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DELTA REPORT

10-Q

RCEL - AVITA MEDICAL, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS 1893

 **CHANGES** 179

 **DELETIONS** 707

 **ADDITIONS** 1007

**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, March 31, 2023 2024**

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
Common Stock, par value \$0.0001 per share	RCEL	The Nasdaq Stock Market LLC

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

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

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

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

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

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

The number of shares of the registrant's common stock, par value \$0.0001, outstanding as of November 6, 2023 May 6, 2024 was
25,550,694 25,799,735

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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)

ASSETS	As of		As of	
	Septe mber 30, 2023	Decem ber 31, 2022	March 31, 2024	December 31, 2023
			(unaudited)	(audited)
Cash and cash equivalents	50,85	18,16	\$ 4	\$ 22,118
Marketable securities		61,17	9,264	51,232
Accounts receivable, net	5,875	3,515		7,081
BARDA receivables	201	898		28
Prepays and other current assets	3,356	1,578	3,523	1,659

Inventory	4,377	2,125	7,171	5,596
Total current assets	73,92	87,45		
	7	8	85,986	104,006
Marketable securities long-term	-	6,930		
Plant and equipment, net	1,862	1,200	4,297	1,877
Operating lease right-of-use assets	2,607	851	3,275	2,440
Corporate-owned life insurance ("COLI") asset	1,923	1,238	2,880	2,475
Intangible assets, net	459	465	542	487
Other long-term assets	236	122	401	355
Total assets	81,01	98,26		
	\$ 4	\$ 4	\$ 97,381	\$ 111,640
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN				
SHARE AWARDS AND STOCKHOLDERS' EQUITY				
Accounts payable and accrued liabilities	3,019	3,002	4,477	3,793
Accrued wages and fringe benefits	7,143	6,623	5,803	7,972
Current non-qualified deferred compensation liability	333	78		
Current non-qualified deferred compensation ("NQDC") liability			429	168
Other current liabilities	1,341	990	1,153	1,266
Total current liabilities	11,83	10,69		
	6	3	11,862	13,199
Long-term debt			41,301	39,812
Non-qualified deferred compensation liability	3,361	1,270	3,913	3,663
Contract liabilities	365	698	349	357
Operating lease liabilities, long term	1,845	306	2,532	1,702
Warrant liability			4,028	3,158
Total liabilities	17,40	12,96		
	7	7	63,985	61,891
Non-qualified deferred compensation plan share awards	629	557	827	693
Commitments and contingencies (Note 12)				
Commitments and contingencies (Note 13)				
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")	(1,29 0)	(127)	
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 25,789,051 and 25,682,078, shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			3
Preferred stock, \$0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at March 31, 2024 and December 31, 2023			-
Company common stock held by the non-qualified deferred compensation plan		(944)	(1,130)
Additional paid-in capital	347,1 92	339,8 25	
			353,205
Accumulated other comprehensive income	7,977	7,627	
Accumulated other comprehensive loss			(3,068)
Accumulated deficit	(290, 904)	(262, 588)	
			(316,627)
Total stockholders' equity	62,97 8 \$ 4	84,74 0 \$ 4	
			32,569
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	81,01 \$ 4	98,26 \$ 4	
			\$ 97,381
			\$ 111,640

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		Nine-Months		Three-Months Ended	
	Ended		Ended			
	Septe mber 30, 2023	Septe mber 30, 2022	Septe mber 30, 2023	Septe mber 30, 2022		
Revenues	13,64		35,94		March 31, 2024	
	\$ 5	\$ 9,092	\$ 8	\$ 6	\$ 11,104	
Cost of sales	(2,113)		(1,530)		(1,513)	
Gross profit	11,53		29,96		20,27	
	2	7,562	4	2	9,591	
BARDA income	212	904	1,369	2,189	-	
Operating expenses:					627	
Sales and marketing	(10,5		(27,0		(15,5	
expenses	32)	(5,411)	75)	71)		
General and administrative			(20,5		(18,0	
expenses	(6,124)	(5,004)	84)	09)		
Research and development			(14,0		(10,4	
expenses	(4,394)	(3,799)	56)	78)		
Sales and marketing					(12,640)	
General and administrative					(8,963)	
Research and development					(5,194)	
Total operating expenses	(21,0	(14,2	(61,7	(44,0	(4,586)	
	50)	14)	15)	58)	(19,421)	

Operating loss	(30,3	(21,5				
	(9,306)	(5,748)	82)	97)		
Interest expense	(10)	(6)	(21)	(10)		
Other income	615	170	2,141	307		
Other income (expense), net					(66)	725
Loss before income taxes		(28,2	(21,3			
	(8,701)	(5,584)	62)	00)		
Income tax expense	(11)	(4)	(54)	(12)		
Net loss		(28,3	(21,3			
	\$ (8,712)	\$ (5,588)	\$ 16)	\$ 12)		
Net loss per common share:					\$ (18,658)	\$ (9,220)
Basic and						
Diluted	\$ (0.34)	\$ (0.22)	\$ (1.12)	\$ (0.85)	\$ (0.73)	\$ (0.37)
Weighted- average common shares:						
Basic and	25,40	25,00	25,28	24,97		
Diluted	1,754	6,995	1,920	2,331	25,637,783	25,202,088

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

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

Three-Months Ended	Nine-Months Ended	Three-Months Ended
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	Septe mber 30, 2023	Septe mber 30, 2022	Septe mber 30, 2023	Septe mber 30, 2022	March 31, 2024	March 31, 2023
Net loss	(8,71	(5,58	(28,3	(21,3	\$ (18,658)	\$ (9,220)
Foreign currency translation loss	\$ 2)	\$ 8)	\$ 16)	\$ 12)	-	(11)
Change in fair value due to credit risk on Long-term debt					(1,092)	-
Net unrealized gain/(loss) on marketable securities, net of tax	65	(90)	407	(522)	(89)	242
Comprehensive loss	(8,69	(5,77	(27,9	(22,0	\$ (19,839)	\$ (8,989)
	\$ 4)	\$ 4)	\$ 66)	\$ 22)		

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

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

Three-Months Ended September 30, 2023

Common Stock

	Shares	Amou	Company	Additional	Accumulated	Accumulat	Total
	nt	nt	common	Paid-in	Other	ed	Stockholde
			stock held by	Capital	Comprehensive	Deficit	rs'
Plan							
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	17,221	-	-	110	-	-	110
Vesting of restricted stock units	45,336	-	-	-	-	-	-
Company common stock held by the NQDC Plan	40,522	-	(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	Additional	Other	Accumulated	ed	Total	Stockholde
	Amou	the NQDC	Paid-in	Comprehensive	Deficit		
	Shares	Plan	Capital	Gain (Loss)		Equity	
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	17,927	-	(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

Common Stock								
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Other Comprehensi ve Gain (Loss)	Accumul ated Deficit	Total Stockhol ders' Equity	
Balance at December 31, 2023	25,682,07					(297,96		
	8	\$ 3	\$ (1,130)	\$ 350,039	\$ (1,887)	\$ 9)	\$ 49,056	
Net loss	-	-	-	-	-	(18,658)	(18,658)	
Stock-based compensation	-	-	-	2,585	-	-	2,585	
Exercise of stock options	106,973	-	-	631	-	-	631	
Distribution/diversification of Company common stock held by the NQDC Plan	-	-	186	78	-	-	264	
Change in redemption value of share awards in NQDC plan	-	-	-	(128)	-	-	(128)	
Net unrealized loss on marketable securities	-	-	-	-	(89)	-	(89)	
Change in fair value due to credit risk on Long-term debt	-	-	-	-	(1,092)	-	(1,092)	
Balance at March 31, 2024	25,789,05				(316,62			
	1	\$ 3	\$ (944)	\$ 353,205	\$ (3,068)	\$ 7)	\$ 32,569	

Nine-Months Ended September 30, 2023								
Common Stock								
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Other Comprehensive Gain (Loss)	Accumulat ed Deficit	Total Stockhol ders' Equity	
Balance at December 31, 2022	25,208,436	\$ 3	\$ (127)	\$ 339,825	\$ 7,627	\$ (262,588)	\$ 84,740	
Net loss	-	-	-	-	-	(28,316)	(28,316)	
Stock-based compensation	-	-	-	5,738	-	-	5,738	
Exercise of stock options	163,750	-	-	942	-	-	942	
Company common stock held by the NQDC Plan	128,172	-	(1,401)	1,401	-	-	-	
Vesting of restricted stock units	50,336	-	-	-	-	-	-	

Distribution of Company common stock held by	-	-	238	284	-	-	522
the NQDC Plan							
Change in redemption value of share awards in							
NQDC plan	-	-	-	(998)	-	-	(998)
Other comprehensive gain	-	-	-	-	350	-	350
Balance at September 30, 2023	25,550,694	\$ 3	\$ (1,290)	\$ 347,192	\$ 7,977	\$ (290,904)	\$ 62,978

Nine-Months Ended September 30, 2022		Common Stock						Total Stockholders' Equity
		Shares	Amount	held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	
Comm on Stock	Acc um ulat ed Oth Ad er Tot diti Co al Compa ona mpr Ac Sto ny I ehe cu ck commo Pai nsi mu hol n stock d- ve lat der S A held by in Gai ed s' ha m the Ca n De Eq re ou NQDC pita (Lo fici uit s nt Plan I ss) t y							

Balance at	2							
December 31,	4							
2021	,							
	9							
		(
	2	3	2	1				
	5	3	3	0				
	,	2,	5,	4,				
	7	4	8,	9	6			
	4	8	06	2	2			
	3	\$3	\$	-	\$4	\$0	\$3)	\$4
	=====							

Balance at								
December 31,								
2022								
Net loss								
		(
			2	(2				
				1,	1,			
				3	3			
				1	1			
				-	-	-	-	(9,220)
				2)	2)			(9,220)
Stock-based								
compensation								
				5,	5,			
				4	4			
				9	9			
				-	-	-	-	2,197
Exercise of								
stock options								
1								
2								
5	-	-	1	-	-	1		
					31,675			
Vesting of								
restricted stock								
units								
,								
1								
0								
7	-	-	-	-	-	-	-	-

Company	1														
common stock	7														
held by the	,														
NQDC Plan	9	1													
	2	2													
	7	-	(127)	7	-	-	-	87,650	-	(765)	765	-	-	-	-
Change in															
classification of															
deferred			(1					(1							
compensation			9					9							
share awards		-	-	-	2)	-	-	2)							
Change in															
redemption															
value of share															
awards in			8					8							
NQDC plan		-	-	-	0	-	-	0		-	-	-	(558)	-	(558)
Other								(7							
comprehensive								(7					1		
loss		-	-	-	-	10)	-	0)							
Balance at	2														
September 30, 2022	,														
	0							(
	3		3					2							
	0		3					5					8		
	,		7,					7,					7,		
	9		9		7,			2					9		
	0		9		35			3					8		
	2	\$	3	\$	(127)	\$	5	\$	0	\$	5)	\$	6		
Other															
comprehensive															
gain													231		
Balance at	231														
March 31, 2023	25,327,761	\$	3	\$	(892)	\$	342,400	\$	7,858	\$	(271,808)	\$	77,561		

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		Three-Months Ended	
	September 30, 2023	September 30, 2022	March 31, 2024	March 31, 2023
	\$	\$	\$	\$
Cash flow from operating activities:				
Net loss	\$ (28,316)	\$ (21,312)	\$ (18,658)	\$ (9,220)
Adjustments to reconcile net loss to net cash used in operating activities:				
Change in fair value of long-term debt			397	-
Change in fair value of warrant liability			870	-
Depreciation and amortization	445	438	203	135
Stock-based compensation	6,213	5,782	2,591	2,640
Non-cash lease expense	531	515	214	167
Loss on fixed asset disposal	83	3		
Investment losses	17	-		
Patent impairment loss	4	-		
Remeasurement and foreign currency transaction gain	(23)	(121)	-	(2)
Excess and obsolete inventory related charges	149	284	83	67
BARDA deferred costs	(147)	(12)	-	(64)
Contract cost amortization	255	253	-	85
Provision for doubtful accounts	113	10		
Provision for credit losses			80	172
Amortization of premium of marketable securities	(794)	(12)	(677)	(328)
Non-cash changes in the fair value of NQDC plan	899	(5)	278	610
Changes in operating assets and liabilities:				

Trade and other receivables	(2,473)	(449)	503	(1,158)
BARDA receivables	697	(484)	2	382
Prepays and other current assets	(2,057)	168	(1,864)	12
Inventory	(2,405)	(119)	(1,659)	(754)
Operating lease liability	(571)	(531)	(224)	(156)
Corporate-owned life insurance asset	(643)	(840)		
Corporate-owned life insurance ("COLI") asset			(215)	(526)
Other long-term assets	(114)	(163)	(46)	(109)
Accounts payable and accrued expenses	(70)	433	(763)	778
Accrued wages and fringe benefits	524	(570)	(2,170)	(2,957)
Current non-qualified deferred compensation liability	(651)	-	473	748
Other current liabilities	345	511	(109)	958
Non-qualified deferred compensation plan liability	1,174	829	(165)	(237)
Contract liabilities	(333)	(212)	(8)	(316)
Other long-term liabilities	-	(50)		
Net cash used in operations	(27,148)	(15,654)	\$ (20,864)	\$ (9,073)
Cash flows from investing activities:				
Purchase of marketable securities	(7,633)	(59,408)	(2,904)	(5,183)
Sale of marketable securities	2,372	-		
Maturities of marketable securities	65,289	43,669	19,200	24,271
Purchase of plant and equipment	(1,085)	(382)	(1,147)	(284)
Patent filing fees	(32)	(53)	(83)	(17)
Net cash provided by/(used in) investing activities	58,911	(16,174)		
Net cash provided by investing activities			\$ 15,066	\$ 18,787
Cash flow from financing activities:				
Proceeds from exercise of stock options	942	1	631	171
Net cash provided by financing activities	942	1	\$ 631	\$ 171
Effect of foreign exchange rate on cash and cash equivalents	(15)	(70)	-	1
Net increase/(decrease) in cash and cash equivalents	32,690	(31,897)	(5,167)	9,886
Cash and cash equivalents beginning of the period	18,164	55,712	\$ 22,118	\$ 18,164
Cash and cash equivalents end of the period	<u>\$ 50,854</u>	<u>\$ 23,815</u>	<u>\$ 16,951</u>	<u>\$ 28,050</u>
Supplemental Disclosure of Cash Flow Information				
Supplemental Disclosure of Cash Flow Information:				

Income taxes paid during the period	\$ 44	\$ 17	\$ 17	\$ 9
Interest paid during the period	\$ 21	\$ 10	\$ 1,355	\$ 4
Non-cash investing activities:				
Plant and equipment purchases not yet paid	\$ 114	\$ 7	\$ 74	\$ 9
Right-of-use-asset obtained in exchange for lease liabilities			\$ 1,053	\$ -

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

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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" "AVITA Medical", "we", "our", "us", or "Company" "Company"), is a commercial-stage regenerative medicine company leading transforming the development standard of care in wound management and commercialization skin restoration with innovative devices. At the forefront of devices the Company's portfolio is its patented and autologous cellular therapies proprietary RECELL® System ("RECELL System" or "RECELL"), approved by the FDA for the treatment of thermal burn wounds and full-thickness skin restoration. The Company's RECELL® System technology platform defects ("FTSD"), and for repigmentation of stable depigmented vitiligo lesions. RECELL harnesses the regenerative properties of a patient's own skin to create an autologous skin cell suspension, Spray-On Skin™ cells. In September 2018, Skin™ Cells, delivering a transformative solution at the point of care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes.

On January 10, 2024, the Company entered into an exclusive multi-year distribution agreement with Stedical Scientific, Inc.

("Stedical") to commercialize PermeaDerm® Biosynthetic Wound Matrix ("PermeaDerm") in the United States Food & Drug Administration ("FDA") (the "Stedical Agreement") granted premarket approval ("PMA") to. PermeaDerm is cleared by the

RECELL System FDA as a transparent matrix for use in the treatment of acute thermal burns in patients eighteen years and older. Following receipt a variety 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 wound types until healing 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, Company holds the exclusive rights to market, sell, and COSMOTEC will be distribute PermeaDerm products, including any future enhancements or modifications, within the sole distributor of United States. The initial term is for five years, with the product in Japan. The Company worked with COSMOTEC option to advance its application renew for approval of the RECELL System in Japan pursuant to Japan's Pharmaceuticals and Medical Devices Act ("an additional PMDA five years"). 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, contingent upon meeting certain minimum requirements.

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

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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** **December 31, 2023** filed with the SEC on **February 23, 2023** **February 22, 2024** and the Australian Securities Exchange ("ASX") on **February 24, 2023** **February 23, 2024** (the "Annual" "2023 Annual Report").

There have been no changes to the Company's significant accounting policies as described in the **2023** 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 **2023** 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 COSMOTECH sales from the United States to Japan.

Recent Accounting Pronouncements

In **October** **November** 2023, the Financial Accounting Standards Board ("FASB issued ASU 2023-07, SFASBegement Reporting (Topic 280): Improvements to Reportable Segment Disclosures." The ASU expands public entities' segment

disclosures by requiring disclosure of significant segment expenses that are regularly reviewed by the Chief Operating Decision Maker ("CODM") issued Accounting Standards Update ("ASU") 2023-06 which amends and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The ASU also allows, in addition to the measure that is most consistent with GAAP, the disclosure of additional measures of segment profit or presentation loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. All disclosure requirements related to various subtopics in under ASU2023-07 are also required for public entities with a single reportable segment. The ASU is effective for the FASB ASC. The amendments in ASU 2023-06 modify Company's 2023 Annual Report on Form 10-K for 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, fiscal year ending December 31, 2025, and subsequent interim periods, 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. permitted. The Company is currently evaluating the provisions impact of the amendments and the impact adopting this ASU on its future consolidated statements. financial statements and disclosures.

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In July December 2023, the SEC adopted the final rule under SEC Release No. 33-11216, "Cybersecurity FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. RiskManagement, 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 amendments require (i) enhanced disclosures in Form 10-K pertaining to (1) cybersecurity risk management connection with an entity's effective tax rate reconciliation 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. (ii) income taxes paid disaggregated by jurisdiction. The Form 10-K disclosures will be due amendments are effective for annual periods 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 December 15, 2024. The Company will comply with is currently evaluating the disclosure requirements set forth in the final rule as each becomes effective.impact of adopting this ASU on its consolidated financial statements and disclosures.

Use of Estimates

The preparation of the accompanying Consolidated Financial Statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts (including **doubtful accounts, estimate of the average selling price for PermeaDerm sales, allowance for credit losses, reserves for inventory excess and obsolescence, carrying value of long-lived assets, the useful lives of long-lived assets, accounting for marketable securities, income taxes, fair value of the debt, fair value of warrants and stock-based compensation, estimated credit losses, and the stand-alone selling price for the Biomedical Advanced Research and Development Authority ("BARDA") contract) compensation**) 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

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comprehensive gain (loss) in Stockholders' Equity. Gains and losses resulting from foreign currency transactions are included in **General and administrative expenses** **earnings** in the Consolidated Statement of Operations. Gains and losses resulting from foreign currency transactions were a gain of \$27,000 and \$76,000 **minimal** for the three-months ended **September 30, 2023** **March 31, 2024** 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. **2023**.

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** **earnings** in the Consolidated Statement of Operations. **During** **Gains and losses for remeasurement and foreign currency transactions were minimal during** the three-months ended **September 30, 2023** **March 31, 2024** 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. **2023**.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash held at deposit institutions and cash equivalents. Cash equivalents consist primarily of **money market funds**. Cash equivalents also includes 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** **purchase**. The Company holds cash at deposit institutions in the amount of \$4.4 **4.9** million and \$4.1 **10.7** million as of **March 31, 2024** and **December 31, 2023**, respectively. The Company does not have cash on deposit denominated in foreign currency in foreign institutions as

of March 31, 2024. As of December 31, 2023, the Company had \$660,000 69,000 and \$737,000 is of cash on deposit denominated in foreign currencies in foreign institutions as of September 30, 2023 and December 31, 2022, respectively. As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, the Company held cash equivalents in the amount of \$46.4 12.0 million and \$14.1 11.4 million, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, trade receivables and debt and other receivables. As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, substantially all of the Company's cash was deposited in accounts at financial institutions, and amounts may exceed federally insured limits and are subject to the risk of bank failure.

As of September 30, 2023 March 31, 2024 and December 31, 2023, no single commercial customer accounted for more than 10% of net accounts receivable. As of December 31, 2022, one commercial customer accounted for receivable or more than 10% of total net accounts receivable. For revenues for the three-months ended March 31, 2024 and nine-months ended September 30, 2023 and 2022, no single customer accounted for more than 10% of revenues. 2023.

Employee Stock Purchase Plan ("ESPP") 10

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:

(in thousands)	As of September 30, 2023				As of March 31, 2024			
	Gross		Gross		Gross		Gross	
	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized
	Amortized	Holding	Holding	Carrying	Amortized	Holding	Holding	Carrying
	ed	g	g	g	Cost	Gains	Losses	Value
	Cost	Gains	Losses	Value	Cost	Gains	Losses	Value
Cash equivalents:								
Money market funds	46,4			46,4				
	\$ 31	\$ -	\$ -	\$ 31	\$ 12,018	\$ -	\$ -	\$ 12,018
	46,4			46,4				
Total cash equivalents	<u>\$ 31</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 31</u>	<u>\$ 12,018</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 12,018</u>
Current marketable securities:								
U.S. Treasury securities	5,45			5,44				
	\$ 1	\$ 3	\$ (14)	\$ 0	\$ 51,225	\$ 11	\$ (4)	\$ 51,232
	1,59			1,58				
Commercial paper	3	-	(5)	8				
Corporate debt securities	550	-	-	550				
U.S. Government agency obligations	1,69			1,68				
	0	-	(4)	6				
Total current marketable securities	<u>9,28</u>			<u>9,26</u>				
	<u>\$ 4</u>	<u>\$ 3</u>	<u>\$ (23)</u>	<u>\$ 4</u>	<u>\$ 51,225</u>	<u>\$ 11</u>	<u>\$ (4)</u>	<u>\$ 51,232</u>

(in thousands)	As of December 31, 2022				As of December 31, 2023			
	Gross		Gross		Gross		Gross	
	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized
	Amortized	Holding	Holding	Carrying	Amortized	Holding	Holding	Carrying
	ed	g	g	g	Cost	Gains	Losses	Value
	Cost	Gains	Losses	Value	Cost	Gains	Losses	Value
Cash equivalents:								
Money market funds	46,4			46,4				
	\$ 31	\$ -	\$ -	\$ 31	\$ 12,018	\$ -	\$ -	\$ 12,018
	46,4			46,4				
Total cash equivalents	<u>\$ 31</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 31</u>	<u>\$ 12,018</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 12,018</u>
Current marketable securities:								
U.S. Treasury securities	5,45			5,44				
	\$ 1	\$ 3	\$ (14)	\$ 0	\$ 51,225	\$ 11	\$ (4)	\$ 51,232
	1,59			1,58				
Commercial paper	3	-	(5)	8				
Corporate debt securities	550	-	-	550				
U.S. Government agency obligations	1,69			1,68				
	0	-	(4)	6				
Total current marketable securities	<u>9,28</u>			<u>9,26</u>				
	<u>\$ 4</u>	<u>\$ 3</u>	<u>\$ (23)</u>	<u>\$ 4</u>	<u>\$ 51,225</u>	<u>\$ 11</u>	<u>\$ (4)</u>	<u>\$ 51,232</u>

Cash equivalents:		14,0				14,0							
Money market funds		\$ 89	\$ -	\$ -	\$ 89	\$ 8,427	\$ -	\$ -	\$ 8,427				
U.S. Treasury securities						2,992							
Total cash equivalents		\$ 89	\$ -	\$ -	\$ 89	\$ 11,419	\$ -	\$ -	\$ 11,419				
Current marketable securities:													
U.S. Treasury securities		\$ 92	\$ 1	\$ (393)	\$ 00	\$ 65,145	\$ 100	\$ (3)	\$ 65,242				
Commercial paper		12,7				12,7							
Corporate debt securities		43				43							
U.S. Government agency obligations		3,86				3,84							
Total current marketable securities		\$ 01	\$ 1	\$ (424)	\$ 78	\$ 66,844	\$ 100	\$ (5)	\$ 66,939				
Long-term marketable securities:													
Asset backed securities		\$ 8	\$ 7	\$ (3)	\$ 2	3,56				3,57			
U.S. Treasury securities		2,41				2,41							
U.S. Government agency obligations		6				(6)				0			
Total long-term marketable securities		\$ 949	\$ -	(1)	948	6,93	\$ (10)	\$ 0	6,93				

The maturities of debt our available-for-sale 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		As of March 31, 2024		As of December 31, 2023	
	Amortized	Carrying	Amortized	Carrying	Amortized	Carrying	Amortized	Carrying
	ed	g	ed	g	ed	g	ed	g
	Cost	Value	Cost	Value	Cost	Value	Cost	Value

Due in one year or less	\$ 9,284	\$ 9,264	\$ 61,601	\$ 61,178	\$ 51,225	\$ 51,232	\$ 66,844	\$ 66,939
Due after one year through three years	\$ -	\$ -	\$ 3	\$ 0				

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Gross unrealized Unrealized gains and losses, net of any related tax effects for available-for-sale securities are excluded from earnings and are included in other comprehensive loss and reported as a separate component of stockholders' equity until realized. Realized gains and losses on the Company's marketable securities were an are included in Other income (expense), net, in the accompanying Consolidated Statements of Operations. The Company had net unrealized gain gains of \$3,000 7,000 and an unrealized loss of \$23,000 95,000 as of September 30, 2023 March 31, 2024 and December 31, 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 not 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. respectively. The Company did not have sales of investments during the three-months ended March 31, 2024 and nine-months ended September 30, 2022.2023 that resulted in realized gains or losses. As of March 31, 2024, and December 31, 2023, the Company did not recognize credit losses. The Company has accrued interest income receivable of \$228,000 182,000 and \$168,000 227,000 as of September 30, 2023 March 31, 2024, and December 31, 2022 December 31, 2023, respectively, in Prepays and other current assets.

4. Fair Value Measurements

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

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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,				As of March 31, 2024			
	2023		2024		Level 1		Level 2	
	Leve l 1	Lev el 2	Lev el 3	Total	Leve l 1	Lev el 2	Lev el 3	Total
Cash equivalents:								
	46,			46,				
	43			43				
Money market funds	\$ 1	\$ -	\$ -	\$ 1	\$ 12,018	\$ -	\$ -	\$ 12,018
	46,			46,				
	43			43				
Total cash equivalents	\$ 1	\$ -	\$ -	\$ 1	\$ 12,018	\$ -	\$ -	\$ 12,018
Current marketable securities:								
	5,							
	44			5,4				
U.S. Treasury securities	\$ -	\$ 0	\$ -	\$ 40	\$ -	\$ 51,232	\$ -	\$ 51,232
	1,							
	58			1,5				
Commercial paper	-	8	-	88				
	55			55				
Corporate debt securities	-	0	-	0				
	1,							
U.S. Government agency obligations		68		1,6				
	-	6	-	86				

	9,										
Total current marketable securities	26	9,2									
\$ -	\$ 4	\$ -	\$ 64	\$		\$ 51,232	\$		\$	\$ 51,232	
Total marketable securities and cash equivalents	46,43	9,26	55,69								
\$ 1	\$ 4	\$ -	\$ 5	\$ 12,018	\$ 51,232	\$	\$ 63,250	\$	\$	\$ 63,250	
Financial liabilities:											
Long-term debt				\$		\$ 41,301	\$		\$ 41,301		
Warrant liability								\$ 4,028	\$		\$ 4,028
Non-qualified deferred compensation plan liability						\$ 4,342				\$	\$ 4,342
Total financial liabilities				\$		\$ 4,342	\$		\$ 45,329	\$	
											\$ 49,671
Financial assets:											
Corporate-owned life insurance policies				\$		\$ 2,880	\$			\$	\$ 2,880
Total financial assets				\$		\$ 2,880	\$			\$	
											\$ 2,880

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	As of December 31, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 8,427	\$ 8,427	\$ 8,427	\$ 8,427
U.S. Treasury securities				
Total cash equivalents	\$ 8,427	\$ 2,992	\$ 2,992	\$ 11,419
Current marketable securities:				
U.S. Treasury securities				
U.S. Government agency obligations				
Total current marketable securities	\$ 8,427	\$ 65,242	\$ 65,242	\$ 66,939
Total marketable securities and cash equivalents	\$ 8,427	\$ 69,931	\$ 69,931	\$ 78,358
Financial liabilities:				
Long-term debt				
Warrant liability				
Non-qualified deferred compensation plan liability				
Total financial liabilities	\$ 8,427	\$ 3,831	\$ 3,831	\$ 46,801
Financial assets:				

Corporate-owned life insurance policies	\$ -	\$ 2,475	\$ -	\$ 2,475
Total financial assets	\$ -	\$ 2,475	\$ -	\$ 2,475

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

	As of March 31, 2024		As of December 31, 2023	
	Long-term debt	Warrant liability	Long-term debt	Warrant liability
Balance beginning of period	\$ 39,812	\$ 3,158	\$ -	\$ -
Fair value on issuance date			37,575	2,425
Change in fair value in earnings	397	870	1,616	733
Change in fair value in other comprehensive loss	1,092	-	621	-
Balance end of period, at fair value	<u>\$ 41,301</u>	<u>\$ 4,028</u>	<u>\$ 39,812</u>	<u>\$ 3,158</u>

(in thousands)	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
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
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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 Treasury securities and U.S. Government agency obligations, corporate debt securities, asset backed securities and U.S Treasury securities. Agency obligations. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. As The corporate-owned life insurance contracts are recorded at cash surrender value, which approximates the fair value and is categorized as Level 2. Non-qualified deferred compensation plan liability is measured at fair value based on quoted prices of September 30, 2023 identical instruments to the investment vehicles selected by the participants and December 31, 2022, the Company had no investments that were measured using unobservable (Level 3) inputs. its recorded as Level 2. There were no transfers between fair value measurement levels as during the period ended March 31, 2024 and December 31, 2023.

Long-term debt

The fair value of September 30, 2023 the debt was determined using a Monte Carlo Simulation ("MCS") in order to predict the probability of different outcomes. The valuation was performed based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the debt is recorded in the Consolidated Balance Sheets. The fair value is estimated by the Company each reporting period and the change in the fair value is recorded in both earnings and other comprehensive income depending on the instrument's inherent credit risk and market risk related to the debt valuation.

As the debt is subject to net revenue requirements, the valuation of the debt was determined using the Monte Carlo Simulation ("MCS"). The underlying metric to be simulated is the projected Trailing Twelve Month ("TTM") revenues at each quarter end through the maturity date of October 18, 2028. Based on the simulated metric, the different levels of simulated TTM revenues may trigger different discounted cash flow scenarios in which the TTM revenues are lower than the targeted revenues per the Credit Agreement or December 31, 2022. TTM is equal to or higher than the targeted revenues per the Credit Agreement. The MCS performs 100,000 iterations of various simulated revenues to determine the fair value of the debt.

The below assumptions were used in the Monte Carlo simulation

	March 31, 2024	December 31, 2023
Risk-free interest rate	4.20 %	3.81 %
Revenue volatility	64.00 %	64.00 %
Revenue discount rate	16.99 %	16.58 %

Warrant Liability

The fair value of the warrant liability is recognized in connection with the Credit Agreement. The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the warrant liability, which is reported within Warrant liabilities on the Consolidated Balance Sheets, is estimated by the Company based on the Black-Scholes option pricing model with the following key inputs:

	March 31, 2024	December 31, 2023
Price of common stock	\$ 16.03	\$ 13.72

Expected term		9.56 years		9.81 years
Expected volatility		31.39 %		31.07 %
Exercise price	\$	10.9847	\$	10.9847
Risk-free interest rate		4.16 %		3.84 %
Expected dividends		0.00 %		0.00 %

5. Revenues

The Company's revenue consists of sale of the RECELL System to hospitals, treatment centers and COSMOTEC ("commercial distributors. Revenue also includes the sale of PermeaDerm to customers" (collectively "commercial customers") and. Revenue also includes maintenance fee received from BARDA to BARDA (collectively "customers"), predominately in ensure first right of access. In the United States. In addition, prior year, the Company records recorded service revenue for the emergency preparedness services provided to BARDA. BARDA (collectively "customers"). Services are included in Revenues within the Consolidated Statements of Operations.

Distributor Transactions

For international markets, the Company exclusively partners with third-party distributors (COSMOTEC and PolyMedics Innovation GmbH). Revenue recognition occurs when the distributors obtain control of the product. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers and do not contain return rights. These transactions are accounted for in accordance with the Company's revenue recognition policy described in Note 2 of the Company's Annual Report for the year-ended December 31, 2023.

PermeaDerm Sales

As provided in the Stedical Scientific Distribution Agreement, the Company's gross margin from the sale of PermeaDerm will be 50% of the average sales price. The Company and Stedical will split the gross revenue from sale of the products evenly through the purchase of products at 50% of Average Sale Price ("ASP"). The Company recognizes revenue when the customer obtains control of promised goods, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods.

Remaining Performance Obligations

Revenues from remaining performance obligations are calculated as the dollar value of the remaining performance obligations on executed contracts. contracts and relate to COSMOTEC. 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 \$469,000 382,000 and \$698,000 390,000 as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, respectively. Approximately These amounts are split between current and long-term in Other current liabilities and other Contract liabilities, respectively, in the Consolidated Balance Sheets. The Company has \$70,000 33,000 in Other current liabilities as of September 30, 2023 March 31, 2024 and December 31, 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 \$399,000 349,000 and \$424,000 357,000 Contract liabilities as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, respectively, relate to our contract with COSMOTEC. respectively. 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 March 31, 2024 and December 31, 2022 December 31, 2023, the Company does not have any contract assets.

Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer. The Company had \$469,000 382,000 and \$698,000 390,000 of total contract liabilities as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, respectively. As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, a total of \$104,000 33,000 and \$0, respectively, was included in Other current liabilities and \$365,000 349,000 and \$698,000 357,000, 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

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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 approximately \$8,000 and \$25,000 of revenue from COSMOTEC for amounts included in the beginning balance of contract liabilities for the three-months ended March 31, 2024 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. 2023.

Disaggregated Revenue

The Company disaggregates revenue from contracts with customers into geographical regions, by customer type and by customer type. product. 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 and product is provided in Segment Note 11, 12.

6. Long-term debt

On October 18, 2023 ("Closing Date") the Company entered into a 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, of which (i) \$40.0 million

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6. Leases was made available on the Closing Date (the "Initial Commitment Amount"), (ii) \$25.0 million is available, at the Company's discretion, on or prior to December 31, 2024, subject to certain net revenue requirements, and (iii) \$25.0 million is available, at the Company's discretion, on or prior to June 30, 2025, subject to certain net revenue requirements. The maturity date of the agreement is October 18, 2028 ("Maturity Date"). On the Closing date, the Company closed on the Initial Commitment Amount of \$40.0 million, less certain fees and expenses payable to or on behalf of the Lender. The Company received net proceeds of \$38.8 million upon closing after deducting the Lender's transaction costs in connection with the issuance.

All obligations under the Credit Agreement are guaranteed by all of the Company's wholly owned subsidiaries (subject to certain exceptions) and secured by substantially all of the Company's and each guarantor's assets. The loan will be due in full on the Maturity Date unless the Company elects to repay the principal amount at any time prior to the Maturity Date. Upon prepayment, the Company will owe the applicable repayment premium and exit fee of 3% on the principal amount of the loans. The repayment premium varies between 0.0% - 3.0%, depending on certain conditions that are defined in the Credit Agreement. The repayment premium incorporates the make-whole amount. The make-whole amount represents the remaining scheduled interest payments on the loan during the period commencing on the prepayment date through the 24-month anniversary of the closing date. The Credit Agreement further states that the Company will be required to repay the principal amount of the loans if the Company does not achieve certain net revenue thresholds. If, for any quarter until the maturity date, the Company's net revenue does not equal or exceed the applicable trailing twelve-month amount as set forth in the Credit Agreement, then the Company shall repay in equal quarterly installments equal to 5.0% of the outstanding principal amount on the date the net revenue amount was not satisfied, together with a repayment premium and exit fee. The Company shall repay amounts outstanding in full immediately upon an acceleration as a result of an event of default as set forth in the Credit Agreement, together with a repayment premium and other fees. As of March 31, 2024, the Company has not made any repayments on the outstanding debt balance.

During February 2023, the term of the Credit Agreement, interest payable in cash by the Company remeasured shall accrue on any outstanding debt at a rate per annum equal to the greater of (x) the SOFR rate for such period and (y) 4.00% plus, in either case, 8.00%. As of March 31, 2024, the interest rate was 13.33%. During an event of default, any outstanding amount will bear interest at a rate of 4.00% in excess of the otherwise applicable rate of interest. The Company will pay certain fees with respect to the Credit Agreement, including an upfront fee, an unused fee on the undrawn portion of the Loan Facility, an administration fee, a repayment premium and an exit fee, as well as certain other fees and expenses of the Lender. The undrawn fee accrues at 0.5% of the undrawn balance and its recorded as an asset in the Consolidated Balance Sheets.

The Credit Agreement contains certain customary events of default, including with respect to nonpayment of principal, interest, fees or other amounts; material inaccuracy of a representation or warranty; failure to perform or observe covenants; material defaults on other indebtedness; bankruptcy and insolvency events; material monetary judgments; loss of certain key permits, persons and contracts; material adverse effects; certain regulatory matters; and any change of control. As of March 31, 2024, the Company was in compliance with all financial covenants in the Credit Agreement.

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

On the Closing Date, the Company issued to an affiliate of the Lender a warrant (the "Warrant") to purchase up to 409,661 shares of the Company's Common Stock, par value \$0.0001 per share ("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 permitted under ASC 825, *Financial Instruments*, the Company elected the fair value option to record the long-term debt and warrant with changes in fair value recorded in the Consolidated Statements of Operations in Other income (expense), net. Changes related to instrument specific credit risk are revalued by comparing the amount of the total change in fair value of the long-term debt to the amount of change in fair value that would have occurred if the Company's credit spread had not changed between the reporting periods, and is recorded in other comprehensive income in the Consolidated Balance Sheet. The difference between the fair value of the long-term debt and the unpaid principal balance of \$40.0 million is an additional liability of \$1.3 million and reduction to the liability of \$188,000 as of March 31, 2024 and December 31, 2023, respectively. For changes in fair value refer to Note 4.

7. Leases

During January 2024, the Company modified the lease liability for an office lease due agreement of the Ventura production facility to an increase in extend the lease term. As a result of the remeasurement of the lease liability, there was. The modification resulted in 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		Three-Months Ended
	Septe mber 30, 2023	Septe mber 30, 2022	Septe mber 30, 2023	Septe mber 30, 2022	
	Ended	Ended	Ended	Ended	
Oper ating lease cost	\$ 260	\$ 194	\$ 655	\$ 582	March 31, 2024
Varia ble lease cost	28	13	43	38	March 31, 2023
Total lea se cos t	\$ 288	\$ 207	\$ 698	\$ 620	35
					331
					\$ 211

Supplemental cash flow information related to operating leases for the three-months ended March 31, 2024 and nine-months ended September 30, 2023 and 2022 was as follows 2023 (in thousands):

	Three-Months Ended		Nine-Months Ended		Three-Months Ended	
	Septe mber 30, 2023	Septe mber 30, 2022	Septe mber 30, 2023	Septe mber 30, 2022	March 31, 2024	
					March 31, 2023	
	_____	_____	_____	_____	_____	_____
Cash paid for amounts included in the measurement of lease liabilities:						
Operating cash outflows from operating leases	\$ 146	\$ 201	\$ 556	\$ 598	\$ 293	\$ 205

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Supplemental balance sheet information, as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, 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		As of	
	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
			_____	_____
Reported as:				
Operating lease right-of-use assets	\$ 2,607	\$ 851	\$ 3,275	\$ 2,440
Total right-of-use assets	\$ 2,607	\$ 851	\$ 3,275	\$ 2,440
Other current liabilities:				
Operating lease liabilities, short-term	\$ 904	\$ 612	\$ 903	\$ 895
Operating lease liabilities, long term	1,845	306	2,532	1,702
Total operating lease liabilities	\$ 2,749	\$ 918	\$ 3,435	\$ 2,597
Operating lease weighted average remaining lease term (years)	3.51	1.44	3.46	3.31
Operating lease weighted average discount rate	8.68 %	6.71 %	9.42 %	8.75 %

As of **September 30, 2023** **March 31, 2024**, maturities of the Company's operating lease liabilities are as follows (in thousands):

	Operating Leases	Operating Leases
Remainder of 2023	\$ 257	
2024	1,028	
Remainder of 2024		\$ 891
2025	738	1,165
2026	684	1,125
2027	318	657
2028	190	190
Total lease payments	3,215	4,028
Less imputed interest	(466)	(593)
Total operating lease liabilities	\$ 2,749	\$ 3,435

As of **September 30, 2023** **March 31, 2024**, there were no leases entered into that had not yet commenced.

7. Inventory 16

8. Inventory

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

	As of		As of	
	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Raw materials	\$ 2,875	\$ 1,131	\$ 2,693	\$ 3,683
Work in process	661	384	446	878
Finished goods	841	610	4,032	1,035

Total inventory \$	4,377	\$	2,125	\$	7,171	\$	5,596
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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 March 31, 2024 and 2022, respectively, and \$149,000 and \$284,000 for the nine-months ended September 30, 2023 and 2022, respectively. The inventory balance as of March 31, 2024, includes inventory purchased from Stedical for the nine-months ended September 30, 2023 and 2022, respectively, sales of PermeaDerm.

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8.9. Intangible Assets

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

	As of		As of		As of March 31, 2024		As of December 31, 2023					
	September 30,		December 31,									
	2023	2022	Ac	Ac								
Weighted					Weighted		Weighted					
ful	un	zati	un	un	Average	Gross	Accumulated	Carry				
Life	t	on	t	t	Useful Life	Amount	Amortization	Amount				
Patent	1	1	1	1	((
1	3	\$ 7	\$ 7)	\$ -	\$ 7	\$ 6)	\$ 1					
Patent	4	3	0	3	2	0						
2	13	0	5)	5	7	8)	9					
Patent	2	(1	1	(1						
3	14	4	0)	4	4	9)	5					

Patent	9	1	8	8	(8							
5	19	8	0)	8	9	6)	3		19	104	(13)	91	99
Patent	4	(3	4	(3							
6	20	4	5)	9	3	4)	9		19	56	(7)	49	56
Patent													
7	13	2	-	2	2	-	2		13	2	-	2	2
Patent	1	(1			1						
8	19	0	1)	9	3	-	3		18	31	(2)	29	29
Patent													
9								3	68	(6)	62	3	-
Patent													3
10	19	3	-	3	3	-	3		19	3	-	3	3
Patent													
11	19	6	1)	5	6	-	6		19	6	(1)	5	6
Ind													
Trade	efin	5		5	5		5						
marks	ite	4	-	4	4	-	4		Indefinite	54	-	54	54
Total													
intan													
gible													
asset													
s	\$ 8	\$ 9)	\$ 9	\$ 8	\$ 3)	\$ 5			\$ 688	\$ (146)	\$ 542	\$ 616	\$ (129)
	<u>\$ 8</u>	<u>\$ 9)</u>	<u>\$ 9</u>	<u>\$ 8</u>	<u>\$ 3)</u>	<u>\$ 5</u>			<u>\$ 688</u>	<u>\$ (146)</u>	<u>\$ 542</u>	<u>\$ 616</u>	<u>\$ (129)</u>

During the three-months ended September 30, 2023, March 31, 2024 and 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, 2023 the Company recorded an impairment charge of approximately \$4,000 in General March 31, 2024 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. 2023 Amortization expense of intangibles included in the Consolidated Statements of Operations were was \$17,000 and \$9,000 and \$8,000 for the three-months three-months ended September 30, 2023 March 31, 2024 and 2022, respectively, and \$26,000 and \$50,000 for the nine-months ended September 30, 2023 and 2022, 2023, respectively.

The Company expects the future amortization of amortizable intangible assets held at September 30, 2023 March 31, 2024 to be as follows (in thousands):

	Estimated Amortizati on Expense	Estimated Amortization Expense	
Remainder of 2023	\$ 9		
2024	35		
Remainder of 2024		\$	48
2025	35		64
2026	35		51
2027	35		37
2028	34		37
Thereafter	222		251
Total	\$ 405	\$	488

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10. Plant and Equipment

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

	As of			As of		
	Septe mber		Decem ber	Useful Lives		March 31, 2024
	Useful Lives	2023	2022			December 31, 2023
Computer equipment	3 years	\$ 951	\$ 755	3 - 5 years	\$ 1,157	\$ 984

Computer software	3 years	840	871	3 years	840	840
Construction in progress		370	258		2,292	87
Furniture and fixtures	7 years	765	439	7 years	847	824
Laboratory equipment	5 years	713	643			
Laboratory and other equipment				3 - 5 years	965	769
Leasehold improvements	Lesser of life or lease term	352	257	Lesser of life or lease term	367	367
RECELL moulds	5 years	128	129	5 years	447	438
Less: accumulated amortization and depreciation		(2,25	(2,15		(2,618)	(2,432)
		7)	2)			
Total plant and equipment, net		<u>\$ 1,862</u>	<u>\$ 1,200</u>		<u>\$ 4,297</u>	<u>\$ 1,877</u>

Construction in progress consists primarily of leasehold improvements for the renovations to the Ventura production facility and materials for the manufacture of the RECELL GO devices.

Depreciation expense related to plant and equipment was \$156,000 \$186,000 and \$130,000 \$126,000 for the three-months ended September 30, 2023 March 31, 2024 and 2022 respectively, and \$419,000 and \$388,000 for the nine-months ended September 30, 2023 and 2022, 2023 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 ended March 31, 2024 and nine-months ended September 30, 2022, 2023, 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 ended March 31, 2024 and nine-months ended September 30, 2022, 2023.

10, 11. Other Current and Long-Term Assets and Liabilities

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

	As of		As of	
	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Prepaid expenses	\$ 1,509	\$ 921	\$ 1,216	\$ 1,376
Investment receivable	1,500	-		
Unsettled investment receivable			1,000	-
Amounts due from Stedical			941	-
Accrued investment income			182	227
Lease deposits	37	110	49	38
Accrued investment income	228	168		
BARDA contract costs	56	252		
Other receivables	26	127	135	18
Total prepaids and other current assets	\$ 3,356	\$ 1,578	\$ 3,523	\$ 1,659

Prepaid expenses primarily consist of prepaid benefits and insurance.

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

	As of		As of	
	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Long-term lease deposits	\$ 151	\$ 25	\$ 151	\$ 155
Long-term prepaids	85	97	135	148
Other long-term assets			115	52
Total other long-term assets	\$ 236	\$ 122	\$ 401	\$ 355

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

	As of		As of	
	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Operating lease liability	\$ 904	\$ 612	\$ 903	\$ 895
BARDA deferred costs	47	194		
BARDA deferred revenue	104	-		
COSMOTECH deferred revenue			33	33
Other current liabilities	286	184	217	338
Total other current liabilities	\$ 1,341	\$ 990	\$ 1,153	\$ 1,266

11.12. 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, March 31, 2024, and December 31, 2022, with an insignificant amount located in Australia and the United Kingdom. December 31, 2023.

Revenue by region for the three-months March 31, 2024 and nine-months ended September 30, 2023 and 2022 2023 were as follows (in thousands):

	Three-Months		Nine-Months		Three-Months Ended	
	Ended		Ended			
	Septe mber	Septe mber	Septe mber	Septe mber		
	30, 2023	30, 2022	30, 2023	30, 2022	March 31, 2024	
Revenue					March 31, 2023	
:						

Revenue by region:	United States	12,9	8,44	33,3	24,1	\$ 61	\$ 1	\$ 79	\$ 17	\$ 10,532	\$ 9,425
Foreign:											
Japan				2,30						461	1,021
		581	555	9	555						
European Union										51	-
Australia	61	57	156	173						17	62
United Kingdom	42	39	104	121						43	42
Total	13,6	9,09	35,9	24,9						11,104	\$ 10,550
	\$ 45	\$ 2	\$ 48	\$ 66	\$						

Revenue and cost of sales by customer type for the three-months ended March 31, 2024 and nine-months ended September 30, 2023 and 2022 were as follows (in thousands):

	Three-Months Ended				Nine-Months Ended		
	September 30,		September 30, 2022	2023	September 30, 2023	September 30, 2022	
	2023	2022					
Revenue:							
Commercial sales	\$ 13,547	\$ 8,999			\$ 35,673	\$ 25,687	
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	
	March 31, 2024	March 31, 2023
Revenue by customer type:		
Commercial sales	\$ 11,068	\$ 10,458
Deferred commercial revenue recognized	8	-

BARDA services for emergency preparedness	-	92
BARDA revenue for right of first access	28	-
Total	\$ 11,104	\$ 10,550

Commercial revenue by product for the three-months ended March 31, 2024 and 2023 were as follows (in thousands):

	Three-Months Ended		Nine-Months Ended	
	September 30,		September 30,	September 30,
	2023	2022	2023	2022
Cost of sales:				
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

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	Three-Months Ended	
	March 31, 2024	March 31, 2023
Commercial revenue by product:		
RECELL	10,962	10,458
Other wound care products	106	-
Total commercial sales	\$ 11,068	\$ 10,458

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Cost of sales by customer type for the three-months ended March 31, 2024 and 2023 were as follows (in thousands):

Three-Months Ended

	March 31, 2024	March 31, 2023
Cost of sales:		
Commercial cost	\$ 1,513	\$ 1,616
BARDA:		
Product cost	-	(34)
Emergency preparedness service cost	-	85
Total	\$ 1,513	\$ 1,667

13. 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** **March 31, 2024** and **December 31, 2022** **December 31, 2023**, the Company did not have any outstanding or threatened litigation that would have a material impact on the financial statements.

Minimum Purchase Commitments with Stedical

The Company is subject to minimum purchase of PermeaDerm product for the initial term of five years. For 2024, the Company has an obligation to purchase a minimum of \$5.0 million of inventory from Stedical. As of March 31, 2024, the Company has purchased \$2.6 million in inventory with another \$2.4 million remaining. This obligation is not recorded in the Company's Consolidated Balance Sheets. For the first three years of the agreement, the minimum purchase should increase annually by an amount equal to the percentage growth in the Company's annual US based revenues excluding PermeaDerm revenue, or a minimum increase of at least 20% over the prior year purchase commitment. For years after the third year, the minimum purchase obligation shall increase annually by an amount equal to the percentage growth of the Company's annual US-based revenues excluding PermeaDerm sales. The minimum purchase obligation should never decrease from the previous year.

13.14. Common and Preferred Stock

The Company's CHESS Depositary Interests ("CDIs" CDIs") are quoted on the ASX under the ticker code, "AVH". The Company's shares of common stock Common Stock are quoted on the Nasdaq Capital Market ("Nasdaq" Nasdaq") under the ticker code, "RCEL". One share of common stock 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, 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** **March 31, 2024**, and **December 31, 2022** **December 31, 2023**, 25,550,694 25,789,051 and 25,208,436 25,682,078 shares of common

stock, Common Stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding during any period.

14.15. 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 and Employee Stock Purchase Plan ("ESPP") expense of \$2.4 million and \$1.4 million for the three-months ended September 30, 2023 March 31, 2024 and 2022, respectively, and \$6.2 million and \$5.8 million for the nine-months ended September 30, 2023 and 2022, 2023, respectively. No income tax benefit was recognized in the Consolidated Statements of Operations for stock-based payment arrangements for the three-months ended March 31, 2024 and nine-months ended September 30, 2023, and 2022, 2023.

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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:

Sales and marketing expenses	Three-Months Ended		Nine-Months Ended		Three-Months Ended	
	Septe mber 30, 2023	Septe mber 30, 2022	Septe mber 30, 2023	Septe mber 30, 2022	March 31, 2024	March 31, 2023

Sales and marketing expenses	\$ 513	\$ 408	\$ 915	\$ 2	\$ 527	\$ 325
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General and administrative expenses	1,534	761	4,442	4,071	1,661	2,090
Research and development expenses	383	267	856	689	403	225
Total operating expenses	2,436	\$ 6	\$ 3	\$ 2		
Total			\$		2,591	\$ 2,640

A summary of share option activity as of **September 30, 2023** **March 31, 2024**, and changes during the period ended is presented below:

	Service Only Share Options	Performance Based Share Options	Total Share Options			
	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			
Outstanding shares at December 31, 2023			2,397,571	292,587	2,690,158	
Granted	919,193	-	919,193	1,156,000	-	1,156,000
Exercised	(133,750)	(30,000)	(163,750)	(86,244)	(20,729)	(106,973)
Expired	(59,812)	(180,473)	(240,285)	(25,786)	(39,174)	(64,960)
Forfeited	(58,963)	(6,958)	(65,921)	(128,185)	(4,656)	(132,841)

Outstanding				
shares at	2,390,92	293,763	2,684,	
September 30,	0		683	
2023	_____	_____	_____	
Exercisable at				
September 30,	875,323	255,629	1,130,	
2023			952	
Outstanding				
shares at			3,313,356	
March 31,				228,028
2024	_____	_____	_____	3,541,384
Exercisable at				
March 31,			839,751	
2024	_____	_____	_____	1,030,283
Vested and				
expected to				
vest - March				
31, 2024			3,313,356	
				228,028
				3,541,384

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A summary of the status of the Company's unvested RSUs as of September 30, 2023 March 31, 2024, and changes that occurred during the period is presented below:

Unvested Shares	Performance			Tenure-Based RSUs	Performance Condition RSUs	Total RSUs
	Tenure-Based	Condit	Total			
	RSUs	RSUs	RSUs			
Unvested RSUs outstanding at December 31, 2022	394,872	65,64	460,6	460,6		
Unvested RSUs outstanding at December 31, 2023				518	207,112	28,020
Granted	57,798	-	57,798	-	-	-

Vested	(149,168)	(29,340)	(178,508)	-	-	-
Forfeited	(39,250)	(8,286)	(47,536)	(17,400)	(3,504)	(20,904)
Unvested RSUs outstanding at September 30, 2023	264,252	28,020	292,272			
Unvested RSUs outstanding at March 31, 2024				189,712	24,516	214,228

Employee Stock Purchase Plan

In June 2023, the stockholders approved the AVITA Medical, Inc. Employee Stock Purchase Plan (the "ESPP"). The ESPP which 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 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 During the three-months ended March 31, 2024, the Company had recorded \$410,000 186,000 in accrued payroll contributions. As of December 31, 2022 ESPP expense. During the three-months ended March 31, 2023, the Company did not have any ESPP expense. The Company had \$583,000 and \$122,000 in accrued payroll contributions. There have been contributions as of March 31, 2024 and December 31, 2023, respectively. As of March 31, 2024, the Company had no 927,681 shares remaining to be issued under the ESPP plan as of September 30, 2023, plan.

15.16. Income Taxes

Tax expense for the three-months ended September 30, 2023 March 31, 2024 and 2022 2023 was \$11,000 30,000 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.

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17. 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		Three-Months Ended March 31, 2024	March 31, 2023
	Septe mber 30, 2023	Septe mber 30, 2022	Septe mber 30, 2023	Septe mber 30, 2022		
	8,71	5,58	28,3	21,3		
	\$ 2	\$ 8	\$ 16	\$ 12		
Net loss					(18,658)	\$ (9,220)
Weighted-average common shares—outstanding, basic and diluted	25,402	25,007	25,282	24,972	25,638	25,202
Net loss per common share, basic and diluted	\$ 0.34	\$ 0.22	\$ 1.12	\$ 0.85	\$ (0.73)	\$ (0.37)

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

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	Three-Months Ended	
	March 31, 2024	March 31, 2023
Anti-dilutive shares excluded from diluted net loss per common share:		
Stock options	3,541,384	2,218,496

Restricted stock units	214,228	371,368
ESPP	83,545	-
Warrants	409,661	-

The Company's basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the relevant period. In accordance with ASC 710-10, *Compensation - General*, 117,909 83,893 shares of common stock 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 17.18. For the purposes of the calculation of diluted net loss per share, options to purchase common stock, restricted stock units and unvested shares of common stock issued upon the early exercise of stock options have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive. Because the Company has reported a net loss for the three-months ended March 31, 2024 and nine-months ended September 30, 2023, and 2022, 2023, diluted net loss per common share is the same as the basic net loss per share for those periods.

17.18. Retirement Plans

The Company offers a 401(k) retirement savings plan (the “401(k) “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 \$263,000 835,000 and \$312,000 423,000 for the three-months ended September 30, 2023 March 31, 2024 and 2022, respectively, and \$934,000 and \$783,000 for the nine-months ended September 30, 2023 and 2022, 2023, respectively.

Non-Qualified Deferred Compensation Plan

The Company's NQDC plan, which became effective on in October 2021 allows for eligible management and highly compensated key employees to elect to defer a portion of their salary, bonus, commissions 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 Plan were \$80,000 34,000 and \$75,000 42,000 for the three-months ended September 30, 2023 March 31, 2024 and 2022, respectively, and \$161,000 and \$197,000 for the nine-months ended September 30, 2023 and 2022, 2023, respectively. The Company's deferred compensation plan liability was \$3.7 4.3 million and \$1.3 3.8 million as

of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, respectively. These amounts liabilities are split between current and long term on the Consolidated Balance Sheets. As of September 30, 2023 March 31, 2024, \$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, \$78,000 429,000 is included in Current non-qualified deferred compensation liability and \$1.3 3.9 million in Non-qualified the long term non-qualified deferred compensation liability. As of December 31, 2023, \$168,000 is included in Current non-qualified deferred compensation liability and \$3.7 million in the long-term non-qualified deferred compensation liability. During the third quarter of 2023, three-months ended March 31, 2024, the Company had a payout distributions of approximately \$753,000 215,000 in the deferred compensation liability for terminated employees. During the three-months ended March 31, 2023, the Company did not have any distributions.

The Company established a COLI to fund the NQDC Plan. Amounts in the COLI are invested in a number of funds. The securities are carried at the cash surrender value on the Consolidated Balance Sheets. We record investment gains and losses of the

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COLI as Other income (expense), net. Refer to Note 4, Fair Value Measurements for 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 COLI policies and the inputs used to measure fair value, see Note 4, Fair Value Measurements. NQDC liability.

(in thousands)	Fair Value as of September, 2023				Fair Value as of December 31, 2022			
					Level			
	Level 1	Level 2	Level 3	Total	1	Level 2	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. Plan. The rabbi trust holds the COLI asset and the common stock Common Stock from deferred RSU awards that have vested. The NQDC Plan 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 March 31, 2024 and December 31, 2023, a total of 117,326 and 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, respectively. Vested shares are converted to common stock Common Stock and are reclassified to permanent equity. Common stock 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 Stock held by the NQDC plan. Plan. As of March 31, 2024 and December 31, 2023 a total of 83,893 and 99,106 shares were held in the rabbi trust at the redemption value of \$944,000 and \$1.1 million, respectively.

The following table summarizes the eligible Non-qualified deferred compensation plan share award activity as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023 (in thousands):

(in thousands)	As of		As of	
	September 30, 2023	December	March 31, 2024	December 31, 2023
		31, 2022		
Non-qualified deferred compensation share awards:				
Balance at inception/beginning of period	\$ 557	\$ -		
Change in classification of deferred compensation share awards	-	192		
Balance at beginning of period			\$ 693	\$ 557
Stock-based compensation expense	475	471	6	518
Change in redemption value	998	21	128	1,019
Vesting of share awards held by NDQC	(1,401)	(127)	-	(1,401)
Ending Balance	\$ 629	\$ 557	\$ 827	\$ 693

18.19. 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 adjustment to our or disclosures in the Consolidated Financial Statements, except as noted below. Statements.

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" "we", "our" "our", "us" "us") is a commercial-stage regenerative medicine company leading transforming the development standard of care in wound care management and commercialization skin restoration with innovative devices. At the forefront of devices and autologous cellular therapies for skin restoration. Our our portfolio is our patented and proprietary RECELL® RECELL® System technology platform ("RECELL System" or "RECELL"), approved by the United States Food & Drug Administration ("FDA") for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. RECELL 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 Spray-On Skin™ Cells, delivering a transformative solution at the patient to regenerate natural healthy skin. point of care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes.

Our objective is to become We are focused on becoming the leading provider of regenerative medicine addressing unmet medical needs in burn injuries, full-thickness skin defects, and in skin repigmentation, such as vitiligo. We will continue to drive commercial revenue growth to generate positive cash flow and achieve operating profit. To achieve this objective, these objectives, we plan intend to:

- Become the standard of care in the U.S. burns industry by increasing RECELL System penetration and adoption in I centers and with burn physicians
- Continue Expand into U.S. trauma centers to commercialize increase utilization of RECELL for the RECELL System in the U.S. for treatment of full-thickness skin defects with both inpatient
- Launch RECELL GO™ following FDA approval to increase market adoption and outpatient reimbursement in

place expand our customer base

- Submit a PMA supplement for RECELL GO mini, which is designed to address smaller wounds.
- 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 distributors
- Continue to build upon commercial activities in Japan through our partnership with COSMOTEC Company, Ltd ("COSMOTEC") with our current PMDA Pharmaceuticals and Medical Devices Act ("PMDA") approval for RECELL with an indication in burns
- Develop and Continue to pursue viable commercial activities outside of the U.S. and Japan following the FDA approval 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 targeted markets, such as the agreement with Stedical Scientific, Inc.
- Improve our margins and profitability by leveraging our current team and infrastructure across an expanding base Establish commercial payor coverage for RECELL in the U.S. for the treatment of business in burns and in future indications vitiligo lesions; initial phase of coverage expected during the fourth quarter of 2025

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Business Environment and Current Trends

The macroeconomic environment may have unexpected adverse effects on businesses and healthcare institutions globally that may continue to negatively impact our consolidated operating results. There remains significant uncertainty in the current macroeconomic environment due to factors including supply chain shortages, increased cost of healthcare, 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, Ukraine or Ukraine, in the Middle East, the continuation of the Russia-Ukraine military conflict in these regions and/or an escalation of the conflict conflicts beyond its their 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 January 10, 2024, we entered into an exclusive multi-year distribution agreement with Stedical Scientific, Inc.

to commercialize PermeaDerm® Biosynthetic Wound Matrix in the United States ("PermeaDerm"). PermeaDerm is cleared by the FDA approved as a PMA supplement transparent matrix for full-thickness skin defects based on results use in the treatment of our trial a variety of wound types until healing is achieved. Under the terms of the agreement, we hold the exclusive rights to market, sell, and distribute PermeaDerm products, including any future enhancements or modifications, within the United States. The initial term is for soft tissue repair and reconstruction. Following this approval, we commenced a commercial launch on June 8, 2023. five years, with the option to renew for an additional five years, contingent upon meeting certain minimum requirements.

On June 16, 2023 January 31, 2024 we entered into an exclusive Distribution Agreement with Fidelis Sustainability Distribution, LLC ("Fidelis"). As part of the agreement, the Company appointed Fidelis as the exclusive distributor of RECELL products in the U.S. Government healthcare facilities such as Veteran Affairs and the Department of Defense.

On February 16, 2024, we executed a contract modification with BARDA to extend the FDA approved period of performance, under the original contract dated September 29, 2015, from December 31, 2023 to September 28, 2025. Under the modified contract, BARDA will have access to AVITA Medical's RECELL inventory in the event of a PMA application national emergency. In the case of a national emergency, BARDA will pay for RECELL devices at a reduced price for the repigmentation first 1,000 units and retail price for any units over 1,000 requested. No additional inventory build will be required as part of stable depigmented vitiligo lesions. To support reimbursement, this modification as the Company is conducting a post-market clinical study which has sufficient inventory in stock to fulfill this requirement. BARDA will evaluate repigmentation and seek pay AVITA Medical approximately \$333,000 in maintenance fees over the term of the contract to measure quality-of-life after treatment ensure first right 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. access.

On June 29, 2023, we submitted a PMA premarket approval ("PMA") supplement to the FDA for RECELL GO™. 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 was required for the continuation of a substantive review for RECELL GO. This request, which is not unique to the Breakthrough Device Devices Program, placed the application file on hold while we address addressed 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 on February 28, 2024. Upon the submission to the FDA, at which point the application will reenter the 180-day cycle, with 90 days remaining in the review period. This timing would imply FDA approval, immediately followed by 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.

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Results of Operations for the three-months ended September 30, 2023 March 31, 2024 compared to the three-months ended September 30, 2022 March 31, 2023.

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

Statement of Operations Data:	Three-Months Ended				Three-Months Ended			
	Septemb er 30, 2023	Septemb er 30, 2022	\$ Ch a nge	% Ch a nge	March 31, 2024	March 31, 2023	\$ Ch a nge	% Ch a nge
Revenues			4,5					
	\$ 13,645	\$ 9,092	53	50 %	\$ 11,104	\$ 10,550	554	5.3 %
Cost of sales			(5	(3				
	(2,113)	(1,530)	83)	8)%	(1,513)	(1,667)	154	9.2 %
Gross profit			3,9					
	11,532	7,562	70	52 %	9,591	8,883	708	8.0 %
BARDA income			(6	(7				
	212	904	92)	7)%	-	627	(627)	-100.0 %

Operating Expenses:					
Sales and marketing expenses	(10,532)	(5,411)	1	5)	(9)%
General and administrative expenses	(6,124)	(5,004)	0)	(2)	(2)%
Research and development expenses	(4,394)	(3,799)	95)	(1)	(6)%
Total operating expenses	(21,050)	(14,214)	83	(4)	(6,838)
Operating loss	(9,306)	(5,748)	8)	(6)	(3,554)
Interest expense	(10)	(6)	(4)	(7)	(6)
Other income	615	170	5	2%	44
Other income (expense), net					(66)
Loss before income taxes	(8,701)	(5,584)	7)	(6)	(3,115)
Income tax expense	(11)	(4)	(7)	75)%	(1)
					(30)
					(30)
					-
					0.0%

Net loss	(3, 12 \$ (8,712)	(5 \$ (5,588)	4 6)%	\$ (18,658)	\$ (9,220)	\$ (9,438)	-102.4%
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*nm = not meaningful

Total net revenues increased by 50% 5.3%, or \$4.6 million \$0.6 million, to \$13.6 million \$11.1 million, compared to \$9.1 million \$10.6 million in the corresponding same period in the prior year. Our commercial revenue which excludes BARDA revenue, was \$13.5 million \$11.1 million in the three-months ended September 30, 2023 March 31, 2024, an increase of \$4.5 million \$0.6 million, or 51% 5.8%, compared to \$9.0 million \$10.5 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 and new accounts for Full Thickness Skin Defect ("FTSD" "FTSD").

Gross profit margin was 84.5% 86.4% compared to 83.2% 84.2% 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, zero, compared to \$0.9 million \$0.6 million in the corresponding period in the prior year due to reimbursable clinical trials winding down. BARDA income in the prior year 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% 38.0% or \$6.8 million \$7.4 million to \$21.1 million \$26.8 million, compared with \$14.2 million \$19.4 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 95% 93.3%, or \$5.1 million \$6.1 million, to \$10.5 million \$12.6 million, compared to \$5.4 million \$6.5 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, professional fees and travel expenses. The increase in salaries and benefits is due to the preparation expansion of the sales force to support our growing commercial launch of FTSD that occurred in June 2023. capabilities. Higher commissions and travel costs were directly associated with the increase in revenues. The increase in professional fees is primarily due to pricing studies for future product development. The increase in travel is due to the expansion of the sales force.

General and administrative expenses increased by 22% 8.1%, or \$1.1 million \$0.7 million, to \$6.1 million \$9.0 million, compared to \$5.0 million \$8.3 million in the same period in the prior year. The increase was attributable to higher stock-based compensation, and salaries and benefits. Higher benefits and an increase in recruitment fees, partially offset by lower stock-based compensation in the current period is driven by the new grants in the current year. compensation.

Research and development expenses increased by 16% 13.3%, or \$0.6 million, to \$4.4 million \$5.2 million, compared to \$3.8 million \$4.6 million in the same period in the prior year. The increase is primarily due to salaries and benefits and share-based compensation, offset by a decrease in professional fees and research and development expenses. The increase in salaries and benefits and stock-based compensation is due to the deployment of a team of Medical Science Liaisons, for the FTSD launch in June 2023, and Liaisons. The decrease was partially offset by lower clinical trial professional fees and diminished development expenses for vitiligo, FTSD and pediatrics as trial participants largely completed follow-up in 2022 reducing RECELL GO due to the associated expenditure in latent development phase of the current period. project.

Results of Operations for the nine-months ended September 30, 2023 compared to the nine-months ended September 30, 2022 same period in the prior year due to interest expense related to the long-term debt as part of the OrbiMed Credit Agreement, for an aggregate principal amount owed of \$40.0 million.

The table below summarizes the results of Other income (expense), net decreased by \$0.8 million or 109% to net expense of \$66,000 from net income of \$725,000 in the periods presented (in thousands).

Statement of Operations Data:	Nine-Months Ended		\$	%
	September 30, 2023	September 30, 2022	Change	Change
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	\$ (28,316)	\$ (21,312)	(7,004)	(33)%

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. We

recognized \$0.4 million and \$0.9 million of non-cash charges due to the change in fair value of the nine-months ended September 30, 2023, debt and the warrant liability, respectively. In addition, we had an increase of \$11 million, or 45%, compared approximately \$0.5 million in income related 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 our investment activities and the FTSD launch along with the commencement of commercial sales with our partner COSMOTECH in Japan. other income.

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 We have 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 securities and the issuance of

September 30, 2023, the Company had approximately \$50.9 million in cash and cash equivalents and \$9.3 million in marketable securities.

debt. On October 18, 2023 (the “**Closing Date**”), the Company we entered into a Credit Agreement (the “**Credit Agreement**”), by and between the Company, as borrower, and with an affiliate of OrbiMed Advisors, LLC, as the lender and administrative agent (the “**Lender**”), LLC. 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**”). drawn during fourth quarter of 2023. In addition, an aggregate of \$50.0 million will be made available in two separate \$25.0 million tranches, at the Company’s our discretion, subject to certain net revenue requirements. The first tranche of \$25.0 million will be made is available on or before December 31, 2024. The second tranche of \$25.0 million will be made is available on or prior to June 30, 2025, only if the first tranche was drawn upon. On We have monthly interest rate payments for 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 debt at a rate equal to the greater of (a) forward-looking one-month term SOFR rate and (b) four percent (4% (4.0%) per annum, plus eight percent (8% (8.0%). In the event that the Company does we do 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% 5.0% of the funded amount through the maturity date. The Credit Agreement contains representations, warranties As of March 31, 2024, our projected revenues, for the trailing twelve months ending December 31, 2024, exceeded the minimum revenue requirements under the credit agreement. We had approximately \$17.0 million in cash 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 cash equivalents and \$51.2 million in certain circumstances. marketable securities.

As of the date of these financial statements, the Company believes it has we believe we have 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		Three-Months Ended	
	September 30, 2023	September 30, 2022	March 31, 2024	March 31, 2023
	(in thousands)	(in thousands)	(in thousands)	(in thousands)
Net cash used in operations	\$ (27,148)	\$ (15,654)	\$ (20,864)	\$ (9,073)
Net cash provided by/(used in) investing activities	58,911	(16,174)		
Net cash provided by investing activities			15,066	18,787
Net cash provided by financing activities	942	1	631	171
Effect of foreign exchange rate on cash and cash equivalents	(15)	(70)	-	1
Net increase/(decrease) in cash and cash equivalents	32,690	(31,897)	(5,167)	9,886
Cash and cash equivalents at beginning of the period	18,164	55,712	22,118	18,164
Cash and cash equivalents at end of the period	50,854	23,815	16,951	28,050

Net cash used in operating activities was \$27.1 million \$20.9 million and \$15.7 million \$9.1 million during the nine-months three-months ended September 30, 2023 March 31, 2024, and 2022, 2023, respectively. The increase in net cash used in operations was primarily due to lower revenue, higher operating costs and increased cash outflow due to the inventory build purchases as part of the FTSD launch, partially offset by increased revenues. Stedical Agreement.

Net cash provided by investing activities was \$58.9 million \$15.1 million and net cash used in investing was \$16.2 million \$18.8 million during the nine-months three-months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively. The increase decrease in cash provided by investing activities is primarily attributable to our lower cash inflows from maturities of marketable securities whereas in the current year compared to the prior year, we purchased marketable securities. offset by an increase in cash outflow for capital expenditures and patent filing fees. The increase in capital expenditures in the current year is primarily related to the leasehold improvement in the Ventura production facility to enhance manufacturing output.

Net cash provided by financing activities was \$0.9 million \$0.6 million and \$1 thousand \$0.2 million during the nine-months three-months ended September 30, 2023 March 31, 2024, and 2022, 2023, 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

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available to the Company. us. We regularly review the Company's our capital structure and seek to take advantage of available opportunities to improve outcomes for the Company us and its our stockholders.

For the nine-months three-months ended September 30, 2023 March 31, 2024, there were no dividends paid and we have no plans to commence the payment of dividends. We As part of the Stedical Agreement, we have no minimum purchase requirements for PermeaDerm inventory of \$5.0 million dollars. As of March 31, 2024, we have purchased \$2.6 million and have approximately \$2.4 million remaining to satisfy the requirement. With the exception of the inventory purchases from Stedical, we do not have any other purchase commitments or long-term contractual obligations, or purchase commitments, except for lease obligations as of September 30, 2023 March 31, 2024. Refer to Note 6 7 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 Quarterly Report on Form 10-K 10-Q for the year-ended December 31, 2022 quarter-ended March 31, 2024.

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** **March 31, 2024**, 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.

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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** **first** quarter of fiscal year **2023** **2024** 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.

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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 2023 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 the 2023 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.

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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.

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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 pressure on the U.S. and global economy and rising interest rates.

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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.

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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 Exclusive Distribution Agreement between AVITA Medical Americas, LLC and Stedical Scientific, Inc., dated October 18, 2023, by and between the Company, as borrower, and ORCO IV LLC as lender and administrative agent \(incorporated by reference to Exhibit 10.1 of the registrant's Form 8-K filed on October 18, 2023\) January 10, 2024*](#)

10.2 [Pledge Second Amendment to Lease Agreement between the registrant and Security Agreement, Hartco Ventura Inc. dated October 18, 2023, January 1, 2024*](#)

10.3 [Amendment of Solicitation/Modification of Contract dated February 16, 2024 by and among between the Company, the guarantors party thereto registrant and ORCO IV LLC \(incorporated by reference to Exhibit 10.2 of the registrant's Form 8-K filed on October 18, 2023\)](#)
BARDA*

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 With Embedded 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 Documents](#)

104 [Cover Page Interactive Data File \(embedded within the Inline XBRL document\)](#)

† Management contract or compensation plan or arrangement

* Filed herewith

** Furnished herewith

Signatures

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

Date: November 9, 2023 May 13, 2024

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)

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

EXCLUSIVE DISTRIBUTION AGREEMENT

This Exclusive Distribution Agreement (this "Agreement"), is effective as of the date of the last signature (the "Effective Date"), and is entered into between AVITA Medical Americas, LLC having its principle place of

business at 28159 Avenue Stanford, Suite 220 Valencia, CA ("Distributor"), and Stedical Scientific, Inc. having its principle place of business at 2888 Loker Avenue East, Suite 319 Carlsbad, CA 92010 ("Seller"), and together with Distributor, the "Parties", and each, a "Party"). This Agreement replaces and supersedes any prior agreements between the Parties, which are of no further effect.

WHEREAS, Seller is in the business of manufacturing and selling the Products (as defined in Schedule A) in the United States;

WHEREAS, Distributor intends to market and sell the Products in the United States (the "Territory");

WHEREAS, Seller desires to appoint Distributor as its exclusive distributor to sell the Products in the field of skin therapeutics in all health care settings (the "Field of Use") to customers located in the Territory and Distributor desires to accept such appointment, subject to the terms and conditions of this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set out herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Exclusive Appointment, Rights of First Negotiation and Refusal, Location of Manufacturing.

1.1. Exclusive Appointment. Seller appoints Distributor as its exclusive authorized distributor of the Products listed in Schedule A within the Territory during the Term and Distributor accepts such appointment. Distributor shall not directly or indirectly actively market, advertise, promote, sell, or distribute the Products to any person or entity located outside the Territory, including selling, or distributing the Products to any person where ultimate resale to any person or entity outside the Territory occurs or is reasonably foreseeable to occur.

1.2. Right of First Negotiation. If at any time, from the Effective Date until the termination of the Agreement (the "ROFN Period"), Seller (1) receives a bona fide written offer from a third-party to acquire more than 50% of Seller's equity or a sale of substantially all of its assets that are the subject of this Agreement, whether by merger, reorganization, acquisition, sale, or otherwise (each a "Change of Control") or (2) Seller intends to explore the market for a Change of Control transaction, Seller shall immediately notify Distributor of the existence of such offer or intent. Upon receipt of such notice, Distributor will have thirty days (a "ROFN Notice Period") to deliver a binding letter of intent to Seller to engage in a Change of Control transaction with Seller. Seller shall not accept any third-party offers during a ROFN Notice Period. Seller is under no obligation to accept Distributor's letter of intent and may enter into a Change of Control transaction with a third-party after the expiration of the ROFN Notice Period.

1.3. **Relocation of Manufacturing.** If Seller desires to relocate its manufacturing facilities (other than to another facility in the State of California approved by Distributor) Seller shall offer to assign its manufacturing contract at its existing location to Distributor. In exchange for the assignment, Distributor shall make a one-time payment of [*****] to Seller within 60 days of the assignment and pay on a quarterly basis, within 30 days after the end of a quarter, a [*****] % royalty on gross revenues generated from sale of Products after the assignment occurs. If such an assignment occurs, Distributor shall no longer make any payments under the terms of this Agreement other than the one-time payment and the royalty payments.

1.4. **Research and Development Collaboration.** The Parties agree that they are open to exploring future collaboration(s) for mutually agreed upon research and development projects or clinical research or trials and entering into a cost-sharing arrangement for such endeavors.

2. **Conduct of the Parties.** The Parties agree that the essence of their business relationship shall be built on providing both Parties with predictability, responsiveness, dependability, and communication. To that end, the Parties agree:

2.1. Upon receipt of a reasonable request for a specific action, the receiving Party shall reply within five business days stating either (i) the date upon which it will provide the corresponding deliverable, (ii) a counter proposal for achieving the same business goal, or (iii) its intent to not comply with the request.

2.2. Should any governmental entity with jurisdiction over the use or sale of the Products in the Territory request information that is in the other Party's possession, that Party shall have three business days from the date of receipt of such request to (i) provide the information to the requesting Party; or (ii) propose an alternative due date for the deliverable.

2.3. Should either Party experience difficulty in meeting the terms in this Section 2, that Party shall promptly communicate the difficulty to the other Party's designated contact.

3. **Distribution Services**

3.1. **Distributor Obligations.** Distributor shall:

- (a) comply with all local laws and regulations regarding the marketing, promotion, and sale of the Products;
- (b) market, advertise, promote, and sell the Products in the Territory in a manner that reflects favorably at all times on the Products and the good name, goodwill, and reputation of Seller and consistent with good business practice, in each case using its reasonable best efforts to maximize the sales volume of the Products;
- (c) not market, advertise, promote, or sell products that are directly competitive with the Products;
- (d) maintain a place or places of business in the Territory, including adequate office, storage, and warehouse facilities and all other facilities as required for Distributor to perform its duties under this Agreement;
- (e) purchase and maintain at all times a representative quantity of each Product sufficient for and consistent with the needs of customers in the Territory;

- (f) have sufficient knowledge of the industry and products competitive with the Products (including specifications, features, and benefits) so as to be able to explain in detail to customers:
 - i. the differences between the Products and competing products; and
 - ii. information on standard protocols and features of each Product;
- (g) utilize a sales and marketing organization predominantly comprised of Distributor employees sufficient to develop to the satisfaction of Seller the market potential for the sale of the Products, and maintain employees and facilities sufficient to make the Products available for shipment by Distributor to each of its customers in the Territory within a reasonable period of time on receipt of order;
- (h) develop and execute a marketing plan sufficient to fulfill its obligations under this Agreement;
- (i) not make any materially misleading or untrue statements concerning Seller or the Products, including refraining from any disparagement of Seller or the Products;
- (j) submit to Seller complete and accurate monthly reports including at a minimum the items listed in Schedule B and maintain books, records and accounts of all transactions and permit full examination thereof by Seller;
- (k) sell and promote the Products as a distinct product line and not as a bundle with other products sold by Distributor; and
- (l) repurchase existing inventory of Seller's Products currently held by [*****] Distributor shall ship the [****] inventory to Seller's Tustin, CA location where it will be relabeled and shipped to Distributor's Ventura, CA location. The Parties shall ultimately bear the cost of the repurchase and repackaging equally in accordance with the terms of Section

3.2. Seller Obligations. Seller shall:

- (a) provide any information and support that may be reasonably requested by Distributor regarding the marketing, advertising, promotion, and sale of Products;
- (b) allow Distributor to participate, at its own expense, in any marketing, advertising, promotion, and sales programs or events that Seller may make generally available to its authorized distributors of Products, provided that Seller may alter or eliminate any program at any time;
- (c) may market and sell the Products outside the Territory, provided that such marketing and sale does not impede Seller's ability to fulfill its obligations under this Agreement;

- (d) provide promotional information and material for use by Distributor in accordance with this Agreement;
- (e) once per calendar year, provide up to four nonconsecutive weeks of in-person training on the technology the Products and their uses to Distributor employees at Distributor's facility. Distributor must explicitly request this training in writing and Seller shall respond within

thirty days. The cost of such training, including reasonable expenses, shall be shared equally between the Parties;

- (f) respond to Distributor's questions related to technical or market access issues within five business days;
- (g) promptly obtain and during the Term always maintain full marketing authorization for the Products in the whole Territory under applicable law; and
- (h) use its best efforts to produce a ready-to-sell [*****], version of the Products within 12 to 24 months of the Effective Date. Product profile and technical specifications to be mutually agreed upon by the Parties. Distributor shall be the exclusive distributor of this Product in the Field of Use in the Territory.

3.3. Regulatory Obligations.

- (a) Distributor shall not, except with the prior written approval of Seller, (i) change the intended purpose of a Product, or (ii) modify a Product in such a way that compliance with the applicable requirements may be affected.
- (b) Distributor shall keep up to date records demonstrating at all times to which customers it has sold any Product and require any of its customers who are not end customers to do so, allowing for the traceability of the Products to the final customer.
- (c) The Parties may specify or change the regulatory obligations with respect to the performance of this Agreement by entering into a separate Quality Agreement.

4. Agreement to Purchase and Sell Products; Minimum Purchase Requirements.

4.1. Terms of Sale; Orders. Seller and Distributor shall effectively split the gross revenue from sale of the Product evenly through the purchase of Products at 50% of average sale price ("ASP") as described in this Section 4. Seller shall ultimately be responsible for the cost of manufacturing the Products.

- (a) All prices are exclusive of all sales, use and excise taxes, and any other similar taxes, duties, and charges of any kind imposed by any governmental authority on any amounts payable by Distributor under this

Agreement.

- (b) Distributor is responsible for all charges, costs, and taxes, provided that, Distributor is not responsible for any taxes imposed on, or regarding, Seller's income, revenues, gross receipts, personnel or real or personal property or other assets.
- (c) Distributor shall pay interest on all late payments, calculated daily and compounded monthly, at the lesser of the rate of ten percent per month or the highest rate permissible under applicable law, whichever is lower.

4.2. Price (First Twelve Months).

- (a) For the first twelve months after the Effective Date, Distributor shall purchase Products from Seller monthly as needed, depending on the supply of Products remaining from the repurchase from [*****].
- (b) During the first quarter after the Effective Date, Distributor shall estimate a monthly average sales price (ASP) for the Products and the price Distributor pays to Seller for Products shall be 50% of the estimated ASP. The ASP shall be expressed in United States Dollars ("USD"). Thereafter, the price Distributor pays to Seller for Products shall be 50% of ASP of the Products from the previous quarter as reported on the report described in Schedule B.
- (c) On a quarterly basis, the Parties will make any necessary true-up payments to account for the [*****] repurchased inventory and any variance in actual ASP.
- (d) By way of example only, if, for the first quarter after the Effective Date, Distributor estimates the ASP of a Product to be \$60, the price Distributor pays to Seller for that Product shall be \$30 (50% of \$60) for that quarter. If the actual ASP for that quarter is \$70, Distributor shall, at the end of that quarter, make a true-up payment to Seller reflecting the additional \$5 (50% of the \$10 difference) per Product owed to Seller and the price Distributor pays to Seller for the following quarter shall be \$35 per Product. Conversely, If the actual ASP for that quarter is \$50, Seller shall, at the end of that quarter, either (i) make a true-up payment to Distributor reflecting the \$5 (again reflecting 50% of the \$10 difference) per product overpayment by Distributor or (ii) provide Distributor with a Product credit equivalent to that true-up payment and the price Distributor pays to Seller for the following quarter shall be \$25 per Product. Such true-up payments or product credits and selling price adjustments shall continue for the Term of the Agreement and any Renewal Terms.

4.3. Price (After First Twelve Months). For every quarter after the one-year anniversary of the Effective Date, the

price of the Products for that quarter shall be 50% of ASP of the Products from the previous quarter as reported on the report described in Schedule B. The ASP shall be expressed in USD. On a quarterly basis, the Parties will make any necessary true-up payments to account for any variance in actual ASP similar to the example provided in Section 4.2(d).

- 4.4. **Payment Terms.** For the first twelve months of the Agreement, Distributor shall pay all amounts due to Seller within ten days of Seller's shipment of ordered Products. For the remainder of the Agreement's Term and any Renewal Term, Distributor shall pay all amounts due to Seller within thirty days of Seller's shipment of ordered Products. Distributor shall make all payments in USD by wire transfer or automated clearing house. Seller's bank wire information is provided in Schedule A.
- 4.5. **Availability/Changes in Products.** Seller may, in its sole discretion, add or make changes to Products in, or remove Products from Schedule A upon one-year prior notice to Distributor, in each case, without obligation to modify or change any Products previously delivered or to supply new goods meeting earlier specifications.
- 4.6. **Minimum Purchase Requirements.** Distributor's purchasing of Products from Seller shall be subject to certain minimum sale requirements, the timing and establishment of which is explained below.
 - (a) For 2024, Distributor shall purchase Products sufficient to achieve [*****] worth of end customer sales ("Initial Minimum Purchase Requirement").
 - (b) No later than November 30, 2024 (and annually thereafter until the termination or expiration of this Agreement), Distributor shall inform Seller the amount of Products required to achieve targeted end customer sales for the upcoming year divided quarterly. For the first three years

of the Agreement, the targeted end customer sales shall increase annually by an amount equal to the percentage growth in Distributor's annual US-based revenue from the prior year (excluding sale of the Products), but in any event shall increase at least 20% over the prior year. For every year after the third year of the Agreement, the targeted end customer sales shall increase annually by an amount equal to the percentage growth in Distributor's annual US-based revenue from the prior year (again excluding sale of the Products), but in any event shall never decrease from the prior year. This end customer sales target requirement shall become the "Minimum Purchase Requirement".

- (c) If Distributor purchases, in a given period of time, less than the Initial Minimum Purchase Requirement or the Minimum Purchase Requirements, as the case may be, Distributor shall be able to cure such failure by

a cash payment equivalent to the shortfall or by purchasing a sufficient amount of the Products to reach the Minimum Purchase Requirement.

5. Distributor Reporting Obligations.

5.1. Customer Complaints and Adverse Events. Distributor shall report to Seller as without undue delay after such complaint has come to Distributor's attention, any complaint from a customer concerning the use of a Product or any report of an adverse patient reaction from being treated with a Product. In the event of death or an unanticipated serious deterioration in a patient's state of health, the report shall be provided by Distributor to Seller immediately.

Reports shall be made to Seller's Quality Assurance Department via e-mail:

[*****]

CC: [*****]

5.2. Monthly Reporting. Beginning on the one-month anniversary of the Effective Date, and continuing until the Agreement expires or is terminated, Distributor shall deliver to Seller a report in compliance with the requirements of Schedule B.

6. Orders Procedure.

6.1. Purchase Orders. Distributor shall issue all purchase orders ("Purchase Order(s)") to Seller in written form via e-mail. By placing an order, Distributor makes an offer to purchase Products under the terms and conditions of this Agreement and the following commercial terms listed in the purchase order ("Purchase Order Transaction Terms"), and on no other terms: (a) the Products to be purchased, including Product names (b) the quantities ordered; and (c) the requested delivery date. Except regarding the Purchase Order Transaction Terms, any variations made to the terms and conditions of this Agreement by Distributor in any Purchase Order are void and have no effect.

6.2. Acceptance and Rejection of Purchase Orders. Seller, in its sole discretion, may accept or reject any Purchase Order. Seller may accept any Purchase Order by confirming the order (whether by written confirmation, invoice, or otherwise) or by delivering the Products, whichever occurs first. If Seller does not accept the Purchase Order under the terms of this Section 6.2 within thirty days of Seller's receipt of the Purchase Order, the Purchase Order will lapse. Distributor has no right to cancel any Purchase Order submitted by it. If Seller rejects a Purchase Order or it lapses, or if Seller does not ship Products under an order, the quantity of Products which was subject of

such Purchase Order shall nevertheless count against Seller's Minimum Purchase Requirements for the respective quarter.

7. Shipment and Delivery.

7.1. **Shipment and Delivery Requirements.** Unless otherwise expressly agreed to by the Parties, Seller shall, at Distributor's expense, deliver the Products to Distributor's facility located [*****], United States, using Seller standard methods for packaging and shipping the Products. Seller may, in its sole discretion, without liability penalty, make partial shipments of Products, each of which constitutes a separate sale, and Distributor shall pay for the units shipped in accordance with the payment terms specified in Section 4 whether such shipment is in whole or partial fulfillment of a Purchase Order, provided, however, that if partial shipments are made, Seller shall re-imburse to Distributor the difference between the transportation costs which Distributor has paid for all partial shipments and the transportation costs which Distributor would have had to pay if all the partial shipments would have been made in one shipment. Seller will use commercially reasonable efforts to timely provide the Products for shipment to meet the times quoted for delivery.

7.2. **Title and Risk of Loss.** Title and risk of loss passes to Distributor upon departure of the Products from a Seller facility.

7.3. **Acceptance of Products.** Distributor shall inspect Products received under this Agreement. Within five business days after receipt of the Products at Distributor's facility, Distributor shall check the Products received match the Products ordered, for quantity and for visible damages. Distributor shall be deemed to have accepted the Products in respect to identity, quantity, and visible defects after such five business days term unless it earlier notifies Seller in writing (e-mail being sufficient) and furnishes written evidence or other documentation as required by Seller that the Products have visible defects or do not conform to the ordered quantity or are not identical to the ordered Products. If Distributor later detects defects of the Products, it shall notify Seller in writing (e-mail being sufficient) within five business days after detection of such defect.

If Distributor notifies Seller pursuant to this Section 7.3, then Seller shall determine, in its sole discretion, whether to repair or replace the Products.

Distributor shall ship at Seller's expense and risk of loss, all goods to be returned, repaired, or replaced under this Section 7.3 to Seller's facility located at [*****]. If Seller exercises its option to replace the Products, Seller shall, after receiving Distributor's shipment of the Products under this provision, ship to Distributor, at Seller's expense and Seller's risk of loss, the replaced Products to an address of Distributor's choosing.

Except as provided under Sections 7.3 and 14.1, all sales of Products to Distributor under this Agreement are made on a one-way basis and Distributor has no other right to return Products purchased under this Agreement.

7.4. **Seller's Trademark License Grant.** Seller hereby grants to Distributor a non-exclusive, non-transferable, and non-sublicensable license in the Territory during the Term solely in connection with the promotion, advertising and sale of the Products in accordance with the terms and conditions of this Agreement to use all Seller's

trademarks and service marks, whether registered or unregistered, including the listed registrations and applications and any registrations which

may be granted pursuant to such applications. On expiration or earlier termination of this Agreement or upon Seller request, Distributor shall promptly discontinue the display or use of any trademark or service mark or change the way it is displayed or used with regard to the Products. Upon expiration or earlier termination of this Agreement, Distributor's rights under this Section 7 shall cease immediately. Other than the express licenses granted by this Section 7, Seller grants no right or license to Distributor, by implication, estoppel or otherwise, to the Products or any intellectual property rights of Seller or its affiliates.

8. Distributor's Handling of Products and Promotional Materials.

- 8.1. The handling and intake of the Products and the storage of the Products by Distributor shall be in strict accordance with any and all instructions and quality requirements of Seller, unless a regulatory body with jurisdiction over the Products in the Territory or Distributor provide stricter requirements, in which case the most stringent requirement shall govern. Distributor shall not re-sterilize without the prior written consent of Seller.
- 8.2. Distributor and Seller shall work together to create mutually agreeable packaging and promotional materials that comply with all relevant legal and regulatory requirements.

9. Term; Termination.

- 9.1. Term. The term of this Agreement commences on the Effective Date and terminates on the fifth anniversary that date, unless terminated earlier under the terms of this Agreement (the "Term"). At least thirty days before the expiration of the Term, the Parties may extend the Term by a mutual written agreement. If Distributor has successfully achieved [*****] in US-based customer sales during the Term, the Agreement shall automatically renew for additional five-year period (a "Renewal Term"), unless terminated earlier under the terms of this Agreement, subject to an adjustment of Minimum Purchase Requirements as set forth in Section 4.6(b) above. At the commencement of the first Renewal Term and any subsequent Renewal Terms, the Parties shall negotiate the US-based customer sales goal necessary to automatically commence the next Renewal Term. This renewal for additional five-year Renewal Term shall be revolving, which means that if at the end of such Renewal Term the conditions for another Renewal Term are met, this Agreement shall again automatically renew.

- 9.2. Mutual Termination Rights. Either Party may terminate this Agreement upon prior written notice to the other

Party if the other Party is in material breach of this Agreement and either the breach cannot be cured or, if the breach can be cured, it is not cured within forty-five days following the other Party's receipt of notice of such breach. Either Party may also terminate this Agreement if the other Party:

- i. becomes insolvent or is generally unable to pay, or fails to pay, its debts as they become due;
- ii. files or has filed against it, a petition for voluntary or involuntary bankruptcy or otherwise becomes subject, voluntarily, or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law;
- iii. seeks reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition, or other relief with respect to it or its debts;
- iv. makes or seeks to make a general assignment for the benefit of its creditors; or
- v. applies for or has a receiver, trustee, custodian, or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.
- vi. is indicted under any Anti-Bribery Law or conducts itself in such a way that raises a reasonable suspicion that it has violated any Anti-Bribery Law as defined in sub-Section 12.1.

9.3. **Seller Termination Rights.** Seller may terminate this Agreement upon one year notice if Distributor (1) fails to reach its Minimum Purchase Obligation for two consecutive years and (2) also fails to cure such shortfall with cash payment or sufficient purchase of Products. By way of example only, if, in the first year after the Effective Date, Distributor fails to purchase sufficient Product to reach the Initial Minimum Purchase Requirement, the Distributor may elect to (i) purchase Products sufficient to eliminate the shortfall, (ii) make an equivalent cash payment to Seller, or (iii) do nothing. In the second year after the Effective Date, if the Distributor fails to purchase sufficient Product to reach the Minimum Purchase Obligation, then Distributor may elect to (i) purchase Products sufficient to eliminate the shortfall, (ii) make an equivalent cash payment to Seller, or (iii) nothing. If Distributor elects to do nothing in these scenarios for two consecutive years, then Seller may exercise its termination rights under this Section 9.3.

9.4. **Effect of Expiration or Termination.** Upon the expiration or earlier termination of this Agreement:

- (a) All outstanding Purchase Orders shall not be affected by the termination;
- (b) Each Party shall promptly return or destroy all documents and tangible materials (and any copies) containing, reflecting, incorporating, or based on the other Party's Confidential Information;

- (c) Distributor shall transfer (or provide an unlimited, worldwide, fully paid-up license to) any and all intellectual property created by Distributor in performance of this Agreement; and
- (d) Seller shall repurchase, in consideration for the original Seller's purchase price, all Distributor's inventory of Product with at least six months shelf life remaining, except for such Products which are subject of a binding purchase agreement between Distributor and a customer.

10. Confidential Information. From time to time during the Term, either Party may disclose or make available to the other Party information about its business affairs, products, confidential intellectual property, trade secrets, third-party confidential information, and other sensitive or proprietary information (collectively, "Confidential Information"). Confidential Information shall not include information that: (a) at the time of disclosure or later is in the public domain; (b) is known to the receiving party at the time of disclosure; or (c) is rightfully obtained by receiving party on a non-confidential basis from a third party or (d) is developed by the receiving party independently from and without use of the disclosing party's Confidential Information.

The receiving party shall not disclose any such Confidential Information to any person or entity, except to the receiving party's employees who have a need to know the Confidential Information for the receiving party to perform its obligations hereunder.

11. Compliance with Laws. Distributor represents and warrants to Seller that (a) Distributor is in compliance with and shall comply with all applicable laws, regulations, and ordinances, including but not limited to all laws in the Territory regarding the sale and promotion of the Products; and (b) Distributor has and shall maintain in effect all the licenses, permissions, authorizations, consents, and permits that it needs to carry out its obligations under this Agreement.

12. Anti-Bribery Representations and Warranties. Each party represents and warrants to the other party that:

12.1 Such party and its shareholders, partners, officers, directors, employees, agents, and anyone acting on its behalf (collectively, the "Representatives") are and shall remain in compliance with all applicable anti-bribery and anti-corruption laws, including the US Foreign Corrupt Practices Act and any laws or regulations of the Territory concerning similar subject matter (collectively, the "Anti-Bribery Laws").

12.2 Neither such party nor any of its Representatives has, directly or indirectly, offered, paid, promised, or authorized the giving of money or anything of value to any:

- (a) Government Official (as defined in Section 12.5(c));

- (b) person or entity; or
- (c) other person or entity while knowing or having reason to believe that some portion or all of the payment or thing of value will be offered, given, or promised, directly or indirectly, to a Government Official or another person or entity; for the purpose of:
 - i. influencing any act or decision of such Government Official or such person or entity in their official capacity, including a decision to do or omit to do any act in violation of their lawful duties or proper performance of functions; or
 - ii. inducing such Government Official or such person or entity to use their influence or position with any Government Entity (as defined in Section 12.5(b)) or other person or entity to influence any act or decision.

in order to obtain or retain business for, direct business to, or secure an improper advantage for a party to this Agreement.

12.3 Neither such party nor any of its Representatives:

- (a) is a Government Official or employs any Government Official or Close Family Member (as defined in Section 12.5(a)) of any Government Official; or
- (b) has a personal, business, or other relationship or association with any Government Official or Close Family Member of any Government Official who may have responsibility for or oversight of any business activities of Seller or any of its subsidiaries, other than any relationships or associations that have been disclosed in writing to the other party.

12.4 Neither such party nor any of its Representatives is or has been the subject of any investigation, inquiry, or enforcement proceeding by any court, governmental, administrative, or regulatory body, or customer regarding any violation or alleged violation of any Anti-Bribery Law. To the knowledge of such party, (i) no such investigation, inquiry, or proceeding has been threatened or is pending; and (ii) there are no circumstances likely to give rise to any such investigation, inquiry, or proceeding.

12.5 For purposes of this Agreement:

- (a) "Close Family Member" means (i) the individual's spouse; (ii) the individual's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; (iii) the spouse's

of any persons listed in subcategory (ii); and (iv) any other person who shares the same household with the individual.

- (b) "Government Entity" means (i) any national, state, regional, or local government (including, in each case, any agency, department, or subdivision of such government); (ii) any political party; (iii) any entity or business that is owned or controlled by any of those bodies listed in subcategory (i) or (ii); or (iv) any international organization, such as the United Nations or the World Bank.
- (c) "Government Official" means (i) any director, officer, employee, agent, or representative (including anyone elected, nominated, or appointed to be a director, officer, employee, agent, or representative) of any Government Entity, or anyone otherwise acting in an official capacity on behalf of a Government Entity; (ii) any political party, political party official, or political party employee; (iii) any candidate for public or political office; (iv) any royal or ruling family member; or (v) any agent or representative of any of those persons listed in subcategories (i) through (iv).

12.6 such party has adopted and maintains adequate policies, procedures, and controls to ensure that Distributor has complied and is in compliance with all Anti-Bribery Laws, including at a minimum policies and procedures relating to prevention of bribery, accounting for financial transactions, due diligence on third parties, and training of personnel.

13. Limited Product Warranty and Disclaimer.

13.1 Limited Product Warranty. Seller warrants that the Products are free from defects in material and workmanship under normal use and service with proper maintenance, that the Products are fit for their intended purpose, and that the Products do not infringe upon Third Party's intellectual property rights, both for a period of time which shall be the shelf life of the Products plus three months. The term for such warranties shall begin upon receipt of the Product by Distributor at its facility. Distributor or its customer shall promptly notify Seller of any known warranty claims and shall cooperate in the investigation of such claims. If any Product is proven to not conform with this warranty during the applicable warranty period, Seller shall, at its exclusive option, either repair or replace the Product or, if such repair or replacement is not successful, refund the purchase price paid by Distributor for each non-conforming Product. Any Product returned under this Section shall follow the return procedure in Section 7.3.

Seller shall have no obligation under the warranty set forth above if Distributor or its customer:

- (a) fails to notify Seller in writing during the warranty period of a non-conformity; or

(b) uses, misuses, or neglects the Product in a manner inconsistent with the Product's specifications or use or maintenance directions, modifies the Product, or improperly installs, handles, or maintains the Product.

Except as explicitly authorized in this Agreement or in a separate written agreement with Seller, Distributor shall not service, repair, modify, alter, replace, reverse engineer, or otherwise change the Products it sells to its customers. Notwithstanding Distributor's statutory warranty towards its customers, Distributor shall not provide its own warranty regarding any Product which goes beyond the statutory warranty.

13.2 DISCLAIMER. EXCEPT FOR THE WARRANTIES SET OUT UNDER THIS SECTION 13, NEITHER SELLER NOR ANY PERSON ON SELLER'S BEHALF HAS MADE OR MAKES FOR DISTRIBUTOR'S OR ITS CUSTOMERS' BENEFIT ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WHATSOEVER, DISTRIBUTOR ACKNOWLEDGES THAT IT HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY MADE BY SELLER, OR ANY OTHER PERSON ON SELLER'S BEHALF EXCEPT THOSE SET FORTH IN THIS AGREEMENT.

14. Distributor's Indemnification. Subject to the terms and conditions of this Agreement, Distributor shall indemnify, hold harmless, and defend Seller and its parent, officers, directors, partners, members, shareholders, employees, agents, affiliates, successors, and permitted assigns (collectively, "Seller Indemnified Party") against any and all losses, damages, liabilities, deficiencies, claims, actions, judgments, settlements, interest, awards, penalties, fines, costs, or expenses of whatever kind, including attorneys' fees, fees and the costs of enforcing any right to indemnification under this Agreement, and the cost of pursuing any insurance providers relating to any claim of a third party or Seller arising out of or occurring in connection with: (a) Distributor's acts or omissions as Distributor of the Products, including negligence, willful misconduct, or breach of this Agreement; (b) Distributor or its employees or agents making assertions or promoting claims about the Product that do not conform with the Products' approved indications; (c) Distributor or its employees or agents whether willfully or negligently, using the Product outside of its approved specifications and instructions for use; (d) any failure by Distributor or its personnel to comply with any applicable laws; or (e) any breach of Distributor of its agreement with a third party as a result or in connection with entering into, performing under, or terminating this Agreement.

15. Seller's Indemnification. Subject to the terms and conditions of this Agreement, Seller shall indemnify, hold harmless, and defend Distributor and its parent, officers, directors, partners, members, shareholders, employees, agents, affiliates, successors, and permitted assigns (collectively, "Distributor Indemnified Party") against any and all losses, damages, liabilities, deficiencies, claims, actions, judgments, settlements, interest, awards, penalties, fines, costs, or expenses of whatever kind, including attorneys' fees, fees and the costs of enforcing any right to indemnification under this Agreement, and the cost of pursuing any insurance providers relating to any claim of a third party or Distributor arising out of or occurring in connection with: (a) Seller's acts or omissions as Seller of the Products, including negligence, willful misconduct, or breach of this Agreement; (b) Seller or its employees or agents making assertions or promoting claims about the Product that do not conform with the Products' approved indications; (c) any failure by Distributor or its personnel to comply with any applicable laws (d) product liability claims of third parties in respect to the Products, except if such Products have been used outside of its approved specifications and instructions, as set forth in

the instruction for use and except if the Products have been modified by the Distributor; (e) any breach of Seller of its agreement with a third party as a result of or in connection with entering into, performing under, or terminating this Agreement; or (f) any claim by a third party that the Products or Distributor's sale of the Products infringes the intellectual property rights of a third party (an "IP Claim"). In addition to the indemnification obligations of this Section, in the event of an IP Claim, Seller shall either (i) modify the Products so that they do not infringe or (ii) provide alternative non-infringing Products, in either case the revised or alternative Products shall have quality and characteristics equal to or greater than the infringing Products.

16. **Limitation of Liability.** IN NO EVENT SHALL A PARTY OR ANY OF ITS REPRESENTATIVES BE LIABLE FOR, OR BE OBLIGED TO INDEMNIFY THE OTHER PARTY FROM, CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, OR ENHANCED DAMAGES, ARISING OUT OF, OR RELATING TO, AND/OR IN CONNECTION WITH ANY BREACH OF THIS AGREEMENT, REGARDLESS OF (A) WHETHER SUCH DAMAGES WERE FORESEEABLE, (B) WHETHER OR NOT SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND (C) THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT OR OTHERWISE) UPON WHICH THE CLAIM IS BASED. IN NO EVENT SHALL A PARTY'S LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER ARISING OUT OF OR RELATED TO BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, EXCEED THE TOTAL OF THE AMOUNTS PAID AND AMOUNTS ACCRUED BUT NOT YET PAID BY DISTRIBUTOR TO SELLER UNDER THIS AGREEMENT IN THE THREE MONTH PERIOD PRECEDING THE EVENT GIVING RISE TO THE CLAIM THE FOREGOING LIMITATIONS APPLY EVEN IF THE OTHER PARTY'S REMEDIES UNDER THIS AGREEMENT FAIL OF THEIR ESSENTIAL PURPOSE.
17. **Insurance.** For a period of two years after the Effective Date, each Party shall, at its own expense, maintain and carry insurance in full force and effect that includes, but is not limited to, commercial general liability (including product liability) with limits no less than \$3MM USD for each occurrence and \$5MM USD in the aggregate with financially sound and reputable insurers. Upon the other party's request, a party shall provide such other party with a certificate of insurance and policy endorsements for all insurance coverage required by this Section 17 and shall not do anything to invalidate such insurance. Each party shall provide the other party with ninety days' advance written notice in the event of a cancellation or material change in its insurance policy.
18. **Seller's Assistance to Distributor.** If Distributor is exposed to claims of third parties related to the performance or failure of the Products (including, but not limited to, customers of Distributor), Seller shall, at Distributor's expense use reasonable best efforts to assist Distributor in the defense against such claims, including but not limited to, through the provision of documents and studies on the Products.
19. **Seller's Representation Regarding Agreement with [*****].** Seller represents and warrants that it is able to terminate its existing contract with [*****] and facilitate Distributor's purchase of existing inventory held by [*****] without violating the rights of any third party including but not limited to [*****].

20. Entire Agreement. This Agreement, including and together with any related exhibits, schedules, and attachments constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements,

representations, and warranties, both written and oral, regarding such subject matter. In the event of conflict between the terms of this Agreement and the terms of any purchase order or other document submitted by one Party to the other, this Agreement shall control unless the Parties specifically otherwise agree in writing.

21. Survival. Subject to the limitations and other provisions of this Agreement: (a) the representations and warranties of the Distributor contained herein will survive the expiration or earlier termination of this Agreement for a period eighteen months after such expiration or termination; and (b) any other provision that, in order to give proper effect to its intent, should survive such expiration or termination, will survive the expiration or earlier termination of this Agreement for the period specified therein, or if nothing is specified for a period of eighteen months after such expiration or termination.

22. Notices. All notices, requests, consents, claims, demands, waivers, and other communications under this Agreement must be in writing and addressed to the other Party at its address set forth below (or to such other address that the receiving Party may designate from time to time in accordance with this Section). Unless otherwise agreed herein, all notices must be delivered by personal delivery, nationally recognized overnight courier, or certified or registered mail (in each case, return receipt requested, postage prepaid). Except as otherwise provided in this Agreement, a notice is effective only (a) on receipt by the receiving Party, and (b) if the Party giving the notice has complied with the requirements of this Section.

Notice to Seller: [*****]

Notice to Distributor: [*****]

[*****]

23. Severability. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect the enforceability of any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or provision is invalid, illegal, or unenforceable, the Parties shall negotiate in good faith to modify this Agreement to affect the original intent of the Parties as closely as possible in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

24. Amendments. No amendment to this Agreement is effective unless it is in writing and signed by an authorized

representative of each Party.

25. **Waiver.** No waiver by any Party of any of the provisions of this Agreement shall be effective unless explicitly set forth in writing and signed by the Party so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any rights, remedy, power, or privilege arising from this Agreement shall operate or be construed as a waiver thereof, nor shall any single or partial exercise of any right, remedy, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.
26. **Change of Control.** Neither Party shall assign any of its rights or delegate any of its obligations under the Agreement without the prior written consent of the other Party; provided, however, that either Party may assign its rights and delegate its obligations upon 90 days prior written notice to the other Party to an entity with which it has completed a Change of Control transaction. No assignment or delegation shall relieve the assigning or delegating Party of any of its obligations under the

Agreement unless the non-assigning or non-delegating Party enters into a novation releasing the assigning or delegating Party of its obligation under the Agreement. Any purported assignment or delegation in violation of this Section 26 shall be null and void.

27. **Successors and Assigns.** This Agreement is binding on and inures to the benefit of the Parties to this Agreement and their respective permitted successors and permitted assigns.
28. **No Third-Party Beneficiaries.** Subject to the next paragraph, this Agreement benefits solely the Parties to this Agreement and their respective permitted successors and permitted assigns and nothing in this Agreement, express or implied, confers on any other Person any legal or equitable right, benefit, or remedy of any nature whatsoever under or by reason of this Agreement.

The Parties hereby designate the Distributor Indemnified Parties and the Seller Indemnified Parties as third-party beneficiaries of Sections 14 and 15 with the right to enforce such Sections.

29. **Arbitration; Choice of Law & Forum.** Any dispute, claim or controversy arising out of or relating to this Agreement or the breach, termination, enforcement, interpretation, or validity thereof, including the determination of the scope or applicability of this agreement to arbitrate, shall be determined by arbitration in Los Angeles, CA before one arbitrator. The arbitration shall be administered by Judicial Arbitration and Mediation Services, Inc. ("JAMS") pursuant to its Comprehensive Arbitration Rules and Procedures and in accordance with the Expedited Procedures in those Rules. Judgment on the award may be entered in any court having jurisdiction. This clause

shall not preclude parties from seeking provisional remedies in aid of arbitration from a court of appropriate jurisdiction. For enforcement of any arbitration award, provisional remedies, or any matters that are not subject to arbitration, the Parties to this Agreement hereby submit to the exclusive jurisdiction of the California courts, both state and federal.

30. **Force Majeure.** No Party shall be liable or responsible to the other Party, or be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement (except for any obligations of the Distributor to make payments to Seller hereunder), when and to the extent such failure or delay is caused by or results from acts beyond the impacted party's ("Impacted Party") control, including, without limitation, the following force majeure events ("Force Majeure Event(s)": (a) acts of God; (b) flood, fire, earthquake, global pandemic, or explosion; (c) war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot or other civil unrest; (d) government order, law, or actions; (e) embargoes or blockades in effect after the Effective Date of this Agreement; and (f) national or regional emergency; The Impacted Party shall give notice within five days of the Force Majeure Event to the other Party, stating the period of time the occurrence is expected to continue. The Impacted Party shall use diligent efforts to end the failure or delay and ensure the effects of such Force Majeure Event are minimized. The Impacted Party shall resume the performance of its obligations as soon as reasonably practicable after the removal of the cause. In the event that the Impacted Party's failure or delay remains uncured for a period of sixty consecutive days following written notice given by it under this Section 30, the other Party may thereafter terminate this Agreement upon ten days written notice.

31. **Relationship of the Parties.** The relationship between the Parties is that of independent contractors. Nothing contained in this Agreement shall be construed as creating any agency, partnership, franchise, business opportunity, joint venture or other form of joint enterprise, employment, or fiduciary relationship between the Parties, and neither Party shall have authority to contract for or bind the other Party in any manner whatsoever.

32. **Counterparts.** This Agreement may be executed in counterparts, each of which is deemed an original, but all of which together are deemed to be one and the same agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the last date written below by their respective officers thereunto duly authorized.

[SIGNATURE PAGE FOLLOWS]

Stedical Scientific, Inc.

By/s/ Lin Sun

Name: Lin Sun

Title: Chairman

Date: January 10, 2024

AVITA Medical Americas, LLC

By /s/ James Corbett

Name: James Corbett

Title: CEO

Date: January 10, 2024

Signature Page to Exclusive Distribution Agreement Between AVITA Medical Americas LLC and Stedical Scientific, Inc.

Schedule A

Products and Price List

- “Product” or “Products” means all models of Seller’s variable porosity dressing products with the trade name PermeaDerm Biosynthetic Wound Matrix and any new releases, enhancements or modifications thereof, agreed by Distributor and Seller from time to time.

- YEAR 1 PRICING

Product	Price
PermeaDerm B	Per Section 4 of the Agreement
PermeaDerm C	Per Section 4 of the Agreement
PermeaDerm Glove	Per Section 4 of the Agreement

- [SELLER BANKING INFORMATION]

Beneficiary Name	Stedical Scientific, Inc.
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]

Schedule B

Monthly Reporting Parameters

Distributor shall provide to Seller, beginning on the tenth business day after the one-month anniversary of the Effective Date, monthly reports that (1) are in English, (2) are in an easily readable, electronic format and (3)

provide the following information from the previous calendar month:

- Summary report of all customer complaints reported in accordance with Section 5;
- Rolling 180 day forecast for Distributor inventory needs. For the first 60 days of the Agreement, the forecast shall not vary by more than 10%; for the next 120 days of the Agreement, the forecast shall not vary by more than 20%.
- Number of Products sold, by Product name;
- Average sale price of Products on both a monthly and quarterly basis, by Product name
- Number of hospitals purchasing;
- Number of new customers;
- Number of patients treated, by indication; (using reasonable commercial efforts to reach a realistic estimate)
- Market intelligence of competitive activity;
- Emerging training deficits (if any);
- New physician studies involving the Products of which Distributor becomes aware; and
- Any other pertinent information related to the performance of the Agreement.

Exhibit 10.2

SECOND AMENDMENT TO LEASE (Units I,J,K,L,M,N,H)

THIS SECOND AMENDMENT TO LEASE made and entered into this 1st day of January, 2024 by and between _Hartco-Ventura, Inc. as current Landlord, hereinafter referred to as "Lessor", and Avita Medical Americas, LLC, A Delaware Limited Liability Company hereinafter referred to as "Lessee".

WITNESSETH

WHEREAS, Lessor leased certain premises in the HARTCO-VENTURA Business Center, at 3007 Bunsen Ave. in the city of Ventura, County of Ventura, State of California, to Lessee, pursuant to the certain lease dated the 25th day of January, 2018; said Lease and amendment(s) thereto

hereinafter collectively referred to as the "Lease", the premises being more particularly described therein; and

WHEREAS, Lessor and Lessee therefore wish to extend said Lease;

NOW THEREFORE, in consideration of these present and the agreement of each other, Lessor and Lessee agree that the said Lease shall be and the same is hereby amended as of the 1st day of January, 2024.

1. The term of the Lease shall be extended 36 months with the amended expiration date of **September 30, 2027**.
2. Rent for the Leased Premises(Units I,J,K,L,M,N,H) from **October 1st, 2023 to September 30, 2024** shall be payable in monthly installments of Thirty Four Thousand Eight Hundred Forty Seven Dollars and 00 Cents (\$34,847.00).
3. Rent for the Leased Premises(Units I,J,K,L,M,N,H) from **October pt, 2024 to September 30, 2025** shall be payable in monthly installments of Thirty Five Thousand Three Hundred Fifty Six Dollars and 80 Cents (\$35,356.80).
4. Rent for the Leased Premises(Units I,J,K,L,M,N,H) from **October 1st, 2025 to September 30, 2026** shall be payable in monthly installments of Thirty Six Thousand Four Hundred Seventy Dollars and 40 Cents (\$36,470.40).
5. Rent for the Leased Premises(Units I,J,K,L,M,N,H) from **October pt, 2026 to September 30, 2027** shall be payable in monthly installments of Thirty Seven Thousand Five Hundred Eighty Four Dollars and 00 Cents (\$37,584.00).
6. The Lessee shall have the right, but not the obligation, to make certain changes at lessee's sole expense to the interior improvements, (including removing office walls) provided that prior to vacating the premises Lessee restores the premises to their original condition, unless lessor indicates his intention to accept the changes and improvements as made..
7. All other terms and conditions of said Lease shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have executed this instrument by proper persons thereunto duly authorized to do the day and year first hereinabove written.

Exhibit 10.2

LESSOR

HARTCO-VENTURA INC.

By: /s/ John Saleh

John Saleh

Date: 1-1-2024

LESSEE

AVITA MEDICAL AMERICAS, LLC

By: /s/ James Corbett

James Corbett

Date: 1/4/2024

Exhibit 10.3

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CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

The purpose of this modification is to add and fund CLINS 0011, 0012, & 0013.

ARTICLE B.3. OPTION PRICES is hereby modified as follows:

<u>CLIN</u>	<u>Period of Performance</u>	<u>Supplies/ Services</u>	<u>Units (# of Product)</u>	<u>Unit Price (\$)</u>	<u>Total (\$)</u>
<u>FIRM FIXED PRICE</u>					
0003 (Option)	36 Months	Phase IV post marketing commitments /Requirements (This is an option that may or may not be exercised during the base period as determined by the need and as established by the FDA)	N/A	N/A	\$[*****] (Not Funded)
0009	09/29/2015 – 09/28/2022	FY 2016/FY2017 Final Rate True Up	N/A	N/A	\$[*****] (Funded)
0010	09/29/2015 – 09/28/2022	FY 2017/FY2018 Final Rate True Up	N/A	N/A	\$[*****] (Funded)
0011	02/16/2024 – 09/28/2025	VMI Maintenance Tasks	N/A	N/A	\$[*****] (Funded)

0012	02/16/2024 – 09/28/2025	VMI Procurement	1000	\$4,500	\$[*****] (Funded)
0013	02/16/2024 – 09/28/2025	Additional VMI Ramp	1103	\$6,500	\$[*****] (Funded)
<u>COST REIMBURSEMENT</u>					
0004 (Option Exercised)	09/18/2017 – 09/28/2025	Pediatric Study (This is an option that may or may not be exercised during the base period for expansion of the label indication with guidance from the FDA)	\$[*****]	\$[*****]	\$[*****] (Funded)
<u>FIRM FIXED PRICE</u>					
0005 (Option)	36 Months	Additional Surge Capacity	[*****]	\$[*****]	\$[*****] (Ceiling – Not Funded)
0006 (Option)	36 Months	Additional Surge Capacity	[*****]	\$[*****]	\$[*****] (Ceiling – Not Funded)
0007 (Option)	36 Months	Additional Surge Capacity	[*****]	\$[*****]	\$[*****] (Ceiling – Not Funded)
0008 (Option)	36 Months	Additional Surge Capacity	[*****]	\$[*****]	\$[*****] (Ceiling – Not Funded)

Exhibit 10.3

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Total	60 Months	See Above Descriptions			\$[*****] (Not Funded)
Unfunded					
Option					
CLINs 3, 5-8					

Total	See Above	See Above Descriptions			\$[*****] (Funded)
Funded					
Option					
CLINs 4, 9-					
13					

ARTICLE B.5. ADVANCE UNDERSTANDINGS Paragraph I.8 is deleted and replaced in its entirety:

I. Additional Understandings

8. It shall be noted that effective as of Modification P00015, there will be no other reporting requirements within this contract beyond what is described in the SoW.

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated Feb 13, 2024, 4 pages

End of Modification #15

Exhibit 31.1

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 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** **May 13, 2024**

/s/ James Corbett

Name: James Corbett

Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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 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 May 13, 2024

/s/ David O'Toole

Name: David O'Toole

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32

**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** **March 31, 2024** 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** **May 13, 2024**

/s/ James Corbett

Name: James Corbett

Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: **November 9, 2023** **May 13, 2024**

/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.

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