

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

FORM 10-Q

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

For the quarterly period ended September 30, 2024

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-39059



AVITA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

85-1021707  
(IRS Employer  
Identification No.)

28159 Avenue Stanford  
Suite 220

Valencia, CA 91355

(Address of principal executive offices and Zip Code)

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

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

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

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

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

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

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

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

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

The number of shares of the registrant's common stock, par value \$0.0001, outstanding as of November 4, 2024 was 26,217,629

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## NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including 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 and marketing organizations to address effectively existing and new markets that we intend to target; future employment and contributions of personnel; tax and interest rates; productivity, business process, rationalization, investment, mergers and acquisitions (and related integration activities), consulting, operational, tax, financial and capital projects and/or initiatives; inflationary pressures on the U.S. and global economies, respectively; changes in the legal or regulatory environments; 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,” “would,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, or “continue” or the negative of these terms or other similar expressions.*

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

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

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

**PART I – Financial Information**

**Item 1. FINANCIAL STATEMENTS**

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

	As of	
	September 30, 2024	December 31, 2023
<b>ASSETS</b>		
Cash and cash equivalents	\$ 18,639	\$ 22,118
Marketable securities	25,766	66,939
Accounts receivable, net	10,288	7,664
BARDA receivables	111	30
Prepays and other current assets	2,892	1,659
Inventory	6,229	5,596
Total current assets	63,925	104,006
Plant and equipment, net	9,151	1,877
Operating lease right-of-use assets	3,780	2,440
Corporate-owned life insurance (“COLI”) asset	3,059	2,475
Intangible assets, net	590	487
Other long-term assets	546	355
Total assets	\$ 81,051	\$ 111,640
<b>LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS’ EQUITY</b>		
Accounts payable and accrued liabilities	\$ 4,187	\$ 3,793
Accrued wages and fringe benefits	9,776	7,972
Current non-qualified deferred compensation (“NQDC”) liability	1,870	168
Other current liabilities	1,308	1,266
Total current liabilities	17,141	13,199
Long-term debt	42,547	39,812
Non-qualified deferred compensation liability	2,742	3,663
Contract liabilities	332	357
Operating lease liabilities, long term	3,079	1,702
Warrant liability	2,759	3,158
Total liabilities	68,600	61,891
Non-qualified deferred compensation plan share awards	224	693
Commitments and contingencies (Note 11)		
<b>Stockholders' equity:</b>		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 26,217,629 and 25,682,078, shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	3	3
Preferred stock, \$0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2024 and December 31, 2023	-	-
Company common stock held by the non-qualified deferred compensation plan	(1,255)	(1,130)
Additional paid-in capital	363,769	350,039
Accumulated other comprehensive loss	(2,065)	(1,887)
Accumulated deficit	(348,225)	(297,969)
Total stockholders’ equity	12,227	49,056
Total liabilities, non-qualified deferred compensation plan share awards and stockholders’ equity	\$ 81,051	\$ 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 Ended		Nine-Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Sales revenue	\$ 19,394	\$ 13,645	\$ 45,681	\$ 35,948
Lease revenue	152	-	164	-
<b>Total revenues</b>	<b>19,546</b>	<b>13,645</b>	<b>45,845</b>	<b>35,948</b>
Cost of sales	(3,190)	(2,113)	(6,814)	(5,984)
<b>Gross profit</b>	<b>16,356</b>	<b>11,532</b>	<b>39,031</b>	<b>29,964</b>
BARDA income	-	212	-	1,369
<b>Operating expenses:</b>				
Sales and marketing	(15,144)	(10,532)	(44,086)	(27,075)
General and administrative	(9,590)	(6,124)	(26,071)	(20,584)
Research and development	(5,428)	(4,394)	(15,510)	(14,056)
<b>Total operating expenses</b>	<b>(30,162)</b>	<b>(21,050)</b>	<b>(85,667)</b>	<b>(61,715)</b>
Operating loss	(13,806)	(9,306)	(46,636)	(30,382)
Interest expense	(1,359)	(10)	(4,063)	(21)
Other (expense) income, net	(1,068)	615	478	2,141
Loss before income taxes	(16,233)	(8,701)	(50,221)	(28,262)
Income tax benefit (expense)	28	(11)	(35)	(54)
<b>Net loss</b>	<b>\$ (16,205)</b>	<b>\$ (8,712)</b>	<b>\$ (50,256)</b>	<b>\$ (28,316)</b>
<b>Net loss per common share:</b>				
Basic and diluted	\$ (0.62)	\$ (0.34)	\$ (1.95)	\$ (1.12)
<b>Weighted-average common shares:</b>				
Basic and diluted	25,983,929	25,401,754	25,794,690	25,281,920

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

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

	<b>Three-Months Ended</b>		<b>Nine-Months Ended</b>	
	<u>September 30, 2024</u>	<u>September 30, 2023</u>	<u>September 30, 2024</u>	<u>September 30, 2023</u>
Net loss	\$ (16,205)	\$ (8,712)	\$ (50,256)	\$ (28,316)
Foreign currency translation loss	-	(47)	-	(57)
Change in fair value due to credit risk on long-term debt loss	(554)	-	(116)	-
Net unrealized gain/(loss) on marketable securities	45	65	(62)	407
Comprehensive loss	<u>\$ (16,714)</u>	<u>\$ (8,694)</u>	<u>\$ (50,434)</u>	<u>\$ (27,966)</u>

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

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

**Three-Months Ended September 30, 2024**

	<b>Common Stock</b>		<b>Company common stock held by the NQDC Plan</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Other Comprehensive Gain (Loss)</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>					
Balance at June 30, 2024	25,949,906	\$ 3	\$ (1,022)	\$ 358,510	\$ (1,556)	\$ (332,020)	\$ 23,915
Net loss	-	-	-	-	-	(16,205)	(16,205)
Stock-based compensation	-	-	-	4,040	-	-	4,040
Vesting of restricted stock units	50,157	-	-	-	-	-	-
Exercise of stock options	183,867	-	-	1,008	-	-	1,008
Distribution/diversification of Company common stock held by the NQDC Plan	-	-	58	(2)	-	-	56
Vesting of Company common stock held by the NQDC Plan	33,699	-	(291)	291	-	-	-
Change in redemption value of share awards in NQDC Plan	-	-	-	(78)	-	-	(78)
Net unrealized gain on marketable securities	-	-	-	-	45	-	45
Change in fair value due to credit risk on long-term debt	-	-	-	-	(554)	-	(554)
Balance at September 30, 2024	26,217,629	\$ 3	\$ (1,255)	\$ 363,769	\$ (2,065)	\$ (348,225)	\$ 12,227

**Three-Months Ended September 30, 2023**

	<b>Common Stock</b>		<b>Company common stock held by the NQDC Plan</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Other Comprehensive Gain (Loss)</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>					
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	-	-	-	-	-	-
Vesting of 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
Net unrealized gain on marketable securities	-	-	-	-	65	-	65
Foreign currency translation gain	-	-	-	-	(47)	-	(47)
Balance at September 30, 2023	25,550,694	\$ 3	\$ (1,290)	\$ 347,192	\$ 7,977	\$ (290,904)	\$ 62,978

**Nine-Months Ended September 30, 2024**

<b>Common Stock</b>							
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2023	25,682,078	\$ 3	\$ (1,130)	\$ 350,039	\$ (1,887)	\$ (297,969)	\$ 49,056
Net loss	-	-	-	-	-	(50,256)	(50,256)
Stock-based compensation	-	-	-	10,603	-	-	10,603
Vesting of restricted stock units	94,123	-	-	-	-	-	-
Exercise of stock options	301,524	-	-	1,701	-	-	1,701
ESPP purchase	96,253	-	-	786	-	-	786
Distribution/diversification of Company common stock held by the NQDC Plan	-	-	245	76	-	-	321
Vesting of Company common stock held by the NQDC Plan	43,651	-	(370)	370	-	-	-
Change in redemption value of share awards in NQDC Plan	-	-	-	194	-	-	194
Net unrealized loss on marketable securities	-	-	-	-	(62)	-	(62)
Change in fair value due to credit risk on long-term debt	-	-	-	-	(116)	-	(116)
Balance at September 30, 2024	<u>26,217,629</u>	<u>\$ 3</u>	<u>\$ (1,255)</u>	<u>\$ 363,769</u>	<u>\$ (2,065)</u>	<u>\$ (348,225)</u>	<u>\$ 12,227</u>

**Nine-Months Ended September 30, 2023**

<b>Common Stock</b>							
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 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
Vesting of 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 the NQDC Plan	-	-	238	284	-	-	522
Change in redemption value of share awards in NQDC Plan	-	-	-	(998)	-	-	(998)
Foreign currency translation loss	-	-	-	-	(57)	-	(57)
Net unrealized gain on marketable securities	-	-	-	-	407	-	407
Balance at September 30, 2023	<u>25,550,694</u>	<u>\$ 3</u>	<u>\$ (1,290)</u>	<u>\$ 347,192</u>	<u>\$ 7,977</u>	<u>\$ (290,904)</u>	<u>\$ 62,978</u>

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



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

	Nine-Months Ended	
	September 30, 2024	September 30, 2023
Cash flow from operating activities:		
Net loss	\$ (50,256)	\$ (28,316)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of long-term debt	2,619	-
Change in fair value of warrant liability	(399)	-
Depreciation and amortization	717	445
Stock-based compensation	10,698	6,213
Non-cash lease expense	633	531
Loss on fixed asset disposal	25	83
Investment losses	-	17
Loss on patent disposal	16	4
Remeasurement and foreign currency transaction gain/(loss)	23	(23)
Excess and obsolete inventory related charges	408	149
BARDA deferred costs	-	(147)
Contract cost amortization	-	255
Provision for credit losses	33	113
Amortization of premium of marketable securities	(1,479)	(794)
Non-cash changes in the fair value of NQDC plan	36	899
Changes in operating assets and liabilities:		
Trade and other receivables	(2,656)	(2,473)
BARDA receivables	(81)	697
Prepays and other current assets	(1,233)	(2,057)
Inventory	(1,041)	(2,405)
Operating lease liability	(667)	(571)
Corporate-owned life insurance (“COLP”) asset	(271)	(643)
Other long-term assets	(192)	(114)
Accounts payable and accrued expenses	(65)	(70)
Accrued wages and fringe benefits	1,804	524
Current non-qualified deferred compensation liability	1,625	(651)
Other current liabilities	112	345
Non-qualified deferred compensation plan liability	(1,242)	1,174
Contract liabilities	(25)	(333)
Net cash used in operations	\$ (40,858)	\$ (27,148)
Cash flows from investing activities:		
Purchase of marketable securities	(18,609)	(7,633)
Sale of marketable securities	-	2,372
Maturities of marketable securities	61,200	65,289
Purchase of plant and equipment	(7,559)	(1,085)
Patent filing fees	(140)	(32)
Net cash provided by investing activities	\$ 34,892	\$ 58,911
Cash flow from financing activities:		
Proceeds from exercise of stock options	1,701	942
Employee stock purchase plan (“ESPP”) purchases	786	-
Net cash provided by financing activities	\$ 2,487	\$ 942
Effect of foreign exchange rate on cash and cash equivalents	-	(15)
Net increase/(decrease) in cash and cash equivalents	(3,479)	32,690
Cash and cash equivalents beginning of the period	\$ 22,118	\$ 18,164
Cash and cash equivalents end of the period	\$ 18,639	\$ 50,854
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid during the period	\$ 21	\$ 44
Interest paid during the period	\$ 4,062	\$ 21
Non-cash investing and financing activities:		
Plant and equipment purchases not yet paid	\$ 407	\$ 114
Right-of-use-asset obtained in exchange for lease liabilities	\$ 2,026	\$ -

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



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

**1. The Company**

***Nature of the Business***

AVITA Medical, Inc. (collectively with its subsidiaries, “AVITA Medical”, “we”, “our”, “us”, or the “Company”) is a commercial-stage regenerative medicine company transforming the standard of care in wound management and skin restoration with innovative devices. At the forefront of the Company’s portfolio is its patented and proprietary RECELL<sup>®</sup> technology (“RECELL”). RECELL harnesses the regenerative properties of a patient’s own skin to create an autologous skin cell suspension, Spray-On Skin<sup>™</sup> 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. The Company also holds the right to market, sell, and distribute PermeaDerm<sup>®</sup>, a biosynthetic wound matrix, in the United States under the terms of an exclusive multi-year distribution agreement with Stedical Scientific, Inc. (“Stedical”). The Company also entered into an exclusive multi-year development and distribution agreement with Regenity Biosciences (“Regenity”). Following 510(k) approval, Regenity will manufacture and supply Cohealyx<sup>™</sup>, an AVITA-medical branded collagen-based dermal matrix. Under the agreement, the Company will hold the exclusive rights to market, sell, and distribute Cohealyx in the U.S., with potential expansion into the European Union, as well as in Australia and Japan.

The single-use RECELL Autologous Cell Harvesting Device (“RECELL Ease-of-Use” or “RECELL EOU”) is approved by the U.S. Food and Drug Administration (the “FDA”) for the treatment of thermal burn wounds and full-thickness skin defects, and repigmentation of stable depigmented vitiligo lesions. The Company’s next-generation device, RECELL GO<sup>™</sup> Autologous Cell Harvesting Device (“RECELL GO”), is FDA-approved to treat thermal burn wounds and full-thickness skin defects. RECELL GO introduces enhanced features that streamline the preparation of Spray-On Skin Cells and improves workflow efficiency in the operating room. It consists of two components: a multi-use, AC-powered RECELL GO Processing Device (the “RPD”) and a RECELL GO Preparation Kit (the “RPK”). The RPK contains the single-use RECELL GO Cartridge, disaggregation head, RECELL Enzyme<sup>™</sup>, and other components. The RPD provides the control for the RPK, manages the pressure applied to disaggregate the donor skin cells, and precisely regulates the incubation times of the RECELL Enzyme and solutions to optimize cell yield and promote cell viability.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying unaudited Consolidated Financial Statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the “SEC”). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the Consolidated Financial Statements reflect all adjustments of a normal and recurring nature that are considered necessary for a fair presentation of the results for the interim periods presented. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited Consolidated Financial Statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year-ended December 31, 2023 filed with the SEC on February 22, 2024 and the Australian Securities Exchange (“ASX”) on February 23, 2024 (the “2023 Annual Report”).

Except for revenue recognition, related to the RECELL GO system, as described below, there have been no changes to the Company’s significant accounting policies as described in the 2023 Annual Report that have had a material impact on the Company’s Consolidated Financial Statements. See the summary of the Company’s significant accounting policies set forth in the notes to its Consolidated Financial Statements included in the 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.

***Recent Accounting Pronouncements***

In November 2023, the Financial Accounting Standards Board (the “FASB”) issued ASU 2023-07, *Segment 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”) 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 loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The ASU is effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting this ASU on its Consolidated Financial Statements and disclosures.

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

### ***Use of Estimates***

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

### ***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 Accumulated other comprehensive loss in the Consolidated Balance Sheets.

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 are included in earnings in the Consolidated Statement of Operations. Gains and losses for remeasurement were minimal during the three-months and nine-months ended September 30, 2024 and 2023.

The Company records certain revenues and operating expenses in foreign currencies. These revenues and expenses are translated into U.S. Dollars based on the average exchange rate for the reporting period. Assets and liabilities denominated in foreign currencies are translated into U.S. Dollars at the exchange rate in effect as of the balance sheet date. For the three and nine-months ended September 30, 2024, the Company incurred approximately \$11,000 and \$23,000 in losses included in Net loss in the Consolidated Statement of Operations, respectively. For the three and nine-months ended September 30, 2023, the Company incurred approximately \$26,000 and \$23,000 in gains included in Net loss in the Consolidated Statement of Operations, respectively.

### ***Cash and Cash Equivalents***

Cash and cash equivalents consist of cash held at deposit institutions and cash equivalents. Cash equivalents consist primarily of money market funds. Cash equivalents also include short-term highly liquid investments with original maturities of three months or less from the date of purchase. The Company holds cash at deposit institutions in the amount of \$5.3 million and \$10.7 million as of September 30, 2024 and December 31, 2023, respectively. The Company does not have cash on deposit denominated in foreign currency in foreign institutions as of September 30, 2024. As of December 31, 2023, the Company had \$69,000 of cash on deposit denominated in foreign currencies in foreign institutions. As of September 30, 2024 and December 31, 2023, the Company held cash equivalents in the amounts of \$13.3 million and \$11.4 million, respectively.

### ***Rabbi Trust***

During April 2022, the Company established a rabbi trust to hold the assets of the NQDC Plan. The rabbi trust holds the COLI asset and the Common stock from deferred restricted stock unit 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. Common stock held in the rabbi trust is classified in a manner similar to treasury stock and presented separately on the Consolidated Balance Sheets as Company common stock held by the NQDC plan. As of September 30, 2024 and December 31, 2023, a total of 91,026 and 81,052 shares awards have been deferred, respectively. Vested shares are converted to Common stock and are reclassified to permanent equity.

### **Concentrations**

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

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

### **Revenue Recognition**

The Company generates revenues primarily from:

- The sale of RECELL EOU, RPK, and PermeaDerm products to hospitals, other treatment centers, and distributors.
- Maintenance fee received from BARDA to ensure first right of access to our inventory. In the prior year, the Company recorded service revenue for the emergency preparedness services provided to BARDA.
- Lease revenue for the RPD.

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

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

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

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

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

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

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

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

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

For these contracts the Company considers the guidance under ASC 842 to determine if furnishing the RPD to the customer during the period of use establishes an embedded lease. To determine if the contract contains a lease, the Company evaluates the customer's rights and ability to control the use of the underlying equipment throughout the contract term, including any equipment substitution rights retained by the Company. As the contract conveys the right to control the use of an identified asset for a period of time, the contract was determined to contain a lease. The Company then evaluated the lease classification based on the below:

- Pursuant to ASC 842-30, the Company will classify a lease as a sales-type lease if: (i) the lease transfers ownership of the underlying asset to the lessee by the end of the lease term, (ii) the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise, (iii) the lease term is for the major part of the remaining economic life of the underlying asset, (iv) the present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments equals or exceeds substantially all (90% or more) of the fair value of the underlying asset, or (v) the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term.
- Pursuant to ASC 842-30, when none of the sales-type lease classification criteria are met, a lessor would classify the lease as a direct financing lease when both of the following criteria are met: (i) the present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments and/or any other third party unrelated to the lessor equals or exceeds substantially all (90% or more) of the fair value of the underlying asset and (ii) it is probable that the lessor will collect the lease payments plus any amount necessary to satisfy a residual value guarantee.
- Pursuant to ASC 842-30, a lessor would classify a lease as an operating lease when none of the sales-type or direct financing lease classification criteria are met. Further, per ASC 842, a lessor is required to classify a lease with variable lease payments that do not depend on an index or rate as an operating lease at lease commencement if the lease would have been classified as a sales-type lease or a direct financing lease in accordance with the classification criteria of ASC 842 and the lessor would have otherwise recognized a loss at the lease commencement date.

In determining whether the lease components are related to a sales-type lease or an operating lease, the Company evaluates if the lease transfers ownership at the end of the lease term, purchase options, the lease term in relation to the economic life of the asset, if the lease payments exceed the fair value of the asset, and if the asset is of a specialized nature. The Company also evaluates if the lease results in a loss at the lease commencement date. As the lease term is for the major part of the economic life, the lease meets the classification criteria for sales-type lease. However, to determine if the contract results in a loss at the lease commencement date the

Company evaluated the consideration in the contract. The consideration at lease commencement does not contain fixed payments, purchase options, penalty payments or residual value guarantees. The variable consideration is related to the sale of the RPK. As the variable lease payments are not dependent on an index or rate, the variable consideration is excluded from consideration at contract inception resulting in a loss at lease commencement. As such, the Company classifies the lease as an operating lease.

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

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

### 3. Marketable Securities

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

	As of September 30, 2024			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 13,357	\$ -	\$ -	\$ 13,357
Total cash equivalents	<u>\$ 13,357</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 13,357</u>
Current marketable securities:				
U.S. Treasury securities	\$ 25,732	\$ 34	\$ -	\$ 25,766
Total current marketable securities	<u>\$ 25,732</u>	<u>\$ 34</u>	<u>\$ -</u>	<u>\$ 25,766</u>
	As of December 31, 2023			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 8,427	\$ -	\$ -	\$ 8,427
U.S. Treasury securities	2,992	-	-	2,992
Total cash equivalents	<u>\$ 11,419</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 11,419</u>
Current marketable securities:				
U.S. Treasury securities	\$ 65,145	\$ 100	\$ (3)	\$ 65,242
U.S. Government agency obligations	1,699	-	(2)	1,697
Total current marketable securities	<u>\$ 66,844</u>	<u>\$ 100</u>	<u>\$ (5)</u>	<u>\$ 66,939</u>

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

(in thousands)	As of September 30, 2024		As of December 31, 2023	
	Amortized Cost	Carrying Value	Amortized Cost	Carrying Value
Due in one year or less	\$ 25,732	\$ 25,766	\$ 66,844	\$ 66,939

Unrealized gains and losses, net of any related tax effects for available-for-sale securities are excluded from earnings and are included in other comprehensive loss and reported as a separate component of stockholders' equity until realized. Realized gains and losses on marketable securities are included in Other income, net, in the accompanying Consolidated Statements of Operations. The Company had net unrealized gains of \$34,000 and \$95,000 as of September 30, 2024 and December 31, 2023, respectively. The Company did not have sales of investments during the three-months and nine-months ended September 30, 2024 and 2023 that resulted in realized gains or losses. As of September 30, 2024, and December 31, 2023, the Company did not recognize credit losses. The Company has accrued interest income receivable of \$154,000 and \$227,000 as of September 30, 2024, and December 31, 2023, respectively, in Prepaids and other current assets in the Consolidated Balance Sheets.

#### 4. Fair Value Measurements

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

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

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

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



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

(in thousands)	As of September 30, 2024			
	Level 1	Level 2	Level 3	Total
<b>Cash equivalents:</b>				
Money market funds	\$ 13,357	\$ -	\$ -	\$ 13,357
Total cash equivalents	\$ 13,357	\$ -	\$ -	\$ 13,357
<b>Current marketable securities:</b>				
U.S. Treasury securities	\$ -	\$ 25,766	\$ -	\$ 25,766
Total current marketable securities	\$ -	\$ 25,766	\$ -	\$ 25,766
Total marketable securities and cash equivalents	\$ 13,357	\$ 25,766	\$ -	\$ 39,123
<b>Financial liabilities:</b>				
Long-term debt	\$ -	\$ -	\$ 42,547	\$ 42,547
Warrant liability	-	-	2,759	2,759
Non-qualified deferred compensation plan liability	-	4,612	-	4,612
Total financial liabilities	\$ -	\$ 4,612	\$ 45,306	\$ 49,918
<b>Financial assets:</b>				
Corporate-owned life insurance policies	\$ -	\$ 3,059	\$ -	\$ 3,059
Total financial assets	\$ -	\$ 3,059	\$ -	\$ 3,059

(in thousands)	As of December 31, 2023			
	Level 1	Level 2	Level 3	Total
<b>Cash equivalents:</b>				
Money market funds	\$ 8,427	\$ -	\$ -	\$ 8,427
U.S. Treasury securities	-	2,992	-	2,992
Total cash equivalents	\$ 8,427	\$ 2,992	\$ -	\$ 11,419
<b>Current marketable securities:</b>				
U.S. Treasury securities	\$ -	\$ 65,242	\$ -	\$ 65,242
U.S. Government agency obligations	-	1,697	-	1,697
Total current marketable securities	\$ -	\$ 66,939	\$ -	\$ 66,939
Total marketable securities and cash equivalents	\$ 8,427	\$ 69,931	\$ -	\$ 78,358
<b>Financial liabilities:</b>				
Long-term debt	\$ -	\$ -	\$ 39,812	\$ 39,812
Warrant liability	-	-	3,158	3,158
Non-qualified deferred compensation plan liability	-	3,831	-	3,831
Total financial liabilities	\$ -	\$ 3,831	\$ 42,970	\$ 46,801
<b>Financial assets:</b>				
Corporate-owned life insurance policies	\$ -	\$ 2,475	\$ -	\$ 2,475
Total financial assets	\$ -	\$ 2,475	\$ -	\$ 2,475

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

(in thousands)	As of September 30, 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	2,619	(399)	1,616	733
Change in fair value in other comprehensive loss	116	-	621	-
Balance end of period, at fair value	\$ 42,547	\$ 2,759	\$ 39,812	\$ 3,158

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. Level 2 assets consist of U.S. Treasury securities and U.S. Government Agency obligations. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. The corporate-owned life insurance contracts are recorded at cash surrender value, which approximates the fair value and is categorized as Level 2. Non-qualified deferred compensation plan liability is measured at fair value based on quoted prices of identical instruments to the investment vehicles

selected by the participants and it is recorded as Level 2. There were no transfers between fair value measurement levels during the periods ended September 30, 2024 and December 31, 2023.

### **Long-term debt**

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

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

The below assumptions were used in the MCS:

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
Risk-free interest rate	3.53 %	3.81 %
Revenue volatility	64.00 %	64.00 %
Revenue discount rate	14.41 %	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 liability on the Consolidated Balance Sheets, is estimated by the Company based on the Black-Scholes option pricing model with the following key inputs:

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
Price of common stock	\$ 10.72	\$ 13.72
Expected term	9.05 years	9.81 years
Expected volatility	51.47 %	31.07 %
Exercise price	\$ 10.9847	\$ 10.9847
Risk-free interest rate	3.73 %	3.84 %
Expected dividends	0.00 %	0.00 %

## **5. Revenues**

The Company generates revenues primarily from:

- The sale of RECELL Ease of Use (“EOU”), RECELL GO RPK, and PermeaDerm products to hospitals, other treatment centers, and distributors.
- Maintenance fee received from BARDA in exchange for first right of access to our inventory. In the prior year, the Company recorded service revenues for the emergency preparedness services provided to BARDA.
- Lease revenue for the RECELL GO RPD.

The Company’s sale of the EOU and PermeaDerm products are accounted for under ASC 606, as discussed in Note 2 of our Consolidated Financial Statements. Revenue for the RECELL GO device is disaggregated between two accounting standards: (1) ASC 606 for the RPK and (2) ASC 842 for the RPD.

### **RECELL GO**

The RECELL GO device consists of a single-use RPK and a durable AC powered device, RPD. The Company enters into contracts with customers where it receives consideration for the single-use RPK and does not receive additional consideration for the RPD. The consideration in the contract is allocated based on the SSP. Upon sale of the RPK the consideration is allocated to the lease and non-lease components. Consideration received for the RPK is recorded in Sales revenues in the Consolidated Statement of Operations and consideration for the lease is recorded in Lease revenue in the Consolidated Statement of Operations. During the three and nine-months ended September 30, 2024, the Company recorded approximately \$7.6 million and \$8.2 million in Sales revenue related to the RPK and \$152,000 and \$164,000 in Lease revenue related to the RPD in the Consolidated Statement of Operations, respectively.

#### ***Distributor Transactions***

For international markets, the Company exclusively partners with third-party distributors (currently, COSMOTEC in Japan, and PolyMedics Innovation GmbH, in Germany). 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, Summary of Significant Accounting Policies in our Consolidated Financial Statements.

#### ***PermeaDerm Sales***

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

#### ***Remaining Performance Obligations***

Contract liabilities are calculated as the dollar value of the remaining performance obligations on executed contracts and primarily relate to COSMOTEC and other customers. The estimated revenue expected to be recognized in the future once the performance obligation is satisfied under the Company's existing customer agreements is \$365,000 and \$390,000 as of September 30, 2024 and December 31, 2023, respectively. These amounts are classified between current and long-term in Other current liabilities and Contract liabilities in the Consolidated Balance Sheets.

#### ***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 September 30, 2024 and 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. Contract liability balance primarily relates to unsatisfied performance obligation with COSMOTEC of \$365,000 and \$390,000 as of September 30, 2024 and December 31, 2023, respectively. This balance is classified between current and long-term. As of September 30, 2024 and December 31, 2023, a total of \$33,000 and \$33,000, respectively, was included in Other current liabilities and \$332,000 and \$357,000, respectively, in Contract liabilities in the Consolidated Balance Sheets.

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 and nine-months ended September 30, 2024 and 2023, respectively.

#### ***Disaggregated Revenue***

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

### **6. Long-term debt**

On October 18, 2023 (the "Closing Date") the Company entered into a credit agreement, by and between the Company, as borrower, and an affiliate of OrbiMed Advisors, LLC (the "Lender") as the lender and administrative agent (the "Credit Agreement"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to \$90.0 million, of which (i) \$40.0 million was made available on the Closing Date (the "Initial Commitment Amount"), (ii) \$25.0 million 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 "Loan Facility"). The maturity date of the Credit Agreement is October 18, 2028 (the "Maturity Date"). On the Closing Date, the Company closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Lender. The Company received net proceeds of \$38.8 million upon closing after deducting the Lender's transaction costs in connection with the Loan Facility. For information regarding an amendment to the Credit Agreement, refer to Note 16 of our Consolidated Financial Statements.

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 Facility during the period commencing on the prepayment date through the 24-month anniversary of the Closing Date. The Credit Agreement further states that the Company will be required to repay the principal amount of the Loan Facility if the Company does not achieve certain net revenue thresholds. If, for any quarter until the maturity date, the Company's net revenue does not equal or exceed the applicable trailing 12-month amount as set forth in the Credit Agreement, then the Company shall repay in equal quarterly installments equal to 5.0% of the outstanding principal amount of the Loan Facility 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 September 30, 2024, the Company has not made any repayments on the outstanding debt balance.

During the term of the Credit Agreement, interest payable in cash by the Company shall accrue on any outstanding debt at a rate per annum equal to the greater of (x) the SOFR rate for such period and (y) 4.00% plus, in either case, 8.00%. As of September 30, 2024, the interest rate was 13.20%. 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 unused fee accrues at 0.5% of the undrawn balance and it is 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 September 30, 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 the guarantors will be required to maintain at least \$10.0 million of unrestricted cash and cash equivalents.

On the Closing Date, the Company issued to an affiliate of the Lender a warrant (the "Warrant") to purchase up to 409,661 shares of the Company's Common Stock, par value \$0.0001 per share, 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, net. Changes related to instrument-specific credit risk are revalued by comparing the amount of the total change in fair value of the long-term debt to the amount of change in fair value that would have occurred if the Company's credit spread had not changed between the reporting periods, and is recorded in Accumulated other comprehensive loss in the Consolidated Balance 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 \$2.5 million and reduction to the liability of \$188,000 as of September 30, 2024 and December 31, 2023, respectively. For changes in fair value, refer to Note 4 of our Consolidated Financial Statements.

## 7. Inventory

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

	As of	
	September 30, 2024	December 31, 2023
Raw materials	\$ 2,731	\$ 3,683
Work in process	427	878
Finished goods	3,071	1,035
Total inventory	\$ 6,229	\$ 5,596

The Company values its inventories to reflect the lower of cost or net realizable value. Charges for estimated excess and obsolescence are recorded in Cost of sales in the Consolidated Statements of Operations and were \$173,000 and \$81,000 for the three-months ended September 30, 2024 and 2023, respectively, and \$408,000 and \$149,000 for the nine-months ended September 30, 2024 and 2023, respectively. The inventory balance as of September 30, 2024, includes inventory purchased from Stedical for the sales of PermeaDerm.

## 8. Intangible Assets

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

	Weighted Average Useful Life	As of September 30, 2024			As of December 31, 2023		
		Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount
Patent 1	-	\$ -	\$ -	\$ -	\$ 17	\$ (17)	\$ -
Patent 2	12	136	(43)	93	141	(39)	102
Patent 3	14	234	(65)	169	206	(54)	152
Patent 5	18	108	(15)	93	99	(11)	88
Patent 6	16	62	(9)	53	56	(6)	50
Patent 7	-	-	-	-	2	-	2
Patent 8	18	42	(3)	39	29	(1)	28
Patent 9	2	117	(28)	89	3	-	3
Patent 10	-	-	-	-	3	-	3
Patent 11	-	-	-	-	6	(1)	5
Trademarks	Indefinite	54	-	54	54	-	54
Total intangible assets		\$ 753	\$ (163)	\$ 590	\$ 616	\$ (129)	\$ 487

For the three-months ended September 30, 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 intangible assets recognized for the three-months ended September 30, 2024 and 2023. For the nine-months ended September 30, 2024 and 2023, the Company recorded a loss on disposal for patents of approximately \$16,000 and \$4,000, respectively, in General and administrative expenses in the Consolidated Statement of Operations. Amortization expense of intangibles included in the Consolidated Statements of Operations was \$23,000 and \$9,000 for the three-months ended September 30, 2024 and 2023, respectively, and \$56,000 and \$26,000 for the nine-months ended September 30, 2024 and 2023, respectively.

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

	<b>Estimated Amortization Expense</b>	
Remainder of 2024	\$	47
2025		93
2026		49
2027		40
2028		40
Thereafter		267
Total	\$	<u>536</u>

## 9. Plant and Equipment

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

	<b>Useful Lives</b>	<b>As of</b>	
		<b>September 30, 2024</b>	<b>December 31, 2023</b>
Computer equipment	3 - 5 years	\$ 1,632	\$ 984
Computer software	3 years	836	840
Construction in progress ("CIP")		90	87
Furniture and fixtures	7 years	1,112	824
Laboratory and other equipment	3 - 5 years	954	769
Leasehold improvements	Lesser of life or lease term	4,196	367
RECELL moulds	5 years	462	438
RECELL GO RPD CIP		1,531	-
RECELL GO RPD		318	-
Operating lease assets - RPD	200 uses	1,071	-
Less: accumulated amortization and depreciation		<u>(3,051)</u>	<u>(2,432)</u>
Total plant and equipment, net		<u>\$ 9,151</u>	<u>\$ 1,877</u>

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

Depreciation expense related to plant and equipment was \$288,000 and \$156,000 for the three-months ended September 30, 2024 and 2023, respectively, and \$661,000 and \$419,000 for the nine-months ended September 30, 2024 and 2023, respectively. No impairment was recorded for the three-months ended September 30, 2024. During the nine-months ended September 30, 2024, the Company recorded a loss on disposal of fixed assets for approximately \$5,000. During the three-months and nine-months ended September 30, 2023, the Company recorded a loss on disposal of fixed assets for approximately \$80,000 and \$83,000, respectively. Amounts are recorded in General and administrative expenses in the Consolidated Statement of Operations.

### ***Lessor Arrangements***

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

The table below summarizes the Company's Lease revenue as presented in the Consolidated Statement of Operations for the three and nine-months ended September 30, 2024 and 2023.

(in thousands)	<b>Three-Months Ended September 30, 2024</b>	<b>Nine-Months Ended September 30, 2024</b>
Variable lease revenue	\$ 152	164

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

	<b>As of September 30, 2024</b>
Rental RPD assets	\$ 1,071
Accumulated depreciation	(24)
Net rental RPD assets	<u>\$ 1,047</u>

## 10. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets are primarily located in the United States as of September 30, 2024, and December 31, 2023.

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

	<b>Three-Months Ended</b>		<b>Nine-Months Ended</b>	
	<b>September 30, 2024</b>	<b>September 30, 2023</b>	<b>September 30, 2024</b>	<b>September 30, 2023</b>
Revenue by region:				
United States	\$ 19,048	\$ 12,961	\$ 44,162	\$ 33,379
Japan	388	581	1,237	2,309
European Union	-	-	155	-
Australia	54	61	132	156
United Kingdom	56	42	159	104
Total	<u>\$ 19,546</u>	<u>\$ 13,645</u>	<u>\$ 45,845</u>	<u>\$ 35,948</u>

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

	<b>Three-Months Ended</b>		<b>Nine-Months Ended</b>	
	<b>September 30, 2024</b>	<b>September 30, 2023</b>	<b>September 30, 2024</b>	<b>September 30, 2023</b>
Revenue by customer type:				
Commercial sales	\$ 19,482	\$ 13,547	\$ 45,681	\$ 35,673
Deferred commercial revenue recognized	8	8	25	25
BARDA revenue for right of first access	56	90	139	250
Total	<u>\$ 19,546</u>	<u>\$ 13,645</u>	<u>\$ 45,845</u>	<u>\$ 35,948</u>

Commercial revenue by product for the three-months and nine-months ended September 30, 2024 and 2023 were as follows (in thousands):

	Three-Months Ended		Nine-Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Commercial revenue by product:				
RECELL	\$ 19,059	\$ 13,547	\$ 44,811	\$ 35,673
Other wound care products	271	-	706	-
Lease revenue	152	-	164	-
Total commercial sales	\$ 19,482	\$ 13,547	\$ 45,681	\$ 35,673

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

	Three-Months Ended		Nine-Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Cost of sales:				
Commercial cost	\$ 3,190	\$ 2,110	\$ 6,814	\$ 5,835
BARDA:				
Product cost	-	(83)	-	(106)
Emergency preparedness service cost	-	86	-	255
Total	\$ 3,190	\$ 2,113	\$ 6,814	\$ 5,984

## 11. Commitments and Contingencies

The Company is subject to certain contingencies arising in the ordinary course of business. The Company records accruals for these contingencies to the extent that a loss is both probable and reasonably estimable. If some amount within a range of loss appears more likely than any other amount within the range, that amount is accrued. Alternatively, when no amount within a range of loss appears to be a better estimate than any other amount, the lowest amount in the range is accrued. The Company expenses legal costs associated with loss contingencies as incurred. As of September 30, 2024 and December 31, 2023, the Company did not have any outstanding or threatened litigation that would have a material impact on the Consolidated Financial Statements.

### *Minimum Purchase Commitments with Stedical*

The Company is subject to minimum purchases of PermeaDerm product for the initial term of five years. For 2024, the Company has an obligation to purchase enough products from Stedical to achieve \$5.0 million in customer sales of that purchased inventory. As of September 30, 2024, this obligation has already been achieved. For the first three years of the Distribution Agreement, the minimum purchase should increase annually by an amount equal to the percentage growth in the Company's annual U.S.-based revenues excluding PermeaDerm revenue, or a minimum increase of at least 20% over the prior year purchase commitment. After the third year, the minimum purchase obligation shall increase annually by an amount equal to the percentage growth of the Company's annual U.S.-based revenues excluding PermeaDerm sales. The minimum purchase obligation should never decrease from the previous year.

### *Development and Distribution Agreement with Regenity*

On July 31, 2024, the Company entered into a multi-year exclusive development and distribution agreement with Collagen Matrix, Inc. dba Regenity Biosciences ("Regenity") to market, sell, and distribute Cohealyx™, a unique collagen-based dermal matrix under the Company's private label in the U.S., with the potential to commercialize the product in countries in the European Union, as well as in Japan and Australia. The initial term of the agreement is five years, with an automatic extension of an additional five years, contingent upon meeting certain criteria. Under the terms of the agreement, the Company will make a \$2.0 million payment upon receipt of 510(k) clearance by Regenity. The Company has a further obligation to make up to an additional \$3.0 million payment on or before January 4, 2026 to guarantee development and manufacturing capacity (and related resources), contingent on positive results of certain clinical studies related to the new dermal matrix. These obligations are not recorded in the Company's Consolidated Balance Sheets.



## 12. Common and Preferred Stock

The Company's CHES Depository Interests ("CDIs") are quoted on the ASX under the ticker code, "AVH." The Company's shares of Common stock are quoted on the Nasdaq Capital Market ("Nasdaq") under the ticker code, "RCEL". One share of Common Stock on Nasdaq is equivalent to five CDIs on the ASX.

The Company is authorized to issue 200,000,000 shares of Common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share, issuable in one or more series as designated by the Company's board of directors. No other class of capital stock is authorized. Common stock held in the rabbi trust is classified in a manner similar to treasury stock and presented separately on the Consolidated Balance Sheets as Common stock held by the NQDC Plan. As of September 30, 2024, and December 31, 2023, 26,217,629 and 25,682,078 shares of Common stock, respectively, were issued and outstanding and no shares of Preferred stock were outstanding during any period.

## 13. Stock-Based Payment Plans

### Stock-Based Payment Expenses

Stock-based payment transactions are recognized as compensation expense based on the fair value of the instrument on the date of grant. The Company uses the graded-vesting method to recognize compensation expense. Compensation cost is reduced for forfeitures as they occur in accordance with ASU 2016-09, *Simplifying the Accounting for Share-Based Payment*. No income tax benefit was recognized in the Consolidated Statements of Operations for stock-based payment arrangements for the three-months and nine-months ended September 30, 2024 and 2023.

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

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

	Three-Months Ended		Nine-Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Sales and marketing expenses	\$ 854	\$ 513	\$ 2,842	\$ 915
General and administrative expenses	2,781	1,534	6,510	4,442
Research and development expenses	445	383	1,346	856
Total	<u>\$ 4,080</u>	<u>\$ 2,430</u>	<u>\$ 10,698</u>	<u>\$ 6,213</u>

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

	Service Only Share Options	Performance-Based Share Options	Total Share Options
Outstanding shares at December 31, 2023	2,397,571	292,587	2,690,158
Granted	1,887,658	55,000	1,942,658
Exercised	(247,795)	(53,729)	(301,524)
Expired	(252,436)	(48,466)	(300,902)
Forfeited	(231,185)	(8,184)	(239,369)
Outstanding shares at September 30, 2024	<u>3,553,813</u>	<u>237,208</u>	<u>3,791,021</u>
Exercisable at September 30, 2024	1,146,550	163,322	1,309,872
Vested and expected to vest - September 30, 2024	3,553,813	237,208	3,791,021

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

Unvested Shares	Performance		Total RSUs
	Tenure-Based RSUs	Condition RSUs	
Unvested RSUs outstanding at December 31, 2023	207,112	28,020	235,132
Granted	55,200	-	55,200
Vested	(122,015)	(15,759)	(137,774)
Forfeited	(20,600)	(3,504)	(24,104)
Unvested RSUs outstanding at September 30, 2024	119,697	8,757	128,454

#### 14. Income Taxes

Tax benefit (expense) for the three-months ended September 30, 2024 and 2023 was a benefit of \$28,000 and expense of \$(11,000), respectively. Tax expense for the nine-months ended September 30, 2024 and 2023 was \$(35,000) and \$(54,000), respectively. These amounts are related to state minimum taxes.

#### 15. Net Loss per Share

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

	Three-Months Ended		Nine-Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
(in thousands, except per share amounts)				
Net loss	\$ (16,205)	\$ (8,712)	\$ (50,256)	\$ (28,316)
Weighted-average common shares—outstanding, basic and diluted	25,984	25,402	25,795	25,282
Net loss per common share, basic and diluted	\$ (0.62)	\$ (0.34)	\$ (1.95)	\$ (1.12)

	Three-Months Ended		Nine-Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Anti-dilutive shares excluded from diluted net loss per common share:				
Stock options	3,791,021	2,684,683	3,791,021	2,684,683
Restricted stock units	128,454	292,272	128,454	292,272
ESPP	75,339	-	75,339	-
Warrants	409,661	-	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*, 122,294 shares of Common stock held by the rabbi trust are excluded from the denominator in the basic and diluted net loss per common share calculations. For the purposes of the calculation of diluted net loss per share, options to purchase common stock, restricted stock units and unvested shares of Common stock issued upon the early exercise of stock options have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive. Because the Company has reported a net loss for the three-months and nine-months ended September 30, 2024 and 2023, diluted net loss per common share is the same as the basic net loss per share for those periods.

#### 16. Subsequent Events

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

On November 7, 2024, an affiliate of OrbiMed Advisors, LLC (the "Lender") and the Company mutually agreed to a third amendment (the "Third Amendment") to the Credit Agreement (See Note 6. Long-term debt). Under the terms of the Third

Amendment and subject to the payment by the Company of a consent fee to the Lender, the Company and the Lender mutually agreed to (1) terminate two additional tranches of available debt in the aggregate amount of \$50.0 million and (2) remove the trailing 12-month revenue covenant for the fourth quarter of 2024, which was set at \$67.5 million. All revenue covenants for subsequent quarters remain in effect.

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

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

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

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

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

*Please see “Note Regarding Forward-Looking Statements” on page 3.*

### Overview

AVITA Medical, Inc. (“we”, “our”, “us”) is a commercial-stage regenerative medicine company transforming the standard of care in wound care management and skin restoration with innovative devices. At the forefront of our portfolio is our patented and proprietary RECELL<sup>®</sup> System (“RECELL System” or “RECELL”), approved by the U.S. Food & Drug Administration (the “FDA”) for the treatment of thermal burn wounds and full-thickness skin defects, 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<sup>™</sup> 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. In the United States, we also hold the rights to market, sell, and distribute PermeaDerm<sup>®</sup>, a biosynthetic wound matrix, under the terms of an exclusive multi-year distribution agreement (the “Stedical Agreement”) with Stedical Scientific, Inc. (“Stedical”). We also entered into an exclusive multi-year development and distribution agreement with Collagen Matrix, Inc. dba Regenity Biosciences (“Regenity”). Following FDA 510(k) clearance, Regenity will manufacture and supply Cohealyx<sup>™</sup>, an AVITA Medical-branded collagen-based dermal matrix. Under the agreement, we will hold the exclusive rights to market, sell, and distribute Cohealyx in the U.S., with potential expansion into the European Union, Australia, and Japan.

The single-use RECELL Autologous Cell Harvesting Device (“RECELL Ease-of-Use” or “RECELL EOU”) is approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects, and repigmentation of stable depigmented vitiligo lesions. Our next-generation device, RECELL GO<sup>™</sup> Autologous Cell Harvesting Device (“RECELL GO”), is FDA-approved to treat thermal burn wounds and full-thickness skin defects. RECELL GO introduces enhanced features that streamline the preparation of Spray-On Skin Cells and improves workflow efficiency in the operating room. It consists of two components: the RECELL GO Processing Device (the “RPD”) and the RECELL GO Preparation Kit (the “RPK”). The RPD is a multi-use, AC-powered device that controls the RPK. The RPK is a single-use cartridge that contains the RECELL Enzyme<sup>™</sup>. The RPD regulates the pressure applied to disaggregate the cells and precisely controls the incubation time of the RECELL Enzyme to optimize cell yield and promote cell viability.

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 these objectives, we intend to:

- Become the standard of care in the U.S. burn care market by increasing penetration and adoption in burn centers with our recently FDA-approved RECELL GO
- Expand adoption of RECELL technology for the treatment of full-thickness skin defects in the U.S. with RECELL GO

- Launch RECELL GO mini, which is designed to address smaller wounds, following FDA approval in December of 2024
- Launch Cohealyx after FDA 510(k) clearance anticipated to be received in December of 2024
- Expand our global presence within the U.K., the European Union and Australia through the exclusive use of third-party distributors
- Continue to grow commercial activities in Japan through our partnership with COSMOTEC Company, Ltd (“COSMOTEC”) by leveraging our current Pharmaceuticals and Medical Devices Act approval for RECELL with an indication in burns
- Continue to pursue business development opportunities that are complementary to our core RECELL technology and/or our targeted markets, such as our exclusive distribution agreements with Stedical and Regenity
- Expect post-market study, TONE, and the health care economics study, both related to our vitiligo initiative to be published in early 2025

### **Business Environment and Current Trends**

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

Changes in reimbursement rates 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 in the Middle East, the continuation of the military conflicts in these regions and/or an escalation of the conflicts beyond their current scope may further weaken the global economy that could result in additional inflationary pressures or supply chain constraints.

### **Recent Developments**

On January 10, 2024, we entered into the Stedical Agreement, an exclusive multi-year distribution agreement with Stedical to commercialize PermeaDerm® Biosynthetic Wound Matrix (“PermeaDerm”) in the United States. PermeaDerm is cleared by the FDA as a transparent matrix for use in the treatment of a variety of wound types until healing is achieved. Under the terms of the Stedical 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 five years, with the option to renew for an additional five years, contingent upon meeting certain minimum requirements.

On February 16, 2024, we amended our contract with 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 (“BARDA”), dated September 29, 2015, to extend the term through September 28, 2025. Under the modified contract, BARDA will have access to our RECELL inventory in the event of a national emergency. In the case of a national emergency, BARDA will pay for RECELL devices at a reduced price for the first 1,000 units and will then pay retail price for any additional units. No additional inventory build will be required as part of this modification as we have sufficient inventory in stock to fulfill this requirement. BARDA will pay us approximately \$333,000 in maintenance fees over the term of the contract to ensure its first right of access to our RECELL inventory.

On May 29, 2024, the FDA approved our premarket approval (“PMA”) supplement for RECELL GO, our next generation autologous cell harvesting device, to treat thermal burn wounds and full-thickness skin defects. Following this approval, we shipped the first RECELL GO order on May 30, 2024, to accommodate the first case for its use on May 31, 2024.

On June 28, 2024, we submitted a PMA supplement for RECELL GO mini, which is designed to address small wounds up to 480 cm<sup>2</sup>. This version retains the same multi-use processing units as RECELL GO but features a smaller cartridge designed for the smaller donor skin samples needed for smaller wounds. This submission maintains the FDA Breakthrough Device designation from predecessor devices, providing a prioritized 180-day review period.

On July 31, 2024, we entered into a multi-year exclusive development and distribution agreement with Regenity to market, sell, and distribute Cohealyx™, an AVITA-Medical branded collagen-based dermal matrix in the U.S., with the potential to commercialize the product in the European Union, Japan, and Australia.

**Results of Operations for the three-months ended September 30, 2024 compared to the three-months ended September 30, 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		\$ Change	% Change
	September 30, 2024	September 30, 2023		
Sales revenue	\$ 19,394	\$ 13,645	5,749	42.1%
Lease revenue	152	-	152	100.0%
Total revenues	19,546	13,645	5,901	43.2%
Cost of sales	(3,190)	(2,113)	(1,077)	(51.0)%
Gross profit	16,356	11,532	4,824	41.8%
BARDA income	-	212	(212)	(100.0)%
Operating expenses:				
Sales and marketing	(15,144)	(10,532)	(4,612)	(43.8)%
General and administrative	(9,590)	(6,124)	(3,466)	(56.6)%
Research and development	(5,428)	(4,394)	(1,034)	(23.5)%
Total operating expenses	(30,162)	(21,050)	(9,112)	(43.3)%
Operating loss	(13,806)	(9,306)	(4,500)	(48.4)%
Interest expense	(1,359)	(10)	(1,349)	nm
Other (expense) income, net	(1,068)	615	(1,683)	nm
Loss before income taxes	(16,233)	(8,701)	(7,532)	(86.6)%
Income tax benefit (expense)	28	(11)	39	nm
Net loss	\$ (16,205)	\$ (8,712)	(7,493)	(86.0)%

\*nm = not meaningful

Total revenues increased by 43.2%, or \$5.9 million, to \$19.5 million, compared to \$13.6 million in the same period in the prior year. Our commercial revenue was \$19.5 million in the three-months ended September 30, 2024, an increase of \$5.9 million, or 43.8%, compared to \$13.5 million in the corresponding period in the prior year. The growth in commercial revenues was largely driven by deeper penetration within customer accounts and new accounts for full-thickness skin defects.

Gross profit margin was 83.7% compared to 84.5% in the corresponding period in the prior year. The decrease in this quarter was due to ongoing engineering and validation of the RECELL GO durable and disposable cartridge.

BARDA income decreased to zero, compared to \$0.2 million in the corresponding period in the prior year due to ending of reimbursable clinical trials. 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 43.3% or \$9.1 million to \$30.2 million, compared with \$21.1 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 43.8%, or \$4.6 million, to \$15.1 million, compared to \$10.5 million in the corresponding period in the prior year. Higher costs in the current year are due to an increase in salaries and benefits of approximately \$1.9 million, commissions expense of \$1.9 million, and stock-based compensation expense of \$0.4 million, plus \$0.4 million in other selling expenses. The increase in salaries and benefits is due to the expansion of the sales force to support our growing commercial capabilities. Higher commissions were directly associated with the increase in revenues. The increase stock-based compensation is due to additional grants related to the expansion of the sales force.

General and administrative expenses increased by 56.6%, or \$3.5 million, to \$9.6 million, compared to \$6.1 million in the same period in the prior year. The increase was attributable to an increase in stock-based compensation of \$1.3 million, an increase in salaries and benefits of \$1.1 million, an increase in severance benefits of \$0.1 million, an increase of \$0.5 million in deferred compensation expenses, and an increase of \$0.5 million in professional fees, offset by lower other corporate expenses. The increase in stock-based compensation and salaries and benefits are primarily attributable to headcount growth to support the expansion of our business. The increased severance payments is due to termination payments for two former executives. The increase in deferred compensation expense is driven by higher stock price used to calculate the deferred compensation liability for the deferred restricted stock awards.

Research and development expenses increased by 23.5%, or \$1.0 million, to \$5.4 million, compared to \$4.4 million in the same period in the prior year. The increase in salaries and benefits of approximately \$0.8 million was due to the increase in headcount resulting from the deployment of a team of Medical Science Liaisons, an increase in development costs of \$0.2 million, an increase of \$0.1 million in deferred compensation expenses, and an increase to all other development expenses of \$0.2 million, offset by a decrease in professional fees of approximately \$0.3 million due to higher expenses in the prior period related to RECELL GO and full-thickness skin defects.

Interest expense increased approximately \$1.3 million in comparison to the same period in the prior year due to the 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.

Other (expense) income, net decreased by \$1.7 million to expense of \$1.1 million from income of \$0.6 million in the prior period. In the current period, other (expense) income consists of non-cash charges of \$1.0 million and \$0.8 million related to the changes in fair value of the debt and warrant liability, respectively, offset by \$0.6 million in income related to our investments and \$0.1 million in other gains, net. The prior period income consisted of \$0.7 million related to our investments offset by \$0.1 million in other losses, net.

#### Results of Operations for the nine-months ended September 30, 2024 compared to the nine-months ended September 30, 2023.

Statement of Operations Data:	Nine-Months Ended		\$ Change	% Change
	September 30, 2024	September 30, 2023		
Sales revenue	\$ 45,681	\$ 35,948	9,733	27.1 %
Lease revenue	164	-	164	100.0 %
Total revenues	45,845	35,948	9,897	27.5 %
Cost of sales	(6,814)	(5,984)	(830)	(13.9)%
Gross profit	39,031	29,964	9,067	30.3 %
BARDA income	-	1,369	(1,369)	(100.0)%
Operating expenses:				
Sales and marketing	(44,086)	(27,075)	(17,011)	(62.8)%
General and administrative	(26,071)	(20,584)	(5,487)	(26.7)%
Research and development	(15,510)	(14,056)	(1,454)	(10.3)%
Total operating expenses	(85,667)	(61,715)	(23,952)	(38.8)%
Operating loss	(46,636)	(30,382)	(16,254)	(53.5)%
Interest expense	(4,063)	(21)	(4,042)	nm
Other income, net	478	2,141	(1,663)	(77.7)%
Loss before income taxes	(50,221)	(28,262)	(21,959)	(77.7)%
Income tax expense	(35)	(54)	19	(35.2)%
Net loss	\$ (50,256)	\$ (28,316)	(21,940)	(77.5)%

Total revenues increased by 27.5%, or \$9.9 million, to \$45.8 million, compared to \$35.9 million in the same period in the prior year. Our commercial revenue was \$45.7 million in the nine-months ended September 30, 2024, an increase of \$10.0 million, or 28.1%, compared to \$35.7 million in the corresponding period in the prior year. The growth in commercial revenues was largely driven by deeper penetration within customer accounts and new accounts for full-thickness skin defect.

Gross profit margin was 85.1% compared to 83.4% in the corresponding period in the prior year. This increase was largely driven by increases in both revenues and the volume of production.

BARDA income decreased to zero, compared to \$1.4 million in the corresponding period in the prior year due to the ending of reimbursable clinical trials. BARDA income in the prior year consisted of funding received 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 38.8% or \$24.0 million to \$85.7 million, compared with \$61.7 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 62.8%, or \$17.0 million, to \$44.1 million, compared to \$27.1 million in the corresponding period in the prior year. Higher costs in the current year were primarily related to increases in salaries and benefits and personnel expenses of approximately \$7.2 million, commissions expense of \$4.9 million, stock-based compensation expense of \$1.7 million, \$1.0 million in other selling expenses, \$0.9 million in professional fees, \$0.7 million in travel expenses, and \$0.2 million in rent expense, plus \$0.4 million in all other expenses, net. The increase in salaries and benefits, personnel related expenses, stock-based compensation, travel expenses, and other selling expenses are due to the expansion of the sales force to support our growing commercial capabilities. Higher commissions were directly associated with the increase in revenues. The increase in professional fees are primarily due to consulting expenses related to our foreign distribution network. The increase in rent is due to increased office space to accommodate our growing operations.

General and administrative expenses increased by 26.7%, or \$5.5 million, to \$26.1 million, compared to \$20.6 million in the same period in the prior year. The increase was attributable to an increase in salaries and benefits and personnel expenses of \$3.2 million, an increase in stock-based compensation of \$2.0 million, an increase in professional fees of \$0.4 million, and an increase of \$0.2 million in travel expenses plus an increase in other corporate expenses of \$0.3 million, partially offset by lower deferred compensation expenses of \$0.6 million. The increase in salaries and benefits and stock-based compensation are primarily attributable to headcount growth to support the expansion of our business. The decrease in deferred compensation expense is driven by a lower stock price used to calculate the deferred compensation liability for the deferred restricted stock awards.

Research and development expenses increased by 10.3%, or \$1.4 million, to \$15.5 million, compared to \$14.1 million in the same period in the prior year. The increase in research and development expenses is primarily due to an increase in salaries and benefits of \$2.6 million, an increase in stock-based compensation of \$0.4 million, and an increase of \$0.3 million in travel expenses, due to the increase in headcount resulting from the deployment of Medical Science Liaisons plus higher other development expenses of \$0.8 million, offset by lower professional fees and development expenses of approximately \$2.7 million related to RECELL GO and full-thickness skin defects.

Interest expense increased approximately \$4.0 million in comparison to the same period in the prior year due to the 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.

Other income, net decreased by \$1.7 million or 77.7% to income of \$0.5 million. In the current period other income, net consists of \$2.3 million in income related to our investments, \$0.4 million due to the change in fair value of warrant liability, and \$0.4 million in other gains, net, offset by a non-cash charge of \$2.6 million due to the change in fair value of the debt. In the prior period, income consisted of \$2.0 million related to our investments and \$0.1 million in other gains, net.

## **Liquidity and Capital Resources**

### Overview

We expect to utilize cash reserves until U.S. sales of our products reach a level sufficient to fund ongoing operations. We have historically funded research and development activities, and more recently have funded a substantial investment in sales and marketing activities, through raising capital by issuing securities and the issuance of debt. On October 18, 2023, we entered into a Credit Agreement with an affiliate of OrbiMed Advisors, LLC. 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 \$40.0 million was drawn during the fourth quarter of 2023. In addition, an aggregate of \$50.0 million will be made available in two separate \$25.0 million tranches, at our discretion, subject to certain net revenue requirements. The first tranche of \$25.0 million is available on or before December 31, 2024. The second tranche of \$25.0 million is available on or prior to June 30, 2025, and only if the first tranche was drawn upon. We have monthly interest rate payments for the debt at a rate equal to the greater of (a) forward-looking one-month term SOFR rate and (b) four percent (4.0%) per annum, plus eight percent (8.0%). In the event that we do not meet certain 12-month trailing revenue targets at the end of certain fiscal quarters, starting December 31, 2024, the outstanding balance of the loan must be repaid in equal quarterly installments of 5.0% of the funded amount through the maturity date. As of September 30, 2024, our projected revenues, for the trailing 12 months ending December 31, 2024, will exceed the minimum revenue requirements under the Credit Agreement. On November 7, 2024, we amended the Credit Agreement, see Note 16, Subsequent Events of our Consolidated Financial Statements.

We had approximately \$18.6 million in cash and cash equivalents and \$25.8 million in marketable securities as of September 30, 2024.

As of the date of these financial statements, we believe we have sufficient cash reserves to fund operations for the next 12-months.



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

(in thousands)	Nine-Months Ended	
	September 30, 2024	September 30, 2023
Net cash used in operations	\$ (40,858)	\$ (27,148)
Net cash provided by investing activities	34,892	58,911
Net cash provided by financing activities	2,487	942
Effect of foreign exchange rate on cash and cash equivalents	-	(15)
Net increase/(decrease) in cash and cash equivalents	(3,479)	32,690
Cash and cash equivalents at beginning of the period	22,118	18,164
Cash and cash equivalents at end of the period	18,639	50,854

Net cash used in operating activities was \$40.9 million and \$27.1 million during the nine-months ended September 30, 2024, and 2023, respectively. The increase in net cash used in operations was primarily due to higher operating costs.

Net cash provided by investing activities was \$34.9 million and \$58.9 million during the nine-months ended September 30, 2024 and 2023, respectively. The decrease in cash provided by investing activities is primarily attributable to higher cash outflows from purchases of marketable securities and lower cash inflows from maturities of marketable securities in the current year compared to the prior year, offset primarily by an increase in cash outflow for capital expenditures. 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 and materials related to our RECELL GO RPDs.

Net cash provided by financing activities was \$2.5 million and \$0.9 million during the nine-months ended September 30, 2024, and 2023, respectively. The increase in cash provided by financing activities is related to proceeds from the exercises of stock options and purchases of stock under the ESPP plan.

#### Capital Management and Material Cash Requirements

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

For the nine-months ended September 30, 2024, there were no dividends paid and we have no plans to commence the payment of dividends. As part of the Stedical Agreement, we have an obligation to Stedical to purchase sufficient products to achieve \$5.0 million in customer sales. As of September 30, 2024, we have fulfilled this obligation. Under the terms of our exclusive development and distribution agreement with Regenity, we will make a \$2.0 million payment upon receipt of 510(k) clearance by Regenity. We have a further obligation to make up to an additional \$3.0 million payment on or before January 4, 2026 to guarantee development and manufacturing capacity (and related resources), contingent on positive results of certain clinical studies. With the exception of the milestone payments related to our exclusive development and distribution agreement with Regenity, we do not have any other purchase commitments or long-term contractual obligations except for lease obligations as of September 30, 2024. In addition, we have no material off-balance sheet arrangements (as defined in the applicable rules and regulations established by the SEC) that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. While we have no committed plans to issue further shares on the market, we will continue to assess market conditions.

#### **Critical Accounting Estimates**

Except as disclosed in Note 2 of our Consolidated Financial Statements, there have been no material changes to our critical accounting policies and estimates from the information provided in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 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, 2024, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Securities Exchange Act”), were effective.

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

### **Changes in Internal Controls over Financial Reporting**

There were no changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the third quarter of fiscal year 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.

## **Part II - Other Information**

### **Item 1. LEGAL PROCEEDINGS**

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

### **Item 1A. RISK FACTORS**

In addition to the other information set forth in this report, you should carefully consider the factors discussed under Part I, Item 1A, “Risk Factors,” in the 2023 Annual Report and as updated from time to time in the Company’s subsequent Quarterly Reports on Form 10-Q. These factors could materially adversely affect our business, financial condition, liquidity, results of operations and capital position, and could cause our actual results to differ materially from our historical results or the results contemplated by the forward-looking statements contained in this report. There have been no material changes to the risk factors described in Part I, Item 1A, “Risk Factors,” included in the 2023 Annual Report.

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

None.

### **Item 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **Item 5. OTHER INFORMATION**

None.

## Item 6. EXHIBITS

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

Exhibit No.	Description
3.1	<a href="#">Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K12B filed on June 30, 2020)</a>
3.2	<a href="#">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)</a>
3.3	<a href="#">Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 of the registrant's Form 10-KT filed on February 28, 2022)</a>
10.1*	<a href="#">Exclusive Development and Distribution Agreement between the registrant and Collagen Matrix, Inc. dba Regenity Biosciences dated July 31, 2024</a>
10.2* †	<a href="#">Executive Employment Agreement between the registrant and Nicole Kelsey dated June 28, 2024</a>
10.3* †	<a href="#">Separation Agreement and Release between the registrant and Donna Shiroma dated June 28, 2024</a>
10.4*	<a href="#">First Amendment to Lease Agreement between the registrant and Hartco Ventura Inc. dated September 12, 2024</a>
31.1*	<a href="#">Rule 13a-14(a) Certification of Chief Executive Officer</a>
31.2*	<a href="#">Rule 13a-14(a) Certification of Chief Financial Officer</a>
32**	<a href="#">18 U.S.C. Section 1350 Certifications</a>
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Management contract or compensation plan or arrangement

\* Filed herewith

\*\* Furnished herewith

## Signatures

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

Date: November 7, 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 DEVELOPMENT AND DISTRIBUTION AGREEMENT**

THIS EXCLUSIVE DEVELOPMENT AND DISTRIBUTION AGREEMENT (this "Agreement") is made and entered into effective as of the 31<sup>st</sup> day of July 2024 (the "Effective Date"), by and between Collagen Matrix, Inc. dba Regenity Biosciences ("Regenity"), having its principal offices at [\*\*\*\*\*], and AVITA Medical, Inc. ("Distributor") having its principal offices at 28159 Avenue Stanford, Suite 220, Valencia, CA USA. Regenity and Distributor are referred to herein collectively as the "Parties," and individually as a "Party."

WHEREAS, Regenity is in the business of manufacturing collagen and mineral-based medical devices;

WHEREAS, Distributor is in the business of distributing such products;

WHEREAS, Regenity and Distributor collaborated to create the Product (as defined below) in response to specifications provided to Regenity by Distributor; and

WHEREAS, Regenity and Distributor desire to enter into an arrangement whereby Regenity will supply Products (as defined below) to Distributor for exclusive distribution in the Territory under Distributor's Private Brand (as defined below).

NOW, THEREFORE, in consideration of the foregoing and the mutual promises and covenants contained herein, the adequacy of which each Party hereby accepts, the Parties mutually agree as follows:

**ARTICLE I**

**Definitions**

1.1 "510(k)" means the Class II Product regulatory clearance obtained by Regenity from the FDA.

1.2 "Accepted Order" means an Order that is accepted in writing by Regenity pursuant to Section 3.1(c).

1.3 "Distributor Private Brand" means the labels, packaging, webpages, and other marketing materials of Distributor, together with all related trademarks, copyrights and associated goodwill.

1.4 "Distributor Product Branding" means the trade names, trademarks, catalog numbers, trade dress, trade styles, logos, symbols, corporate names and other branding elements, that Distributor will use to promote and sell Products hereunder. For clarity, (i) Distributor Product Branding shall include the Distributor Private Brand, and (ii) a Regenity Mark within Distributor Product Branding shall not comprise part of the Distributor Product Branding.

1.5“FDA” means the U.S. Food and Drug Administration.

1.6“Field” means, with respect to a given Product in the Territory, the uses of such Product in accordance with received Regulatory Approval.

1.7“Governmental Authority” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.8“Law” means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority.

1.9“PMA” means the Pre-Market Approval obtained by Distributor from the FDA for a Class III product that includes Distributor’s RECELL® platform.

1.10“PMA Alternative” means a clinical study that evaluates use of the Product together with the RECELL platform in a two-stage procedure with the following two endpoints: 1) time to graft and 2) time to closure. The endpoints need to demonstrate that use of the Product together with the RECELL platform demonstrates a level of performance at least equivalent to that of well-established, objective performance criteria of other comparable dermal matrices. The PMA Alternative will allow for the gathering of clinical data to support Distributor’s marketing, sales and distribution efforts as provided in this Agreement; in addition, the PMA Alternative may also be used as the basis for a future PMA application, upon mutual agreement of the Parties.

1.11“Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

1.12 “Product” or “Products” means the specific Regenity product(s) listed in Schedule A when they are packaged, labeled, marketed and sold hereunder using Distributor Product Branding.

1.13 “Regulatory Approval” means all technical, medical and scientific licenses, registrations, authorizations and approvals of any Regulatory Authority, necessary for the use, development, manufacture, and commercialization of a medical device in a regulatory jurisdiction.

1.14 “Regulatory Authority” means, with respect to the Territory, any national (e.g., the FDA), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a Regulatory Approval for medical devices in such country.

1.15 “Representatives” means, with respect to a Party, such Party’s officers, directors, employees, consultants, contractors and agents.

1.16 “Return Policy” means Regenity’s internal policy regarding returns, as in effect

from time to time.

1.17 “Specifications” means, with respect to a given Product, the specifications for such Product set forth in Schedule D.

1.18 “Statement of Work” means a document to be attached to this Agreement after the Effective Date that outlines additional work agreed upon by the Parties including, but not limited to, regulatory filings and development of new products.

1.19 “Territory” means the country specified in Schedule B which may be amended by the Parties from time to time.

1.20 “Third Party” means any Person other than Regenity, Distributor or their respective affiliates or Representatives.

1.21 “Unit” means one packaged unit of a given Product.

1.22 “Unit Purchase Price” means, with respect to one (1) Unit of a given Product, the corresponding unit purchase price set forth in Schedule A, as adjusted from time to time in accordance with Section 3.2.

1.23 “Warranty Period” means, with respect to a given delivery of Products, the time period from the receipt of Products by Distributor to the expiration date of the Products following delivery of such Products pursuant to Section 3.2(b).

1.24 Cross Reference Table. The following terms are defined elsewhere in this Agreement in the Sections set forth below:

<u>Term</u>	<u>Section</u>
Agreement	Preamble
Carrier	3.2(b)
Regenity	Preamble
Regenity Marks	7.2
Confidential Information	6.1
Damages	5.2(a)
Defense Costs	5.2(b)
Disclosing Party	6.1
Distributor	Preamble
Distributor Marks	7.4
Indemnities	5.2(a)
Indemnitor	5.2(a)
Marketing Materials	2.5(a)(ii)
Orders	3.1(b)
Parties	Preamble
Party	Preamble
Product IP	7.5
Product Issues	2.7(b)
Product Warranty	3.5(a)



Recall Action	2.7(c)
Recipient	6.1
Returns	3.6
Term	4.1
Territory Commitment	2.3

**ARTICLE II**  
**Distribution of the Product**

2.1 Exclusive Distribution. Subject to the terms and conditions of this Agreement, Regenity hereby appoints Distributor as the exclusive distributor, and Distributor accepts such exclusive engagement to market, sell and distribute Product(s) to customers within the Territory for use in the Field. While Distributor’s Exclusive Distribution (as defined below) is granted by Regenity as of the Effective Date, Distributor’s right to such Exclusive Distribution shall be automatically triggered upon receipt by Regenity of 510(k) clearance by the FDA for the intended use and indications for use as a Class II medical device as agreed between the Parties (the “FDA Clearance Date”). Distributor shall purchase the Products supplied by Regenity and resell such Products in its own name, for its own account, and at its own risk except for Products subject to manufacturing defects, or recall, modification or discontinuation events as provided under Sections 2.4(b) and 2.7 (as applicable) whereby any risk related to the marketing, sale and distribution of the Products will be borne by Regenity. Distributor is an independent distributor and is not an agent of Regenity for any purpose.

2.2 Exclusivity.

(a) *Payments by Distributor.* In consideration of the rights to exclusive distribution of the Products to the Field in the Territory (which will include branding services provided by Regenity for the Distributor Private Brand) (the “Exclusive Distribution”), Distributor will make certain payments totaling up to five million United States Dollars (US\$ 5,000,000) to Regenity, as follows:

(i) A payment of two million United States Dollars (US\$ 2,000,000) due on, and payable within 10 business days of, the FDA Clearance Date;

(ii) A payment of three million United States Dollars (US\$ 3,000,000) on or before January 4, 2026 which shall be utilized by Regenity to prioritize the allocation of additional resources to guarantee the development and manufacturing capacity necessary to meet Distributor’s distribution plans for the Product; *for the avoidance of doubt*, Distributor will make this third payment in consideration of the Exclusive Distribution. Distributor will make this \$3,000,000 payment only in the event that Distributor has made neither the First Termination Payment nor the Second Termination Payment as provided by Section 4.1(a) below.

(b) *Termination of Exclusivity.* As of January 1, 2027, Regenity may terminate exclusivity rights if Distributor does not meet the target product revenues for each of the applicable years as set forth on Schedule E (the “Target Product Revenues”) and does not exercise its options to cure the failure of any such Target Product Revenue as provided by Section 2.2(c) below. In the event Regenity terminates Distributor’s exclusive distribution rights in accordance with this

sub-Section 2.2(b), such termination shall not result in termination of the Agreement nor in any compensation claims of Regenity.

(c) *Distributor's Cure Options.* If Distributor fails to meet the Revenue Forecast for any of the years as set forth on Schedule E, in order to maintain its exclusive distribution rights under this Agreement, Distributor may, at its sole discretion, within 30 days after the end of such applicable year, either (a) make a lump sum dollar payment to Regenity, with the payment equal to the Guaranteed Regenity Target Product Revenue (as defined on Schedule E) less the amount paid to Regenity for the Product during the applicable year; or (b) purchase an additional amount of the Product so that the Guaranteed Regenity Target Product Revenue (as set forth on Schedule E) for the prior year is satisfied.

### 2.3 The Territory.

(a) *No Sales Outside the Territory or the Field.* Distributor shall not market, sell or distribute the Products to customers located outside the Territory or otherwise solicit or encourage customers located outside the Territory to submit orders for Products to the Distributor. Distributor shall limit its marketing, sales and distribution activities to those designed to attract orders from customers in the Territory who use the Products in the Field. Distributor shall promptly forward to Regenity all inquiries relating to Products or potential purchases of Products from customers or potential customers outside the Territory.

(b) *Expansion of the Territory.* Distributor shall have the right, at any time from the Effective Date through December 31, 2025 to request that Regenity submits for regulatory clearance(s) of the Products in the countries of the European Union, as well as Australia and Japan. The submission of these regulatory filings shall be reflected through a Statement of Work to be attached to this Agreement, executed by the Parties, by no later than December 31, 2025. Upon regulatory approval, the expansion of the Territory shall be reflected through an amendment of Schedule B. Distributor's Exclusive Distribution rights in the Territory as expanded in accordance with this section 2.3(b) shall remain in place for the Term unless its distribution rights are terminated in accordance with the provisions of this Agreement.

(The obligations of, and limitations on, Distributor under this Section 2.3 are referred to collectively as Distributor's "Territory Commitment").

### 2.4 Product Additions, Modifications and Discontinuation.

(a) *New or Additional Products.* Upon mutual written agreement of the Parties, other Regenity products may be added to Schedule A. Upon the effective date of such change to Schedule A, such additional products shall be deemed to be "Products" for purposes of this Agreement. Any such change to Schedule A, to be effective, must be in writing, signed by an authorized representative of each Party, and must specify the price at which such Products will be sold to Distributor.

(b) *Product Modifications and Discontinuation.* Regenity cannot modify or discontinue any Product at any time during the Term to the extent such modification impacts either the supply of, or any regulatory status (whether 510(k) or PMA) related to, the Product without developing a mutually agreed transition agreement with Distributor.

## 2.5 Additional Responsibilities of Distributor.

### (a) *Sales and Marketing Activity.*

(i) *Marketing Efforts.* Consistent with the terms and conditions of this Agreement, Distributor shall use commercially reasonable efforts to promote the sale of Products to customers within the Territory for use in the Field.

(ii) *Sales Activities and Materials.* Distributor shall produce promotional materials in commercially reasonable quantities to support the marketing of the Products in the Field within the Territory. Any marketing and sales activities conducted by Distributor shall be at Distributor's sole cost and expense, unless otherwise agreed to by the Parties in writing. Distributor shall not market or promote any Product in any manner that is inconsistent with the approved labeling of the Product or its use solely within the Field. Distributor shall ensure that all of its brochures, technical data sheets, marketing, product catalogs, website content, white papers and other marketing and sales material that identifies or is used in connection with any Product (collectively, "Marketing Materials") complies with all applicable Laws. All Marketing Materials must be approved by Regenity prior to print and/or distribution. Subject to the provisions of Article VI, Regenity shall provide Distributor with available technical information that is reasonably necessary for Distributor to produce appropriate Marketing Materials for use during the Term. Distributor may use its web site to promote the Products in the Territory for use in the Field, provided that any links to Regenity's web site must be approved in advance by Regenity and such usage otherwise complies with the requirements of this Section 2.45a.

(iii) *Qualified Personnel.* Distributor, at its sole expense, shall maintain qualified sales and distribution personnel to perform the sales, marketing, and clinical support efforts required to satisfy its obligations under this Agreement. Distributor shall be responsible for the training of its Representatives and its sales representatives, sub-distributors, and end-users of the Products.

(iv) *Authorized Customers.* Distributor shall sell Products only to licensed physicians, hospitals and other Persons who are permitted by applicable Law to possess and use the Products in the course of providing patient care services. Distributor shall not sell a Product to any Person who resells, or intends to resell, such Product without Regenity's written authorization to resell Products.

(b) *Business Standards.* As a distributor of the Products, Distributor shall conduct its business to the highest ethical and business standards in a manner that reflects favorably on the Products and on the reputation of Regenity. Further, Distributor shall not, and shall not permit its Representatives to, engage in any activity that may imply or express any false or misleading statements about Regenity or the Products.

### (c) *Compliance with Applicable Law.*

(i) *General.* Distributor shall, and shall cause its Representatives to, comply with all applicable Laws in the performance of its activities under this Agreement, including, without limitation, anti-bribery and anti-corruption laws, accounting and record keeping laws, and laws relating to interactions with healthcare professionals or healthcare providers and government officials.

(ii) *No Improper Payments or Incentives.* Without limiting Distributor's other obligations under this Section 2.5(c) (A) with respect to any Product, payment, service or activity under this Agreement, Distributor shall not, and shall not permit its Representatives to, take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any government official or any other Person in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment and (B) Distributor certifies that in connection with this Agreement, such Distributor's compensation system for its Representatives that perform any marketing, sales or distribution activities related to the Products is designed to ensure that financial incentives do not inappropriately motivate such Representatives to engage in improper or illegal marketing, sales or distribution of the Products (including off-label promotion), and excludes from employee incentive compensation sales that may be attributable to the off-label use of the Products.

(iii) *Licenses and Permits.* Except for Regulatory Approvals for the Products themselves (which shall be held by Regenity, except for the PMA which shall be held by Distributor), Distributor shall obtain and maintain at its sole expense all licenses, permits and other authorizations required by each political jurisdiction within the Territory that are required for Distributor (and its Representatives, as applicable) to (x) market, sell and distribute the Products, (y) market, sell and distribute any product requiring a PMA, and (z) otherwise support its customers in accordance with the terms of this Agreement.

(v) *No Debarment or Exclusion.* In connection with its activities under this Agreement, Distributor will not use any Representative, either itself or through a subsidiary or affiliate, that has been debarred or excluded by any Regulatory Authority or, to Distributor's knowledge, is the subject of debarment or exclusion proceedings by any Regulatory Authority. If Distributor learns that any Representative performing on its behalf under this Agreement has been debarred or excluded by any Regulatory Authority, or has become the subject of debarment or exclusion proceedings by any Regulatory Authority, then Distributor shall promptly notify Regenity and shall prohibit such Representative from performing further on Distributor's behalf under this Agreement.

(d) *Regulatory Approvals.* Regenity shall be responsible for obtaining FDA 510(k) clearances. All Regulatory Approvals relating to the Products in the Territory, including, without limitation, all Distributor Requested Approvals, shall be (i) filed in the name of Regenity or its authorized designee and (ii) owned exclusively by Regenity or its authorized designee, except for any Regulatory Approval related to a product for which a PMA or a PMA Alternative is being sought (Regenity and RECELL). In the event of expiration or termination of this Agreement, if Distributor is Regenity's authorized designee in certain Territories, then Distributor shall transfer all Regulatory Approvals in its name in such Territories to Regenity or its new authorized designee.

(e) *Product Handling and Packaging.* Distributor shall ship all Products to its customers in Regenity's standard packaging, which will include instructions for use and the Product Warranty, if any, and feature Distributor Product Branding. Without the express, prior written consent of Regenity, Distributor shall not (i) alter or modify in any manner any Product package or label, including the exterior or interior of any Product package, (ii) repackage any Product and/or (iii) alter, remove, cover, or add to, in any manner whatsoever, any patent notice,

copyright notice, serial number, model number, Mark or legend that Regenity or its designee may attach or affix to any Product. Distributor shall store, transport and distribute the Products in accordance with all instructions in the Product packaging and shall take all necessary steps to prevent the sterility and security of the Products and Product packaging from being compromised. Product supplied from Regenity to Distributor shall be packaged in Regenity's standard packaging with such packaging featuring Distributor Product Branding. Distributor Product Branding packaging elements (including but not limited to brand names and logos) will be communicated to Regenity by Distributor in writing in formats useful for Regenity to produce such packaging; provided however, Distributor shall give Regenity at least ninety (90) days prior written notice of any changes to Distributor Product Branding packaging elements, and Regenity shall be entitled to recover, and Distributor shall be responsible to pay Regenity, all reasonable out-of-pocket costs that Regenity actually incurs associated with such changes.

## 2.6 Responsibilities of Regenity.

(a) Regenity shall adhere to the requirements of applicable regulatory requirements of ISO 13485 and the United States FDA (21 CFR Part 820 FDA Quality System Regulations for Medical Devices).

(b) Regenity shall provide technical support and training as reasonably requested, at the expense of Distributor, by Distributor in providing distribution services related to the Products to those individuals who will be representing the Products on behalf of Distributor.

(c) Regenity shall scale up its manufacturing operations and production capacity for the Products in order to meet the annual demands of Distributor's distribution plans. Further, Regenity shall conduct its manufacturing and operations in accordance with the mutual undertaking of the Parties set forth in Section 3.7 below.

## 2.7 Adverse Events, Recalls and Corrective Actions.

(a) *Traceability.* During the term of this Agreement and for ten (10) years thereafter, Distributor shall maintain complete and accurate distribution records by customer and by lot number (including, without limitation, date of distribution; description of Product by name, model and ID number; and the name and address of the purchaser) for all sales of Products by Distributor within the Territory for purposes of complying with regulatory requirements. In the event of a Recall Action relating to one or more Products, or otherwise upon Regenity's reasonable request, such records shall be made accessible by Distributor to Regenity and independent certified public accountants selected by Regenity.

(b) *Reporting and Assistance.* Distributor shall report immediately to Regenity any defects, adverse events, Product failures or faults, and user complaints (collectively, "Product Issues") that have been detected by Distributor or reported to Distributor by a customer. Distributor shall assist Regenity in the investigation and resolution of any Product Issues with respect to Products distributed by Distributor. Further, Distributor shall comply with all applicable Laws relating to documentation and record keeping for vigilance reporting (including, without limitation, the Medical Device Directive, 93/42/EEC: 1993). Distributor shall report to Regenity any events that could require a vigilance report of which Distributor becomes aware.

(c) *Recall Actions.* Any decision to initiate a recall, market withdrawal, replacement or any other corrective action with respect to any Product in the Territory (a “Recall Action”) shall be made by Regenity in its sole discretion, in compliance with and to the extent permitted by Applicable Law. If Regenity determines that a Recall Action is necessary with respect to a Product in the Territory, then Distributor shall provide Regenity with any and all assistance necessary to effect such Recall Action. Regenity shall reimburse Distributor for all reasonable costs incurred by Distributor as a result of such Recall Action to the extent that such Recall Action results from Regenity’s failure to comply with its obligations under this Agreement. Further, Distributor shall have the right to return the Products that are subject to such Recall Action to the extent that such Recall Action results from Regenity’s failure to comply with its obligations under this Agreement. Regenity shall have no obligation to reimburse or pay Distributor any amounts with respect to any Recall Action to the extent that such Recall Action results from Distributor’s or its Representatives’ failure to comply with any of its obligations under this Agreement.

### **ARTICLE III**

#### **Supply of Products**

##### 3.1 Order of Products.

(a) *Forecasts.* Distributor shall provide Regenity with a 12-month rolling forecast for each Product in accordance with the information set forth on Schedule E, of which the first three (3) months of each forecast shall be binding. Such forecasts shall be updated by Distributor monthly for production planning purposes.

(b) *Submission of Orders.* Distributor shall order Products by submitting to Regenity written or electronic purchase orders (each, an “Order”) signed or otherwise authorized by an authorized representative of Distributor. Each Order must include, at a minimum, (i) Part Number, quantities, requested shipping dates, shipping instructions and then current applicable Unit Purchase Price, (ii) a ship date at least four (4) weeks from the date of placing the Order and (iii) a minimum of ten (10) units per item code. No terms or conditions of any Order shall be binding on Regenity to the extent that such terms and conditions are inconsistent with those contained in this Agreement.

(c) *Confirmation and Acceptance of Orders.* No Order shall be binding on Regenity until accepted by Regenity in writing. Regenity shall use commercially reasonable efforts to acknowledge and provide written notice of acceptance or rejection of Orders within three (3) days of receiving the Order. Regenity’s written acknowledgement of each Accepted Order shall indicate the expected date(s) that Regenity will deliver the Product quantities covered by such Order. All Orders accepted by Regenity shall be binding on Distributor.

##### 3.2 Delivery of Products.

(a) *Fulfillment of Accepted Orders.* Regenity shall use commercially reasonable efforts to (i) supply to Distributor the quantity of Products specified in each Order that is accepted by Regenity pursuant to Section 3.1(c) and (ii) meet Distributor’s requested shipping dates. All orders will be appropriately individually packaged by Regenity for delivery to Distributor.

(b) *Delivery.* Regenity shall deliver the quantity of Product specified in each Accepted Order to the Carrier (as defined below) for shipment to Distributor. Title and risk for loss or damage shall pass to Distributor upon delivery of the Products to the Carrier for shipment to Distributor and any loss or damage thereafter shall not relieve Distributor of any obligation hereunder. Distributor shall be responsible for selecting a carrier (the “Carrier”) to ship the Products from Regenity’s designated warehousing facility(ies) to Distributor. Shipping, handling and insurance charges are at the expense of Distributor, as provided in Section 3.3(d).

(c) *Delays in Delivery.* If Regenity is not able to deliver Products to Distributor on the date specified in the applicable Accepted Order, then Regenity shall use commercially best efforts to so notify Distributor as soon as possible. Regenity shall make commercially best efforts to meet delivery dates confirmed, and in the event that Regenity fails to meet such delivery dates, Regenity shall comply with the provisions of Section 3.2 (d) below.

(d) *Failure to Supply.* It shall be considered a “Failure to Supply” if either (i) Regenity notifies Distributor that it is unable for any reason, except for a Force Majeure Event, to supply the Product in accordance with the quantities and/or delivery dates specified by Distributor for such Product via the Orders which have been accepted by Regenity, or (ii) Regenity delivers less than eighty percent (80%) of the Product quantities specified in an Order more than forty-five (45) days later than the target delivery dates contained in such Order on three (3) consecutive occasions, or on four (4) occasions in any twelve-month period, except for a Force Majeure Event (per Section 8.7). Upon the occurrence of a Failure to Supply, Distributor may, in its sole discretion (a) cancel any outstanding Orders with Regenity and upon notice to Regenity, purchase from a third party of its choosing or self-Manufacture replacement Product, or (b) require Regenity to supply the undelivered Product at a future date agreed upon by the Parties. Product purchased from a third party as a result of a Failure to Supply shall be considered when calculating Distributor’s performance against the Minimum Purchase Requirements. If during the Term, Regenity is able to demonstrate to Distributor reasonable satisfaction that Regenity is capable of re-establishing a satisfactory supply of Product, then Distributor shall have the obligation to resume purchasing Product from Regenity under this Agreement for the remainder of the Term.

### 3.3 Pricing Terms.

(a) *Product Pricing.* Distributor shall purchase, and Regenity shall sell to Distributor, the Products ordered by Distributor pursuant to Accepted Orders at the applicable Unit Purchase Prices set forth in Schedule A, as adjusted from time to time in accordance with this Section 3.3. For 2025, it shall be noted that the Unit Purchase Price shall be based on [\*\*\*\*\*]. During the first quarter after December 31, 2025, Distributor shall estimate the quarterly average sales price for the Product (the “ASP”) and the price Distributor pays to Regenity for the Product shall be 50% of the estimated ASP for the applicable quarter, and shall be expressed in United States Dollars. Thereafter, the price Distributor pays to Regenity for the Products shall be 50% of the ASP from the previous quarter. Further, on a quarterly basis, Distributor will make any necessary true-up payments to account for any variance in the actual ASP.

(b) *Taxes and Other Fees.* Taxes are not included in the Unit Purchase Prices set forth in Schedule A, as the same may be modified pursuant to this Section 3.3(b). Distributor shall pay all applicable sales, use, excise and any other taxes imposed under the authority of any national, state or local taxing jurisdiction. Distributor shall not reduce any fees or charges owed

to Regenity as a result of any such taxes or duties. Distributor shall furnish Regenity with a valid tax exemption certificate issued by each taxing jurisdiction or entity where such certificate is required as a condition for the avoidance of applicable sales or use taxes covering any Product to be sold under this Agreement.

(c) *Insurance Costs and Freight Charges.* The Unit Purchase Prices set forth in Schedule A, as the same may be modified pursuant to Section 3.3(b), do not include freight charges and insurance costs. All freight charges and insurance costs associated with the shipment of Products under this Agreement shall be borne solely by Distributor.

### 3.4. Payment Terms.

(a) *Timing of Payment.* Payment in full for Products ordered hereunder is due net thirty (30) days from the date of shipment.

(b) *Late Payments.* Delinquent amounts shall bear interest at a rate equal to one percent (1%) per month (twelve percent (12%) per year) or, if lower, at the maximum rate allowed by applicable law. Regenity reserves the right to withhold delivery of additional Products during any period in which Distributor has any amounts outstanding and past due.

(c) *Currency.* Distributor shall make all payments required under this Agreement in United States dollars by check or wire transfer to an account specified by Regenity.

(d) *Revenue-Sharing.* Distributor agrees to make payments to Regenity from revenue generated from sales of the Products by Distributor in the Territory in accordance with the revenue-sharing percentage set forth in the table on Schedule E within 30 days of each year-end during the Term...For clarity, the amount to be paid by Distributor to Regenity in accordance with the revenue-sharing percentage for each year of the Term is reduced by the amount of Product purchased in a given year, but not below the Guaranteed Regenity Target Product Revenue (as set forth on Schedule E) for any applicable year. In the event that Distributor fails to meet the Target Product Revenue set forth on Schedule E for any given year, the Parties shall follow the process provided in Section 2.2(c) of this Agreement.

### 3.5 Product Warranty.

(a) *Warranty Terms.* Regenity grants to Distributor the limited warranties contained in the warranty terms for the Products, as modified from time to time by Regenity (“Product Warranty”). The scope of the Product Warranty applicable to each Product is set forth on Schedule C hereto. Regenity reserves the right to modify the Product Warranty for each Product from time to time and shall notify Distributor of any changes thereto. In the event that any Product does not conform to its Product Warranty, Distributor’s sole and exclusive remedy shall be to return such Product to Regenity, who shall, in its sole discretion, either replace such defective Product or refund the net purchase price of such defective Product to the customer or Distributor. Regenity’s warranty obligations with respect to each Product shall only endure during the Warranty Period, and Distributor must raise any warranty claims within the Warranty Period. Regenity’s obligations under the limited Product Warranty do not extend to a Product where the sterility or integrity of the Product or its packaging has been compromised by Distributor or a customer, or where the Product is used after the Warranty Period. Regenity is not responsible for breaches of the Product Warranty caused by use, operation or storage not in



accordance with Regenity's instructions, unauthorized modification of a Product, or Distributor's or any of its Representative's failure to comply with Distributor's obligations under this Agreement.

(b) *Warranty Disclaimer.* EXCEPT AS EXPRESSLY SET FORTH IN SECTION 3.5(a), (i) REGENITY MAKES NO WARRANTIES TO DISTRIBUTOR, CUSTOMERS OR ANY OTHER PERSON WITH RESPECT TO THE PRODUCTS OR SERVICES PROVIDED HEREUNDER, WHETHER EXPRESS OR IMPLIED, (ii) REGENITY SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND (iii) NO REPRESENTATION OR WARRANTY, INCLUDING BUT NOT LIMITED TO STATEMENTS OF QUALITY, SUITABILITY FOR USE OR PERFORMANCE, WHETHER MADE BY REPRESENTATIVES OF REGENITY OR DISTRIBUTOR, SHALL BE CONSIDERED A WARRANTY BY REGENITY FOR ANY PURPOSE OR CREATE ANY LIABILITY OF REGENITY. IN NO EVENT SHALL REGENITY BE LIABLE FOR CONSEQUENTIAL DAMAGES OF ANY TYPE OR NATURE.

(c) *No Modification of Product Warranty by Distributor.* Distributor shall not modify or supplement the limited Product Warranty included in Regenity's standard packaging without the express written consent of an authorized representative of Regenity, and Distributor may not provide any additional warranty to any customer that is binding on Regenity. Distributor shall indemnify and hold Regenity harmless from all liabilities, claims, damages and expenses, including reasonable attorneys' fees, that may be incurred by Regenity during or after the term of this Agreement that result from or arise out of Distributor's failure to comply with the terms of this Section 3.5(c).

3.6 Return of Products. Subject to the provisions of Section 2.7(c) and Section 3.5(a), return of Products ("Returns") must be authorized by Regenity and otherwise comply with Regenity's Return Policy. Any authorized Returns shall be shipped by Distributor to Regenity at Distributor's expense and risk of loss and are subject to a re-stocking fee. Authorized Returns shall be credited upon receipt and verification that the goods are in saleable condition, and such credit shall be netted against the balance due from Distributor. Products damaged or destroyed during shipment or returned after termination or expiration of this Agreement do not constitute Returns for purposes of this Agreement.

3.7 Product Supply and Development Meetings. Within 30 days from January 1, 2025, the Parties hereby will meet and establish a bi-annual meeting schedule (the "Product Supply and Development Meetings") whereby Regenity provides status updates on its current and projected production capacity and other key manufacturing operations deliverables to Distributor. The Parties hereby acknowledge and agree that the purpose of the Product Supply and Development Meetings is for Regenity to confirm its ability to satisfy both the quantity and timing of supply of the Product necessary to meet Distributor's distribution plans through the Term.

#### **ARTICLE IV**

##### **Term and Termination**

4.1Term. This Agreement shall commence on the Effective Date and shall continue through December 31, 2029 (the “Initial Term”, along with any automatic renewal terms, the “Term”).

(a) *Early Termination and Payments.* In the event that Distributor determines, between January 1 and June 30, 2025, that the clinical data resulting from the trial conducted pursuant to the PMA Alternative is insufficient to achieve the PMA Alternative purpose (in accordance with its definition in Section 1.10 above), Distributor shall make a payment of [\*\*\*\*\*] to Regenity (the “First Termination Payment”). Upon payment by Distributor of the First Termination Payment, no further payments are required under this Agreement and this Agreement shall automatically terminate. However, if Distributor does not make the First Termination Payment, but determines at some point after June 30, 2025, and by no later than December 31, 2025, that the trial conducted pursuant to the PMA Alternative has failed, Distributor shall then make a payment to Regenity of [\*\*\*\*\*] (the “Second Termination Payment”). Upon payment by Distributor of the Second Termination Payment, this Agreement shall automatically terminate, and Distributor shall no longer be required to make the \$3,000,000 payment in accordance with Section 2.2(a)(ii) above. Distributor shall communicate to Regenity, via electronic mail, on or before each of June 30, 2025 and December 31, 2025 (as applicable), its intention to either terminate the Agreement and make either the First Termination Payment or the Second Termination Payment (as applicable) or to continue to market, sell and distribute the Product through its Exclusive Distribution in accordance with this Agreement. *For the avoidance of doubt*, the maximum amount that Distributor shall be required to pay to Regenity under this Section 4.1(a) is [\*\*\*\*\*].

(b) *Extension.* This Agreement will automatically renew for an additional five-year term upon the occurrence of any of the following events: (a) Distributor receives approval of its PMA application by December 31, 2027, (b) Distributor meets the Target Product Revenues set forth on Schedule E, (c) Distributor follows the process set forth in Section 2.2(b); or (d) Distributor makes the payment in accordance with Section 2.2(a)(ii) of this Agreement. Such automatic renewals shall not restrict in any way a Party’s right to terminate this Agreement pursuant to Section 4.2.

#### 4.2Termination.

(a) *For Cause.* Either Party may terminate this Agreement for cause: (i) upon the material breach of any obligation or responsibility by the other Party which breach remains uncured for thirty (30) days after written notice thereof; (ii) immediately and without the necessity for notice, upon the bankruptcy, insolvency or similar filing by or against the other Party; and/or (iii) immediately and without the necessity for notice, upon a material breach of applicable Law by the other Party. A material breach by Distributor under this Agreement includes but is not limited to the following: (A) uncured failure of Distributor to make any payment when due; (B) Distributor’s breach of its Territory Commitment; (C) Distributor’s uncured use of Regenity’s Marks or other intellectual property rights in a manner not in accordance with this Agreement; and (D) any action by Distributor that implies or expresses any false or misleading statements about Regenity or the Products. A material breach by Regenity under this Agreement includes but is not limited to the following: (A) failure of Regenity to satisfy its Product modification and discontinuation obligations in accordance with Sections 2.4 (b), (B) failure of Regenity to timely supply the Product to Distributor in accordance with Section 3.2(c); (C) Regenity’s use of Distributor’s intellectual property in a manner not in

accordance with this Agreement; and (D) any action by Regenity that implies or expresses any false or misleading statements about Distributor, its obligations under this Agreement or its intellectual property.

4.3 Effects of Termination. Expiration or termination of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination, including damages arising from any breach under this Agreement. Expiration or termination of this Agreement shall not relieve either Party from any obligation which is expressly indicated to survive such expiration or termination. Expiration or termination of this Agreement for any reason shall not prevent or excuse either Party from settling accounts, collecting funds, or engaging in any activity necessary to successfully bring to completion any transaction outstanding at the time of the termination or expiration of this Agreement. Notwithstanding any provision of this Agreement to the contrary, immediately upon expiration or termination of this Agreement, Distributor shall, at its sole expense (a) remove from any catalogs, price lists or other media employed or used by Distributor any and all references to Regenity and the Products, (b) cease use of all Regenity trademarks and trade names, including, without limitation, the Product trademarks and (c) return all unsold Products to Regenity in accordance with Regenity's Return Policy. In the event that Distributor has contractual obligations to deliver the Product, Regenity shall supply an adequate amount of Product to Distributor, per Distributor's indications, to ensure that Distributor meets such distribution obligations. If the Agreement expired or was terminated by Regenity for Distributor's breach, Distributor shall not be entitled to any refund from Regenity for unsold Products returned under this Section. However, if the Agreement was terminated by Regenity for convenience under Section 4.2(b) or by Distributor for Regenity's breach, Distributor shall receive a refund for all unsold Products returned to Regenity in accordance with Regenity's Return Policy for such post-Term returns. The provisions of Article I, Section 2.5(c), Section 3.5, Section 4.3, Article V, Article VI, Section 7.1, Section 7.3, Section 7.4, Section 7.5, and Article VIII shall survive expiration or termination of this Agreement for any reason.

## **ARTICLE V**

### **Indemnification; Limitation of Liability**

5.1 Intellectual Property Indemnification by Regenity. Regenity shall indemnify and hold Distributor harmless from and against any damages awarded in actions against Distributor based upon a finding that the Products infringe any patent rights or other intellectual property rights of a Third Party in the Territory, provided that Distributor gives Regenity timely notice of the claim and the opportunity to assume sole control of the defense and settlement and provided further that Distributor does not settle such a claim without Regenity's prior written consent; *provided however that*, if Distributor incurs any costs or expenses in managing any such potential Third-Party infringement, Regenity shall reimburse Distributor in full (including any reasonable attorney's fees) within 30 days of final determination or settlement of the Third-Party infringement matter. The foregoing provision does not apply to infringements caused by Distributor's unauthorized use or modification of the Product or its use in combination with other products, except, in the latter case, any mutually agreed combination of the Parties' products. If a court of competent jurisdiction determines, or Regenity concludes in its discretion, that a risk exists for a determination that a Product infringes the rights of a Third Party, then Regenity shall have, at its option, the right to either: (a) procure for Distributor and its customers the right to continue using and selling the Product; (b) replace the Product with a non-infringing product; (c) modify the Product so that it becomes non-infringing; or (d) require the return of the Product to

Regenity against a refund of payments made by Distributor to Regenity. The foregoing sets forth the entire liability of Regenity for Third-Party intellectual property infringement.

#### 5.2 Mutual Indemnification.

(a) *General.* Except for Damages arising from a claim that the Products infringe patent rights or other intellectual property rights of a Third Party, and subject to the requirements of Section 5.2(b) below, each Party (the “Indemnitor”) hereby agrees to indemnify and hold the other Party and its Representatives (the “Indemnitees”) harmless for any loss, claim, damage, cost, expense (including reasonable attorney’s fees), or liability by or to a Third Party (collectively, “Damages”) arising out of (a) the negligence or willful misconduct of the Indemnitor or any of its Representatives or (b) a breach by the Indemnitor of any of its obligations under this Agreement.

(b) *Conditions and Process.* If any claim is asserted against an Indemnitee by any Third Party, which claim is subject to indemnity under this Section 5.2, then the Indemnitee shall notify the Indemnitor thereof promptly after its receipt of a writing making the claim, but any delay in giving such notice shall not affect the Indemnitee’s rights under this Section 5.2 except to the extent the Indemnitor is actually prejudiced thereby. The Indemnitor shall have the right to take charge of the defense of such claim by giving notice to the Indemnitee within ten (10) days after Indemnitee’s notice. If the Indemnitor so assumes the defense, (i) the defending counsel shall be selected by the Indemnitor and shall be free of material conflicts with the Indemnitee’s interests and otherwise reasonably satisfactory to the Indemnitee, (ii) all costs and expenses of defense, including without limitation all attorney, witness, investigation, and court fees and expenses, (collectively, “Defense Costs”) shall be borne and promptly paid by the Indemnitor, and (iii) any engagement of separate counsel by Indemnitee shall be solely at the Indemnitee’s expense. If the Indemnitor does not so assume the defense, or if the Indemnitor fails to diligently pursue such defense or timely pay any Defense Costs, then the Indemnitee may take charge of the defense of such claim, including the designation of defense counsel, and all Defense Costs, including without limitation the reasonable fees and expenses of counsel designated by the Indemnitee, shall be borne and promptly paid by the Indemnitor. No settlement of a claim for which indemnification will be sought under this Section 5.2 shall be made without the consent of the Indemnitor, which shall not unreasonably be withheld. No settlement of a claim shall be entered into without the consent of the Indemnitee unless it fully and finally releases the Indemnitee from all obligations and liability relating to or arising out of the subject matter of the claim and imposes no restrictions or burdens on the Indemnitee.

5.3 Insurance. Regenity shall maintain general liability insurance, including product liability coverage, in a minimum amount of Ten Million Dollars (\$10,000,000) per occurrence and Ten Million Dollars (\$10,000,000) in the aggregate annually.

5.4 Limitation of Liability. Notwithstanding any provision of this Agreement to the contrary, except with respect to liability arising from (a) a breach of Article VI or Article VII, (b) willful misconduct or intentionally wrongful act of a Party, or (c) a Party’s indemnification obligations under this Article V, in no event will either Party or its Representatives be liable under this Agreement for any special, indirect, incidental, consequential or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise, including loss of profits or revenue suffered by either Party or any of its Representatives. Without limiting the preceding sentence and notwithstanding any provision of this Agreement to the contrary but

subject to Section 3.4, except with respect to liability arising from (i) a breach of Article VI or Article VII, (ii) willful misconduct or intentionally wrongful act of a Party, or (iii) a Party's indemnification obligations under this Article V, in no event shall either Party's aggregate liability arising out of or related to this Agreement, whether in contract, tort or under any other theory of liability, exceed the payments made or payable by Distributor to Regenity under this Agreement in the six (6) months preceding the incident giving rise to such liability.

## **ARTICLE VI**

### **Confidential Information**

6.1 Confidential Information. "Confidential Information" shall mean all information disclosed by a Party (the "Disclosing Party") to the other Party or its Representatives (the "Recipient") in any manner, whether orally, visually, or in tangible form (including documents, devices, and computer readable media) and all copies thereof, whether or not created by the Disclosing Party, in each case to the extent that such information is identified by the Disclosing Party as being confidential or proprietary at the time of disclosure. Notwithstanding the foregoing, Confidential Information shall not include any information that Recipient can demonstrate: (i) was in Recipient's possession prior to disclosure by the Disclosing Party; (ii) was known to the public at the time of disclosure to Recipient under this Agreement, or becomes publicly known after such disclosure, through no act of Recipient or its employees, agents, or independent contractors; (iii) comes into the possession of Recipient from any Person who is not under any obligation to the Disclosing Party to maintain the confidentiality of such information; or (iv) is independently developed by the Recipient without the aid, use or application of Confidential Information of the Disclosing Party. Further, the terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties.

6.2 Disclosure of Confidential Information. Except as expressly permitted by this Agreement or as necessary to satisfy its obligations under this Agreement, Recipient shall not disclose Confidential Information of the Disclosing Party and shall prevent the disclosure of such Confidential Information by Recipient's Representatives. Recipient shall disclose Confidential Information of the Disclosing Party only to those of its Representatives who have a need to know such Confidential Information for the purpose of satisfying its obligations under this Agreement. Recipient shall use Confidential Information of the Disclosing Party solely for the purpose of satisfying its obligations under this Agreement. Each Party agrees that the restrictions under this Section 6 will continue to apply after this Agreement terminates or expires, regardless of the reason for such termination or expiration.

6.3 Disclosure Required by Law. In the event that Recipient is ordered to disclose Confidential Information of the Disclosing Party pursuant to a judicial or governmental request, requirement, or order, Recipient shall immediately notify the Disclosing Party and take reasonable steps to assist the Disclosing Party in contesting such request, requirement, or order or otherwise protecting the Disclosing Party's rights. If the Recipient is ultimately compelled to disclose Confidential Information of the Disclosing Party, it shall only disclose such Confidential Information to the extent required to comply with applicable Law.

6.4 Return or Destruction of Confidential Information. Upon termination or expiration of this Agreement (or upon demand by the Disclosing Party), Recipient shall return promptly to the Disclosing Party or destroy, at the Disclosing Party's option, all tangible materials that disclose or embody the Disclosing Party's Confidential Information.

6.5 Remedies of Disclosing Party. The Parties acknowledge that it will be impossible to measure the damages that would be suffered by Disclosing Party if Recipient fails to comply with its obligations under this Article VI and that, in the event of any such failure, the Disclosing Party will not have an adequate remedy at law. The Disclosing Party shall, therefore, be entitled in addition to any other rights and remedies to seek specific performance of Recipient's obligations under this Article VI and to seek immediate injunctive relief without having to post a bond. Recipient shall not urge, as a defense to any proceeding for such specific performance or injunctive relief, that the Disclosing Party has an adequate remedy at law.

## **ARTICLE VII**

### **Intellectual Property Rights**

7.1 Trademarks and Trade Names. Each Party recognizes that the other Party owns certain trademarks, trade names, service marks, and Internet domain names that identifies them and their products (including, without limitation, the Products) and each Party acknowledges that it has no ownership right or interest in any of the trademarks, trade names, service marks, and Internet domain names of the other Party or relating to any of the other Party's products (including, without limitation, the Products). Regenity expressly acknowledges that it has no ownership right or interest in any of the proprietary designations for use in connection with the Products that are elements of Distributor Product Branding.

7.2 Use of Marks. As used herein, "Regenity Marks" means the trademarks, trade names, names, brands, logos, symbols, and other proprietary designations of Regenity approved by Regenity for use in connection with the Products, other than those that are elements of Distributor Product Branding. During the Term, and subject to the terms and conditions of this Agreement, Distributor may use the Regenity Marks solely (i) in connection with its marketing and distribution of the Products in the Territory for use in the Field, and (ii) in compliance with the trademark guidelines communicated by Regenity to Distributor from time to time. Distributor shall use the Regenity Marks, and except for marks that are elements of Distributor Product Branding, no other trademarks, trade names, names, brands, logos, symbols, and other proprietary designations, to identify the Products in connection with the marketing, distribution, and sale of the Products by Distributor under this Agreement. Distributor is not authorized to use any of the Regenity Marks, or any derivative or partial use thereof, or any other trade names, trademarks, service marks, Internet domain names, logos, symbols, or indicia of proprietary designations of Regenity or any of its affiliates. Distributor shall not merge, co-join, or use any Regenity Mark in conjunction with any other trade names, trademarks, service marks, logos, symbols, or indicia, including but not limited to Distributor's trade names or trademarks. Without limiting Distributor's obligations under Section 2.4(a)(ii), prior to any use or distribution of any Marketing Materials bearing any Regenity Marks, Distributor shall submit to Regenity copies of such Marketing Materials for Regenity's review to assure compliance with Regenity's then-current trademark usage standards, applicable Laws, and the terms and conditions of this Agreement.

7.3 Regenity Marks are the Property of Regenity. The Regenity Marks, and any reputation and goodwill in them, are, and will remain, the exclusive property of Regenity, and Distributor does not have and will not in the future have, any right to use such Regenity Marks other than through this Agreement. All use of the Regenity Marks shall inure solely to the benefit of Regenity. Distributor shall not: (i) use the Regenity Marks, or any word, symbol, or design

confusingly similar to the Regenity Marks or other Regenity trademarks or service marks, as part of its corporate or legal name or in connection with any product sold by Distributor; (ii) do or suffer to be done any act or thing which will in any way impair the rights of Regenity in and to any Regenity Mark; (iii) apply for any registration of any trademark or other designation which includes in whole or in part any Regenity Mark or which otherwise would affect the ownership of any Regenity Mark, nor file any document with any Governmental Authority to take any action that would affect the ownership of any Regenity Mark or assist any other Person or entity to undertake any such action; or (iv) acquire or claim any title to any Regenity Mark adverse to Regenity by virtue of this Agreement or through Distributor's use of any Regenity Mark pursuant to this Agreement.

7.4 Distributor Marks. As used herein, "Distributor Marks" means the trademarks, trade names, names, brands, logos, symbols, and other proprietary designations of Distributor including all the elements of Distributor Product Branding. The Distributor Marks, and any reputation and goodwill in them, are, and will remain, the exclusive and solely-owned property of Distributor, and Regenity does not have and will not in the future have, any right to use such Distributor Marks other than through this Agreement. All use of the Distributor Marks shall inure solely to the benefit of Distributor. Regenity shall not: (i) use the Distributor Marks, or any word, symbol, or design confusingly similar to the Distributor Marks or other Distributor trademarks or service marks, as part of its corporate or legal name or in connection with any product sold by Regenity; (ii) do or suffer to be done any act or thing which will in any way impair the rights of Distributor in and to any Distributor Mark; (iii) apply for any registration of any trademark or other designation which includes in whole or in part any Distributor Mark or which otherwise would affect the ownership of any Distributor Mark, nor file any document with any Governmental Authority to take any action that would affect the ownership of any Distributor Mark or assist any other Person or entity to undertake any such action; or (iv) acquire or claim any title to any Distributor Mark adverse to Distributor by virtue of this Agreement or through Regenity's use of any Distributor Mark pursuant to this Agreement. Regenity shall not (i) use any of the Distributor Marks, or any derivative or partial use thereof, or any other trade names, trademarks, service marks, Internet domain names, logos, symbols, or indicia of proprietary designations of Distributor or any of its affiliates, or (ii) merge, co-join, or use any Distributor Mark in conjunction with any other trade names, trademarks, service marks, logos, symbols, or indicia, including but not limited to Regenity's trade names or trademarks, without prior written permission from Distributor.

7.5 Intellectual Property. Distributor acknowledges that all patents, copyrights, design rights, trade secrets, and other intellectual property rights in or related to the Products (collectively, "Product IP") shall be and remain the exclusive property of Regenity. Except as expressly provided under this Agreement, Distributor has no right to, and shall not, make, use, modify, reproduce, disassemble, reverse engineer, translate, reconstruct, or improve the Products, or practice any of Regenity's intellectual property rights, except upon the prior written consent of Regenity. Distributor agrees to and hereby does assign to Regenity, without payment of royalty or other consideration, all of Distributor's rights in any Product IP, whether now existing or that hereafter arises.

7.6 Notification of Adverse Use. Each Party shall promptly notify the other Party of any action undertaken by any Person that may constitute an infringement of any Product IP or that Party's marks (including, without limitation, any adverse use of marks by any Person that is

confusingly similar to any of either Party's marks), in each case to the extent that the same comes to such Party's attention.

## ARTICLE VIII

### Miscellaneous

8.1 Relationship of the Parties. The relationship of Regenity and Distributor as the result of this Agreement is that of principal and independent contractor. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

8.2 Warranty and Representation. Each Party warrants and represents to the other that it is legally free to enter into this Agreement in accordance with its terms and conditions, and that this Agreement does not interfere with any legal or contractual obligations it may have with any Third Party.

8.3 Non-Assignment and Change of Control. Neither party may assign any of its rights or obligations hereunder without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed. In the event of a transfer by either Party of its rights or obligations under this Agreement incident to a merger, consolidation, reorganization or acquisition of substantially all the assets, or other form of transaction effecting a change of control, of such Party, this Agreement shall automatically transfer in its entirety to, and be binding upon, the party that acquires or assumes the transferring Party's assets and obligations. Notwithstanding any provision of this Agreement to the contrary, any of Regenity's obligations to be performed under this Agreement may be performed by any subsidiary, affiliate or qualified third-party subcontractor of Regenity, subject to Distributor's prior approval.

8.4 Notices. Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including any notice of force majeure, breach, termination, change of address, etc.) shall be in writing and shall be deemed given upon receipt if delivered personally or by facsimile transmission (receipt verified), five days after deposited in the mail if mailed by registered or certified mail (return receipt requested) postage prepaid, or on the next business day if sent by overnight delivery using a nationally recognized express courier service and specifying next business day delivery (receipt verified), to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as shall be specified by like notice, *provided, however*, that notices of a change of address shall be effective only upon receipt thereof):

All correspondence to Regenity shall be addressed as follows:

Collagen Matrix, Inc.

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Attn: Chief Executive Officer

All correspondence to Distributor shall be addressed as follows:

AVITA Medical, Inc.



28159 Avenue Stanford, Suite 220  
Valencia, CA 91355  
Attn: Chief Legal Officer

8.5 Severability. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause or portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable Law.

8.6 Waiver of Breach. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

8.7 Force Majeure. Nonperformance by either Party shall be excused to the extent that performance is rendered impossible by acts of God, civil or military authority, war, riots, fire, earthquakes, floods, embargo, explosion, prohibition of import or export of the Products, governmental orders, regulations, restrictions, or by strike, lockout, or other labor troubles or any other reason where failure to perform is beyond the reasonable control of and is not caused by the negligence of the non-performing Party.

8.8 Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws in the state of New York, U.S.A., including the United States Federal Court located in the state of New Jersey shall have exclusive jurisdiction to hear and determine all disputes and claims whether for injunction, declaration, damage or otherwise, and shall have exclusive jurisdiction to hear and determine all questions as to the validity, existence or enforceability of this Agreement, all without regard to choice or conflict of law rules.

8.9 Modification. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

8.10 Entire Agreement. This Agreement contains the entire agreement of the Parties hereto with respect to the subject matter hereof and shall be deemed to supersede all prior agreements concerning such subject matter, whether written or oral, and the terms and provisions of any such prior agreement are hereby terminated, are null and void, and shall be without further force or effect. Notwithstanding the foregoing, any agreements with respect to the confidentiality and/or non-disclosure of confidential or proprietary information disclosed by one Party to the other Party prior to the Effective Date shall remain in full force and effect and govern the receiving Party's obligations with respect to such confidential or proprietary information.

8.11 Counterparts. This Agreement may be executed in two or more counterparts,

each of which shall be deemed an original and all of which together shall constitute one instrument.

8.12 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns.

8.13 Descriptive Headings. The descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

8.14 No Third-Party Rights. No provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

**COLLAGEN MATRIX, INC.    AVITA MEDICAL, INC.**

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Print: Peggy Hansen

Print: \_\_\_\_\_

Title: GM CDM / SVP RA/CA/QA

Title: \_\_\_\_\_

**SCHEDULE A**

**PRODUCTS AND PRICES**

<b>Regenity Item Code</b>	<b>Distributor Item Code TBD</b>	<b>SIZE</b>
BDTWD22		2cm x 2cm
BDTWD55		5cm x 5cm
BDTWD1010		10cm x 10cm
BDTWD1020		10cm x 20cm
BDTWD2035		20cm x 35cm

\*Product Handling Demos: Non-Sterile, Bulk Packed

**SCHEDULE B**

**TERRITORY**

United States of America

## **SCHEDULE C**

### **LIMITED PRODUCT WARRANTY (IN EFFECT AS OF THE EFFECTIVE DATE)**

Regenity warrants that, at the time Regenity delivers the Product to the Carrier, the Product (a) will conform with applicable Specifications, (b) will be packaged in accordance with the final packaging and labeling agreed upon between Regenity and Distributor with respect to such Product, (c) will have been manufactured in compliance with US FDA Quality System Regulations 21 CFR 820 and ISO 13485, and (d) will have at least fifty percent (50%) of the maximum shelf-life for such Product (as specified in the applicable Specifications) remaining.

## SCHEDULE D

### PRODUCT SPECIFICATIONS

All Products shall: (1) meet applicable FDA acceptance specifications, (2) conform to applicable sizing as shown in Schedule A, (3) be sterile and non-pyrogenic, and (4) be packaged and labeled in final box for distribution to end users in accordance with Trademark and Private Brand specifications supplied by Distributor.

Material Composition	Collagen derived from bovine dermis
Sizes and shapes	Square and rectangular shapes 2cm x 2 cm 5cm x 5 cm 10cm x 10cm 10cm x 20cm 20cm x 35cm
Packaging	Single blister tray with Tyvek lid or Single Tyvek/film pouch  Single unit to be labeled and packaged in a box with Instructions for Use
Sterility	Terminally sterilized, SAL 10 <sup>-6</sup>
Non-pyrogenic	Non-pyrogenic
*Maximum Shelf Life	3 years

## **SCHEDULE E**

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For successive periods subsequent to the Initial Term, Guaranteed Regenity Target Product Revenues shall be 105% of the previous year. For example, the Guaranteed Regenity Target Product Revenues for Year 6 of this agreement shall be 105% of the [\*\*\*\*\*] shown above for Year 5.



**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**

**EXECUTIVE EMPLOYMENT AGREEMENT**

This EXECUTIVE EMPLOYMENT AGREEMENT (the “Agreement”) is made and entered into by and between AVITA Medical, Inc. and AVITA Medical Americas, LLC. (collectively, the “Company”) and Nicole Kelsey, an individual (the “Executive”) with reference to the following:

**RECITALS**

WHEREAS, the Company desires to employ Executive to serve as the Chief Legal and Compliance Officer and Corporate Secretary (CLO) of the Company;

WHEREAS, the Executive is willing to serve in the role of Chief Legal and Compliance Officer and Corporate Secretary of the Company and provide services to the Company and its subsidiaries and affiliates under the terms and conditions stated herein,

WHEREAS, the Executive would serve as Chief Legal and Compliance Officer and Corporate Secretary of the Company, effective as of July 1, 2024 (the “Effective Date”),

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, and intending to be legally bound, it is hereby agreed by and between the parties hereto as follows:

**1. Employment and Duties**

1.1 Employment. The Company hereby employs the Executive as the CLO of the Company and the Executive hereby accepts such employment as of the Effective Date pursuant to the terms and conditions set forth herein. The Executive will perform policy- making functions in her role and will be deemed to be an officer under Section 16 of the Securities Exchange Act of 1934. The Executive shall report directly to the Chief Executive Officer (“CEO”).

1.2 Duties. The Executive shall perform, to the best of her ability and in a manner satisfactory to the CEO, all such duties that are consistent with Executive’s title and position, and such other duties as may reasonably be assigned to her by the CEO. The Executive’s duties will be conducted principally from the Company’s North America office, currently located in Valencia, California, or at such other location as determined by the CEO (but subject to the terms of this Agreement), with travel to such other locations from time to time as reasonably required.

1.3 Time and Efforts. The Executive shall devote her full business time and provide her best efforts, attention, and energies to the business of the Company, and its subsidiaries and affiliates, and to the performance of Executive’s duties hereunder, and Executive shall not engage in any other business, profession or occupation for compensation or otherwise during the employment period without the prior written consent of the Board of Directors (the “Board”); provided that, nothing herein shall preclude Executive from serving in any capacity with any civic, educational, or charitable organization, and provided, further that, in each case, and in the aggregate, such services do not materially conflict or interfere with Executive’s obligations to the

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Company, and its subsidiaries and affiliates hereunder and such service is disclosed in advance by Executive to the Board. Executive has disclosed that she is a board member of the following non-profit organizations and Company agrees for her continuance:

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Executive further acknowledges that she owes the Company both a fiduciary duty and a duty of loyalty while employed during the employment period to act at all times in the best interests of the Company, and its subsidiaries and affiliates.

## 2. **Compensation**

As the total consideration for the Executive's services rendered hereunder, Executive shall be entitled to the following:

2.1 Base Salary. The Executive shall be paid an annual base salary of Four Hundred Fifty Thousand Dollars (\$450,000.00) per year ("Base Salary"), subject to applicable tax deductions and withholdings, beginning on the Effective Date of the Agreement and payable in regular installments in accordance with the customary payroll practices of the Company. The Executive's salary will be subject to annual review by the Board and may be increased in the sole discretion of the Board.

### 2.2 Bonus.

(a) Annual Performance Bonus. In addition to Base Salary, the Executive shall be eligible to receive an annual performance bonus ("Annual Bonus") based upon the Company's performance and Executive's performance for the preceding year as measured against certain performance targets as mutually established by the parties to this Agreement as determined by the Board and CEO. The Annual Bonus, if earned, shall be paid on or around the March timeframe of the following year. The amount of the Annual Bonus shall be fifty percent (50%) of Executive's Base Salary ("Target Bonus"). For 2024, Executive will be eligible to receive an Annual Bonus of up to fifty percent (50%) of the pro-rata share of the Base Salary (excluding any other bonus or compensation) Executive earned in 2024. Executive may be entitled to an additional amount of up to fifty percent (50%) of the Target Bonus based upon performance. For the Annual Bonus to be deemed earned, and in order to be eligible and entitled to receive any Annual Bonus payment, the Executive must be employed by, and not have given notice of resignation to the Company, or have been given notice of termination by the Company at the time the Annual Bonus is determined and paid to Executive.

2.3 Equity. Subject to approval of the Company's Board, Executive shall be eligible for 150,000 options which will vest as follows:

- 150,000 options will vest based on Executive's continued employment with the Company at a rate of 50,000 per year for three (3) years, commencing with the first 50,000 option installment, which will vest upon the completion of Executive's first year of service.

Any such equity grants shall be subject to the terms of a Share Option Agreement and the governing equity plan which will be provided to the Executive within thirty (30) days of her Effective Date. In addition, Executive shall be eligible for the annual equity grants under the

Amendment to the 2020 Omnibus Incentive Plan. For avoidance of doubt, such option terms shall provide that Executive is entitled to immediate acceleration of Executive's stock options so that 100% of any then unvested stock options shall immediately vest and become exercisable upon a Change in Control.

2.4Relocation Expenses. The company recognized that the Executive will need to relocate to the Southern California area. To offset some of these expenses the Company will provide a one time relocation bonus of [\*\*\*\*\*] upon proof of moving.

The bonus will be paid in one payment on AVITA Medical's first normal pay period following the receipt of proof of move. You must be actively employed at the time of the Bonus payment to receive any such payment. You understand that the Bonus is paid at AVITA Medical's discretion and is not tied to your job performance or any other metric. You understand and agree that if your employment with AVITA Medical ends before the 12-month anniversary of your first date of employment, you must re-pay the Bonus in its entirety to AVITA Medical within five business days of your last date of employment. You understand and agree that you are not entitled to any pro-rata share or credit of any portion of the Bonus for an incomplete year of service.

2.5Business Expenses. During employment, the Executive is entitled to reimbursement for reasonable and necessary business expenses incurred by Executive in connection with the performance of Executive's duties, subject to proper documentation and approval as required pursuant to the applicable Company expense reimbursement policies.

2.6Fringe Benefits. The Executive shall be entitled to fringe benefits in accordance with the plans, practices, programs and policies applicable to other peer executives of the Company.

2.7Vacation. The Executive shall be entitled each year to a vacation, during which time her compensation shall be paid in full. The time allotted for such vacation shall be four (4) weeks per year. Executive can accrue up to six (6) weeks of vacation time, at which point no additional vacation may accrue beyond the six (6) weeks until a portion thereof is used. Any accrued vacation will roll over into the following calendar year and will not be forfeited. The Executive agrees to schedule planned vacation to be taken at a time mutually convenient to the Executive, CEO, and the Company.

2.8Health Insurance and Benefits. The Executive shall be eligible to participate in the Company's health, dental and vision plans, as well as the Company's 401k program and non-qualified deferred compensation plan, pursuant to the terms of these plans and programs.

### **3. Term and Termination of Employment**

3.1At-Will Employment. The Company and the Executive hereby agree that the Executive's employment by the Company shall be "at-will" and for an indefinite period of time. Subject to the provisions of this Section, both the Executive and the Company shall have the right to terminate this Agreement and the employment relationship at any time and for any reason, with or without Cause, with or without Good Reason, and with or without advance notice.

### 3.2 Definitions.

(a) **Cause.** For purposes of this Agreement, “Cause” shall mean the occurrence of one or more of the following: (i) conviction of, or a plea of guilty or nolo contendere to, a felony or crime involving moral turpitude; (ii) participation in an act of fraud or theft against the Company; (iii) willful and material breach of any contractual, statutory, fiduciary, or common law duty owed to the Company including without limitation Section 4.1 of this Agreement; (iv) willful and repeated failure to satisfactorily perform job duties; or (v) any willful act that is likely to and which does in fact have the effect of injuring the reputation, business, or a business relationship of the Company.

(b) **Good Reason.** For purposes of this Agreement, “Good Reason” shall mean: (i) a material diminution in Executive’s authority, duties, or responsibilities in effect at the time of this Agreement; (ii) any reduction in the Executive’s then-current base salary; (iii) relocation of Executive’s principal place of work by a distance of fifty (50) miles or more from the Executive’s then-current principal place of work without the Executive’s consent; (iv) material breach by the Company of any provision of this Agreement; or (v) the occurrence of a Change in Control of the Company as defined in Section 3.2(c) below, provided, however, that the conduct described in the foregoing subsections (i) through (iv) will only constitute Good Reason if such conduct is not cured within thirty (30) days after the Company’s receipt of written notice from the Executive specifying the particulars of the conduct the Executive believes constitutes Good Reason and such notice shall be given within thirty (30) days of the occurrence of such event or conduct.

(c) **Change in Control.** For purposes of this Agreement, “Change in Control” shall mean any of the following events occurring after the date of this Agreement: (i) a sale or transfer of all or substantially all of the assets of the Company; (ii) any merger, consolidation or acquisition of the Company with, by or into another corporation, entity or person; (iii) any change in ownership of more than fifty percent (50%) of the voting capital stock of Company in one or more related transactions such as a buy out or exit of the Company (but excluding any change in stock listing).

### 3.3 Termination.

(a) **Termination for Cause or Resignation without Good Reason.** In the event that the Company terminates the Executive’s employment for Cause or the Executive resigns her employment without Good Reason, this Agreement will terminate without further obligations to Executive other than the following: Executive shall be entitled to receive her unpaid base salary earned through her last day of employment, accrued but unused vacation pay, and vested benefits through and including Executive’s last day of employment.

(b) **Involuntary Termination Without Cause or Resignation With Good Reason.** In the event of either an involuntary termination of the Executive’s employment Without Cause or a voluntary resignation by the Executive for Good Reason, in exchange for the Executive signing a separation and release of all claims agreement in a form acceptable to the Company, the Company shall provide the Executive with the following severance benefits in accordance with the timing set forth in Section 3.3(b)(v) below:

- (i) Base Salary: The Company shall pay the Executive the equivalent of twelve (12) months of the Executive's annual base salary in effect at the time of the termination Without Cause or resignation with Good Reason in one lump sum payment, less standard deductions and withholdings.
- (ii) Benefits Coverage. The Company shall continue to provide group health, vision, and dental plan benefits to the Executive for a period of twelve (12) months from and after the date of termination, with the cost of all regular premiums for such benefits paid by the Company (or its successor). The Executive will pay the monthly cost of the premium and submit to the Company (or its successor) for reimbursement of such monthly expense.
- (iii) Equity. Executive's stock options shall immediately accelerate so that 100% of any then unvested stock options shall immediately vest and become exercisable upon the date of Executive's termination Without Cause or resignation with Good Reason and shall continue to be exercisable for three (3) months.
- (iv) Timing of Payments. The severance benefits in the above subsection 3.3(b)(i) shall be paid to Executive no later than fifteen (15) days from the date the Executive signs the severance and release agreement and the revocation period, if any, has expired.

#### **4. Proprietary Information**

The Executive acknowledges that: (i) the Executive has a major responsibility for the operation, development and growth of the Company's business, and its subsidiaries and affiliates; (ii) the Executive's work for the Company, and its subsidiaries, and affiliates has brought the Executive and will continue to bring the Executive into close contact with "Confidential Information" (as defined below); and (iii) the agreements and covenants contained in this Section 4 are essential to protect the business interests of the Company, and its subsidiaries and affiliates, and that the Company will not enter into this Agreement but for such agreements and covenants. Accordingly, the Executive covenants and agrees to the following:

4.1 Confidential Information. Both during the term of the Executive's employment under this Agreement and indefinitely after the Executive is no longer employed as CLO of the Company, the Executive shall not, directly or indirectly, (i) knowingly use for an improper personal benefit any "Confidential Information" that was acquired by, learned by or disclosed to Executive by reason of the Executive's employment as CLO of the Company (before or after the date of this Agreement), or (ii) disclose any such Confidential Information to any person, business or entity, except in the proper course of the Executive's duties as CLO, of the Company. As used in this Agreement, "Confidential Information" means any and all confidential or proprietary information of the Company, and its subsidiaries and affiliates that is not generally known to the public, including, without limitation, business, financial, marketing, technical, developmental, operating, performance, know-how, and process information, drawings and designs, customer information (including contact information, pricing and buying trends and needs), employee information (including the skills, abilities and

compensation of other employees), and other trade secret information, now existing or hereafter discovered or developed. Confidential Information shall include information in any form whatsoever, including, without limitation, any digital or electronic record-bearing media containing or disclosing such information. The provisions of this Section 4 shall not apply to information that has become generally available to the public other than as a result of a disclosure by the Executive. In the event that the Executive is requested or required (by oral question or request for information or documents in any legal proceeding, interrogatory, subpoena, civil investigative demand, or similar process) to disclose any Confidential Information, then the Executive will notify the Company within two (2) business days of receiving the request or requirement so that the Company may seek an appropriate protective order. If, in the absence of a protective order or the receipt of a waiver hereunder, the Executive is, on the advice of counsel, compelled to disclose any Confidential Information to any tribunal or else stand liable for contempt, the Executive may disclose such Confidential Information to the tribunal; provided, however, that the Executive shall use the Executive's reasonable best efforts to obtain, at the expense and reasonable request of the Company, an order or other assurance that confidential treatment will be accorded to such portion of the Confidential Information required to be disclosed as the Company shall designate. The Executive acknowledges that all Confidential Information is the exclusive property of the Company. The Executive further acknowledges that the Executive's entire work product, including working drafts and work sheets, shall be the sole property of the Company, and that the Executive will have no rights, title or interest in any such material whether prepared by the Executive alone, by others or by the Executive in conjunction with others. Executive agrees as a condition of continued employment to execute the Company's Proprietary Information Agreement protecting the trade secrets and other intellectual property of the Company. ***Defend Trade Secrets Act Notice.*** Executive is hereby notified in accordance with the Defend Trade Secrets Act of 2016 that she will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. Executive is further notified that if Executive files a lawsuit for retaliation by an employer for reporting a suspected violation of law, Executive may disclose the employer's trade secrets to Executive's attorney and use the trade secret information in the court proceeding if Executive: (i) files any document containing the trade secret under seal; and (ii) does not disclose the trade secret, except pursuant to court order.

**4.2Duty of Loyalty and Non-Competition.** While employed by the Company, the Executive shall not, without the prior written consent of the Company, participate, directly or indirectly, as an individual proprietor, partner, stockholder, officer, employee, director, manager, joint venture participant, investor, lender, consultant or in any capacity whatsoever (within the United States of America, or in any country where the Company or its subsidiaries or affiliates do business or have reasonable plans to do business) in a business engaged in competition with the Company or any of its subsidiaries or affiliates, or in a business that the Company or any of its subsidiaries or affiliates has taken reasonable steps to engage in (including, but not limited to, meeting with management teams or entering into preliminary or definitive term sheets, letters of intent, purchase agreements, or other similar arrangements or agreements) of which the Executive has knowledge at the time of Executive's employment; provided, however, that such participation shall not include the mere ownership of not more than one percent (1%) of the total outstanding stock of a publicly held company. At all times following the termination of Executive's employment as CLO of the Company for any reason, Executive shall not, either directly or indirectly, engage in any unlawful competitive activities or use confidential trade secret information for any purpose.

**4.3 Non-Solicitation.** For a period beginning on the Effective Date and ending two

(2) years after the date on which the Executive is no longer employed CLO of the Company (the “Non-Solicitation Period”), the Executive shall not in any capacity, either separately or in association with others: (i) unlawfully solicit for employment or endeavor in any way to unlawfully entice away from employment with the Company, its subsidiaries or affiliates any employee of the Company, its subsidiaries or its affiliates, or any person or entity that had been an employee of the Company or its subsidiaries or affiliates within the six (6) month period preceding the commencement of such activity; nor (ii) use confidential trade secret information to solicit or use any other unlawful means to induce or influence any supplier, customer, agent, consultant or other person or entity that has a business relationship with the Company, or its subsidiaries or affiliates to discontinue, reduce or modify such relationship with the Company or its subsidiaries or affiliates.

4.4 Non-disparagement. The Executive agrees (whether during or after Executive’s employment as CLO of the Company) not to issue, circulate, publish or utter any comments or statements to the press or other media, or to any third parties, or to any employees of the Company, and its subsidiaries and affiliates, or any consultants or any individual or entity with whom the Company or its subsidiaries or affiliates has a business relationship, which could reasonably be expected to adversely affect in any manner: (i) the conduct of the business of the Company, or its subsidiaries or affiliates (including, without limitation, any products, services, or business plans or prospects); or (ii) the business reputation of the Company or its subsidiaries or affiliates (including its financial condition or the direction of the business), or any of their respective products or services, or their past or present officers, directors, executives or employees. Notwithstanding the foregoing, nothing contained in this Agreement will be deemed to restrict Executive from providing truthful information to any governmental or regulatory agency (or in any way limit the content of any such information) to the extent requested or required to provide such information pursuant to applicable law or regulation. Nothing in this section is intended to limit Executive’s rights under Section 7 of the National Labor Relations Act.

4.5 Return of Property. Upon termination of her employment as CLO of the Company or at any time as the Company requests, the Executive will promptly deliver to the Company all documents (whether prepared by the Company, a subsidiary, an affiliate, the Executive or a third party) relating to the Company, any of its subsidiaries or affiliates or any of their businesses or property that the Executive may possess or have under the Executive’s direction or control other than documents provided to the Executive in the Executive’s capacity as a participant in any employee benefit plan, policy or program of the Company.

4.6 Remedies. The Executive acknowledges that (i) the Executive has had an opportunity to seek the advice of counsel in connection with this Agreement; (ii) the provisions of this Section 4 are reasonable in scope and in all other respects; (iii) any violation of these provisions will result in irreparable injury to the Company; (iv) money damages may not be an adequate remedy for the Company in the event of a breach of any of these provisions by the Executive; and (v) specific performance in the form of injunctive relief would be an appropriate remedy for the Company. If the Executive breaches or threatens to breach any of these provisions, the Company shall be entitled, in addition to all other

remedies, to seek an injunction restraining any such breach, without any bond or other security being required and without the necessity of showing actual damages.

## **5. Assignment**

This Agreement is personal in nature, and neither this Agreement nor any part of any obligation herein shall be assignable by Executive. The Company shall be entitled to assign this Agreement to any subsidiary or affiliate of the Company or any entity that assumes the ownership and control of the business of the Company.

## **6. Severability**

Should any term, provision, covenant or condition of this Agreement be held to be void or invalid, the same shall not affect any other term, provision, covenant or condition of this Agreement, but such remainder shall continue in full force and effect as though each such voided term, provision, covenant or condition is not contained herein.

## **7. Binding Arbitration**

Any and all disputes which involve or relate in any way to this Agreement and/or to Executive's employment or termination of employment as CLO of the Company, whether initiated by Executive or by the Company and whether based on contract, tort, statute, or common law, shall be submitted to and resolved by final, binding and confidential arbitration as the exclusive method for resolving all such disputes. The arbitration shall be private and confidential and conducted in Los Angeles, California pursuant to the Federal Arbitration Act and applicable California law, and pursuant to the applicable rules of the Judicial Arbitration and Mediation Services ("JAMS") relating to employment disputes, unless the parties otherwise mutually agree to modify the JAMS Rules. A copy of the AAA Employment Rules are available for review at <https://www.jamsadr.com/rules-employment-arbitration> and are incorporated herein by reference.

The party demanding arbitration shall submit a written claim to the other party, setting out the basis of the claim or claims, within the time period of any applicable statute of limitations relating to such claim(s). If the parties cannot mutually agree upon an arbitrator, then the parties shall select a neutral arbitrator through the procedures established by the AAA. The arbitrator shall have the powers provided under the Federal Arbitration Act relating to the arbitration of disputes, except as expressly limited or otherwise provided in this Agreement. The parties shall have the right to reasonable discovery. The parties agree that the Company shall pay the administration costs of the AAA arbitration, including payment of the fees for the Arbitrator, and any other costs directly related to the administration of the arbitration. The parties shall otherwise be responsible for their own respective costs and attorneys' fees relating to the dispute, such as deposition costs, expert witnesses and similar expenses, except as otherwise provided in this Agreement to the prevailing party.

The Arbitrator may award, if properly proven, any damages or remedy that a party could recover in a civil litigation and shall award costs and reasonable attorneys' fees to the



prevailing party as provided by law. The award of the Arbitrator shall be issued in writing, setting forth the basis for the decision, and shall be binding on the parties to the fullest extent permitted by law, subject to any limited statutory right to appeal as provided by law.

Judgment upon the award of the Arbitrator may be entered in any state or federal court sitting in Los Angeles, California.

Nothing in this Section shall prevent Executive from filing or maintaining a claim for workers' compensation, state disability insurance, or unemployment insurance benefits, and nothing in this section shall be construed to prevent or excuse Executive or the Company from using existing internal procedures for the resolution of complaints. Employee may bring claims before administrative agencies when the law permits the agency to adjudicate those claims, even when there is an agreement to arbitrate; examples include claims or charges with the United States Equal Employment Opportunity Commission (or comparable state agency), the National Labor Relations Board, the U.S. Department of Labor, or the Office of Federal Contract Compliance Programs. Nothing in this Section shall require arbitration of disputes that are excluded from coverage by this section or by law.

The Company and Executive agree that any dispute in arbitration will be brought on an individual basis only, and not on a class, collective, or representative basis on behalf of others (this agreement to be referred to hereafter as the "Class Action Waiver"). The Class Action Waiver does not apply to any claim that Executive brings on behalf of both herself and others under the California Private Attorney General Act of 2004. Executive will not be subject to any retaliation or discrimination if Executive seeks to challenge this arbitration provision or participate in a class, collective, or representative action in any forum, but Company may lawfully seek enforcement of this Agreement under the Federal Arbitration Act and seek dismissal of any class, collective, or representative actions or claims to the fullest extent allowed by law.

## **8. Governing Law**

This Agreement shall be governed by and construed in accordance with the laws of the State of California applicable to contracts made and to be carried out in California. Each of the parties agrees to submit to the personal jurisdiction of any state or federal court sitting in Los Angeles, California in any action or proceeding arising out of or relating to this Agreement.

## **9. Notice**

All notices and other communications under this Agreement shall be in writing and mailed, telegraphed, telecopied, or delivered by hand (by a party or a recognized courier service) to the other party at the following address (or to such other address as such party may have specified by notice given to the other party pursuant to this provision):

If to the Company:  
AVITA Medical Americas, LLC Attn: General  
Counsel  
28159 Avenue Stanford  
Suite 220  
Valencia, CA 91355

If to Executive:  
Nicole Kelsey  
At current home address on file with the Company

## **10. Miscellaneous**

**10.1 Binding Agreement.** This Agreement shall inure to the benefit of and shall be binding upon the Company, its successors and assigns.

**10.2 Entire Agreement.** This Agreement contains the entire agreement of the parties relating to the subject matter hereof, and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement that are not set forth otherwise herein. In this regard, each of the parties represents and warrants to the other party that such party is not relying on any promises or representations that do not appear in writing herein. This Agreement supersedes any prior verbal or written agreements with the Company regarding Executive's employment or offer of employment, except as specifically referenced herein. Each of the parties further agrees and understands that this Agreement can be amended or modified only by a written agreement signed by all parties.

**10.3 Representations and Warranties.** Executive and the Company hereby represent and warrant to the other that: (a) she or it has full power, authority and capacity to execute and deliver this Agreement, and to perform her or its obligations hereunder; (b) such execution, delivery and performance will not (and with the giving of notice or lapse of time or both would not) result in the breach of any agreements or other obligations to which she or it is a party or she or it is otherwise bound; (c) this Agreement is a valid and binding obligation in accordance with its terms for both parties; (d) Executive represents and warrants that she is under no other obligations, contractual or otherwise, that could impair her ability to perform fully and satisfactorily all of her obligations under this Agreement; (e) Executive has had full opportunity to review this Agreement, to obtain all legal advice she has deemed necessary or appropriate and has either done so, or voluntarily and knowingly declined to do so; and (f) neither party has been induced to enter into this Agreement through any promises, threats, coercion, or benefits not set forth expressly in writing in this Agreement.

**10.4 Attorney's Fees.** In the event that any party shall bring an action or proceeding in connection with the performance, breach or interpretation of this Agreement, then the prevailing party in any such action or proceeding, as determined by the court, arbitrator or other body having jurisdiction, shall be entitled to recover from the losing party all reasonable costs and expenses of such action or proceeding, including reasonable attorneys' fees and court costs.

**10.5 Counterparts.** This Agreement may be executed on separate copies, any one of which need not contain signatures of more than one party but all of which taken together shall constitute one and the same Agreement.

[Signatures to follow on next page]

IN WITNESS WHEREOF, this Agreement is executed as of June , 2024.

“COMPANY”

**AVITA Medical, Inc. and AVITA Medical Americas, LLC**

By:

\_\_\_\_\_  
Name: James Corbett

Title: Chief Executive Officer  
\_\_\_\_\_

Date:

and

“EXECUTIVE”

**Nicole Kelsey**

By:

Name: Nicole Kelsey

Date:

**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**

**SEPARATION AGREEMENT AND RELEASE**

This Separation Agreement and Release (“Agreement”) is made by and between Donna Shiroma (“Employee”) and AVITA Medical, Inc. and AVITA Medical Americas, LLC (collectively, the “Company”) (Employee and the Company collectively referred to as the “Parties” or individually referred to as a “Party”).

**RECITALS**

WHEREAS, Employee was employed by the Company;

WHEREAS, Employee entered into an employment agreement with the Company with an Effective Date of June 25, 2018 (“Executive Employment Agreement”);

WHEREAS, the Parties mutually agree Employee’s employment with the Company will terminate effective July 1, 2024 (the “Termination Date”); and

WHEREAS, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that the Employee may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Employee’s employment with or separation from the Company;

NOW, THEREFORE, in consideration of the mutual promises made herein, the Company and Employee hereby agree as follows:

**COVENANTS**

1.Consideration. In consideration of Employee’s execution of this Agreement and Employee’s fulfillment of all of its terms and conditions, and provided that Employee does not revoke the Agreement under the Acknowledgement of Waiver of Claims under ADEA Section below, and subject to approval by the Company’s Board of Directors (the “Board”), along with any other required approvals from the Board of Directors for any Company affiliates, subsidiaries, or successor corporations, the Company agrees as follows:

a. Payment. The Company agrees to provide Employee the following in accordance with Employee’s Executive Employment Agreement Section 3.3 (b):

- i. Base Salary: A lump sum payment of[\*\*\*\*\*], less applicable withholdings, representing one year of Employee’s base annual salary on the Termination Date, in lieu of notice, payable no later than the sixtieth day from the Effective Date, as defined below.
- ii. Prorated Bonus: A lump sum payment of [\*\*\*\*\*]less applicable withholdings, representing your prorated bonus for 2024 at 100% of achievement.
- iii. Benefits Coverage: If Employee timely elects COBRA coverage and Employee signs up for such benefits within the time (60 days) as provided under COBRA terms, the Company shall pay the full cost of the premium to provide group health, vision, and dental plan benefits to the Employee for a period of twelve (12) months beginning July 1, 2024.
- iv. Equity: Employee’s stock options and RSUs shall immediately accelerate so that 100% of any then unvested stock options and RSUs shall immediately vest and become exercisable upon the Effective Date and shall continue to be exercisable for three (3) months under the terms and conditions of the Company’s equity incentive plan(s) (collectively, the “Incentive Plan”). Employee’s equity awards under the Incentive Plan shall continue to be governed by the terms and conditions of Employee’s equity agreements pursuant to the Incentive Plan (“Equity Agreements”).

2. Benefits. Employee's health insurance benefits ceased on the Termination Date, subject to Employee's right to continue Employee's health insurance under COBRA or comparable state law, if applicable. Employee's participation in all benefits and incidents of employment, including, but not limited to, vesting in stock options, and the accrual of bonuses, vacation, and paid time off, ceased as of the Termination Date. All applicable group term life insurance, long-term disability, short-term disability, and other welfare benefits, if any, will terminate in accordance with the provisions of the applicable plans. The Company or any applicable insurance providers will provide separate information regarding individual coverage rights. Employee's benefits under the Company's 401(k) Retirement Plan (the "Section 401(k) Plan"), if any, will be handled in accordance with the provisions of the Section 401(k) Plan.

3. Payment of Salary and Receipt of All Benefits. All base salary and accrued but unused vacation owed to Employee through the Termination Date will be paid to Employee on the effective date. Employee must timely submit a reimbursement request for all business expenses that are reimbursable per the Company's expense policies. Employee acknowledges and represents that, other than the consideration set forth in this Agreement, the Company and its agents have paid or provided all salary, wages, bonuses, accrued vacation/paid time off, notice periods, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, stock, stock options, vesting, and any and all other benefits and compensation due to Employee. Employee acknowledges and agrees that California Labor Code § 206.5 is not applicable. That section provides in pertinent part as follows:

*No employer shall require the execution of any release of any claim or right on account of wages due, or to become due, or made as an event on wages to be earned, unless payment of such wages has been made*

4. Release of Claims. Employee agrees that the foregoing consideration represents settlement in full of all outstanding obligations owed to Employee by the Company and its current and former officers, directors, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, professional employer organization or co-employer, insurers, trustees, divisions, and subsidiaries, and predecessor and successor corporations and assigns, including, but not limited to, AVITA Medical Inc, and AVITA Medical Americas, LLC. (collectively, the "Releasees"). Employee, on Employee's own behalf and on behalf of Employee's respective heirs, family members, executors, agents, and assigns, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, demand, or cause of action relating to any matters of any kind, on an individual or representative basis, whether presently known or unknown, suspected or unsuspected, that Employee may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the Effective Date of this Agreement, including, without limitation:

a. any and all claims relating to or arising from Employee's employment relationship with the Company and the termination of that relationship;

b. any and all claims relating to, or arising from, Employee's right to purchase, or actual purchase of shares of stock of the Company or AVITA Medical, Inc. or AVITA Medical Pty. Limited, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law or under the laws of any other country, and securities fraud under any state or federal law or under the laws of any other country;

c. any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

d. any and all claims for violation of any federal, state, or municipal statute or of any statute of any other country, including, but not limited to, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Equal Pay Act, the Fair Labor Standards Act, the Fair Credit Reporting Act and similar state laws, the Age Discrimination in Employment Act of 1967, the Older Workers

Benefit Protection Act, the Employee Retirement Income Security Act of 1974, the Worker Adjustment and Retraining Notification Act, the Family and Medical Leave Act, the Sarbanes-Oxley Act of 2002, the Immigration Reform and Control Act, the California Family Rights Act, the California Labor Code, the California Workers' Compensation Act, the California Fair Employment and Housing Act and the Corporations Act 2001 (Cth);

- e. any and all claims for violation of the federal or any state constitution;
- f. any and all claims arising out of any other laws and regulations of any country relating to employment or employment discrimination;
- g. any and all claims arising out of any laws and regulations relating in any way to employment, or the holding of any office (including any directorship) related to employment, under the Australian Commonwealth or any Australian State or Territory jurisdiction;
- h. any claim for any loss, cost, damage, or expense arising out of any dispute over the nonwithholding or other tax treatment of any of the proceeds received by Employee as a result of this Agreement; and
- i. any and all claims for attorneys' fees and costs.

Employee agrees that the release set forth in this section shall be in effect and remain in effect in all respects as a complete general release as to the matters released. This release does not extend to any obligations incurred under this Agreement. This release does not release claims that cannot be released as a matter of law, including any Protected Activity (as defined below). This release does not extend to any right Employee may have to unemployment compensation benefits or workers' compensation benefits. Employee represents that Employee has made no assignment or transfer of any right, claim, complaint, charge, duty, obligation, demand, cause of action, or other matter waived or released by this Section.

5.Acknowledgment of Waiver of Claims under ADEA. Employee acknowledges that Employee is waiving and releasing any rights Employee may have under the Age Discrimination in Employment Act of 1967 ("ADEA") against the Releasees, and any and all damages and disputes that have arisen prior to the Effective Date of this Agreement, except as expressly stated herein, and that this waiver and release is knowing and voluntary. Employee agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Employee signs this Agreement. Employee acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Employee was already entitled. Employee further acknowledges that Employee has been advised by this writing that: (a) Employee should consult with an attorney of his own choosing regarding this Agreement and its effects prior to executing this Agreement and he acknowledges and represents that he has done so, or has knowingly and voluntarily waived the right to do so; (b) Employee has twenty-one (21) days within which to consider this Agreement; (c) Employee has seven (7) days following Employee's execution of this Agreement to revoke this Agreement; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Employee from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Employee signs this Agreement and returns it to the Company in less than the 21-day period identified above, Employee hereby acknowledges that Employee has freely and voluntarily chosen to waive the time period allotted for considering this Agreement. Employee acknowledges and understands that revocation must be accomplished by a written notification to the undersigned Company representative that is received prior to the Effective Date. The Parties agree that changes, whether material or immaterial, do not restart the running of the 21-day period.

6.California Civil Code Section 1542. Employee acknowledges that Employee has been advised to consult with legal counsel and is familiar with the provisions of California Civil Code Section 1542, a statute that otherwise prohibits the release of unknown claims, which provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD

HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

Employee, being aware of said code section, agrees to expressly waive any rights Employee may have thereunder, as well as under any other statute or common law principles of similar effect.

7.Return of Company Equipment. Upon execution of the Agreement, Employee will deliver to the Company any Company equipment as well as all drawings, notes, memoranda, specifications, devices, formulas and documents, together with all copies thereof, and any other material containing or disclosing any Company inventions or confidential information of the Company. Employee agrees that Employee will not copy, delete, or alter any information contained upon Employee's Company computer or Company equipment before Employee returns it to the Company. In addition, if Employee has used any personal computer, server, or e-mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, confidential information, Employee agrees to provide the Company with a computer-useable copy of all such Confidential Information or permanently delete and expunge such confidential information from those systems; and Employee agrees to provide the Company access to Employee's system as reasonably requested to verify that the necessary copying and/or deletion is completed.

8.No Pending or Future Lawsuits. Employee represents and warrants that Employee is the sole owner of all claims released in this Agreement, and that Employee has not assigned, transferred, or otherwise disposed of Employee's right or interest in those matters. Employee has no lawsuits, claims, or actions pending in Employee's name, on Employee's behalf, or on behalf of any other person or entity, against the Company or any of the other Releasees. Employee also represents that Employee does not intend to bring any claims on Employee's own behalf or on behalf of any other person or entity against the Company or any of the other Releasees. Employee agrees to immediately cause the withdrawal or dismissal with prejudice of any such lawsuit, if filed by Employee or anyone acting on Employee's behalf.

9.Confidentiality. Employee agrees to maintain in complete confidence the existence of this Agreement, the contents and terms of this Agreement, and the consideration for this Agreement (hereinafter collectively referred to as "Separation Information"). Except as required by law, Employee may disclose Separation Information only to Employee's immediate family members, the Court in any proceedings to enforce the terms of this Agreement, Employee's counsel, and Employee's accountant and any professional tax advisor to the extent that they need to know the Separation Information in order to provide advice on tax treatment or to prepare tax returns, and must prevent disclosure of any Separation Information to all other third parties. Employee agrees that Employee will not publicize, directly or indirectly, any Separation Information.

The Parties agree that Company is permitted to disclose the Separation Information to its Board of Directors, officers and managers, investors, and as required by applicable law, including without limitation, requirements imposed upon public companies for disclosure of agreements and Separation Information.

10.No Third Party Cooperation. Employee agrees that Employee will not knowingly encourage, counsel, or assist any attorneys or their clients in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints by any third party against any of the Releasees, unless complying with applicable law, under a subpoena, in connection with any investigation or proceeding conducted by a Government Agency or other court order to do so or as related directly to the ADEA waiver in this Agreement. Employee agrees both to immediately notify the Company upon receipt of any such subpoena or court order, and to furnish, within three (3) business days of its receipt, a copy of such subpoena or other court order. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints against any of the Releasees, Employee shall state no more than that Employee cannot provide counsel or assistance.

11.Cooperation with the Company. Employee agrees that Employee will assist and cooperate with the Company in connection with the defense or prosecution of any claim that may be made against or by the Company or any Releasees, or in connection with any ongoing or future investigation or dispute or claim of any kind involving the Company, including meeting with the Company's counsel, any proceeding before any arbitral, administrative, judicial, legislative, or other body or agency, including testifying in any proceeding to the extent such claims, investigations or proceedings relate to services performed or required to be performed by Employee, pertinent knowledge possessed by Employee, or any act



or omission by Employee. Employee further agrees to perform all acts and execute and deliver any documents that may be reasonably necessary to carry out the provisions of this paragraph.

12. Communications. Employee agrees to refrain from any disparagement, defamation, libel, or slander of any of the Releasees, and agrees to refrain from any tortious interference with the contracts and relationships of any of the Releasees, including, but not limited to, anonymous or named reviews, tweets, posts, or other comments published on the Internet. Employee affirms that Employee has not disparaged the Company from the Termination Date through the date Employee signs this Agreement. Subject to Section 18 below, Employee further agrees that, by no later than the Effective Date, Employee shall delete or otherwise remove any and all disparaging public comments or statements that Employee made prior to the Effective Date about or relating to the Company, including, but not limited to, comments in online forums or on websites (including, but not limited to, Facebook, Glassdoor, Yelp, and LinkedIn). Employee shall direct any inquiries by potential future employers to the Company's human resources department, which shall use its best efforts to provide only the Employee's last position and dates of employment. Employee agrees to revise and update publicly available information, including professional and social networking websites such as LinkedIn and Facebook, within one (1) week of the Effective Date to remove any indication that Employee is employed by the Company. Employee's violation of this provision shall be a material breach of this Agreement.

13. Breach. In addition to the rights provided in the "Attorneys' Fees" section below, Employee acknowledges and agrees that any material breach of this Agreement, unless such breach constitutes a legal action by Employee challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, shall entitle the Company immediately to recover and/or cease providing the consideration provided to Employee under this Agreement and to obtain damages, except as provided by law, provided, however, that the Company shall not recover One Hundred Dollars (\$100.00) of the consideration already paid pursuant to this Agreement and such amount shall serve as full and complete consideration for the promises and obligations assumed by Employee under this Agreement.

14. No Admission of Liability. Employee understands and acknowledges that this Agreement constitutes a compromise and settlement of any and all actual or potential disputed claims by Employee. No action taken by the Company hereto, either previously or in connection with this Agreement, shall be deemed or construed to be (a) an admission of the truth or falsity of any actual or potential claims or (b) an acknowledgment or admission by the Company of any fault or liability whatsoever to Employee or to any third party.

15. Costs. The Parties shall each bear their own costs, attorneys' fees, and other fees incurred in connection with the preparation of this Agreement.

16. ARBITRATION. THE PARTIES AGREE THAT ANY AND ALL DISPUTES, CLAIMS, OR CONTROVERSIES OF ANY NATURE WHATSOEVER ARISING FROM, OR RELATING TO, THIS AGREEMENT OR ITS INTERPRETATION, ENFORCEMENT, BREACH, PERFORMANCE OR EXECUTION, EMPLOYEE'S EMPLOYMENT OR THE TERMINATION OF SUCH EMPLOYMENT (INCLUDING, BUT NOT LIMITED TO, ANY STATUTORY CLAIMS) (COLLECTIVELY, "**CLAIMS**", EACH A "**CLAIM**"), SHALL BE RESOLVED, PURSUANT TO THE FEDERAL ARBITRATION ACT, 9 U.S.C. §1-16, AND TO THE FULLEST EXTENT PERMITTED BY LAW, BY FINAL, BINDING AND CONFIDENTIAL ARBITRATION IN LOS ANGELES, CALIFORNIA (OR ANOTHER MUTUALLY ACCEPTABLE LOCATION) CONDUCTED BEFORE A SINGLE NEUTRAL ARBITRATOR BY JAMS, INC. ("**JAMS**") OR ITS SUCCESSOR, UNDER THE THEN APPLICABLE JAMS ARBITRATION RULES AND PROCEDURES FOR EMPLOYMENT DISPUTES (AVAILABLE AT [HTTP://WWW.JAMSADR.COM/RULES-EMPLOYMENT-ARBITRATION/](http://www.jamsadr.com/rules-employment-arbitration/)). **BY AGREEING TO THIS ARBITRATION PROCEDURE, BOTH EMPLOYEE AND THE COMPANY WAIVE THE RIGHT TO HAVE ANY CLAIM RESOLVED THROUGH A TRIAL BY JURY OR JUDGE OR AN ADMINISTRATIVE PROCEEDING.** EMPLOYEE WILL HAVE THE RIGHT TO BE REPRESENTED BY LEGAL COUNSEL AT ANY ARBITRATION PROCEEDING, AT EMPLOYEE'S OWN EXPENSE. THIS PARAGRAPH SHALL NOT APPLY TO ANY CLAIM THAT CANNOT BE SUBJECT TO MANDATORY ARBITRATION AS A MATTER OF LAW, AND THE APPLICABLE LAW(S) ARE NOT PREEMPTED BY THE FEDERAL ARBITRATION ACT OR OTHERWISE INVALID (COLLECTIVELY, THE "**EXCLUDED CLAIMS**"). THE PARTIES AGREE THAT ANY DISPUTE IN ARBITRATION WILL BE BROUGHT ON AN INDIVIDUAL BASIS ONLY, AND NOT ON A CLASS, COLLECTIVE, OR REPRESENTATIVE BASIS. IN THE EVENT EMPLOYEE INTENDS TO BRING MULTIPLE CLAIMS, INCLUDING ONE OF THE EXCLUDED

CLAIMS LISTED ABOVE, THE EXCLUDED CLAIMS MAY BE PUBLICLY FILED WITH A COURT, WHILE ANY OTHER CLAIMS WILL REMAIN SUBJECT TO MANDATORY ARBITRATION. THE ARBITRATOR SHALL HAVE SOLE AUTHORITY FOR DETERMINING IF A CLAIM IS SUBJECT TO ARBITRATION, AND ANY OTHER PROCEDURAL QUESTIONS RELATED TO THE DISPUTE AND BEARING ON THE FINAL DISPOSITION. IN ADDITION, THE ARBITRATOR SHALL: (A) HAVE THE AUTHORITY TO COMPEL ADEQUATE DISCOVERY FOR THE RESOLUTION OF THE DISPUTE AND TO AWARD SUCH RELIEF AS WOULD OTHERWISE BE AVAILABLE UNDER APPLICABLE LAW IN A COURT PROCEEDING; AND (B) ISSUE A WRITTEN STATEMENT SIGNED BY THE ARBITRATOR REGARDING THE DISPOSITION OF EACH CLAIM AND THE RELIEF, IF ANY, AWARDED AS TO EACH CLAIM, THE REASONS FOR THE AWARD, AND THE ARBITRATOR'S ESSENTIAL FINDINGS AND CONCLUSIONS ON WHICH THE AWARD IS BASED. THE COMPANY SHALL PAY ALL JAMS ARBITRATION FEES. NOTHING IN THIS AGREEMENT SHALL PREVENT EMPLOYEE OR THE COMPANY FROM OBTAINING INJUNCTIVE RELIEF IN COURT TO PREVENT IRREPARABLE HARM PENDING THE CONCLUSION OF ANY ARBITRATION. ANY AWARDS OR ORDERS IN SUCH ARBITRATIONS MAY BE ENTERED AND ENFORCED AS JUDGMENTS IN THE FEDERAL AND STATE COURTS OF ANY COMPETENT JURISDICTION.

17. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Employee represents and warrants that Employee has the capacity to act on Employee's own behalf and on behalf of all who might claim through Employee to bind them to the terms and conditions of this Agreement. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

18. Protected Activity. Employee understands that nothing in this Agreement shall in any way limit or prohibit Employee from engaging for a lawful purpose in any Protected Activity, provided, however, that Employee agrees not to seek or accept any monetary award from such a proceeding (except with respect to proceedings before the Securities and Exchange Commission). For purposes of this Agreement, "Protected Activity" shall mean (a) filing a charge, complaint, or report with, or otherwise communicating with, cooperating with or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission (the "SEC"), the Equal Employment Opportunity Commission, the California Civil Rights Department, the Occupational Safety and Health Administration, and the National Labor Relations Board ("Government Agencies"), (b) discussing the terms and conditions of Employee's employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act, (c) disclosing or discussing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that Employee has reason to believe is unlawful, or, (d) complying with any applicable law, regulation, or a valid order of a court of competent jurisdiction or an authorized Government Agency, provided that Employee's compliance does not exceed the requirements of such law, regulation, or order. Employee understands that in connection with such Protected Activity, Employee is permitted to disclose documents or other information to Government Agencies as permitted by law, and without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Employee agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company confidential information to any parties other than the relevant Government Agencies. Employee further understands that "Protected Activity" does not include the disclosure of any Company attorney-client privileged communications, and that any such disclosure without the Company's written consent shall constitute a material breach of this Agreement. However, Employee covenants and promises that Employee waives, releases, and will not seek or accept compensation or other personal benefits from Company arising out of any Government Agency action related to any Released Claims, except for any award in exchange for providing information to the SEC. If Employee is ever awarded or recovers in any forum any amount from Company as to any claim released by this Agreement (except under the ADEA, if Employee is lawfully allowed to pursue such a claim, or any bounty awarded to Employee by the SEC), Employee hereby assigns the right to any such amounts to Company and agrees to immediately tender the same to Company. In addition, pursuant to the Defend Trade Secrets Act of 2016, Employee is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the

individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

19.No Representations. Employee represents that Employee has had an opportunity to consult with an attorney, and has carefully read and understands the scope and effect of the provisions of this Agreement. Employee has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement. Employee acknowledges that there has been an opportunity to negotiate the terms of this Agreement and that the Agreement will not be interpreted as an employer promulgated agreement.

20.Waiver. No Party shall be deemed to have waived any right, power or privilege under this Agreement or any provisions hereof unless such waiver shall have been duly executed in writing and delivered to the Party to be charged with such waiver. The failure of any Party at any time to insist on performance of any of the provisions of this Agreement shall in no way be construed to be a waiver of such provisions, nor in any way to affect the validity of this Agreement or any part hereof. No waiver of any breach of this Agreement shall be held to be a waiver of any other subsequent breach.

21.Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, such provision may be modified to the extent necessary so that it is no longer in violation of law, unenforceable or void, and such provision will otherwise be enforced to the fullest extent permitted by law. If such modification is not possible, such provision, except Sections 4 and 5, will be severed and the remainder of this Agreement shall continue in full force and effect without said provision or portion of provision.

22.Attorneys' Fees. Except with regard to a legal action challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, in the event that either Party brings an action to enforce or effect its rights under this Agreement, the prevailing Party shall be entitled to recover its costs and expenses, including the costs of mediation, litigation, court fees, and reasonable attorneys' fees incurred in connection with such an action to the extent permitted by law.

23.Entire Agreement. This Agreement represents the entire agreement and understanding between the Company and Employee concerning the subject matter of this Agreement and Employee's employment with and separation from the Company and the events leading thereto and associated therewith, and supersedes and replaces any and all prior agreements and understandings concerning the subject matter of this Agreement and Employee's relationship with the Company, including the Executive Employment Agreement, with the exception of Employee's obligations to Company that survive Employee's employment termination pursuant to the Executive Employment Agreement, and the Equity Agreements.

24.No Oral Modification. This Agreement may only be amended in a writing signed by Employee and the Company's Chief Executive Officer.

25.409A Compliance. This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. Any payments to be made under this Agreement upon a termination of employment shall only be made if such termination of employment constitutes a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Employee on account of non-compliance with Section 409A.

26. Governing Law. This Agreement shall be governed by the laws of the State of California, without regard for choice-of-law provisions. Employee consents to personal and exclusive jurisdiction and venue in Los Angeles, California.

27. Effective Date. Employee understands that this Agreement shall be null and void if not executed by Employee, and returned to the Company, by the twenty-one (21) day period set forth above. Each Party has seven (7) days after that Party signs this Agreement to revoke it. This Agreement will become effective on the eighth (8th) day after Employee signed and returned this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date").

28. Counterparts. This Agreement may be executed in counterparts that may be executed, exchanged, and delivered by facsimile, photo, e-mail PDF, SignNow or a similarly accredited secure signature service, or other electronic transmission or signature. Each counterpart will be deemed an original and all of which counterparts taken together shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned.

29. Voluntary Execution of Agreement. Employee understands and agrees that Employee executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Employee's claims against the Company and any of the other Releasees. Employee acknowledges that:

- (a) Employee has read this Agreement;
- (b) Employee has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Employee's own choice or has elected not to retain legal counsel;
- (c) Employee understands the terms and consequences of this Agreement and of the releases it contains; and
- (d) Employee is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Donna Shiroma, an individual

Dated: \_\_\_ By \_\_  
Donna Shiroma

AVITA MEDICAL AMERICAS, LLC AND AVITA MEDICAL, INC.

Dated: \_\_\_ By \_\_

James Corbett  
Chief Executive 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

**FIRST AMENDMENT TO LEASE ( UNIT -G)**

THIS FIRST AMENDMENT TO LEASE made and entered into this 12<sup>th</sup> day of September , 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 6<sup>th</sup> day of December , 2023 ; 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 12<sup>th</sup> day of September , 2024.

1. The term of the Lease shall be extended 12 months per paragraph 49 of the lease with the amended expiration date of **December 31, 2025**.
2. Rent for the Leased Premises(Unit- G) from **January 1 st, 2025to December 31st, 2025**shall be payable in monthly installments of [\*\*\*\*\*].
3. The Lessee has the option to extend the lease for another 12 months with a 90 day notice with the amended expiration of **December 31, 2026**.
4. Rent for the Leased Premises(Unit- G) from **January 1 st, 2026 to December 31st, 2026** shall be payable in monthly installments of [\*\*\*\*\*].
5. 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..
6. 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 herein above written.

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**LESSOR**

**HARTCO-VENTURA INC.**

By: \_\_\_\_\_

Date: 09/13/2024

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**LESSEE**

**AVITA MEDICAL AMERICAS ,LLC**

By: Jim Corbett, CEO

Date: 09/13/2024

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

I, James Corbett, certify that:

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

Date: November 7, 2024

/s/ James Corbett

Name: James Corbett

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

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

I, David O'Toole, certify that:

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

Date: November 7, 2024

/s/ David O'Toole

Name: David O'Toole

Title: Chief Financial Officer  
(Principal Financial and Accounting Officer)

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

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

The Quarterly Report on Form 10-Q for the period ended September 30, 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 7, 2024

/s/ James Corbett

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

Dated: November 7, 2024

/s/ David O'Toole

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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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