

10.9847
per share, with a term of 10 years from the issuance date. The Warrant contains customary share adjustment provisions, as well as weighted average price protection in certain circumstances.

Settlement and Release Agreement

The Company has entered into a settlement and release agreement (the "**Agreement**") with former Company CEO Dr. Michael Perry. Under the terms of the Agreement, Dr. Perry will receive both wage and non-wage payments in consideration of a general release of claims in favor of the Company. Dr Perry was entitled to receive the majority of these payments under the terms of his executive employment agreement. The Agreement also contains a mutual non-disparagement agreement. The Company did not admit to any allegations under the terms of the Agreement.

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 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 identified 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 of the SEC and the ASX, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on 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 "Special Statement Regarding Forward-Looking Statements" on page 3.

Overview

AVITA Medical, Inc. ("we", "our", "us") is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. Our patented and proprietary RECELL® System technology platform harnesses the regenerative properties of a patient's own skin to create Spray-On Skin™ Cells, an autologous skin cell suspension that is sprayed onto the patient to regenerate natural healthy skin.

Our objective is to become the leading provider of regenerative medicine addressing unmet medical needs in burn injuries, full-thickness skin defects, and in skin repigmentation, such as vitiligo. To achieve this objective, we plan to:

- Become the standard of care in the U.S. burns industry by increasing RECELL System penetration in burn centers and with burn physicians
- Continue to commercialize the RECELL System in the U.S. for treatment of full-thickness skin defects with both inpatient and outpatient reimbursement in place
- Expand our global presence within the European Union and Australia through the exclusive use of third-party distributors.
- Launch RECELL GO following FDA approval to increase market adoption, expand our customer base, and facilitate international commercialization
- Establish commercial payor coverage for the RECELL System in the U.S. for the treatment of vitiligo lesions, which we expect will begin during the third quarter of 2025
- Further invest in our RECELL System platform to automate and improve workflow, speed, and ease of use as it relates to specific indications, as well as to build upon our intellectual property estate
- Continue to build upon commercial activities in Japan through our partnership with COSMOTEC Company, Ltd with our current PMDA approval for RECELL with an indication in burns
- Develop and pursue viable commercial activities outside of the U.S. and Japan following the FDA approvals of the RECELL System for full-thickness skin defects and vitiligo
- Pursue business development opportunities that are complementary to our core RECELL System indications and/or our targeted markets
- Improve our margins and profitability by leveraging our current team and infrastructure across an expanding base of business in burns and in future indications

Business Environment and Current Trends

There remains significant uncertainty in the current macroeconomic environment due to factors including supply chain shortages, increased cost of healthcare, increased inflation rates, a competitive and tight labor market, and other related global economic conditions and geopolitical conditions. Additionally, there have been various economic indicators that the United States economy may be entering a recession in upcoming quarters. If these conditions continue or worsen, they could adversely impact our future operating results. An economic recession could potentially impact the general business environment and the capital markets, which may have a material negative impact on our financial results.

Changes in reimbursement rates 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 or Ukraine, the continuation of the Russia-Ukraine military conflict and/or an escalation of the conflict beyond its current scope may further weaken the global economy and could result in additional inflationary pressures and supply chain constraints.

Recent Developments

On June 7, 2023, the FDA approved a PMA supplement for full-thickness skin defects based on results of our trial for soft tissue repair and reconstruction. Following this approval, we commenced a commercial launch on June 8, 2023.

On June 16, 2023, the FDA approved a PMA application for the repigmentation of stable depigmented vitiligo lesions. To support reimbursement, the Company is conducting a post-market clinical study which will evaluate repigmentation and seek to measure quality-of-life after treatment of stable vitiligo lesions and, initiating a separate health care economic study to capture the longitudinal health care cost of vitiligo patients. Following publication of these studies, the Company will begin discussions with commercial payors to establish reimbursement during the first quarter of 2025.

On June 29, 2023, we submitted a PMA supplement to the FDA for RECELL GO™. RECELL GO maintains the FDA Breakthrough Device designation from predecessor devices.

On September 29, 2023, we received notice from the FDA that additional information regarding the PMA is required for the continuation of a substantive review for RECELL GO. This request, which is not unique to the Breakthrough Device Program, placed the application file on hold while we address the FDA's questions. A category of questions posed by the FDA will require additional in-house testing. We have already made significant progress in developing the data plan for testing with some testing underway. Consequently, we expect to submit our complete response to the FDA no later than February 28, 2024. Upon the submission to the FDA, the application will reenter the 180-day cycle, with 90 days remaining in the review period. This timing would imply a product launch on May 31, 2024.

On October 18, 2023, the Company entered into a Credit Agreement with an affiliate of OrbiMed, 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 Company drew \$40.0 million on the closing date.

Results of Operations for the three-months ended September 30, 2023 compared to the three-months ended September 30, 2022.

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
	September 30, 2023	September 30, 2022		
Revenues	\$ 13,645	\$ 9,092	4,553	50%
Cost of sales	(2,113)	(1,530)	(583)	(38)%
Gross profit	11,532	7,562	3,970	52%
BARDA income	212	904	(692)	(77)%
Operating Expenses:				
Sales and marketing expenses	(10,532)	(5,411)	(5,121)	(95)%
General and administrative expenses	(6,124)	(5,004)	(1,120)	(22)%
Research and development expenses	(4,394)	(3,799)	(595)	(16)%
Total operating expenses	(21,050)	(14,214)	(6,836)	(48)%
Operating loss	(9,306)	(5,748)	(3,558)	(62)%
Interest expense	(10)	(6)	(4)	(67)%
Other income	615	170	445	262%
Loss before income taxes	(8,701)	(5,584)	(3,117)	(56)%
Income tax expense	(11)	(4)	(7)	(175)%
Net loss	\$ (8,712)	\$ (5,588)	\$ (3,124)	(56)%

Total net revenues increased by 50%, or \$4.6 million, to \$13.6 million, compared to \$9.1 million in the corresponding period in the prior year. Our commercial revenue, which excludes BARDA revenue, was \$13.5 million in the three-months ended September 30, 2023, an increase of \$4.5 million, or 51%, compared to \$9.0 million in the corresponding period in the prior year. The growth in commercial revenues was largely driven by deeper penetration within individual customer accounts along with the launch into Full Thickness Skin Defect ("FTSD").

Gross profit margin was 84.5% compared to 83.2% in the corresponding period in the prior year. The increase was largely driven by higher production associated with our increase in revenues and lower shipping costs.

BARDA income decreased by 77% or \$0.7 million to \$0.2 million, compared to \$0.9 million in the corresponding period in the prior year due to reimbursable clinical trials winding down. BARDA income consisted of funding from the Biomedical Advanced Research and Development Authority, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C.

Total operating expenses increased by 48% or \$6.8 million to \$21.1 million, compared with \$14.2 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 95%, or \$5.1 million, to \$10.5 million, compared to \$5.4 million in the corresponding period in the prior year. Higher costs in the current year were primarily related to an increase in salaries and benefits, commissions and travel expenses. The increase in salaries and benefits is due to the preparation of the commercial launch of FTSD that occurred in June 2023. Higher commissions and travel costs were directly associated with the increase in revenues.

General and administrative expenses increased by 22%, or \$1.1 million, to \$6.1 million, compared to \$5.0 million in the same period in the prior year. The increase was attributable to higher stock-based compensation, and salaries and benefits. Higher stock-based compensation in the current period is driven by the new grants in the current year.

Research and development expenses increased by 16%, or \$0.6 million, to \$4.4 million, compared to \$3.8 million in the same period in the prior year. The increase is due to the deployment of a team of Medical Science Liaisons, for the FTSD launch in June 2023, and was partially offset by lower clinical trial expenses for vitiligo, FTSD and pediatrics as trial participants largely completed follow-up in 2022 reducing the associated expenditure in the current period.

Results of Operations for the nine-months ended September 30, 2023 compared to the nine-months ended September 30, 2022.

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

Statement of Operations Data:	Nine-Months Ended		\$ Change	% Change
	September 30, 2023	September 30, 2022		
Revenues	\$ 35,948	\$ 24,966	10,982	44%
Cost of sales	(5,984)	(4,694)	(1,290)	(27)%
Gross profit	29,964	20,272	9,692	48%
BARDA income	1,369	2,189	(820)	(37)%
Operating Expenses:				
Sales and marketing expenses	(27,075)	(15,571)	(11,504)	(74)%
General and administrative expenses	(20,584)	(18,009)	(2,575)	(14)%
Research and development expenses	(14,056)	(10,478)	(3,578)	(34)%
Total operating expenses	(61,715)	(44,058)	(17,657)	(40)%
Operating loss	(30,382)	(21,597)	(8,785)	(41)%
Interest expense	(21)	(10)	(11)	(110)%
Other income	2,141	307	1,834	597%
Loss before income taxes	(28,262)	(21,300)	(6,962)	(33)%
Income tax expense	(54)	(12)	(42)	(350)%
Net loss	<u>\$ (28,316)</u>	<u>\$ (21,312)</u>	<u>(7,004)</u>	<u>(33)%</u>

Total net revenues increased by 44%, or \$11.0 million, to \$36.0 million, compared to \$25.0 million in the corresponding period in the prior year. Our commercial revenue, which excludes BARDA revenue, was \$35.7 million in the nine-months ended September 30, 2023, an increase of \$11 million, or 45%, compared to \$24.7 million in the corresponding period in the prior year. The growth in commercial revenues was largely driven by deeper penetration within individual customer accounts and the FTSD launch along with the commencement of commercial sales with our partner COSMOTEC in Japan.

Gross profit margin increased by 2% to 83.4% compared to 81.2% in the corresponding period in the prior year. The increase in gross profit margin is largely driven by higher production along with lower shipping costs.

BARDA income decreased 37% or \$0.8 million to \$1.4 million, compared to \$2.2 million in the corresponding period in the prior year due to reimbursable clinical trials winding down.

Total operating expenses increased by 40% or \$17.7 million to \$61.7 million, compared with \$44.1 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 74%, or \$11.5 million, to \$27.1 million, compared to \$15.6 million incurred in the corresponding period in the prior year. Higher costs in the current year were primarily attributed to higher salaries and benefits, commissions, recruitment fees and travel costs. The increase in salaries and benefits and recruitment fees are due to the preparation of the commercial launch of FTSD in June 2023. Higher commissions and travel costs were directly associated with the increase in revenues.

General and administrative expenses increased by 14%, or \$2.6 million, to \$20.6 million, compared to \$18.0 million incurred in the same period in the prior year. The increase was attributable to deferred compensation expense, professional fees, and severance costs. The increase in deferred compensation expense is driven by our deferred compensation liability which generally tracks the movements in the stock market. Higher professional fees were primarily due to the timing of our annual general meeting in the current year. Severance costs in the current year were due to the termination of two former executive officers.

Research and development expenses increased by 34%, or \$3.6 million, to \$14.1 million, compared to \$10.5 million incurred in the same period in the prior year. The increase is due to the development of the next generation RECELL GO for preparation of Spray-On Skin Cells, which resulted in a PMA submission in June 2023, and additional costs associated with the deployment of a team of Medical Science Liaisons, for the FTSD launch in June 2023. The increase was partially offset by lower clinical trial expenses for vitiligo, soft tissue and pediatrics as trial participants largely completed follow-up in 2022 reducing the associated expenditure in the current period.

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. AVITA Medical has historically funded its research and development activities, and more recently its substantial investment in sales and marketing activities, through raising capital by issuing securities. As of September 30, 2023, the Company had approximately \$50.9 million in cash and cash equivalents and \$9.3 million in marketable securities.

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 (the “**Initial Commitment Amount**”). In addition, an aggregate of \$50.0 million will be made available in two separate \$25.0 million tranches, at the Company’s discretion, subject to certain net revenue requirements. The first tranche of \$25.0 million will be made available on or before December 31, 2024. The second tranche of \$25.0 million will be made available on or prior to June 30, 2025, only if the first tranche was drawn upon. 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 indebtedness under the Credit Agreement will be 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 twelve-month trailing revenue targets at the end of certain 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. The Credit Agreement contains representations, warranties and covenants that are customary for this type of agreement.

On the Closing Date, the Company issued to an affiliate of the Lender a warrant (the “**Warrant**”) to purchase up to 409,661 shares of the Company’s common stock, at an exercise price of \$10.9847 per share, with a term of 10 years from the issuance date. The Warrant contains customary share adjustment provisions, as well as weighted average price protection in certain circumstances.

As of the date of these financial statements, the Company believes it has sufficient cash reserves to fund operations for the next 12-months. If the Company is unable to raise capital in the future, the Company may need to curtail expenditures by scaling back certain research and development or other programs.

Financing Activities

On March 1, 2021, the Company completed an underwritten offering of its common stock for gross proceeds of approximately \$69.1 million. AVITA Medical has benefited from cash inflows from the BARDA contract. We entered into the contract on September 29, 2015, and the scope has expanded through a number of amendments to the contract. The current contract period continues to December 31, 2023, with the option by BARDA to terminate earlier. The contract provided funding for the development of the RECELL System.

On April 14, 2023, the Company entered into a Sales Agreement with Cowen and Company, LLC pursuant to which the Company may sell from time-to-time up to 3,799,164 shares of its common stock (the “**2023 ATM Program**”). During the quarter ended September 30, 2023, the Company did not make any sales under the 2023 ATM Program.

On October 18, 2023, as discussed above, the Company closed a credit agreement with the Lender for an aggregate amount up to \$90.0 million dollars. On the closing date of the agreement the Company drew \$40.0 million dollars.

On October 18, 2023, as discussed above, the Company issued to an affiliate of the Lender a warrant to purchase up to 409,661 shares of the Company’s common stock, at an exercise price of \$10.9847 per share, with a term of 10 years from the issuance date.

Given the above, we believe there is presently sufficient working capital to support our committed activities, our research and development programs and other activities over the next twelve months.

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

(In thousands)	Nine-Months Ended	
	September 30, 2023	September 30, 2022
Net cash used in operations	\$ (27,148)	\$ (15,654)
Net cash provided by/(used in) investing activities	58,911	(16,174)
Net cash provided by financing activities	942	1
Effect of foreign exchange rate on cash and cash equivalents	(15)	(70)
Net increase/(decrease) in cash and cash equivalents	32,690	(31,897)
Cash and cash equivalents at beginning of the period	18,164	55,712
Cash and cash equivalents at end of the period	50,854	23,815

Net cash used in operating activities was \$27.1 million and \$15.7 million during the nine-months ended September 30, 2023, and 2022, respectively. The increase in net cash used in operations was primarily due to higher operating costs and increased inventory build as part of the FTSD launch, partially offset by increased revenues.

Net cash provided by investing activities was \$58.9 million and net cash used in investing was \$16.2 million during the nine-months ended September 30, 2023 and 2022, respectively. The increase in cash provided by investing activities is primarily attributable to our maturities of marketable securities, whereas in the prior year we purchased marketable securities.

Net cash provided by financing activities was \$0.9 million and \$1 thousand during the nine-months ended September 30, 2023, and 2022, respectively. The increase 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 the Company. We regularly review the Company's capital structure and seek to take advantage of available opportunities to improve outcomes for the Company and its stockholders.

For the nine-months ended September 30, 2023, there were no dividends paid and we have no plans to commence the payment of dividends. We have no purchase commitments or long-term contractual obligations or purchase commitments, except for lease obligations as of September 30, 2023. Refer to Note 6 of our Consolidated Financial Statements for further details on our lease obligations. In addition, we have no off-balance sheet arrangements (as defined in the rules and regulations of the SEC) that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors. We have no committed plans to issue further shares on the market but will continue to assess market conditions.

Critical Accounting Estimates

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 Company's Annual Report on Form 10-K for the year-ended December 31, 2022.

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 September 30, 2023, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures, as defined in Securities Exchange Act Rule 13a-15(e) and 15d-15(e), were effective.

Our disclosure controls and procedures have been formulated to ensure (i) that information that we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) that the 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 was no change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the third quarter of fiscal year 2023 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 pending 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 and legal actions arising in the ordinary course of business from time to time.

Item 1A. RISK FACTORS

In addition to the risk factors set forth below and the other information set forth in this report, you should carefully consider the factors discussed under Part I, Item 1A, "Risk Factors" in the Company's Annual Report on Form 10-K for the year-ended December 31, 2022 (the "2022 Annual Report") and as updated 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. Except as disclosed below, there have been no material changes to the risk factors described in Part I, Item 1A, "Risk Factors," included in our 2022 Annual Report.

The Company's cash, cash equivalents and marketable securities could be adversely affected by bank failures or other events affecting financial institutions and could adversely affect our liquidity and financial performance.

We regularly maintain domestic cash deposits in Federal Deposit Insurance Corporation ("FDIC") insured banks, which exceed the FDIC insurance limits. We also maintain cash deposits in foreign banks where we operate, some of which are not insured or are only partially insured by the FDIC or other similar agencies. The failure or rumored failure of a bank, or events involving limited liquidity, defaults, non-performance, bankruptcy, receivership or other adverse developments in the financial or credit markets impacting financial institutions, may lead to disruptions in access to our bank deposits. These disruptions may adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. or applicable foreign government, or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a failure or liquidity crisis. As such, those funds in bank deposit accounts in excess of the standard FDIC insurance limits are uninsured and subject to the risk of bank failure.

Currently, the Company has full access to all funds in deposit accounts or other money management arrangements. The failure of any bank in which the Company deposits its funds could reduce the amount of cash the Company has available for its operations or delay its ability to access such funds. In the event of such failure, the Company may experience delays or other issues in meeting its financial obligations, the Company's ability to access its cash and cash equivalents may be threatened and could have a material adverse effect on the Company's business and financial condition.

Future adverse developments with respect to specific financial institutions or the broader financial services industry may also lead to market-wide liquidity shortages.

Development and commercialization of our products require successful completion of the regulatory approval process and any delays or failures in obtaining regulatory approvals for improvements to or expanded indications for our current offerings, could prevent, delay or adversely impact commercialization of our products.

In the United States, as well as other jurisdictions, we have been and will be required to apply for and receive regulatory authorization before we can market our products. For instance, our RECELL System has been approved by the U.S. Food and Drug Administration and regulatory authorities in Australia, the EU and Japan for use in certain treatments of burns, acute wounds, scars and vitiligo. However, we will require additional clinical data or approvals from regulatory authorities within these countries to market the product for the treatment of other indications, and from any other jurisdictions in which we seek to market the product. This process can be time-consuming and complicated and may be unsuccessful or otherwise result in unanticipated delays or fail altogether. To secure marketing authorization, an applicant generally is required to submit an application that includes the data supporting preclinical and clinical safety and effectiveness as well as detailed information on the manufacturing and control of the product, proposed labeling and other additional information. Before marketing authorization is granted, regulatory authorities may require the inspection of the manufacturing facility or facilities and quality systems (including those of third parties) at which the product candidate is manufactured and tested, as well as potential audits of the non-clinical and clinical trial sites that generated the data cited in the marketing authorization application.

We cannot predict whether any additional marketing authorizations will ultimately be granted or how long the applicable regulatory authority or agency will take to do so. Regulatory agencies, including the FDA, have substantial discretion in the approval process. In addition, the approval process and the requirements governing clinical trials vary from country to country. The policies of the FDA or other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay the necessary approval of any products we may develop and commercialize. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are slow or unable to adapt to new or changed requirements, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Additionally, any future regulatory approvals that we receive may also contain requirements for costly post-marketing testing and surveillance to monitor the safety and effectiveness of the product. Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and record keeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post-marketing reports, registration, and continued compliance with good manufacturing practices for any clinical trials that we conduct post-approval.

Finally, per FDA regulations, changes made to products, specifications, or test data evaluation methodology would generally require communication with the FDA. There are several pathways for communicating with the FDA of such changes. As part of such review, the FDA may request additional information, at which time the product may become temporarily unavailable.

Certain of our products are dependent on specialized sources of supply potentially subject to disruption which could have a material, adverse impact on our business.

Due to the cost and regulatory requirements associated with qualifying multiple suppliers, in the prior year we single-sourced some of our material components. To the extent that any of these single sourced suppliers experienced disruptions in deliveries due to production, quality, or other issues, we were potentially subject to similar production delays or unfavorable cost increases. In the current quarter, we invested resources in obtaining additional suppliers for some of our key raw materials.

Servicing our debt requires a significant amount of cash and we are subject to a number of restrictive covenants relating to our indebtedness, which may restrict our business and financing activities.

Pursuant to the Credit Agreement that the Company entered with OrbiMed Advisors, LLC, we have incurred \$40.0 million of indebtedness secured by substantially all of our assets, and have the ability to potentially incur an additional \$50.0 million of indebtedness. This level of debt could have significant consequences on future operations, including increasing our vulnerability to adverse economic and industry conditions and limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete.

Our ability to make scheduled payments of interest depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt in cash and make necessary capital expenditures. In addition, if the Company's net revenue does not equal or exceed a certain amount for upcoming fiscal periods as set forth in the Credit Agreement, then the Company will be required to repay in equal quarterly installments of five percent of the outstanding principal amount of its indebtedness along with a repayment fee and a prepayment fee.

If we are unable to generate sufficient cash flow to satisfy payment obligations under the Credit Agreement, we may be required to adopt one or more alternatives, such as obtaining additional equity capital on terms that may be onerous or highly dilutive. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

The restrictions and covenants in the Credit Agreement may also prevent us from taking actions that we believe would be in the best interests of our business, and may make it difficult for us to successfully execute our business strategy or effectively compete with companies that are not similarly restricted. Our ability to comply with these covenants in future periods will largely depend on the success of our products, and our ability to successfully implement our overall business strategy. We cannot assure you that we will be granted waivers or amendments to restrictions and covenants in the agreements. The breach of any of these covenants and restrictions could result in a default under the Credit Agreement, which could result in an acceleration the repayment of our indebtedness.

Our stock price may be volatile and purchasers of our securities could incur substantial losses.

Our stock price has been volatile. The market price for our common stock may be influenced by many factors, including the other risks described in our Annual Report on Form 10-K for the year ended December 31, 2022, subsequently filed Quarterly Reports on Form 10-Q, additional SEC filings we incorporate by reference herein and the following:

- actual or expected fluctuations in our operating results;
- actual or expected changes in our growth rates or our competitors' growth rates;
- results of clinical trials of our product candidates;
- results of clinical trials of our competitors' products and announcements by competitors of related regulatory approvals;
- our ability to expand our sales organization to address effectively existing and new markets that we intend to target;
- regulatory actions with respect to our products or our competitors' products;
- reports of one or more patient serious adverse events;
- publication of research reports by securities analysts about us or our competitors in the industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- the impact of inflation, interest rates and the war in Ukraine, as well as other global economic and social events on the capital markets and equity share prices;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- issuances by us of debt or equity securities;
- litigation involving our company, including shareholder litigation;
- investigations or audits by regulators into the operations of our company;
- proceedings initiated by our competitors or clients;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- sales or perceived potential sales of the common stock or CDIs by us, our directors, senior management or our stockholders in the future;
- short selling or other market manipulation activities;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks;
- our inability to raise additional capital;
- changes in market prices for our product or for our raw materials;
- changes in market valuations of similar companies;
- changes in key personnel for us or our competitors;
- speculation in the press or investment community;
- changes or proposed changes in laws and regulations affecting our industry; and
- conditions in the financial markets in general or changes in general economic conditions, including inflationary pressures on the U.S. and global economy and rising interest rates.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of the issuer. Furthermore, the trading price of our common stock may be adversely affected by third parties trying to drive down the market price. Short sellers and others, some of whom post anonymously on social media, may be positioned to profit if our stock declines and their activities can negatively affect our stock price. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

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	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K12B filed on June 30, 2020)
3.2	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)
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 of the registrant's Form 10-KT filed on February 28, 2022)
4.1	Warrant Certificate, dated October 18, 2023, by and between the Company, and OrbiMed Royalty & Credit Opportunities IV, LP (incorporated by reference to Exhibit 4.1 of the registrant's Form 8-K filed on October 18, 2023)
10.1	Credit Agreement, dated October 18, 2023, by and between the Company, as borrower, and ORCO IV LLC as lender and administrative agent (incorporated by reference to Exhibit 10.1 of the registrant's Form 8-K filed on October 18, 2023)
10.2	Pledge and Security Agreement, dated October 18, 2023, by and among the Company, the guarantors party thereto and ORCO IV LLC (incorporated by reference to Exhibit 10.2 of the registrant's Form 8-K filed on October 18, 2023)
31.1*	Rule 13a-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a) Certification of Chief Financial Officer
32**	18 U.S.C. Section 1350 Certifications
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
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: November 9, 2023

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)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Corbett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVITA Medical, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ James Corbett
Name: James Corbett
Title: President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David O'Toole, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVITA Medical, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared.
 - b) designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ David O'Toole
Name: David O'Toole
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), each of the undersigned officers of AVITA Medical, Inc. (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the period ended September 30, 2023 of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2023

/s/ James Corbett

Name: James Corbett
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 9, 2023

/s/ David O'Toole

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

These certifications are furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certifications will not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates them by reference.
