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 June 30, 2026

or

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

For the transition period from _____ to

Commission File Number: 001-39059

AVITA MEDICAL, INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-1021707**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

28159 Avenue Stanford
Suite 220
Valencia, CA 91355
(Address of principal executive offices and Zip Code)

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

The number of shares of the registrant's common stock, par value $0.0001, outstanding as of August 3, 2026 was 30,926,847.

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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 expectations of future revenue; or future growth in revenue, profit, or gross and/or operating margins; or the ability to achieve or sustain profitability are forward-looking statements. Forward-looking statements in this Quarterly Report may refer to a variety of topics including, but not limited to industry market conditions; increased competition; changes in our production capacity; ability to obtain and/or maintain regulatory approvals and comply with applicable regulations; the conduct or outcome of pre-clinical or clinical (human) studies; operational and management restructuring activities; our ability to find and maintain partnerships relating to collaborations, strategic arrangements, and licensing arrangements; performance by third parties of their contractual duties or expected deadlines; our ability to obtain and maintain favorable coverage and reimbursement determinations from third party payors; market reaction to growth or product initiatives; our ability to expand our sales and marketing organizations to address existing and new markets that we intend to target; market penetration of our products; the ability to continue to scale our manufacturing operations to meet the demand for our products; our ability to attract and retain qualified personnel, including management; solvency; non-compliance with debt covenants, which may result in the acceleration of our debt obligations or the need for renegotiations with our lenders; taxes, interest rates, and inflationary pressures, and future working capital costs; changes in the legal or regulatory environments; productivity, business process, consulting, operational, financial, and capital projects and/or initiatives. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

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

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the year-ended December 31, 2025 filed with the SEC on February 12, 2026 and lodged with the Australian Securities Exchange ("ASX") on February 13, 2026, as updated from time to time in the Company's subsequent Quarterly Reports on Form 10-Q (the "Risk Factors"). These Risk 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 Quarterly Report on Form 10-Q. There have been no material changes to the Risk Factors.

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 that may impact our business or operations.

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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
AVITA Medical, Inc.

Results of review of interim financial statements
We have reviewed the accompanying consolidated balance sheet of AVITA Medical, Inc. (a Delaware corporation) and subsidiaries (the "Company") and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows as of June 30, 2026, and for the three-month and six-month periods ended June 30, 2026 and 2025, and the related notes (collectively referred to as the "interim financial statements"). Based on our reviews, we are not aware of any material modifications that should be made to the accompanying interim financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheet of the Company as of December 31, 2025, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year then ended (not presented herein); and in our report dated February 12, 2026, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying consolidated balance sheet as of December 31, 2025, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

Going concern
As indicated in Note 1, certain conditions indicate that the Company may be unable to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for review results
These interim financial statements are the responsibility of the Company's management. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our reviews in accordance with the standards of the PCAOB. A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the PCAOB, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

/s/ GRANT THORNTON LLP

Newport Beach, California
August 6, 2026

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	
	June 30, 2026	**December 31, 2025**
ASSETS		
Cash and cash equivalents	$ 9,139	$ 10,243
Marketable securities	1,996	7,942
Accounts receivable, net	9,867	9,086
Prepaids and other current assets	2,105	1,293
Inventory	5,287	6,926
Total current assets	28,394	35,490
Plant and equipment, net	7,678	8,630
Operating lease right-of-use assets	2,655	2,899
Corporate-owned life insurance (“COLI”) asset	3,208	3,116
Intangible assets, net	5,249	5,645
Other long-term assets	593	612
Total assets	$ 47,777	$ 56,392
LIABILITIES AND STOCKHOLDERS’ EQUITY (DEFICIT)		
Accounts payable and accrued liabilities	$ 6,423	$ 8,959
Accrued wages and fringe benefits	8,821	7,813
Loan facility	46,659	42,984
Current non-qualified deferred compensation (“NQDC”) liability	506	276
Contingent liability	3,000	-
Other current liabilities	3,305	2,645
Total current liabilities	68,714	62,677
Non-qualified deferred compensation liability	3,927	3,697
Contract liabilities	273	290
Operating lease liabilities, long-term	1,822	2,135
Contingent liability, long-term	-	3,000
Warrant liabilities	879	1,243
Total liabilities	75,615	73,042
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 30,926,847 and 30,571,662, shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at June 30, 2026 and December 31, 2025	-	-
Company common stock held by the non-qualified deferred compensation plan	(625)	(1,293)
Additional paid-in capital	399,541	394,408
Accumulated other comprehensive loss	(82)	(1,367)
Accumulated deficit	(426,675)	(408,401)
Total stockholders’ equity (deficit)	(27,838)	(16,650)
Total liabilities and stockholders’ equity (deficit)	$ 47,777	$ 56,392

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		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Sales revenue	$ 21,489	$ 18,226	$ 40,553	$ 36,551
Lease revenue	213	192	400	381
Total revenues	21,702	18,418	40,953	36,932
Cost of sales	(3,935)	(3,469)	(7,458)	(6,303)
Gross profit	17,767	14,949	33,495	30,629
Operating expenses:				
Sales and marketing	(13,573)	(14,314)	(26,414)	(29,147)
General and administrative	(5,971)	(6,666)	(12,032)	(13,057)
Research and development	(5,078)	(5,117)	(10,707)	(11,400)
Total operating expenses	(24,622)	(26,097)	(49,153)	(53,604)
Operating loss	(6,855)	(11,148)	(15,658)	(22,975)
Interest expense	(1,463)	(1,252)	(2,887)	(2,485)
Other income, net	688	2,484	293	1,693
Loss before income taxes	(7,630)	(9,916)	(18,252)	(23,767)
Income tax expense	(33)	(4)	(22)	(12)
Net loss	$ (7,663)	$ (9,920)	$ (18,274)	$ (23,779)
Net loss per common share:				
Basic and diluted	$ (0.25)	$ (0.38)	$ (0.60)	$ (0.90)
Weighted-average common shares:				
Basic and diluted	30,749,894	26,367,548	30,645,960	26,400,366

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

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

	Three-Months Ended		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Net loss	$ (7,663)	$ (9,920)	$ (18,274)	$ (23,779)
Change in fair value due to credit risk on loan facility	(731)	(1,667)	1,289	(126)
Net unrealized gain (loss) on marketable securities	1	1	(4)	(14)
Comprehensive loss	$ (8,393)	$ (11,586)	$ (16,989)	$ (23,919)

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

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

	Common Stock						
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at March 31, 2026	30,776,689	$ 3	$ (635)	$ 395,830	$ 648	$ (419,012)	$ (23,166)
Net loss	-	-	-	-	-	(7,663)	(7,663)
Stock-based compensation	-	-	-	1,988	-	-	1,988
Vesting of restricted stock units	6,916	-	-	-	-	-	-
ESPP purchase	143,242	-	-	437	-	-	437
Distribution of Company common stock held by the NQDC Plan	-	-	10	(4)	-	-	6
Reclassification of warrant liability to equity due to issuance	-	-	-	1,290	-	-	1,290
Net unrealized gain on marketable securities	-	-	-	-	1	-	1
Change in fair value due to credit risk on loan facility	-	-	-	-	(731)	-	(731)
Balance at June 30, 2026	30,926,847	$ 3	$ (625)	$ 399,541	$ (82)	$ (426,675)	$ (27,838)

	Common Stock						
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at March 31, 2025	26,434,658	$ 3	$ (1,308)	$ 370,820	$ (413)	$ (373,673)	$ (4,571)
Net loss	-	-	-	-	-	(9,920)	(9,920)
Stock-based compensation	-	-	-	2,671	-	-	2,671
Vesting of restricted stock units	62,116	-	-	-	-	-	-
Exercise of stock options	2,117	-	-	11	-	-	11
ESPP purchase	114,787		-	548			548
Distribution/diversification of Company common stock held by the NQDC Plan	-	-	12	-	-	-	12
Change in redemption value of share awards in NQDC Plan	-	-	-	23	-	-	23
Net unrealized gain on marketable securities	-	-	-	-	1	-	1
Change in fair value due to credit risk on loan facility	-	-	-	-	(1,667)	-	(1,667)
Balance at June 30, 2025	26,613,678	$ 3	$ (1,296)	$ 374,073	$ (2,079)	$ (383,593)	$ (12,892)

	Common Stock						
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2025	30,571,662	$ 3	$ (1,293)	$ 394,408	$ (1,367)	$ (408,401)	$ (16,650)
Net loss	-	-	-	-	-	(18,274)	(18,274)
Issuance of common stock due to exercise of penny warrants	144,895	-	-	718	-	-	718
Stock-based compensation	-	-	-	3,089	-	-	3,089
Vesting of restricted stock units	67,048	-	-	-	-	-	-
ESPP purchase	143,242	-	-	437	-	-	437
Reclassification of warrant liability to equity due to issuance	-	-	-	1,290	-	-	1,290
Distribution of Company common stock held by the NQDC Plan	-	-	668	(401)	-	-	267
Net unrealized loss on marketable securities	-	-	-	-	(4)	-	(4)
Change in fair value due to credit risk on loan facility	-	-	-	-	1,289	-	1,289
Balance at June 30, 2026	30,926,847	$ 3	$ (625)	$ 399,541	$ (82)	$ (426,675)	$ (27,838)

	Common Stock						
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2024	26,354,042	$ 3	$ (1,319)	$ 367,568	$ (1,939)	$ (359,814)	$ 4,499
Net loss	-	-	-	-	-	(23,779)	(23,779)
Stock-based compensation	-	-	-	5,346	-	-	5,346
Vesting of restricted stock units	62,116	-	-	-	-	-	-
Exercise of stock options	68,125	-	-	374	-	-	374
ESPP purchase	114,787	-	-	548	-	-	548
Distribution of Company common stock held by the NQDC Plan	-	-	159	15	-	-	174
Vesting of Company common stock held by the NQDC Plan	14,608	-	(136)	136	-	-	-
Change in redemption value of share awards in NQDC Plan	-	-	-	86	-	-	86
Net unrealized loss on marketable securities	-	-	-	-	(14)	-	(14)
Change in fair value due to credit risk on loan facility	-	-	-	-	(126)	-	(126)
Balance at June 30, 2025	26,613,678	$ 3	$ (1,296)	$ 374,073	$ (2,079)	$ (383,593)	$ (12,892)

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

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

	Six-Months Ended	
	June 30, 2026	**June 30, 2025**
Cash flow from operating activities:		
Net loss	$ (18,274)	$ (23,779)
Adjustments to reconcile net loss to net cash used in operating activities:		
Debt issuance costs	319	-
Change in fair value of loan facility	(409)	(155)
Change in fair value of warrant liabilities	601	(1,532)
Depreciation and amortization	1,232	1,073
Stock-based compensation	3,089	5,369
Non-cash lease expense	473	438
Loss on fixed asset disposal	241	343
Loss on patent disposal	2	6
Remeasurement and foreign currency transaction loss	19	-
Excess and obsolete inventory related charges	122	543
Provision for credit losses	14	(6)
Amortization of premium of marketable securities	(120)	(193)
Non-cash changes in the fair value of NQDC plan	154	(1,097)
Changes in operating assets and liabilities:		
Trade and other receivables	(794)	1,373
Prepaids and other current assets	(811)	375
Inventory	1,517	(810)
Corporate-owned life insurance ("COLI") asset	187	406
Other long-term assets	17	(294)
Accounts payable and accrued expenses	(2,548)	901
Accrued wages and fringe benefits	1,008	(2,510)
Current non-qualified deferred compensation liability	496	(1,709)
Other current liabilities	430	(403)
Operating lease liability	(313)	(467)
Non-qualified deferred compensation plan liability	(203)	1,607
Contract liabilities	(17)	(17)
Net cash used in operating activities	(13,568)	(20,538)
Cash flow from investing activities:		
Purchase of marketable securities	(3,937)	(3,460)
Maturities of marketable securities	10,000	22,000
Purchase of plant and equipment	(127)	(745)
Patent filing fees	(6)	(13)
Net cash provided by investing activities	5,930	17,782
Cash flow from financing activities:		
Proceeds from loan facility, net of issuance costs	49,081	-
Repayment of Previous Credit Agreement	(42,984)	-
Proceeds from exercise of stock options	-	374
Employee stock purchase plan ("ESPP") purchases	437	548
Net cash provided by financing activities	6,534	922
Net decrease in cash and cash equivalents	(1,104)	(1,834)
Cash and cash equivalents beginning of the period	10,243	14,050
Cash and cash equivalents end of the period	$ 9,139	$ 12,216
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid during the period	$ 44	$ -
Interest paid during the period	$ 2,875	$ 2,479
Non-cash investing and financing activities:		
Capital expenditures not yet paid	$ 11	$ 169
Exercise of penny warrants	$ 718	$ -
Warrant liability recognized upon issuance of loan facility	$ 1,043	$ -
Reclassification of warrant liability to equity due to issuance	$ 1,290	$ -

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

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

1. The Company

Nature of the Business

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

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

RECELL GO mini® Autologous Cell Harvesting Device ("RECELL GO mini"), which was approved by the FDA in December of 2024, is a line extension of RECELL GO, designed specifically to treat smaller wounds up to 480 cm^2. It utilizes the same RPD but features a RECELL GO mini Preparation Kit (the "mini RPK"), which includes a single-use RECELL GO mini Cartridge optimized for smaller skin samples. These modifications are intended to address the needs of clinicians treating smaller wounds, and to support broader adoption of the RECELL GO platform in trauma centers.

The Company holds the rights to market, sell, and distribute Cohealyx®, a unique collagen-based dermal matrix, under the terms of an exclusive multi-year development and distribution agreement (the "Regenity Agreement") with Collagen Matrix, Inc. dba Regenity Biosciences ("Regenity"). Under the terms of the Regenity Agreement, Regenity manufactures and supplies Cohealyx and the Company markets, sells, and distributes it under its private label in the U.S. The Company also holds the rights to manufacture, market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, in the United States under the terms of an exclusive multi-year distribution agreement (the "Distribution Agreement") and a contract manufacturing agreement (the "Manufacturing Agreement") with Stedical Scientific, Inc. ("Stedical"). See Note 11 to the Consolidated Financial Statements for additional information regarding the Company's commitments with each of Regenity and Stedical.

Liquidity, Capital Resources, and Going Concern

The Company's Consolidated Financial Statements have been prepared on the basis of the Company continuing as a going concern for the next twelve months. The Company has incurred operating losses and negative cash flows from operations since its inception and has an accumulated deficit of $426.7 million as of June 30, 2026. For the six months ended June 30, 2026 and 2025, the Company used $13.6 million and $20.5 million, respectively, of cash in its operating activities. For the years ended December 31, 2025 and 2024, the Company used $31.2 million and $48.9 million, respectively, of cash in its operating activities. As of June 30, 2026, the Company had cash, cash equivalents, and marketable securities of $11.1 million. To date, the Company has funded its operations principally through the sales of its products, issuance of equity securities, and debt financing.

On January 13, 2026, the Company entered into the Credit Agreement, as defined in Note 6 to the Consolidated Financial Statements, which provides for a five-year senior secured credit facility in an aggregate principal amount of up to $60.0 million, of which (i) $50.0 million was funded at issuance and (ii) $10.0 million will be made available, at the Company's discretion, on or before March 31, 2027, subject to satisfaction of a certain net revenue requirement.

Simultaneously with the closing of the Initial Commitment Amount (as defined in Note 6 to the Consolidated Financial Statements), the Company repaid in full and terminated all of its obligations and commitments (the "Refinancing Transaction") under the Previous Credit Agreement as defined in Note 6 to the Consolidated Financial Statements. As a result, the Company and the guarantors under the Previous Credit Agreement have no further obligations under the Previous Credit Agreement or the related guarantees other than with respect to the warrants previously issued under the Previous Credit Agreement, some of which remain outstanding. The Company received total net proceeds after the Refinancing Transaction of approximately $6.0 million.

Pursuant to the terms of the Credit Agreement, the Company's minimum cash balance covenant was lowered to $5.0 million. In addition, there is no right to accelerate repayment of the outstanding debt due to the Company's Quarterly Reports on Form 10-Q containing any qualification or statement which is of a "going concern" or similar nature during the year ending December 31, 2026.

Based on the Company's liquidity position and the Company's current forecast of operating results and cash flows, management determined there is substantial doubt about the Company's ability to continue as a going concern over the next twelve months following the date of issuance of these Consolidated Financial Statements due to the Company's debt repayment obligations, recurring losses, and historical negative cash flows. As a result, the Company may require additional liquidity to continue its operations over the next twelve months.

As a result of this conclusion, and due to the Company's current debt servicing obligations, the long-term portion of the credit facility has been classified as a current liability in the accompanying Consolidated Financial Statements as of June 30, 2026, and as of December 31, 2025.

The Company continues to evaluate strategies to obtain additional funding for future operations. These strategies include, but are not limited to, requesting the Additional Commitment Amount as defined in Note 6 to the Consolidated Financial Statements, or obtaining additional equity financing. However, there can be no assurance that such funding will be available to the Company when needed, either on favorable terms or at all. The Company's Consolidated Financial Statements do not include any adjustments to the carrying amount of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

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, 2025 filed with the SEC on February 12, 2026, and lodged with the Australian Securities Exchange ("ASX") on February 13, 2026 (the "2025 Annual Report").

There have been no changes to the Company's significant accounting policies as described in the 2025 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 2025 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 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income (Topic 220): Expense Disaggregation Disclosures*, which requires disaggregated disclosures of certain costs and expenses in the notes to financial statements. This guidance will be effective for annual reporting periods beginning after December 15, 2026, and for interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting this ASU No. 2024-03 on its Consolidated Financial Statements and disclosures.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, which addresses changes in software development methods and increases the operability of the recognition guidance for improved financial reporting. This guidance is effective for annual reporting periods beginning after December 15, 2027, and for interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the impact of adopting this ASU No. 2025-06 in 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, useful lives of long-lived assets, accounting for marketable securities, income taxes, fair value of loan facility, fair value of warrants and stock-based compensation) and related disclosures. Estimates have been prepared based on the current and available information. However, actual results could differ from estimated amounts.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash held at deposit institutions and cash equivalents. Cash equivalents consist primarily of money market funds. Cash equivalents also include short-term, highly liquid investments with original maturities of three months or less from the date of purchase. The Company held cash at deposit institutions in the amount of $1.7 million and $1.8 million as of June 30, 2026 and December 31, 2025, respectively. The Company does not have cash on deposit denominated in foreign currency in foreign institutions as of June 30, 2026 and December 31, 2025. As of June 30, 2026 and December 31, 2025, the Company held cash equivalents in the amounts of $7.4 million and $8.4 million, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, trade receivables, and debt and other liabilities. As of June 30, 2026 and December 31, 2025, 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, therefore, subject to the risk of bank failure.

As of June 30, 2026 and December 31, 2025, no customer accounted for more than 10% of net accounts receivable. For the three and six-months ended June 30, 2026 and 2025, no single customer accounted for more than 10% of total revenues.

Revenue Recognition

The Company generates revenues primarily from:

- The sale of RECELL EOU, RPK and mini RPK (collectively, the "RPKs"), Cohealyx, and PermeaDerm products to hospitals, other treatment centers, and distributors.
- Maintenance fee received from BARDA to ensure first right of access to our inventory.
- Lease revenue for the RPD.

The Company's sale of the RECELL EOU, Cohealyx, and PermeaDerm products are accounted for under ASC 606, *Revenue from contracts with customers* ("ASC 606"). Revenue for RECELL GO is disaggregated between two accounting standards: (1) ASC 606 for the RPKs 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 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. The Company utilizes the observable SSP when available, which represents the price charged for the promised product or service when sold separately. When the SSP for the Company's products or services are not directly observable, the Company determines the SSP using relevant information available and applies 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.

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 both ASC 606 and ASC 842

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

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

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

Assets in the Company's lease program are reported in Plant and equipment, net on the Consolidated Balance Sheets and are depreciated over the useful life of the RPD device's 200 uses, as indicated in the Instructions for Use that were approved by the FDA, and expensed as Costs of goods sold in the Consolidated Statements of Operations. The RPD depreciation has a direct relationship to the number of RPKs sold. Based on customer usage, each purchase of an RPK 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 June 30, 2026			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
Cash equivalents:				
Money market funds	$ 7,418	$ -	$ -	$ 7,418
Total cash equivalents	$ 7,418	$ -	$ -	$ 7,418
Current marketable securities:				
U.S. Treasury securities	$ 1,996	$ -	$ -	$ 1,996
Total current marketable securities	$ 1,996	$ -	$ -	$ 1,996

	As of December 31, 2025			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
Cash equivalents:				
Money market funds	$ 8,448	$ -	$ -	$ 8,448
Total cash equivalents	$ 8,448	$ -	$ -	$ 8,448
Current marketable securities:				
U.S. Treasury securities	$ 7,938	$ 4	$ -	$ 7,942
Total current marketable securities	$ 7,938	$ 4	$ -	$ 7,942

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

	As of June 30, 2026		As of December 31, 2025	
(in thousands)	Amortized Cost	Carrying Value	Amortized Cost	Carrying Value
Due in one year or less	$ 1,996	$ 1,996	$ 7,938	$ 7,942

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 a net unrealized loss of $0 and net unrealized gain of $4,000 as of June 30, 2026 and December 31, 2025, respectively. The Company did not have sales of investments during the three and six-months ended June 30, 2026 and 2025 that resulted in realized gains or losses. As of June 30, 2026 and December 31, 2025, the Company did not recognize credit losses. The Company has accrued interest income receivable of $19,000 and $21,000 as of June 30, 2026 and December 31, 2025, respectively, recorded in Prepaids and other current assets in the Consolidated Balance Sheets.

4. Fair Value Measurements

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

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

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

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

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

	As of June 30, 2026			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 7,418	$ -	$ -	$ 7,418
Total cash equivalents	$ 7,418	$ -	$ -	$ 7,418
Current marketable securities:				
U.S. Treasury securities	$ -	$ 1,996	$ -	$ 1,996
Total current marketable securities	$ -	$ 1,996	$ -	$ 1,996
Total marketable securities and cash equivalents	$ 7,418	$ 1,996	$ -	$ 9,414
Financial liabilities:				
Loan Facility	$ -	$ -	$ 46,659	$ 46,659
Warrant liabilities	-	-	879	879
Non-qualified deferred compensation plan liability	-	4,433	-	4,433
Total financial liabilities	$ -	$ 4,433	$ 47,538	$ 51,971
Financial assets:				
Corporate-owned life insurance policies	$ -	$ 3,208	$ -	$ 3,208
Total financial assets	$ -	$ 3,208	$ -	$ 3,208

(in thousands)	As of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 8,448	$ -	$ -	$ 8,448
Total cash equivalents	$ 8,448	$ -	$ -	$ 8,448
Current marketable securities:				
U.S. Treasury securities	$ -	$ 7,942	$ -	$ 7,942
Total current marketable securities	$ -	$ 7,942	$ -	$ 7,942
Total marketable securities and cash equivalents	$ 8,448	$ 7,942	$ -	$ 16,390
Financial liabilities:				
Loan Facility	$ -	$ -	$ 42,984	$ 42,984
Warrant liabilities	501	-	742	1,243
Non-qualified deferred compensation plan liability	-	3,973	-	3,973
Total financial liabilities	$ 501	$ 3,973	$ 43,726	$ 48,200
Financial assets:				
Corporate-owned life insurance policies	$ -	$ 3,116	$ -	$ 3,116
Total financial assets	$ -	$ 3,116	$ -	$ 3,116

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

(in thousands)	As of June 30, 2026		As of December 31, 2025	
	Loan facility	Warrant liability	Loan facility	Warrant liability
Balance beginning of period	$ 42,984	$ 742	$ 42,245	$ 3,432
Extinguishment of Previous Credit Agreement	(42,984)	-	-	-
Loan Facility fair value, at issuance	48,357	1,043	-	-
Reclassification of warrant liability to equity due to issuance	-	(1,290)	-	-
Change in fair value in earnings	(409)	384	1,322	(2,690)
Change in fair value in other comprehensive loss	(1,289)	-	(583)	-
Balance end of period, at fair value	$ 46,659	$ 879	$ 42,984	$ 742

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. The Company's Level 1 liabilities included the Penny Warrant (as defined below) which was valued based upon observable market prices. Level 2 assets consist of U.S Treasury securities. 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 is recorded as Level 2. There were no transfers between fair value measurement levels during the periods ended June 30, 2026 and December 31, 2025.

Loan Facility

The fair value of the loan facility was determined using a discounted cash flow method to value the initial term loan using a risk-free interest rate of 4.17% as of June 30, 2026. 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 loan facility 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 both the instrument's inherent credit risk and the market risk related to the debt valuation.

Warrant Liabilities

Perceptive Warrant

On the Closing Date, as defined in Note 6 to the Consolidated Financial Statements, the Company agreed to issue, subject to shareholder approval, a warrant to purchase up to 650,000 shares of the Company's common stock ("Common Stock"), par value $0.0001 per share, at an exercise price set at the lower of two 10-day VWAPs: (i) the 10-day VWAP ending on the business day immediately prior to the Closing Date, which VWAP is $3.4019; or (ii) the 10-day VWAP ending on the business day immediately prior to the issuance date of the warrant. On June 3, 2026 (the "Shareholder Approval Date"), shareholders approved the issuance of the warrant and a warrant to purchase up to 650,000 shares of Common Stock was issued with an exercise price of $3.4019 (the "Perceptive Warrant"). The Perceptive Warrant is immediately exercisable for 500,000 shares of Common Stock, with an additional 150,000 shares of Common Stock that will vest and become exercisable if the Company closes on the Additional Commitment Amount.

The fair value of the Perceptive Warrant 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 Perceptive Warrant, which was reported within Warrant liabilities on the Closing Date and subsequently reclassified on the Shareholder Approval Date to Additional paid-in capital on the Consolidated Balance Sheets, was estimated by the Company based on the Black-Scholes option pricing model with the following key inputs as of the Shareholder Approval Date:

	As of June 3, 2026	
Price of common stock	$	4.16
Expected term		10.00 years
Expected volatility		37.51%
Exercise price	$	3.4019
Risk-free interest rate		4.44%
Expected dividends		0.00%

Penny Warrant

On February 13, 2025, the Company issued a warrant to purchase 145,180 shares of Common Stock with an exercise price of $0.01 per share (the "Penny Warrant"). The Penny Warrant was issued in connection with the Previous Credit Agreement as defined in Note 6 of the Consolidated Financial Statements. On March 4, 2026, the Penny Warrant was exercised and 144,895 shares of Common Stock were issued.

The fair value of the Penny Warrant liability was determined based on quoted prices in active markets, which represents a Level 1 measurement within the fair value hierarchy. The fair value of the Penny Warrant liability, which was reported within Warrant liabilities on the Consolidated Balance Sheets, was estimated by the Company based on the closing price of the Common Stock as quoted on the Nasdaq Capital Market ("Nasdaq") under the ticker code, "RCEL."

$10.218 Warrant

On October 18, 2023, the Company issued a warrant to purchase 409,661 shares of Common Stock with an exercise price of $10.9847 per share as consideration for the Previous Credit Agreement as defined in Note 6 to the Consolidated Financial Statements. As a result of the issuance of Common Stock via a private placement on the ASX on August 12, 2025, the exercise price to purchase the Common Stock as provided in the warrant was adjusted to $10.218 (the "$10.218 Warrant"). The fair value of the $10.218 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 $10.218 Warrant liability, which is reported within Warrant liabilities on the Consolidated Balance Sheets, is estimated by the Company based on the Black-Scholes option pricing model with the following key inputs:

	As of	
	June 30, 2026	December 31, 2025
Price of common stock	$ 4.13	$ 3.45
Expected term	7.31 years	7.80 years
Expected volatility	66.80%	68.94%
Exercise price	$ 10.2180	$ 10.2180
Risk-free interest rate	4.27%	3.97%
Expected dividends	0.00%	0.00%

5. Revenues

The Company generates revenues primarily from:

- The sale of EOU, RECELL GO RPK, RECELL GO mini RPK, Cohealyx, 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.
- Lease revenue for the RECELL GO RPD.

EOU, Cohealyx, and PermeaDerm Sales

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

RECELL GO and RECELL GO mini Sales

Revenue for the RECELL GO device is disaggregated between two accounting standards: (1) ASC 606 for the RPK, and (2) ASC 842 for the RPD. The RECELL GO and RECELL GO mini devices consist of single-use RPKs and a durable AC powered device, the RPD. The Company enters into contracts with customers where it receives consideration for the single-use RPKs and does not receive additional consideration for the RPD. The consideration in the contract is allocated based on the SSP. Upon sale of the RPKs, the consideration is allocated to the lease (RPD) and non-lease (RPK) components. Consideration received for the RPK is recorded in Sales revenue 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 six-months ended June 30, 2026, the Company recorded approximately $10.6 million and $20.0 million in Sales revenue related to the RPKs, respectively, and $213,000 and $400,000 in Lease revenue related to the RPD, respectively, in the Consolidated Statement of Operations. During the three and six-months ended June 30, 2025, the Company recorded approximately $9.3 million and $19.0 million in Sales revenue related to the RPKs, and $192,000 and $381,000 in Lease revenue related to the RPD, respectively, in the Consolidated Statement of Operations.

Distributor Transactions

For international markets, the Company exclusively partners with third-party distributors (currently, Aleamed in Benelux, Asclepios GmbH in Germany, COSMOTEC in Japan, Joint Operations Ltd in the United Kingdom, medicalsol in Switzerland, Revolution Surgical Pty Ltd in Australia and New Zealand, Innova Nordic in Nordic, IGIAS in Greece, and Sorbion in Austria). 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 to the Consolidated Financial Statements.

Variable Consideration

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

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

Contract Balances

Accounts receivable are recorded net of customer allowances for expected credit losses. Accounts receivable, net as of June 30, 2026, December 31, 2025, and December 31, 2024 were $9.9 million, $9.1 million, and $11.8 million, respectively.

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 June 30, 2026 and December 31, 2025, the Company does not have any contract assets.

Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer. The Company had deferred revenue of $306,000 and $323,000 as of June 30, 2026 and December 31, 2025, respectively. These balances are classified between current and long-term. As of June 30, 2026 and December 31, 2025, a total of $33,000 was included in Other current liabilities and $273,000 and $290,000, respectively, in Contract liabilities in the Consolidated Balance Sheets. As of December 31, 2024, the Company had deferred revenue of $357,000.

For the three and six-months ended June 30, 2026, the Company recognized revenue of approximately $89,000 and $97,000, respectively, for amounts included in the beginning balance of Contract liabilities. For the three and six-months ended June 30, 2025, the Company recognized revenue of approximately $64,000 and $128,000, respectively, for amounts included in the beginning balance of Contract liabilities.

Remaining Performance Obligations

The Company's remaining performance obligations are calculated as the dollar value of the remaining unsatisfied performance obligations on executed contracts. The estimated revenue expected to be recognized in the future once the performance obligations are satisfied under the Company's existing customer agreements was $306,000 and $323,000, as of June 30, 2026 and December 31, 2025, respectively. These amounts are classified between current and long-term in Other current liabilities and Contract liabilities in the Consolidated Balance Sheets. The Company expects to recognize approximately $33,000 as revenue in the next twelve months.

Cost to Obtain and Fulfill a Contract

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

BARDA Contract

On April 6, 2026, the Company entered into a ten-year agreement with the Biomedical Advanced Research and Development Authority ("BARDA"), part of the U.S. Department of Health and Human Services. Under the agreement, BARDA shall have access to the Company's RECELL inventory in the event of a national emergency. The agreement provides approximately $4.0 million in access and maintenance fees over the ten-year term, with additional potential revenue tied to procurement options if exercised by BARDA. The access and maintenance services are a stand ready performance obligation that is satisfied over time and recognized on a straight-line basis during the term of the contract. Costs to fulfill the BARDA emergency preparedness performance obligation, which consist of billed costs to BARDA incurred in connection with emergency deployment services, are incremental and expected to be recovered.

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 (Note 10 to the Consolidated Financial Statements), 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.

6. Loan Facility

On January 13, 2026 (the "Closing Date"), the Company entered into a Credit Agreement and Guaranty (the "Credit Agreement"), and Security Agreement, by and between the Company, as borrower, and Perceptive Advisors LLC (the "Lender"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to $60.0 million (the "Loan Facility"), of which $50.0 million was borrowed on the Closing Date (the "Initial Commitment Amount"). In addition, an aggregate of $10.0 million will be made available, at the Company's discretion, on or before March 31, 2027, subject to a net revenue requirement (the "Additional Commitment Amount").

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. Also on the Closing Date, and in connection with the entry into the Credit Agreement, the Company repaid in full and terminated all of its obligations and commitments under the Previous Credit Agreement (as defined below). The Company received net proceeds of approximately $6.0 million upon closing after repaying in full the Previous Credit Agreement and deducting the Lender's transaction costs in connection with the Loan Facility.

The indebtedness under the Credit Agreement is secured by substantially all of the Company's assets and will accrue interest at a rate equal to the greater of (a) forward-looking one-month term SOFR rate and (b) four percent (4%) per annum, plus seven and a half percent (7.5%). As of June 30, 2026, the interest rate was 11.5%. During an event of default, any outstanding amount will bear interest at a rate of 4% in excess of the otherwise applicable rate of interest. The Company paid certain fees with respect to the Loan Facility, including an upfront fee and certain other fees and expenses of the Lender.

On the Closing Date, the Company agreed to issue to the Lender, subject to shareholder approval, warrants to purchase up to 650,000 shares of Common Stock, par value $0.0001 per share, at an exercise price set at the lower of two 10-day VWAPs: (i) the 10-day VWAP ending on the business day immediately prior to the Closing Date, which VWAP is $3.4019; or (ii) the 10-day VWAP ending on the business day immediately prior to the issuance date of the warrants, with a term of 10 years from the issuance date. On June 3, 2026, shareholders approved the issuance of the Perceptive Warrant (as defined in Note 4) and on June 8, 2026, the Company issued the Perceptive Warrant, of which 500,000 shares of Common Stock are immediately exercisable at an exercise price of $3.4019 per share, with an additional 150,000 shares of Common Stock that will vest and become exercisable if the Company closes on the Additional Commitment Amount. The Perceptive Warrant contains customary share adjustment provisions, as well as weighted average price protection in certain circumstances.

Under the terms of the Credit Agreement, and as set forth in a fee letter between us and the Lender (the "Fee Letter"), the Company will pay certain fees with respect to the Loan Facility, including a prepayment premium ranging from 1% to 10% of the amount of the Loan Facility that is prepaid upon any voluntary or mandatory prepayment (including as a result of an acceleration), together with certain other fees and expenses of the Lender.

The Credit Agreement contains certain customary events of default, including with respect to nonpayment of principal, interest, fees or other amounts; material inaccuracy of a representation or warranty; failure to perform or observe covenants; material defaults on other indebtedness; insolvency; loss of certain key permits, persons and contracts; material adverse effects; certain regulatory matters; and change of control.

The Credit 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; redeem or repurchase certain debt; engage in certain transactions with affiliates; and enter into certain restrictive agreements. Among such covenants, the Credit Agreement includes a financial maintenance test, beginning at the end of the fiscal quarter ending March 31, 2026, that requires the Obligors to maintain a specified minimum net revenue for each trailing twelve-month period ending on the last day of a fiscal quarter occurring prior to the maturity date of the Loan Facility. In addition, the Credit Agreement requires the Company to ensure that the Obligors maintain in the aggregate at least $5 million of unrestricted cash at all times.

As permitted under ASC 825, the Company elected the fair value option to account for the Credit Agreement and recorded the Loan Facility and the Perceptive Warrant at fair value with changes in fair value recorded in the Consolidated Statements of Operations in Other income, net. Changes related to instrument specific credit risk are recorded in other comprehensive income in the Consolidated Balance Sheets. The Company incurred debt issuance costs of approximately $0.4 million, which were expensed as incurred and recorded in Other income, net. The difference between the fair value of the Loan Facility and the unpaid principal balance of $50.0 million is a reduced liability of $3.3 million as of June 30, 2026. The difference between the fair value of the Previous Credit Agreement and the unpaid principal balance of $40.0 million is an additional liability of $3.0 million as of December 31, 2025. For changes in fair value refer to Note 4 to the Consolidated Financial Statements.

Previous Credit Agreement

In connection with the Refinancing Transaction, the Company repaid all outstanding indebtedness under its credit agreement with an affiliate of OrbiMed Advisors, LLC (the "Previous Credit Agreement") and terminated all obligations and commitments thereunder. As a result, the Company and the guarantors under the Previous Credit Agreement have no further obligations under the Previous Credit Agreement or the related guarantees other than with respect to the $10.218 Warrant previously issued under the Previous Credit Agreement, which remain outstanding. For further details, refer to Note 4 to the Consolidated Financial Statements.

7. Inventory

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

	As of	
	June 30, 2026	December 31, 2025
Raw materials	$ 2,032	$ 1,895
Work in process	167	116
Finished goods	3,088	4,915
Total inventory	$ 5,287	$ 6,926

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 $65,000 and $230,000 for the three-months ended June 30, 2026 and 2025, respectively and $122,000 and $543,000 for the six-months ended June 30, 2026 and 2025, respectively.

8. Intangible Assets

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

		As of June 30, 2026			As of December 31, 2025		
	Weighted Average Useful Life In Years	Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount
Patent 1	7	143	(62)	81	143	(57)	86
Patent 2	8	238	(97)	141	238	(87)	151
Patent 3	14	118	(27)	91	118	(24)	94
Patent 4	14	84	(14)	70	80	(12)	68
Patent 5	5	55	(18)	37	55	(15)	40
Patent 6	1	152	(103)	49	154	(84)	70
Regenity License	8	5,000	(750)	4,250	5,000	(500)	4,500
Capitalized Software	2	635	(159)	476	635	(53)	582
Trademarks	Indefinite	54	-	54	54	-	54
Total intangible assets		$ 6,479	$ (1,230)	$ 5,249	$ 6,477	$ (832)	$ 5,645

For the three and six-months ended June 30, 2026 and 2025, 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 and six-months ended June 30, 2026 and 2025. Amortization expense of intangibles included in the Consolidated Statements of Operations was $196,000 and $152,000 for the three-months ended June 30, 2026 and 2025, respectively, and $400,000 and $288,000 for the six-months ended June 30, 2026 and 2025, respectively. Due to Regenity receiving 510(k) clearance for Cohealyx in December 2024, the Company recorded a license (the "Regenity License") of $5.0 million. For further details refer to Note 11 to the Consolidated Financial Statements.

The Company expects the future amortization of amortizable intangible assets held at June 30, 2026 to be as follows (in thousands):

	Estimated Amortization Expense
Remainder of 2026	$ 383
2027	758
2028	705
2029	547
2030	547
Thereafter	2,255
Total	$ 5,195

9. Plant and Equipment

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

		As of	
	Useful Lives	June 30, 2026	December 31, 2025
Computer equipment	3 - 5 years	$ 1,890	$ 1,867
Computer software	3 years	923	923
Construction in progress ("CIP")		-	17
Furniture and fixtures	7 years	1,221	1,221
Laboratory and other equipment	3 - 5 years	1,308	1,247
Leasehold improvements	Lesser of life or lease term	4,882	4,882
RECELL molds	5 years	606	606
RECELL GO RPD CIP		845	999
RECELL GO RPD		271	343
Operating lease assets - RPD	200 uses	1,650	1,630
Less: accumulated amortization and depreciation		(5,918)	(5,105)
Total plant and equipment, net		$ 7,678	$ 8,630

RECELL GO RPD CIP consists of materials for the manufacture of the RPDs. RPDs have a useful life of 200 uses and are being amortized based on customer usage as determined by orders placed for the sales of the RPKs. RECELL GO RPD represents assets available to be leased by customers and are not depreciated until leased.

Depreciation expense related to plant and equipment was $385,000 and $400,000 for the three-months ended June 30, 2026 and 2025, respectively, and $785,000 and $785,000 for the six-months ended June 30, 2026 and 2025, respectively. No impairment was recorded for the three and six-months ended June 30, 2026 and 2025.

Lessor Arrangements

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

The table below summarizes the Company's Lease revenue as presented in the Consolidated Statement of Operations for the three and six-months ended June 30, 2026 and 2025.

	Three-Months Ended		Six-Months Ended	
(in thousands)	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Variable lease revenue	$ 213	$ 192	$ 400	$ 381

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

	As of	
	June 30, 2026	December 31, 2025
Rental RPD assets	$ 1,650	$ 1,630
Accumulated depreciation	(131)	(98)
Net rental RPD assets	$ 1,519	$ 1,532

10. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. The Company's chief operating decision-maker ("CODM") is its Chief Executive Officer, who evaluates financial information and assesses the performance of resources on a consolidated basis. Long-lived assets are primarily located in the United States as of June 30, 2026 and December 31, 2025.

The key measure of segment profit or loss that the CODM uses to allocate resources and in assessing performance is the Company's consolidated net loss, as reported on the Consolidated Statements of Operations. The CODM uses net loss to monitor actual results against budgeted and prior period operating results for the purpose of evaluating operational efficiency, and to evaluate income generated from the assets in making strategic decisions on organizational resource allocation.

Revenue by region for the three and six-months ended June 30, 2026 and 2025 were as follows (in thousands):

	Three-Months Ended		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Revenue by region:				
United States	$ 20,846	$ 17,896	$ 39,416	$ 35,652
Japan	387	427	826	1,061
European Union	182	-	315	49
Australia	194	40	234	80
United Kingdom	93	55	162	90
Total	$ 21,702	$ 18,418	$ 40,953	$ 36,932

Revenue by customer type for the three and six-months ended June 30, 2026 and 2025 were as follows (in thousands):

	Three-Months Ended		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Revenue by customer type:				
Commercial sales	$ 21,613	$ 18,354	$ 40,856	$ 36,804
Deferred commercial revenue recognized	9	8	17	17
BARDA revenue for right of first access	80	56	80	111
Total	$ 21,702	$ 18,418	$ 40,953	$ 36,932

Commercial revenue by product for the three and six-months ended June 30, 2026 and 2025 were as follows (in thousands):

	Three-Months Ended		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Commercial revenue by product:				
RECELL	$ 19,049	$ 16,819	$ 36,170	$ 34,494
Cohealyx	1,744	330	3,244	357
PermeaDerm	607	1,013	1,042	1,572
Lease revenue	213	192	400	381
Total commercial sales	$ 21,613	$ 18,354	$ 40,856	$ 36,804

Consolidated net loss by segment for the three and six-months ended June 30, 2026 and 2025 were as follows (in thousands):

	Three-Months Ended		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Total revenues	$ 21,702	$ 18,418	$ 40,953	$ 36,932
Purchases of inventory	(3,483)	(3,277)	(6,261)	(5,775)
Other cost of sales	(452)	(192)	(1,197)	(528)
Gross profit	17,767	14,949	33,495	30,629
Operating expenses:				
Sales and marketing	(13,573)	(14,314)	(26,414)	(29,147)
General and administrative	(5,971)	(6,666)	(12,032)	(13,057)
Research and development	(5,078)	(5,117)	(10,707)	(11,400)
Total operating expenses	(24,622)	(26,097)	(49,153)	(53,604)
Operating loss	(6,855)	(11,148)	(15,658)	(22,975)
Interest expense	(1,463)	(1,252)	(2,887)	(2,485)
Other income, net	688	2,484	293	1,693
Loss before income taxes	(7,630)	(9,916)	(18,252)	(23,767)
Income tax expense	(33)	(4)	(22)	(12)
Net loss	$ (7,663)	$ (9,920)	$ (18,274)	$ (23,779)

Other cost of sales consists of shipping costs, manufacturing scrap and overhead variances, and depreciation.

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 June 30, 2026 and December 31, 2025, the Company did not have any outstanding or threatened litigation that would have a material impact on the Consolidated Financial Statements.

Development and Distribution Agreement with Regenity

On July 31, 2024, the Company entered into the Regenity Agreement to market, sell, and distribute Cohealyx, a unique collagen-based dermal matrix under the Company's private label in the U.S. The initial term of the Regenity Agreement is five years, with an automatic extension of an additional five years, contingent upon meeting certain criteria. The Regenity Agreement also requires the Company to meet certain revenue targets, which may be reduced by the amount of product purchased during a given year, in order to maintain its exclusive distribution rights. In the event the Company fails to meet those revenue targets, Regenity may end the Company's exclusivity under the Regenity Agreement unless the Company makes a cash payment to Regenity equal to the difference between what Regenity would have received if the revenue target were met and the amount of payments that were made to Regenity during the year.

Under the terms of the Regenity Agreement, the Company made a $2.0 million payment upon receipt of 510(k) clearance by Regenity in December 2024. Depending on the results of certain clinical studies related to Cohealyx, the Company had an additional obligation to pay $3.0 million on or before January 4, 2026, to guarantee development and manufacturing capacity (and related resources). As such, upon Regenity receiving 510(k) clearance in December 2024, the Company recorded $5.0 million in Intangible assets, net on the Consolidated Balance Sheets.

On December 17, 2025, the Company entered into Amendment One to the Regenity Agreement (the "Regenity Amendment"). Under the terms of the Regenity Amendment, the Company's obligation to pay $3.0 million was amended to on or before January 4, 2027 to guarantee development and manufacturing capacity (and related resources). As of June 30, 2026 and December 31, 2025, the Company recorded this $3.0 million obligation in Contingent liability and Contingent liability, long-term, respectively, on the Consolidated Balance Sheets. The Regenity Amendment also extended the 50/50 revenue split between the Company and Regenity through 2027, after which it will convert to 60 (the Company)/40 (Regenity).

Commitments with Stedical

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

On March 17, 2025, the Company and Stedical entered into an Amendment Two (the "Amendment") of the Distribution Agreement. Under the terms of the Amendment, the Company's share of revenue from PermeaDerm sales increased from 50% to 60% and Stedical becomes eligible for certain milestone payments conditioned upon AVITA Medical's achievement of specified sales targets. In addition, Stedical's share from the sale of PermeaDerm is reduced by the Company's actual cost to manufacture PermeaDerm. For 2025, the Company was required to reach $6.0 million in gross sales of PermeaDerm. For every year thereafter, the Company must achieve a minimum 20% increase in revenue from sales of PermeaDerm. In the event the Company fails to achieve the specified growth rate for two subsequent years, the Company has the option to make a cash payment to Stedical equal to the difference between what Stedical would have received if those two growth targets had been met for those two consecutive years and the amount of payments that were made to Stedical over that two-year period. The Amendment revises the initial term of the Distribution Agreement to ten years from the date of the Amendment. For details regarding an additional amendment to the agreements with Stedical, refer to Note 16 to the Consolidated Financial Statements.

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

12. Common and Preferred Stock

The Company's CHESS Depositary Interests ("CDIs") are quoted on the ASX under the ticker code, "AVH." Shares of Common Stock are quoted on Nasdaq under the ticker code, "RCEL." Every five CDIs on ASX represents one share of Common Stock.

The Company is authorized to issue 200,000,000 shares of Common Stock, par value $0.0001 per share, and 10,000,000 shares of Preferred stock, par value $0.0001 per share, issuable in one or more series as designated by the Company's Board of Directors. No other class of capital stock is authorized. As of June 30, 2026 and December 31, 2025, 30,926,847 and 30,571,662 shares of Common Stock, respectively, were issued and outstanding and no shares of Preferred stock were issued and outstanding during any period.

Common Stock held in the rabbi trust is classified in a manner similar to treasury stock and presented separately on the Consolidated Balance Sheets as Common Stock held by the NQDC Plan. As of June 30, 2026 and December 31, 2025, a total of 75,391 and 135,493 shares underlying awards have been deferred, respectively. Vested shares are converted to Common Stock and are reclassified to permanent equity.

13. Stock-Based Payment Plans

On June 3, 2026, at the Company's 2026 Annual Meeting of Stockholders, the Company's stockholders approved the issuance of 16,133 service-only stock options and 22,214 tenure-based RSUs to each of the Company's six non-executive members of the Board of Directors, as well as the issuance of 48,509 service-only stock options and 66,797 tenure-based RSUs to two non-executive members of the Board of Directors for their initial grants in accordance with ASX rules. These awards are subject to vesting conditions as denoted in the individual grants.

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- and six-months ended June 30, 2026 and 2025.

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

	Three-Months Ended		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Sales and marketing expenses	$ 548	$ 594	$ 1,031	$ 1,098
General and administrative expenses	954	1,439	1,128	3,017
Research and development expenses	486	636	930	1,246
Total	$ 1,988	$ 2,669	$ 3,089	$ 5,361

A summary of share option activity as of June 30, 2026, 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, 2025	4,365,603	171,301	4,536,904
Granted	872,777	-	872,777
Exercised	-	-	-
Expired	(250,852)	(27,112)	(277,964)
Forfeited	(43,372)	-	(43,372)
Outstanding shares at June 30, 2026	4,944,156	144,189	5,088,345
Exercisable at June 30, 2026	2,693,385	134,595	2,827,980
Vested and expected to vest - June 30, 2026	4,944,156	144,189	5,088,345

A summary of the status of the Company's unvested RSUs as of June 30, 2026, and changes that occurred during the period, is presented below:

	Tenure-Based RSUs
Unvested RSUs outstanding at December 31, 2025	67,048
Granted	951,648
Vested	(67,048)
Forfeited	(16,270)
Unvested RSUs outstanding at June 30, 2026	935,378

14. Income Taxes

Tax expense was $33,000 and $4,000, for the three-months ended June 30, 2026 and 2025, respectively. Tax expense was $22,000 and $12,000 for the six-months ended June 30, 2026 and 2025, respectively. For 2026 and 2025, 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		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
(in thousands, except share and per share amounts)				
Net loss	$ (7,663)	$ (9,920)	$ (18,274)	$ (23,779)
Weighted-average common shares—outstanding, basic and diluted	30,749,894	26,367,548	30,645,960	26,400,366
Net loss per common share, basic and diluted	$ (0.25)	$ (0.38)	$ (0.60)	$ (0.90)

	Three-Months Ended		Six-Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Anti-dilutive shares excluded from diluted net loss per common share:				
Stock options	5,088,345	5,149,976	5,088,345	5,149,976
Restricted stock units	935,378	99,504	935,378	99,504
ESPP	131,680	58,959	131,680	58,959
Warrants	909,661	554,841	909,661	554,841

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, shares of Common Stock held by the rabbi trust are excluded from the denominator in both the basic and the diluted net loss per common share calculations. As of June 30, 2026 and 2025, a total of 75,391 and 125,276 shares of Common Stock were excluded, respectively. 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- and six-months ended June 30, 2026 and 2025, 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 August 5, 2026, the Company and Stedical entered into a Global Amendment of the Distribution and Manufacturing Agreements with Stedical (the "Global Amendment"). Under the terms of the Global Amendment, in exchange for a $500,000 fee the Company will hold the right of first offer and refusal to expand its exclusive distribution territory to include all or a portion of the European Union, the United Kingdom, and/or Australia. In addition, the Company's share of revenue from PermeaDerm sales will increase to 67% for products sold in sheet form, subject to increased revenue sharing in the event the Company's gross margin on those products exceeds 50%, and to 80% for products sold in glove form, subject to increased revenue sharing in the event the Company's gross margin on those products exceeds 35%. For 2026, the Company is required to reach total PermeaDerm revenue sharing payments of $1.0 million, with 20% growth minimums each year through 2030. All previous minimum revenue sharing payment requirements under the Distribution Agreement were waived.

Also under the Global Amendment, Stedical may pursue the commercialization of PermeaDerm in certain U.S. markets not currently served by the Company. The Company will sell PermeaDerm for such sales to Stedical at a ten percent premium to the Company's actual manufacturing costs. For PermeaDerm manufactured for Stedical to sell outside of the U.S., primarily in Asia, the Company will sell such PermeaDerm to Stedical at $200 per carton plus a 10% manufacturing fee, subject to a reasonable volume cap.

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

The following discussion and analysis of AVITA Medical, Inc.'s ("we", "our", or "us") 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 as well as the "Note Regarding Forward-Looking Statements" on page 3.

Overview

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

The single-use RECELL Autologous Cell Harvesting Device ("RECELL Ease-of-Use" or "RECELL EOU") is approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects. Our next-generation device, RECELL GO® Autologous Cell Harvesting Device ("RECELL GO"), is FDA-approved to treat thermal burn wounds and full-thickness skin defects. RECELL GO introduces enhanced features that improve consistency and standardization across clinical settings. It consists of two components: the RECELL GO Processing Device (the "RPD") and the RECELL GO Preparation Kit (the "RPK"). The RPD is a multi-use, AC-powered device that controls the RPK. The RPK contains a single-use cartridge and the RECELL Enzyme™. The RPD regulates the pressure applied to disaggregate the cells and precisely controls the incubation time of the RECELL Enzyme to optimize cell yield and promote cell viability. RECELL GO mini® Autologous Cell Harvesting Device ("RECELL GO mini"), which was approved by the FDA in December 2024, is a line extension of RECELL GO, designed specifically to treat smaller wounds up to 480 cm^2. It utilizes the same RPD but features a RECELL GO mini Preparation Kit, which includes a single-use RECELL GO mini cartridge optimized for smaller skin samples. These modifications are intended to align with the needs of clinicians treating smaller wounds, and to support broader adoption of the RECELL GO platform in trauma centers.

We are executing a focused commercial strategy centered on approximately 200 U.S. burn and trauma centers that represent the highest value and procedural volume within the acute wound care market. These institutions are core to our commercialization efforts due to their high concentration of complex inpatient cases and consistent procedural throughput. By prioritizing burn and trauma centers, we are targeting the most critical segments of acute wound care to maximize clinical impact and drive adoption across our portfolio.

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

- Increasing market penetration in U.S. burn centers, positioning RECELL as the standard of care in burn management;
- Expanding adoption of RECELL for the treatment of traumatic and surgical wounds throughout the U.S.;
- Expanding adoption of Cohealyx as a dermal matrix that supports wound bed preparation and meaningfully reduces mean time to skin grafting;
- Repositioning PermeaDerm as an alternative to allograft (cadaver skin), leveraging its clinical, economic, and operational advantages to establish a higher-value role in burn care.
- Driving adoption of RECELL GO mini in burn and trauma centers treating smaller wounds;
- Complete analysis of the results of the clinical studies for Cohealyx and PermeaDerm and prepare for submission of the data for publication;
- Expanding RECELL internationally through distributor-led commercialization upon receipt of regulatory approvals;
- Driving commercial revenue growth, improving operating leverage, generating positive cash flow, and achieving long-term operating profitability; and

- Pursuing additional business development opportunities complementary to our target wound care markets.

Business Environment and Current Trends

Changes in reimbursement rates and coverage policy by third party payors may place additional financial pressure on hospitals and the broader healthcare system. These changes could reduce demand for our products, particularly if healthcare providers face lower margins or additional administrative burdens. For example, in 2025 the Centers for Medicare & Medicaid Services ("CMS") designated pricing responsibility for the Current Procedural Terminology ("CPT") code used with RECELL to the seven regional Medicare Administrative Contractors ("MACs"). Delay by the MACs in establishing and publishing reimbursement rates temporarily slowed clinician use of RECELL. As of March 2026, all seven MACs had published rates, restoring reimbursement clarity and supporting a return toward normalized utilization.

In July 2026, CMS released the 2027 Medicare Physician Fee Schedule ("PFS"), Hospital Outpatient Prospective Payment System, and Ambulatory Surgical Center ("ASC") proposed rules addressing Medicare payment for Skin Cell Suspension Autograft, the procedure performed using RECELL The proposed rules reflect the new Category I CPT code family effective January 1, 2027 and include proposed national physician relative value units based on American Medical Association recommended valuation, as well as proposed increases to hospital outpatient and ASC facility payment rates. If finalized, RECELL physician reimbursement would transition from the current regional MACs contractor-priced methodology to a more transparent, nationally published PFS. CMS is expected to issue final rules later this year, with implementation effective January 1, 2027.

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

Geopolitical conditions may also impact our operations. Although we do not have operations in Russia, Ukraine, the Middle East, or Asia (outside of Japan), the continuation or threat of military conflicts in these regions or any escalation of conflicts beyond their current scope may further weaken the global economy resulting in additional inflationary pressures or supply chain constraints.

Recent Developments

On January 13, 2026, we entered into a five-year credit facility with Perceptive Advisors LLC providing up to $60 million in available capital. At closing, we drew $50 million and used a portion of the proceeds to repay our existing debt, resulting in net proceeds of approximately $6.0 million after repayment of our prior debt and certain related transaction fees. This credit facility includes an option to access an additional $10.0 million through the first quarter of 2027, subject to the achievement of a certain revenue milestone. This facility also establishes trailing twelve-month revenue covenants aligned with our current operating trajectory, including $68.5 million for the quarter ended March 31, 2026, $69.0 million for the quarter ended June 30, 2026, and $73.0 million for the year ending December 31, 2026. As of June 30, 2026, we were in compliance with these covenants. For additional information, see *Liquidity and Capital Resources* below.

On April 6, 2026, we entered into a ten-year agreement with the Biomedical Advanced Research and Development Authority ("BARDA"), part of the U.S. Department of Health and Human Services, with a total potential value of up to $25.5 million. Under the agreement, we will maintain a supply of RECELL for deployment in burn mass casualty incidents and provide associated readiness and support services. The agreement provides approximately $4.0 million in access and maintenance fees over the ten-year term, with additional potential revenue tied to procurement options exercised by BARDA. Costs to fulfill the BARDA emergency preparedness performance obligation, which consist of billed costs to BARDA incurred in connection with emergency deployment services, are incremental and expected to be recovered.

In April 2026, we announced positive interim results from our Cohealyx I post-market clinical study, demonstrating a statistically significant reduction in mean time to autografting readiness of approximately 20 days compared to a literature-derived benchmark (13.6 days versus 33.2 days; $p<0.001$). These findings support the potential of Cohealyx to improve clinical outcomes and enhance efficiency in the treatment of full-thickness wounds.

We participated in the American Burn Association 2026 Annual Meeting in April, where independent investigators and clinical partners presented data and case studies reflecting real-world use of RECELL, Cohealyx, and PermeaDerm across a range of wound care applications. These presentations highlighted evolving clinical experience with our products and their use across different stages of wound management.

In April 2026, RECELL GO received Therapeutic Goods Administration certification in Australia and was listed on New Zealand's Web Assisted Notification of Devices database by Medsafe, enabling commercialization in both markets. These regulatory authorizations expand the international availability of RECELL GO and support our distributor-led commercialization strategy in Australia and New Zealand.

In June 2026, clinical data highlighting the first documented use of RECELL GO in the United Kingdom was presented at the 2026 British Burn Association Annual Meeting. The case series, involving 17 patients treated at Stoke Mandeville Hospital, demonstrated successful use of RECELL GO across burn and reconstructive procedures, with investigators reporting favorable clinical outcomes, uncomplicated donor-site healing, and workflow benefits through standardized cell preparation.

Results of Operations for the three-months ended June 30, 2026 compared to the three-months ended June 30, 2025.

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

	Three-Months Ended			
Statement of Operations Data:	**June 30, 2026**	**June 30, 2025**	**$ Change**	**% Change**
Sales revenue	$ 21,489	$ 18,226	3,263	18%
Lease revenue	213	192	21	11%
Total revenues	21,702	18,418	3,284	18%
Cost of sales	(3,935)	(3,469)	(466)	13%
Gross profit	17,767	14,949	2,818	19%
Operating expenses:				
Sales and marketing	(13,573)	(14,314)	741	(5)%
General and administrative	(5,971)	(6,666)	695	(10)%
Research and development	(5,078)	(5,117)	39	(1)%
Total operating expenses	(24,622)	(26,097)	1,475	(6)%
Operating loss	(6,855)	(11,148)	4,293	(39)%
Interest expense	(1,463)	(1,252)	(211)	17%
Other income, net	688	2,484	(1,796)	nm
Loss before income taxes	(7,630)	(9,916)	2,286	(23)%
Income tax expense	(33)	(4)	(29)	nm
Net loss	$ (7,663)	$ (9,920)	2,257	(23)%

*nm = not meaningful

Total revenues increased by 18%, or $3.3 million, to approximately $21.7 million, compared to $18.4 million in the same period in the prior year. The growth in revenues was largely driven by increased contributions from Cohealyx, RECELL GO mini in trauma and smaller wounds, and continued normalization in RECELL utilization following the resolution of MAC-related reimbursement headwinds.

Gross profit margin was 81.9% compared to 81.2% in the corresponding period in the prior year. Note that the gross margin for RECELL products only was 86.0% for the quarter, which we believe will remain in this range for future quarters. The increase in the overall gross margin percentage from the prior year was primarily caused by lower volume discounts offset by product mix. The Company shares the average sales price for Cohealyx at 50% and for PermeaDerm at 60%. Although these arrangements are highly beneficial, they inevitably result in an overall decrease in gross margin percentage. Therefore, the product mix is expected to continue to impact the overall gross margin percentage while increasing the gross profit and, given that expenses associated with this revenue do not increase significantly, the operating profit on a quarterly basis.

Total operating expenses decreased by 6% or $1.5 million to $24.6 million, compared with $26.1 million in the corresponding period in the prior year.

Sales and marketing expenses decreased by 5%, or $0.7 million, to $13.6 million, compared to $14.3 million in the corresponding period in the prior year. Lower costs in the current year are due to decreases in selling expenses of $0.9 million, offset by higher other selling expenses of $0.2 million. The decrease in selling expenses is due to lower commissions and marketing spend.

General and administrative expenses decreased by 10%, or $0.7 million, to $6.0 million, compared to $6.7 million in the same period in the prior year. Lower costs in the current year are due to decreases in stock-based compensation of $0.5 million and professional fees of $0.4 million, offset by an increase in salaries and benefits of $0.2 million. The decrease in stock-based compensation is due to reduced grant activity.

Research and development expenses of $5.1 million were consistent compared to the same period in the prior year.

Other income, net decreased by $1.8 million to $0.7 million from $2.5 million in the prior period. In the current period, other income, net consists of $0.5 million in income related to our investments and a non-cash gain of $0.2 million related to the change in fair value of the loan facility. The prior period income consisted of non-cash gains of $1.2 million related to the change in fair value of warrants, $0.9 million related to the change in fair value of loan facility, and $0.4 million in income related to our investments.

Results of Operations for the six-months ended June 30, 2026 compared to the six-months ended June 30, 2025.

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

	Six-Months Ended			
Statement of Operations Data:	**June 30, 2026**	**June 30, 2025**	**$ Change**	**% Change**
Sales revenue	$ 40,553	$ 36,551	4,002	11%
Lease revenue	400	381	19	5%
Total revenues	40,953	36,932	4,021	11%
Cost of sales	(7,458)	(6,303)	(1,155)	18%
Gross profit	33,495	30,629	2,866	9%
Operating expenses:				
Sales and marketing	(26,414)	(29,147)	2,733	(9)%
General and administrative	(12,032)	(13,057)	1,025	(8)%
Research and development	(10,707)	(11,400)	693	(6)%
Total operating expenses	(49,153)	(53,604)	4,451	(8)%
Operating loss	(15,658)	(22,975)	7,317	(32)%
Interest expense	(2,887)	(2,485)	(402)	16%
Other income, net	293	1,693	(1,400)	nm
Loss before income taxes	(18,252)	(23,767)	5,515	(23)%
Income tax expense	(22)	(12)	(10)	nm
Net loss	$ (18,274)	$ (23,779)	5,505	(23)%

*nm = not meaningful

Total revenues increased by 11%, or $4.0 million, to approximately $41.0 million, compared to $36.9 million in the same period in the prior year. The growth in revenues was largely driven by increased contributions from Cohealyx, RECELL GO mini in trauma and smaller wounds, and continued normalization in RECELL utilization following the resolution of MAC-related reimbursement headwinds.

Gross profit margin was 81.8% compared to 82.9% in the corresponding period in the prior year. Note that the gross margin for RECELL products only was 85.5% for the six-months ended June 30, 2026, which we believe will remain in this range for future quarters. The decrease in the overall gross margin percentage from the prior year was primarily caused by product mix. The Company shares the average sales price for Cohealyx at 50% and for PermeaDerm at 60%. Although these arrangements are highly beneficial, they inevitably result in an overall decrease in gross margin percentage. Therefore, the product mix is expected to continue to impact the overall gross margin percentage while increasing the gross profit and, given that expenses associated with this revenue do not increase significantly, the operating profit on a quarterly basis.

Total operating expenses decreased by 8% or $4.5 million to $49.2 million, compared with $53.6 million in the corresponding period in the prior year.

Sales and marketing expenses decreased by 9%, or $2.7 million, to $26.4 million, compared to $29.1 million in the corresponding period in the prior year. Lower costs in the current year are due to decreases in selling expenses of $1.5 million, salaries and benefits of approximately $0.8 million, and professional fees of $0.8 million, offset by higher other selling expenses of $0.4 million. The decrease in salaries and benefits is due to the reduction of our sales force as part of cost savings initiatives which began in the second quarter of the prior year. The decrease in selling expenses is due to lower commissions and reduced marketing spend. The decrease in professional fees is due to lower consulting costs. The increase in other selling expenses is due to higher travel spend.

General and administrative expenses decreased by 8%, or $1.0 million, to $12.0 million, compared to $13.1 million in the same period in the prior year. Lower costs in the current year are due to a decrease in stock-based compensation of $1.9 million, offset by an increase in deferred compensation expense of $0.9 million. The decrease in stock-based compensation is due to higher forfeitures, decreased headcount, and reduced grant activity. The increase in deferred compensation expense is driven by a higher stock price used to calculate the deferred compensation liability.

Research and development expenses decreased by 6%, or $0.7 million, to $10.7 million, compared to $11.4 million in the same period in the prior year. Lower costs in the current year are due to decreases in research and development expenses of $0.5 million and professional fees of $0.2 million. The decrease in research and development expenses is due to lower product testing costs. The decrease in professional fees is due to lower clinical trial costs associated with PermeaDerm and Cohealyx post-market studies.

Other income, net decreased by $1.4 million to $0.3 million from $1.7 million in the prior period. In the current period, other income, net consists of a non-cash gain of $0.5 million related to the change in fair value of the loan facility and $0.5 million in income related to our investments, offset by a non-cash charge of $0.6 million related to the change in fair value of warrants and $0.1 million in other income, net. The prior period expense consisted of non-cash gains of $1.5 million related to the change in fair value of warrants and $0.2 million related to the change in fair value of loan facility, plus $0.8 million in income related to our investments offset by $0.8 million in debt issuance costs.

Liquidity and Capital Resources

Overview

Our Consolidated Financial Statements have been prepared on the basis that we will continue as a going concern for the next 12 months. We had approximately $9.1 million in cash and cash equivalents and $2.0 million in marketable securities as of June 30, 2026. We have funded our research and development activities, and more recently our substantial investment in sales and marketing activities, through the sales of our products, the issuance of equity securities, and debt financing. If capital is not available to us when amounts are needed, we could be required to delay, scale back, or abandon commercial activities and development programs and other operations, which could adversely impact our business, financial condition, and operating results.

Based on our liquidity position and current forecast of operating results and cash flows, management determined there is substantial doubt about our ability to continue as a going concern over the next twelve months following the date of issuance of these Consolidated Financial Statements, due to our debt repayment obligations, historical negative cash flows, and recurring losses. As a result, we may require additional liquidity to continue our operations over the next twelve months.

On January 13, 2026 (the "Closing Date"), we entered into a Credit Agreement and Guaranty (the "Credit Agreement"), and Security Agreement (the "Security Agreement"), by and among us, as borrower, Avita Medical Americas, LLC, a wholly-owned subsidiary of the Company, as guarantor (the "Guarantor," taken together with the Company, the "Obligors") and Perceptive Credit Holdings V, LP as a lender and the administrative agent (the "Lender," and the "Administrative Agent," as applicable). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to $60 million (the "Loan Facility"), of which (i) $50 million was funded on the Closing Date (the "Initial Commitment Amount"), and (ii) $10 million will be made available, at our discretion by notice to the Administrative Agent on or before March 31, 2027, subject to satisfaction of a certain net revenue requirement (the "Additional Commitment Amount"). On the Closing Date, we closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Lender. Simultaneously with the closing of the Initial Commitment Amount, we repaid in full and terminated all of our obligations and commitments under our previous credit agreement (the "Refinancing Transaction").

During the term of the Loan Facility, interest payable in cash shall accrue on any outstanding amounts under the Loan Facility 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, 7.50%. Upon the occurrence and during the continuance of an event of default, any outstanding amount under the Loan Facility will bear interest at a rate of 4% in excess of the otherwise applicable rate of interest.

On the Closing Date, we agreed to issue to the Lender, subject to shareholder approval, warrants to purchase up to 650,000 shares of Common Stock, par value $0.0001 per share, at an exercise price set at the lower of two 10-day VWAPs: (i) the 10-day VWAP ending on the business day immediately prior to the Closing Date, which VWAP is $3.4019; or (ii) the 10-day VWAP ending on the business day immediately prior to the issuance date of the warrants. On June 3, 2026, our shareholders approved the issuance of such warrants. On June 8, 2026, we issued a warrant covering up to 650,000 shares of Common Stock at an exercise price of $3.4019 per share, of which 500,000 shares are immediately exercisable, with an additional 150,000 shares that will vest and become exercisable if we close on the Additional Commitment Amount.

Under the terms of the Credit Agreement, and as set forth in a fee letter between us, and the Lender and the Administrative Agent (the "Fee Letter"), we will pay certain fees with respect to the Loan Facility, including a prepayment premium ranging from 1% to 10% of the amount of the Loan Facility that is prepaid upon any voluntary or mandatory prepayment (including as a result of an acceleration), together with certain other fees and expenses of the Lender.

The Credit Agreement contains certain customary events of default, including with respect to nonpayment of principal, interest, fees or other amounts; material inaccuracy of a representation or warranty; failure to perform or observe covenants; material defaults on other indebtedness; insolvency; loss of certain key permits, persons and contracts; material adverse effects; certain regulatory matters; and change of control.

The Credit Agreement contains a number of customary representations, warranties, and covenants that, among other things, will limit or restrict our ability 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; redeem or repurchase certain debt; engage in certain transactions with affiliates; and enter into certain restrictive agreements. Among such covenants, the Credit Agreement includes a financial maintenance test that requires us to maintain a specified minimum net revenue for each trailing twelve-month period ending on the last day of a fiscal quarter occurring prior to the maturity date of the Loan Facility, with the first such test occurring as of the fiscal quarter ended March 31, 2026. In addition, the Credit Agreement requires us to maintain, in the aggregate, at least $5 million of unrestricted cash at all times. Pursuant to the Security Agreement, all obligations under the Credit Agreement are guaranteed and secured by substantially all of our assets.

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

	Six-Months Ended	
(in thousands)	June 30, 2026	June 30, 2025
Net cash used in operating activities	$ (13,568)	$ (20,538)
Net cash provided by investing activities	5,930	17,782
Net cash provided by financing activities	6,534	922
Net decrease in cash and cash equivalents	(1,104)	(1,834)
Cash and cash equivalents at beginning of the period	10,243	14,050
Cash and cash equivalents at end of the period	9,139	12,216

Net cash used in operating activities was $13.6 million and $20.5 million during the six-months ended June 30, 2026 and 2025, respectively. The decrease in net cash used in operations was primarily due to increased gross profit, decreased operating expenses, and the timing of working capital outlays.

Net cash provided by investing activities was $5.9 million and $17.8 million during the six-months ended June 30, 2026 and 2025, respectively. The decrease in cash provided by investing activities is primarily attributable to lower cash inflows from maturities of marketable securities in the current year.

Net cash provided by financing activities was $6.5 million and $0.9 million during the six-months ended June 30, 2026 and 2025, respectively. The increase in cash provided by financing activities is primarily due to the Loan Facility entered into on January 13, 2026.

Capital Management and Material Cash Requirements

We aim to manage capital so that we can continue as a going concern while also maintaining optimal returns to stockholders, as well as other benefits for our 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 six-months ended June 30, 2026, there were no dividends paid and we have no plans to commence the payment of dividends.

Under the terms of the Regenity Agreement, we have an obligation to make an additional $3.0 million payment on or before January 4, 2027 to guarantee development and manufacturing capacity (and related resources), contingent on positive results of certain clinical studies. With the exception of the milestone payments under the Regenity Agreement, we do not have any other purchase commitments or long-term contractual obligations, except for lease obligations as of June 30, 2026.

Subsequent to June 30, 2026, on August 5, 2026, we entered into a Global Amendment of the Distribution and Manufacturing Agreements with Stedical (the "Global Amendment"). Under the terms of the Global Amendment, in exchange for a $500,000 fee we will hold the right of first offer and refusal to expand our exclusive distribution territory to include all or a portion of the European Union, the United Kingdom, and/or Australia. In addition, our share of revenue from PermeaDerm sales will increase to 67% for products sold in sheet form, subject to increased revenue sharing in the event our gross margin on those products exceeds 50%, and to 80% for products sold in glove form, subject to increased revenue sharing in the event our gross margin on those products exceeds 35%. For 2026, we are required to reach total PermeaDerm revenue sharing payments of $1.0 million, with 20% growth minimums each year through 2030. All previous minimum revenue sharing payment requirements under the Distribution Agreement were waived.

Also under the Global Amendment, Stedical may pursue the commercialization of PermeaDerm in certain U.S. markets not currently served by us. We will sell PermeaDerm for such sales to Stedical at a ten percent premium to our actual manufacturing costs. For PermeaDerm manufactured for Stedical to sell outside of the U.S., primarily in Asia, we will sell such PermeaDerm to Stedical at $200 per carton plus a 10% manufacturing fee, subject to a reasonable volume cap.

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 to 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 2025 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Financial Officer evaluated, with the participation of our management, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. As of June 30, 2026, 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 Securities Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Part II - Other Information

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed under Part I, Item 1A, "Risk Factors," in the 2025 Annual Report, and as updated from time to time in the Company's subsequent Quarterly Reports on Form 10-Q (the "Risk Factors"). These Risk 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 Quarterly Report on Form 10-Q. There have been no material changes to the Risk Factors as of the filing of this Quarterly Report on Form 10-Q.

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

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

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

Exhibit No.	Description
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K12B filed on June 30, 2020)
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.2 of the registrant's Form 10-KT filed on February 28, 2022)
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the registrant's Form 8-K filed on May 15, 2025)
4.1	Warrant Certificate (incorporated by reference to Exhibit 4.1 of the registrant's Form 8-K filed on June 5, 2026)
10.1	Award Contract dated April 6, 2026 by and between the registrant and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA)* ***
10.2	Executive Employment Agreement between the registrant and Cary Vance dated April 30, 2026 (incorporated by reference to Exhibit 10.1 of the registrant's Form 8-K filed on May 1, 2026)†
10.3	Sixth Amendment to the Lease Agreement between the registrant and 28159 Avenue Stanford Properties, LLC, (formerly RIF III-Avenue Stanford LLC), dated June 3, 2026, as amended)*
31.1*	Rule 13a-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a) Certification of Chief Financial Officer
32**	18 U.S.C. Section 1350 Certifications
101.INS	Inline XBRL Instance Document
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
*** Certain confidential portions of this exhibit have been omitted and redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K because the identified information is both not material and is the type that the registrant treats as private or confidential and/or would be competitively harmful if publicly disclosed

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: August 6, 2026

AVITA MEDICAL, INC.

By: /s/ Cary Vance
Cary G. Vance
Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 10.1

Certain identified information (as indicated by "[***]") has been excluded from the exhibit because it both (i) is not material and (ii) is the type that the company treats as private or confidential.

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER	PAGE	OF
ASP348803	1	45

2. CONTRACT NO.	3. AWARD/ EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	. SOLICITATION ISSUE DATE
75A50126C00003			75A50125R00003	06/04/2025

FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER *(No collect calls)*	B. OFFER DUE DATE/LOCAL TIME ET
	RICHARD HALL		

9. ISSUED BY — CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave. , S.W.
Room 640-G
Washington DC 20201

10. THIS ACQUISITION IS
☒ UNRESTRICTED OR
☐ SET ASIDE: FOR:
☐ SMALL BUSINESS
☐ WOMEN-OWNED SMALL BUSINESS (WOSB)
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS (SDVOSB)
☐ ECONOMICALLY DISADVANTAGED WOMEN-OWNED SMAL BUSINESS (EDWOSB
☐ B(A)

NORTH AMERICAN INDUSTRY CLASSIFICATION STANDARD (NAICS): 339113
SIZE STANDARD: 800

11. DELIVERY FOR FREE ON BOARD (FOB) DESTINATION UNLESS BLOCK IS MARKED
☒ SEE SCHEDULE

12. DISCOUNT TERMS

13a. THIS CONTRACT IS A RATED ☐ ORDER UNDER THE DEFENSE PRIORITIES AND ALLOCATIONS SYSTEM - DPAS (15 CFR 700)

13b. RATING

14. METHOD OF SOLICITATION — REQUEST FOR
☐ REQUEST FOR QUOTE (RFQ) ☐ INVITATION FOR BID (IFB) ☒ PROPOSAL (RFP)

15. DELIVER TO — CODE ASPR-BARDA

ASPR-BARDA

US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVEL
200 INDEPENDENCE AVE, S.W; ROOM 640
Washington DC 20201

1 . ADMINISTERED BY — CODE ASPR-BARDA

ASPR-BARDA

200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

17a. CONTRACTOR/ OFFEROR — CODE 1476585 — FACILITY CODE

AVITA MEDICAL AMERICAS, LLC 1476585
Attn: NIRAJ DOSHI
AVITA MEDICAL AMERICAS, LLC
28159 AVENUE STANFORD STE 220
VALENCIA CA 91355

28

TELEPHONE NO. 661-7554023

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

1Ba. PAYMENT WILL BE MADE BY — CODE PSC

PSC
Program Support Center
7700 Wisconsin Ave
Bethesda MD 20814

1Bb. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 1Ba UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Tax ID Number: 20-2578762 UEI: JY1HRCEKX2L4 Period of Performance: [***]/2026 to [***]/2036				
1	CLIN 001 - Initial procurement of FDA approved Access-Maintenance Agreement products upon notification of requirement purchase for commercially available Autograft Sparing Devices. Obligated Amount: $[***] Continued ... ***(Use Reverse and/or Attach Additional Sheets as Necessary)***				[***]

25. ACCOUNTING AND APPROPRIATION DATA
See schedule

2 . TOTAL AWARD AMOUNT (*or overn ent Use nly*)
$25,500,730.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE (FEDERAL ACQUISITION REGULATION) FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED.

☒ 2B. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: REFERENCE _____ OFFER DATED _____ YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR

31a. UNITED STATES OF AMERICA (S NA UR N RA N R)

Richard A. Hall -S

Digitally signed by Richard A. Hall -S
Date: 2026.04.06 13:19:25 -04'00'

30b. NAME AND TITLE OF SIGNER *(y e or rint)*	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(y e or rint)*	31c. DATE SIGNED
Niraj Doshi, SVP R&D, PMO, & BD	April 02, 2026	RICHARD A. HALL	

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 11/2021)
! " !# $SA % FAR (4& CFR) '(.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Accounting Info: 2026.Q99BS25.26088 Appr. Yr.: 2026 CAN: Q99BS25 Object Class:26088 Funded: $[***]				
2	CLIN 002 - Vender Managed Inventory FDA approved commercial device maintenance fee. Contractor shall ensure Access-Maintenance Agreement products expiry dates, rotation of product through commercial sales, and provide monthly reports to BARDA. Obligated Amount: $[***]				[***]
	Accounting Info: 2026.Q99BS25.25235 Appr. Yr.: 2026 CAN: Q99BS25 Object Class: 25235 Funded: $[***]				
3	CLIN 003 - Emergency Deployment of Access-Maintenance Agreement products up to a [***] units per written notification of the Contracting Officer or designated representative of the current VMI stock being held to be packaged and forwarded to the designated burn/trauma center within the United States and it territories. Obligated Amount: $[***]				[***]
	Accounting Info: 2026.Q99BS25.22006 Appr. Yr.: 2026 CAN: Q99BS25 Object Class: 22006 Funded: $[***]				
4	CLIN 004 - Additional procurement of FDA approved Access-Maintenance Agreement products upon Continued ...				[***]

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE		325. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
		32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE	

33. SHIP NUMBER ☐ PARTIAL ☐ FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	3. PAYMENT ☐ COMPLETE ☐ PARTIAL ☐ FINAL	37. CHECK NUMBER
3B. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY *(Print)*	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41c. DATE	42b. RECEIVED AT *(Location)*	
		42c. DATE REC'D *(YY/MM/OO)*	42d. TOTAL CONTAINERS

STANDARD FORM 1449 (REV. 11/2021) BACK

NAME OF OFFEROR OR CONTRACTOR

AVITA MEDICAL AMERICAS, LLC 1476585

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	notification of requirement purchase for commercially available Autograft Sparing Devices up to a maximum of [***] units. Accounting Info: 2026.Q99BS25.26088 Appr. Yr.: 2026 CAN: Q99BS25 Object Class:26088 Funded: $[***] Accounting Info: 2026.Q990133.26088 Appr. Yr.: 2026 CAN: Q990133 Object Class: 26088 Funded: $[***]				
5	CLIN 005 - Emergency Deployment of Access-Maintenance Agreement products up to a [***] units per written notification of the Contracting Officer or designated representative of the additional VMI stock being procured to be packaged and forwarded to the designated burn/trauma center within the United States and it territories. Obligated Amount: $[***] Accounting Info: 2026.Q99BS25.22006 Appr. Yr.: 2026 CAN: Q99BS25 Object Class: 22006 Funded: $[***]				[***]

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

Treatment and care for burn injuries is both resource and labor intensive. The national capacity is typically limited and presents a significant limitation to when a sudden surge capacity is required in a burn mass casualty incident (BMCI). A BMCI in a geographic area could overwhelm a regional existing capacity and present substantial resource constraints. To mitigate this challenge, BARDA has collaboratively worked with the burn care community to identify areas of improvement in the delivery of this care. This collaboration has identified numerous area which BARDA has systematically addressed over the years. The two major areas where enhanced treatment options could provide a meaningful difference are in the initial care and triage of patients, and secondly, in the long-term treatment and recovery steps of burn care. The focus of this RFP is to address the long-term treatment and recovery steps of burn care.

Autografting is the current standard of care for long term treatment and recovery of deep partial and full thickness burn injuries. This involves removing healthy skin from an uninjured area of the patient's body and affixing it on top of the burn wound. The autografting procedure is labor-intensive, requires training, is time consuming and invokes additional risk to the patient due to the operative procedures at multiple sites. Discussions with the professional burn community and market research data indicates that products that reduce the amounts of autograft needed to provide wound closure (autograft-sparing) can provide an advantage for rapid and effective care of severe burn injuries. Such products also have the potential to reduce the morbidity of the donor sites. Such products should be compatible with current procedures to allow easy integration so they could be also used during a mass casualty scenario involving significantly high numbers of burn patients. Additionally, such products that have indications for full thickness skin defects due to traumatic injury would be advantageous to address additional injuries resulting from an MCI. This Statement of Objective (SOO) focuses on products which could contribute to autograft-sparing in burn and trauma patients and potentially accelerate the healing process while leading to better outcomes.

Based on this background, the objective of this RFP is to support procurement of an approved autograft sparing device. The technology must be capable of treating both full thickness thermal burn wounds as well as full thickness skin defects resulting from trauma. Procurement strategies would include use of an Access-Maintenance Vendor Managed Inventory (AM-VMI) contract covering the period of performance. Via this Access-Maintenance VMI, the Offeror will maintain a cache of product determined by the shelf life and sales volume. This cache will be maintained by the Offeror monthly to ensure all product is within expiry and report total inventory numbers to BARDA. In return, BARDA will pay for this monthly maintenance cost and the right to access/procure this VMI cache in the event of a national emergency.

The negotiated terms include the price per unit as well as the size of the product inventory. This system allows for maximum national preparedness while limiting waste of unused product by only procuring the product if it is needed to respond to a mass casualty incident.

B.1.1. Definitions

Access-Maintenance Vendor Managed Inventory (AM-VMI) – The Contractor and U.S. Government (USG) agree the USG shall pay a fee for the contractor to hold, and maintain in reserve, a negotiated level of commercially useable product for its intended purpose in delivery of care; and the entire product inventory shall be available for purchase by USG. The Contractor and the USG also agree to a pre-negotiated price for procurement on demand of the products in the inventory, to mutual terms for periodically expanding the size of the inventory, and for the contractor to deploy the procured product via their commercial processes and infrastructure or in collaboration with the Strategic National Stockpile (SNS).

Commercial Product – As defined in FAR 2.101.

Food and Drug Administration (FDA) Approved - The FDA approval of a medical product (e.g., drug, device or biologic) means the product's safety and effectiveness have been reviewed by the FDA and the product's known and potential benefits outweigh the known and potential risks. If the FDA grants an approval, it means the agency has determined the product is safe and effective for its intended use.

Government Furnished Property (GFP) - All property owned or leased by the Government. Government property includes both Government-furnished property and contractor-acquired property. Government property includes material, equipment, special tooling, special test equipment, and real property.

Government property does not include intellectual property and software. The Government shall not own any property under this contract.

B.2. PRICES / COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror. It is anticipated that the final contract will consist of a base period of performance of up to ten (10) years.

The Base Period consists of five Firm Fixed Price CLINs to support procurement, maintenance, and emergency deployment of autograft sparing devices. This requirement has no proposed or required options at this time.

B.2.1. BASE PERIOD

Base Period Firm Fixed Price CLINs					
Estimated Period of Performance	**CLIN**	**Description of Supplies/Services**	**Quantity**	**Unit Price ($)**	**Total ($)**
04/06/2026 to 04/05/2036	CLIN 001	Initial procurement of FDA approved Access-Maintenance Agreement products up to a maximum of [***]]units for commercially available Autograft Sparing Devices.	Up to [***]	$[***]	$[***]
04/06/2026 to 04/05/2036	CLIN 002	Vender Managed Inventory FDA approved commercial device maintenance fee. Contractor shall ensure Access-Maintenance Agreement products expiry dates, rotation of product through commercial sales, and provide monthly reports to BARDA.	[***] months	$[***]	$[***]
04/06/2026 to 04/05/2036	CLIN 003	Emergency Deployment of Access-Maintenance Agreement products up to a [***] units per written notification of the Contracting Officer or designated representative of the current VMI stock being held to be packaged and forwarded to the designated burn/trauma center within the United States and it territories.	1	$[***]	$[***]
04/06/2026 to 04/05/2036	CLIN 004	Additional procurement of FDA approved Access-Maintenance Agreement products upon notification of requirement purchase for commercially available Autograft Sparing Devices up to a maximum of [***] units.	Up to [***]	$[***]	$[***]
04/06/2026 to 04/05/2036	CLIN 005	Emergency Deployment of Access-Maintenance Agreement products up to a [***] units per written notification of the Contracting Officer or designated representative of the additional VMI stock being procured to be packaged and forwarded to the designated burn/trauma center within the United States and it territories.	1	$[***]	$[***]
TOTAL COST					**$25,500,730.00**

B.2.2. PBS Contract Authority: 42 USC 247d-6b(c) and (g), the Project BioShield Act of 2004.

B.2.3. Multi-Year Contract: Multi-year Project BioShield (PBS) contract means a contract for the purchase of supplies or services for more than one, but not more than ten, program years. A multi-year contract may provide that performance under the contract during the option periods and subsequent years of the contract is contingent upon the appropriation of funds, and (if it does so provide) may provide for a cancellation payment to be made to the contractor if appropriations are not made. The key distinguishing difference between multi-year contracts and multiple year contracts is that multi-year contracts, defined in the statutes cited at 17.101, buy more than one year's requirement (of a product or service) without establishing and having to exercise an option for each program year after the first.

B.2.4. Type of Contract: The Contracting Officer has determined this to be a Firm-Fixed Priced (FFP) Contract.

B.3. ADVANCE UNDERSTANDINGS

The final contract may contain advance understandings between the Government and the Offeror. Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost will be included in this Section if the Contracting Officer has granted his/her approval prior to contract award.

B.3.1. The Contracting Officer shall designate in writing the specific delivery date, location, and any additional information required for delivery of up to a maximum of [***] units of Autograft Sparing Devices. Avita Medical Americas, LLC shall provide the specific delivery date, shipping company information, driver information (may or may not be required), quantity and inventory information. Additional requirements may be required by the receiving location, if so, this information shall be provided in writing by the Contracting Officer or designated representative.

B.3.2. The Contractor shall provide a Quality Agreement to BARDA within sixty-days of the awarded contract for review and approval. This Quality Agreement shall outline the responsibilities of both the Contractor and BARDA for product shipping, receiving, and storage. These documents shall be bilaterally signed once approved by both parties. This Quality Agreement will be a deliverable on the contract and will not supersede the terms and conditions of the overarching contract.

B.3.3. The Contractor shall notify the Government of changes impacting the product availability and/or their delivery (such as but not restricted to manufacturing processes, component systems, including those may or may not be reported to the FDA). The Contractor shall notify the Government of changes to the product delivery system. The Government, in collaboration with the Contractor, shall have the right to adjust the total products available for procurement within the Access Management – Vendor Managed Inventory (AM-VMI) or establish a new CLIN for additional procurements based upon technological or manufacturing advancements and the Governments requirements.

B.3.4. In addition to the planned potential procurement of the total established number of units under the contract ([***] units), should there be a need to procure additional units, BARDA would like to have the right of first refusal for any additional units available and/or the production planned by Avita Medical Americas, LLC. The delivery schedule and price per unit for these units would match the best commercial price available at the time of need.

Rights In Data

Shall be in accordance with 52.227-14 Rights in Data-General.

Travel

No travel is anticipated for this award at this time.

Person-in-Plant

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's or Subcontractor's facility, who shall be subject to the Contractor's or Subcontractor's policies and procedures regarding security and facility access at all times while in the Contractor's or Subcontractor's facility. The Government's representative shall be provided reasonable access, during normal business hours, of the production areas being utilized in performance on the Contract. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor or subcontractor plant.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

Security

A security plan will be submitted for approval within 90 days of award. See Section J.

Subcontracts

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

- Is of the cost-reimbursement type; or
- Is of the fixed price type and exceeds $350,000 or 5% of the contract, whichever is less.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer within ten (10) calendar days.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Section. In accordance with Health and Human Services Acquisition Regulation 352.231-70 Salary Rate Limitation - (a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds. This applies to subcontractors and consultants.

Overtime Compensation

No overtime (premium) compensation is authorized under the subject contract.

Invoice Submission during end of Fiscal Year

The government will not accept invoices for processing from September 15th through first week in October for processing because of end of year fiscal requirements. Any invoices received from September 15th through the first week in October, will be processed when financial systems are available.

B.4 ORGANIZATIONAL CONFLICT OF INTEREST

General: For the purpose of this provision/clause, “consultant” is defined as a company, firm, LLC, sole proprietor, joint venture member, independent contractor, subcontractor, affiliate, or similar entity that is not an employee of the Contractor.

Disclosure: The Contractor shall report contacts with consultants who are paid to furnish advice, information, direction, or assistance to the Contractor or any subcontractor in support of the preparation or submission of the Contractor’s business or technical proposal. The report shall include the following information:

a. The name, title, and contact information for the consultant, including the name and contact information for his/her company/firm/etc.
b. The name, title, and contact information for a Contractor point of contact, including the name and contact information for the prime contractor if the consulting services were received by a subcontractor.
c. The nature of the consulting services received.

Resolution: The responsible Contracting Officer will review the Contractor’s disclosure to determine whether an actual or appearance of a conflict of interest exists based on the information disclosed by the Contractor and/or from other sources. The framework for the Contracting Officer’s review will be FAR Subpart 9.5, Organizational and Consultant Conflicts of Interest. If an actual or appearance of a conflict of interest exists, the Contracting officer will take action which may include, but is not limited to, requesting a mitigation plan from the Contractor.

B.5. PROVISIONS TO APPLICABLE COSTS

This section prohibits or restricts the use of contract funds which includes the following items (costs unallowable unless otherwise approved by the Contracting Officer):

a) Acquisition, by purchase or lease, of any interest in real property.
b) Rearrangement or alteration of facilities.
c) Purchase of lease of any item of general-purpose office furniture or office equipment regardless of dollar value.
d) Accountable Government Property.
e) Overtime
f) General scientific meetings/conferences.
g) Travel costs including foreign travel.
h) Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements).
i) Costs to be paid for the performance of a fixed-price subcontract that exceeds $250,000.00;
j) Refreshments and Meal Expenditures.
k) Promotional Items
l) Printing

SECTION C – DESCRIPTION / SPECIFICATIONS / WORK STATEMENT

C.1. STATEMENT OF OBJECTIVES

BACKGROUND and PURPOSE

Treatment and care for burn injuries is labor intensive and influenced by the unique properties of each case with complicating factors including patient age, pre-existing health conditions, burn wound size, depth, and location. The challenges of providing definitive burn care are heightened when delivering treatment after a mass casualty event in a resource strained environment. The anticipated high number of injured in a mass casualty incident especially in a geographical area would pose significant limitations on the ability to provide conventional standards of care for victims. To mitigate some of these challenges

BARDA has collaboratively worked with the burn care community to identify areas to improve the delivery of care and treatment procedures. Two major areas where enhanced medical countermeasures (MCM) can provide a meaningful difference are in the triage of initial care and in a definitive burn care setting.

A large burn mass casualty incident could quickly overwhelm the US healthcare infrastructure. Severe burn injuries (especially, >10% Total Body Surface Area (TBSA) typically require highly specialized care for effective delivery of resource-intensive therapies including surgeries. Nationally, this capability is critically limited at multiple levels and would challenge timely access and treatment of those injured even in a relatively small incident. This makes it imperative to leverage technology that reduces the amount of donor skin required for full thickness and large deep partial thickness burns. Reducing the required amount of donor skin for delivery of definitive care has the potential to greatly improve the patient's quality of life while reducing hospital length of stay and the need for reconstructive surgery.

OBJECTIVE

For building national burn care preparedness under the conditions described above, BARDA intends to procure FDA approved products which can reduce the amount of autograft required to provide definitive coverage for any traumatic injuries or for full and deep partial thickness burn injuries. Such autograft sparing technologies significantly reduce the amount of donor skin required to treat full thickness burns and other full thickness skin defects in trauma to reduce patient morbidity and mortality.

To build national preparedness and address the unmet needs identified in both burn and trauma care, products shall meet both the capabilities:

(1) FDA approved to treat full-thickness thermal burn wounds and full-thickness skin defects resulting from other traumatic injuries, in both adults and pediatrics.
(2) Demonstrated evidence in clinical use for autograft sparing, as in reduction in the amount of donor skin required for definitive care treatment.

As an FDA approved product, it is expected the product use case settings would include both burn and trauma centers. Information on the integration of the products in these routine healthcare settings would be important towards the indicated purpose to build national preparedness and availability for use and trained physicians.

Under this RFP, BARDA plans to establish an access-maintenance vendor-managed inventory (VMI) system. In this system, the Offeror is required to maintain as part of the normal (commercial) operations a pre-specified (negotiated) inventory stock of devices which are accessible on demand. In the event of a mass casualty incident and upon notification by the U.S. Government (USG), the stock shall be available in its entirety for immediate procurement and deployment to identified burn and trauma centers within 24 hours.

SCOPE

This Access-Maintenance Vendor Managed Inventory (AM-VMI) procurement of an FDA-approved autograft-sparing product. Critical attributes of the device shall include the capability to reduce the amount of donor skin required to treat full thickness wounds from burns and trauma in children and adults. The following areas of work are considered within the overall scope:

1) Initial procurement of FDA approved Access-Maintenance Vendor Managed Inventory products for commercially available Autograft Sparing Devices. (CLIN 001)

The vendor would maintain a cache of ready for use product units as part of the commercial inventory management. The product units are part of the vendor's commercial operation inventory management. The inventory is actively managed under first in- first out principle to ensure the newly manufactured product unit remains in the inventory. If a mass casualty occurs or other emergency at the USG discretion, the vendor may be notified of USG's intent to procure a part or the entire cache of the devices in the inventory. The size of the initial cache would be subject to negotiations up to a maximum of [***]

unit devices. At any point during the duration of the contract, the USG may notify the Offeror of an intent to procure up to [***] units from the Access-Maintenance VMI. At that time, the Offeror shall provide all necessary documentation for quality assurance and acceptance of the product by the USG. In the case of a commercial product, only what is consistent with customary commercial practice under FAR 12.301(a) will be required (e.g., Certificate of Conformance).

The Offeror shall include commercial sales data to demonstrate the capability to manufacture and store a surplus inventory of a minimum of [***] unit devices. The Offeror shall also provide data supporting their manufacturing capacity.

2) Vendor Managed Inventory FDA approved commercial device maintenance fee. Contractor shall ensure Access-Maintenance Vendor Managed Inventory product expiry dates, rotation of product through commercial sales, and provide monthly reports to BARDA. (CLIN 002)

The Offeror shall maintain a cache of devices available for emergency deployment purposes. The stock in this inventory shall be rotated as part of routine sales using the principle of "First Expiry, First Out". The final number of units in the inventory would be subject to finalization as part of the negotiation but should address capability to maintain a minimum of [***]devices up to a total ramp up of [***] devices. Ideally, with increased sales and growth in the market share over time, USG anticipates the Offeror would be able to increase the size of the cache by an additional [***] devices (to a total of [***] devices maintained under VMI). Each unit shall have at least 3 months of shelf-life as part of the access-maintenance VMI.

Under this CLIN, the Offeror shall provide information on the availability of resources for inventory maintenance / management activities. The Offeror shall include data demonstrating the approved shelf-life of the device, tracking and shuffling inventory and the ability to ensure a minimum shelf-life for all products in the access-maintenance VMI. The Offeror shall specify how the process is organized and managed with Standard Operating Procedures (SOPs).

3) Emergency Deployment of Access-Maintenance Vendor Managed Inventory products up to [***] units per written notification of the Contracting Officer or designated representative of the current VMI stock being held to be packaged and forwarded to the designated burn/trauma center within the United States and its territories. (CLIN 003)

If the USG procures up to [***]units from the Access-Maintenance VMI, the offeror will be required to prepare the specified number of units for emergency deployment within 24 hours of notification.

i) Notification to release product(s) under this Contract shall be provided in writing to the Contractor by the Contracting Officer.
ii) The Offeror shall package and ship device units via standard commercial shipping methods directly to burn and trauma centers as identified by the USG. The Offeror's deployment plan shall also include an alternative shipment method whereby devices are deployed directly by ASPR/SNS to burn and trauma centers.
iii) At least three times during the duration of the contract, USG and Offeror shall synchronize a mock-deployment exercise to ensure the procedures and personnel are trained to react to an emergency deployment. Any deficiencies identified shall be documented and rectified.

4) Additional procurement of FDA approved Access-Maintenance Agreement products for commercially available Autograft Sparing Devices (up to a maximum of [***] units).(CLIN 004)

Towards the original goals for national preparedness, USG may consider the need to increase in the size of the cache to be held as part of inventory available for procurement. An anticipated increase in the size of the cache would be up to [***] devices (or as negotiated) for access and maintenance and available for procurement to be delivered within an agreed upon timeframe. If the commercial market cannot sustain maintenance of the larger cache, the Offeror shall provide the shortest ramp up plan to manufacture and deliver the additional devices and timeframe required. At any point during the duration of the contract, the USG may notify the Offeror of an intent to procure from these additional units. At that time, the Offeror shall provide all necessary documentation for quality assurance and acceptance of the product by the

USG. In the case of a commercial product, only what is consistent with customary commercial practice under FAR 12.301(a) will be required (e.g., Certificate of Conformance).

5) Emergency Deployment of Access-Maintenance Agreement products up to a [***] units per written notification of the Contracting Officer or designated representative of the additional VMI stock being procured to be packaged and forwarded to the designated burn/trauma center within the United States and its territories.(CLIN 005)

Upon purchase of additional devices in CLIN 004 above, the offeror will be required to prepare a specified number of units for emergency deployment within 24 hours of notification.

i) Notification to release product(s) under this Contract shall be provided in writing to the Contractor by the Contracting Officer.
ii) The offeror shall package and ship device units via standard commercial shipping methods directly to burn and trauma centers as identified by the USG. An option for an alternative shipment method as directed by ASPR/SNS shall be part of the deployment plan.

6) Project Management Objectives (CLINs 001 - 005)

The Offeror is directed towards details provided in the section on Reporting Requirements. The work here is intended to be performed in the Base period. Hence, all SOW activities generated for the duration of the contract shall have a Project Management and Risk Mitigation section covering objectives in this CLIN.

(i) The Offeror shall provide a monthly inventory spreadsheet detailing the product available (under access-maintenance) to procure and deploy within 24 hours notification from the Government.
(ii) AM-VMI costs must be tracked and invoiced at the negotiated frequency.
(iii) The Offeror shall participate in regular meetings at the negotiated frequency to coordinate and oversee the contracting effort.
(iv) The Offeror shall provide a list of individuals to serve as primary and secondary points of contact who will be available 24 hours a day, seven days a week, for the purpose of a public health emergency notification.
(v) The Offeror shall provide a security plan that includes physical and information technology (IT) security associated with all aspects of manufacture of product, process, storage, and inventory of the critical assets such as devices or components when under the Offeror's direct control.

C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

Performance of the contract will be monitored by the Contracting Officer (CO)/Contracting Officer's Representative (COR) on a regular basis. The Contracting Officer will be responsible for inspection and acceptance of deliverables and services. Monitoring of the contract will be based on periodic reporting by the Offeror.

C.3. MEETINGS / SITE VISITS

The Contractor and BARDA/CMA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the CO/COR. Such meetings may include, but are not limited to, a kickoff meeting to be held at a location determined by the COR, status update meetings and/or teleconferences, site visits to the Contractor's and/or subcontractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and contractual aspects of the program. The Contractor shall provide data, reports, and presentations to USG personnel and USG-contracted subject matter experts as required by the CO/COR facilitating review of activities.

The purpose of the kickoff meeting will be to orient the Contractor to HHS/BARDA and review contract requirements. This meeting usually occurs within a month after contract award. Monthly status update meetings/teleconferences will be held. The schedule for these meetings will be established by the CO and COR.

Periodic site visits shall occur on an ad hoc basis.

Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, related to the Contracted Products, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

Other U.S. Government Audits

The USG reserves the right to conduct an audit of the Contractor with 48 hours advance notice. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits/audits of subcontractor(s). At the discretion of the USG and independent of testing conducted by the Contractor, BARDA reserves the right to conduct site visits/audits and collect samples of product held by the Contractor and subcontractor(s).

Pre-award site visits may be made with short notice. Contractors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. PACKAGING OF PRODUCT

Packaging shall be consistent with the FDA-approved labeling and packaging for this product at the time of manufacture.

D.2. MARKING

Marking of product and shipping packages shall be in accordance with FDA-approved labeling direction to be provided at the time of manufacture.

D.3. DISTRIBUTION AND DEPLOYMENT/SHIPPING SERVICES

Shipping/deployment of products shall be in accordance with written authorization by the CO for each shipment. The USG may request a number of units to be delivered to the location of the emergency as requested by the CO in the Notification of Release of Product for each shipment.

All Products shall be labeled and packaged in accordance with GCP (Good Clinical Practices) and/or cGMP (Current Good Manufacturing Practices) as appropriate. Products shall be packed to ensure compliance with known product stability requirements that maintain satisfactory product temperatures during transit and arrival at destination. Products shall be packed to ensure maintenance of FDA recommended temperature during transit and safe arrival at destination

Concurrence on planned shipment protocols shall be obtained from HHS prior to transport.

D.3.1. SPECIFIC SHIPPING SERVICES

The USG may issue a Notification of Release of Product for shipment for a requested number of units to be delivered to a location as requested by the Contracting Officer or by an authorized representative designated by the CO.

The Contractor shall perform the following activities for distribution. Following the completion of packaging the product into cartons and master cartons, the master cartons shall be palletized in a pattern suitable for storage and eventual shipment. The pallet pattern shall be standardized for each product type such that the quantity shall be uniform across all full pallets in a lot. The master cartons on the full pallets and partial pallets, if one exists, shall be securely stretch wrapped to the pallet itself in order to prevent damage in transit.

The Contractor shall be responsible for delivering USG-owned product in a condition fit for its intended use to shorten the recovery time.

D.3.2. PACKAGE PRODUCT FOR PICKUP BY THE USG

The CO may request the Contractor to transfer product to the USG for pick up at the Contractor's VMI facility(s). The Contractor shall perform the following activities to prepare the product for pickup by the USG. Following the completion of packaging the product into cartons and master cartons, the master cartons shall be palletized in a pattern suitable for storage and eventual shipment. The pallet pattern shall be standardized for each product type such that the quantity shall be uniform across all full pallets in a lot. The master cartons on the full pallets and partial pallets, if one exists, shall be securely stretch wrapped to the pallet itself in order to prevent damage in transit.

D.3.3. AVITA MEDICAL PRODUCT SHIPPING

D3.3.1. Formal agreement with the following shipping carriers for domestic shipments:

- Air Shipments: UPS and FedEx, Landstar
- Ground Shipments: UPS, FedEx, LTL Select, Uber Freight, Landstar

D.3.3.2. Typical Delivery Timeframes:

- Domestic Air Shipping 1-2 business days

D.3.3.3. Risk Mitigation and Redundancy Measures:

- Multiple carriers
- Monthly carrier performance reviews
- Finished goods are stored in two separate buildings

Assuming air carriers are operating normally, then the most expedient way to deploy the devices will be to use the common carriers with whom we have contracts as delineated previously. If air travel is not operating normally, then ground transportation would be the alternative. Timeframes for delivery, assuming cross-country from California via air would be 24 hours or less, and ground transportation will depend on routes taken and delivery location, typically 5 business days.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

Inspection and acceptance of the product, services, and documentation (Certificate of Conformance) shall be shared via email with Contracting Officer or the designated Contracting Officer's Representative prior to product acceptance. Acceptance of a commercial product will be consistent with customary commercial practice under FAR 12.301(a).

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the designated COR within 30-days of receipt.

E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clauses by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR 52.246-2, Inspection of Supplies – Fixed-price (August 1996) (CLINs 001 – 005)
FAR 52.246-4 Inspection of Services-Fixed-Price (Aug 1996) (CLIN 002)
FAR 52.246-16, Responsibility for Supplies (April 1984) (CLINs 001 – 005)

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or designated COR consistent with customary commercial practice under FAR 12.301(a).

At the discretion of the Government and independent of activities conducted by the Contractor, with 48-hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48-hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance:

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within five business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The base period of performance of this contract is anticipated for a maximum of [***]-months from the date of award.

F.2. DELIVERIES

Successful performance of the final contract shall be deemed to occur upon performance of the work described in SECTION C of this RFP and upon delivery and acceptance of the items described in SECTION F.3 by the Contracting Officer or designated COR.

F.2.1. Place and method of delivery for Product purchased will be determined at the time of procurement or as determined necessary to respond to an emergency scenario. Refer to SECTIONS F.2.2, F.2.3, and F.2.4. for place and method of delivery requirements for those Items.

F.2.2. When distribution and shipping of product is ordered, delivery of the product and other deliverables shall be in accordance with FAR 52.247-34 entitled F.O.B. DESTINATION.

F.2.3. When product preparation for pick-up by the USG is ordered, delivery of drug product and other deliverables shall be in accordance with FAR 52.247-30 entitled F.O.B. ORIGIN, CONTRACTOR's FACILITY.

F.2.4. Place of Delivery: The Product shall be delivered as requested by the CO or authorized representative prior to time of delivery.

F.2.5. Manufacturers product stability requirements shall be maintained during shipping. If the Product is determined to be out of compliance, (if determined) will not be accepted or off-loaded from the Contractor's own or subcontracted conveyance but will be immediately returned to Contractor by the

same transport used for delivery, at the Contractor's cost. The Contractor shall be responsible for replacing the product that is not with compliance, at no additional cost to the Government.

F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.3.1. Submission of Contract Deliverables

Documents shall be delivered electronically via email to the Contracting Officer (CO), R. Anthony Hall at [***] and the Contracting Officer Representative (COR), Janelle Hurwitz at [***]. No hard copies will be accepted.

F.3.1. Reporting Requirements

The Contractor shall submit to the CO and the COR technical progress reports as identified in any potential resultant contract. These reports shall be subject to the technical inspection and requests for clarification by the COR, and approval by the CO/COR. These reports shall be brief, factual, and prepared in accordance with the following format:

A. Monthly Inventory Report

This report shall include a table of the available products within the Access-Maintenance VMI during each reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Inventory Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

The inventory report shall contain the following information:
a. Device/Unit SKU
b. Device/unit description/identifier (e.g., device/unit name, component name, etc.)
c. Quantity
d. Expiration date

Contracting Officer's Approvals – This section shall include a table indicating each Contracting Officer Approval (COA) request, its current status (e.g. date submitted, date approved, date returned), amount requested, and the vendor for which the COA authorizes subcontracted work to be performed.

Invoices: Summary of any invoices submitted during the reporting period.

A Monthly Inventory Report will not be required in the same month Annual Inventory Report is due.

B. Annual Inventory Report

This report shall include a summation of the product inventory rotations during the reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Inventory Report on or before the 30th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

The inventory report shall contain the following information:
a. Device/Unit SKU
b. Device/unit description/identifier (e.g., device/unit name, component name, etc.)
c. Quantity
d. Expiration date

Contracting Officer's Approvals – This section shall include a table indicating each Contracting Officer Approval (COA) request, its current status (e.g. date submitted, date approved, date returned), amount requested, and the vendor for which the COA authorizes subcontracted work to be performed.

Invoices: Summary of any invoices submitted during the reporting period.

C. FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions.

1. Within five business days of any formal meeting with the FDA or other regulatory agency related to the Contracted Products, the Offeror shall forward the initial draft minutes to the COR. The Offeror shall forward the final minutes when available. The Offeror may redact any information it deems to be confidential, strategic, proprietary, or unrelated to its performance under this RFP.

2. Within five business days of any informal meeting with the FDA or other regulatory agency related to the Contracted Products, the Offeror shall forward the initial draft minutes to the COR. The Offeror shall forward the final minutes when available and if applicable. The Offeror may redact any information it deems to be confidential, strategic, proprietary, or unrelated to its performance under this RFP.

3. The Offeror shall forward the dates and times of any meeting with the FDA and other regulatory agencies to the COR as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.

4. The Offeror shall provide the COR the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Offeror shall provide the COR with five (5) business days in which to review and provide comments back to the Offeror prior to the Offeror's submission to the FDA.

5. The Offeror shall forward Standard Operating Procedures (SOPs) upon request from the COR.

6. The Offeror shall provide raw data and/or specific analysis of data generated with USG funds upon request from the COR.

7. The Offeror shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency. The Offeror shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Offeror shall provide the Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. The Offeror shall also provide redacted copies of any FDA audits received from sub-Offerors that occur as a result of this contract or for this product. The redactions shall be limited to issues that are unrelated to the sub-offeror's performance on any award made under this RFP. The Offeror shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

D. Other Requirements/Deliverables

a) Risk Mitigation Plan/Matrix

The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template (See http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx) to be completed by any prospective Contractor. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

b) Press Releases

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

c) Security Report

The Contractor shall report to the government any activity; or incident that is in violation of established security standards; or indicates the loss or theft of government products. Reports shall be due within 24 hours after occurrence of an activity or incident.

d) Security Plan

See attachment 8 for security requirements and a template for the Security Plan.

e) Quality Management System Plan

The Contractor shall submit to the COR a Quality Management System Plan for approval no later than 60 days from the date of award.

f) Manufacturing Plan

The Contractor shall submit to the COR a comprehensive manufacturing plan for review and approval no later than 60 days from the date of award.

F.4. DELIVERABLE SCHEDULE

Item No.	Description	Email	Deliverable Schedule
1	Kickoff Meeting	CO: (1) electronic copy COR: (1) electronic copy	Within 30 days of award. Contractor shall provide agenda to CO/COR at least 5 business days in advance of meeting, and minutes within 5 business days after the meeting.
2	Monthly Meetings and Meeting Minutes	CO: (1) electronic copy COR: (1) electronic copy	Meeting minutes are due no later than five business days following each meeting.
3	Monthly Inventory Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 15th of each month following the end of each reporting period.
4	Annual Inventory Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 30th calendar day following the end of each reporting period.
5	Publications	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 30 calendar days for manuscripts and 15 calendar days for abstracts.
6	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices are due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
7	Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 24 hours after occurrence of an activity or incident.
8	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Final plan due within 30 days of contract award.
9	Manufacturing Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 60 days of contract award.
10	Quality Management System Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of contract award
11	Risk Mitigation Plan/Matrix	CO: (1) electronic copy COR: (1) electronic copy	Report is due within 90 days of contract award. Updates are due as requested by the COR.

SECTION G – CONTRACT ADMINISTRATION

AUTHORITIES OF GOVERNMENT PERSONNEL

Notwithstanding the Contractor's responsibility for total management during the period of performance, the administration of this contract will require maximum coordination between the Government and the Contractor.

The following individuals will be the Government's points of contact during the performance of this contract:

G.1. CONTRACTING OFFICER (CO)

R. Anthony Hall (Tony)
Contracting Officer – CBRN Contracts
Contract Management and Acquisition (CMA)
Center for the Biomedical Advanced Research & Development Authority (BARDA)
Administration for Strategic Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (DHHS)
Email: [***]

All communications pertaining to contractual and/or administrative matters under this contract shall be sent to the Contracting Officer.

The Contracting Officer is the only individual who can legally commit and bind the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract. Any other commitment, either explicit or implied, is invalid.

The CO is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of objectives; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) obligate or de-obligate funds into the contract; (6) sign written licensing agreements; or (7) otherwise change any terms and conditions of this contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract. NOTE: An unauthorized commitment is an agreement that is not binding solely because the Government representative who made it lacked the authority to enter into that agreement on behalf of the Government. An unauthorized commitment (UC) usually results in the receipt of goods or services on behalf of the Government by someone with apparent authority, but that lacks the authority to obligate the Government; it can be intentional or unintentional. Only a warranted contracting officer has authority to obligate government funds and contractually bind the government for supplies and services within their warrant authority.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The Government's Contracting Officer's Representative (COR) is:

Janelle Hurwitz MS, MBA, PMP
Biologist/Project Officer COR III, Burn and Blast Medical Countermeasures
Division of Chemical, Biological, Radiological and Nuclear Countermeasures
Center for the Biomedical Advanced Research and Development Authority
Administration for Strategic Preparedness and Response
U.S. Department of Health and Human Services
[***]

As delegated by the CO, the COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The COR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

Additionally, the COR is not empowered to, nor does he/she have the authority to, perform any of the following duties since, in accordance with FAR, they are reserved only for a Contracting Officer:

- Make changes to the contract terms and conditions,
- Direct the contractor to perform work or make deliveries not specifically required under the contract;
- Waive or relax the Government's rights, with regard to the Contractor's compliance with the specifications, price, delivery or any other terms or conditions of the task order; or,
- Make any commitments or approve any actions that would create any financial obligation on the part of the Government.

G.3. CONTRACTOR'S POINTS OF CONTACT

The Contractor shall provide primary and secondary points of contact that will be available 24 hours per day, 7 days per week, to be notified in case of a public health emergency.

Name and Title	Contract Role	Email	Phone
Niraj K. Doshi, Sr. Vice President – R&D, Product Dev. & Program Management	Program Manager	[***]	[***]
David E. Melbye, Sr. Vice President - Operations	Operations Manager	[***]	[***]

G.4. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) days' notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. **Key Personnel shall be limited to the minimal amount of personnel for successful completion of the contract as reasonably determined by Contractor.**

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Key Personnel Name and Title	Contract Role
Niraj K. Doshi, Sr. Vice President – R&D, Product Dev. & Program Management	Program Manager
David E. Melbye, Sr. Vice President - Operations	Operations Manager
Ron Lagerquist, Sr. Vice President - Regulatory, Clinical, and Quality	Regulatory, Clinical, and Quality Manager

G.5. INVOICE SUBMISSION

(a) The Contractor shall submit invoices electronically in accordance with HHSAR 352.232-71. As prescribed in HHSAR 332.7003, use the following clause :

Electronic Submission of Payment Requests

(a) Definitions. As used in this clause—

(1) "Payment request" means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at **www.ipp.gov** or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of Clause)

(b) Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP)

- All Invoice submissions for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).
- Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is : **https://www.ipp.gov.**
- The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.

    - Registration emails are sent via email from [***]. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to [***] or phone [***].
    - The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

- If your company is already registered to use IPP, you will not be required to re-register.
- If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

The Contractor agrees to include (as a minimum) the following information on each invoice:

(1) Contractor's Name & Address
(2) Contractor's Tax Identification Number (TIN)
(3) Requisition Number per CLIN or Task or as appropriate
(4) Contract Number
(5) Invoice Number
(6) Invoice Date
(7) Contract Line-Item Number and requisition
(8) Quantity
(9) Unit Price & Extended Amount for each line item
(10) Total Amount of Invoice
(11) Name, title and telephone number of the person(s) to be notified in the event of a defective invoice
(12) Payment Address, if different from the information in (b)(1).

The invoice shall be signed by a person authorized to bind the Contractor.

The Contractor shall not submit an invoice prior to delivery of goods or services.

The Contractor shall provide all invoices to the Contracting Officer and Contracting Officer's Representative for review and approval prior to submission to IPP.

G.6. GOVERNMENT PROPERTY

Not applicable at this time because the Government does not anticipate purchasing property for this performance of this acquisition apart from the deliverables. The USG shall pay a fee for the contractor to hold, and maintain in reserve, a negotiated level of commercially useable products for its intended purpose in delivery of care; and the entire reserved product inventory shall be made available to the USG under the Access-Maintenance Vendor Managed Inventory. Once products are shipped to a designated area, they will not be returned to the contractor's inventory or to the USG. If any Government Property shall be produced under this award, it shall be in accordance with 52.245-1 Government Property.

G.7. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number on all correspondences.

G.8. POST AWARD EVALUATION OF OFFEROR PERFORMANCE

In accordance with FAR Subpart 42.11 - Contractor Performance Information.

42.1100 Scope of subpart. This subpart provides policies and establishes responsibilities for recording and maintaining contractor performance information.

42.1101 General.

(a) Past performance information (including the ratings and supporting narratives) is relevant information, for future purposes, regarding a contractor's actions under previously awarded contracts or orders. It includes, for example, the contractor's record of-

(1) Conforming to requirements and to standards of good workmanship;

(2) Forecasting and controlling costs;\

(3) Adherence to schedules, including the administrative aspects of performance;

(4) Reasonable and cooperative behavior and commitment to customer satisfaction;

(5) Complying with the requirements of the small business subcontracting plan (see part 19), including:

(i) Favorable consideration of a mentor with an SBA-approved mentor-protégé agreement (see 13 CFR 125.9) that subcontracts to its protégé, and
(ii) That protégé is a covered territory business or that protégé's principal office is located in the Commonwealth of Puerto Rico (see 15 U.S.C. 632(ff));

(6) Reporting into databases (see part 4, and reporting requirements in the solicitation provisions and clauses referenced in part 9);

(7) Integrity and business ethics (see part 9); and

(8) Business-like concern for the interest of the customer.

(b) Agencies must monitor their compliance with the past performance evaluation requirements (see 42.1102) and use the Contractor Performance Assessment Reporting System (CPARS) metric tools to measure the quality and timely reporting of past performance information. CPARS is the official source for past performance information.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1- 800-HHS-TIPS (1-800- 447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services TIPS HOTLINE
P.O. Box 23489 Washington, D.C. 20026

H.2. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.3. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.4. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

H.5. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, and that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

H.6. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.7. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.8. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

H.9. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.10. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) Regulations (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packaging of this product.

If at any time during the life of the Contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, and purity of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the Contract may be terminated.

H.11. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded or furnished without proprietary restrictions under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.12. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment), all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.13. ACKNOWLEDGMENT OF FEDERAL FUNDING

Contractors funded with Federal dollars, in whole or in part, shall acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity. The Offeror shall acknowledge the support of the Department of Health and Human Services, Administration for Strategic Preparedness and Response, Center for the Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows: “This project has been funded in whole or in part with Federal funds from the Administration for Strategic Preparedness and Response, Center for the Biomedical Advanced Research and Development Authority, under Contract No. 75A50126C00003”.

Publication and Publicity (Not Including Press Releases)
No information related to data obtained under this contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in Section I of this contract, Contractors are required to state:

(1) The percentage and dollar amount of the total program or project costs financed with Federal money and;

(2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract “publication” is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows: “This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Center for the Biomedical Advanced Research and Development Authority, under Contract No. 75A50126C00003”.

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations; the Contractor shall ensure that the COR has

received an advance copy of any press release related to the contract not less than five (5) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Administration for Strategic Preparedness and Response, Center for the Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Center for the Biomedical Advanced Research and Development Authority, under Contract No. 75A50125C00012"

H.14. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive- legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

H.15. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

H.16. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under this contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.17. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty- eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.18. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.19. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days.

H.20. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

a. The Contractor shall not use any funds obligated under this contract for any abortion.
b. The Contractor shall not use any funds obligated under this contract for the following:

    i. The creation of a human embryo or embryos for research purposes; or

    ii. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

c. The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
d. The Contractor shall not use any Federal funds for the cloning of human beings.

H.21. FOREIGN TRANSFER OF ASSETS OR TECHNOLOGY

This clause shall remain in effect during the term of the Contract and for five (5) years thereafter.

a. Definitions

AFFILIATES: Associated business concerns, non-profit organizations, or individuals if, directly or indirectly, (1) either one controls or can control the other; or (2) a third party controls or can control both.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government ("USG") and Contactor in this Contract.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government (the "USG") and Contactor in this Contract.

FOREIGN FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of a country other than the United States of America (U.S.), its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

TECHNOLOGY: Technical Data, Computer Software, manufactured materials and Subject Inventions funded by the USG under this Contract. Technology also includes contractor know how and personnel expertise, as well as other Assets necessary to assure successful completion of this Contract.

U.S. FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of the United States, its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of the USG; and firms, institutions or business organizations which are owned or substantially controlled by U.S. citizens, firms, institutions, governmental agencies or individuals.

b. General

The Parties agree that research findings and technological developments made under this Contract constitute an investment by the USG on behalf of its citizens in the interest of their economic and national health security. These investments are made for the primary benefit of the citizenry of the U.S. with those same benefits potentially accruing to the people of all nations. Therefore, the USG has a fiduciary responsibility to protect the full invested value of the Assets and Technology developed under this Contract. The USG is also cognizant of the duty the Contractor has to its shareholders and other stakeholders with a vested interested in the economic success of the Contractor. At times both parties are aware their respective interests may diverge. Therefore, in the course of conducting business though the Contract, access to technology developments under this Contract by Foreign Firms or Institutions must be carefully considered.

c. Export Controls

Contractor agrees to comply with all applicable laws regarding export controls and not to export any Asset or Technology to any U.S. embargoed countries.

d. Post-award Transfer of Ownership of Assets or Technology

The Contractor shall provide notice to the Contracting Officer and COR within three (3) business days of any discussions of a proposed transfer of ownership or establishment of a licensing agreement of any Asset or Technology funded under this Contract from the Contractor to a Foreign Firm or Institution.Notice will also be given within three (3) business days of any discussions of a proposed transfer of operational, corporate, or economic control of Assets and Technology funded under this Contract to Foreign Firms or Institutions. This Article shall not apply to transfers by the Contractor to Affiliated entities of the Contractor, as well as technology transfers for the purposes of manufacturing in accordance with the Statement of Work.

Prior to transferring any Asset funded by the USG under this Contract, the Contractor should carefully review the USG rights under FAR Subpart 42.9 - Novation and Change-of-Name Agreements, specifically FAR section 42.903 Applicability of novation agreements. That provision provides that the USG may recognize a third party assignment only if the transfer of Assets and Technology is determined to be in the USG's interests. The Contractor should be aware that the USG is under no obligation to recognize a successor in interest. If the Contracting Officer determines that a transfer of Assets and Technology may have adverse consequences to the economic well-being or national health security interests of the U.S., the Contractor, and the Contracting Officer shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which may provide substantially equivalent benefits to the Contractor.

In addition to the USG licensing rights to subject inventions and technical data funded under this Contract, see FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor) and FAR Clause 52.227-14 (Rights in Data - General), the USG shall have a first right of refusal for the purchase of the Asset and/or Technology funded under the Contract. The USG may waive this first right of refusal in writing submitted to the Contractor within ninety (90) calendar days of the initial notification to the USG of the Contractor's intent to conduct any form of Asset or corporate transfer.

Except for transfers to affiliates of the Contractor, including those entities necessary to complete the Statement of Work, the Contractor shall provide written notice to the Contracting Officer and COR of the scheduled transfer to a Foreign Firm or Institution at least ninety (90) calendar days prior to the scheduled date of transfer. Such notice shall cite this Article and shall specifically identify the Asset or Technology proposed for the transfer and the general terms of the transfer. No transfer shall take place without written concurrence from the Contracting Officer.

e. Transfer to a Prohibited Source

In the event of a transfer of an Asset and/or Technology by the Contractor to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to Federal Acquisition Regulation Subpart 25.7: (a) the Government may terminate this contract for cause and (b) the license rights to the technical data and subject invention under the relevant FAR IP Clauses (FAR Clause 52.227-11 and FAR Clause 52-227-14) shall survive the termination. Upon request of the USG, the Contractor shall provide written confirmation of such licenses.

f. Lower Tier Agreements

The Contractor shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier.

H.22. SUBCONTRACTING PROVISIONS (Not Required)

H.23. NOTICE PRIOR TO PUBLICATION

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this Contract without written advanced notice to the CO, provided that no such notice is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any USG entity; for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing, or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.24. DISSEMINATION OF INFORMATION

No information related to data obtained under this Contract shall be released or publicized without the prior written notice to the CO, whose response shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any USG entity for submission to any securities exchange on which the

Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.25. CERTIFICATION OF FILING AND PAYMENT OF TAXES

The Contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

H.26. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.27. INSPECTIONS & COLLECTION OF SAMPLES

At the discretion of the USG and independent of testing conducted by the Contractor, the USG reserves the right to conduct site visits and collect samples of Product held by the Contractor. The USG reserves the right to conduct inspections of all aspects of the contracted project including, but not limited to, the manufacturing plant and production records, testing and development laboratories, regulatory files and QMS records.

H.28. REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF CONTRACTORS

The Representations, Certifications and Other Statements of Contractors submitted by the Contractor dated March 1 2013 are hereby incorporated by reference, with the same force and effect as if they were given in full text.

H.29. MATERIAL COMPLIANCE REQUIREMENT

Contractor agrees that full compliance with the terms of Executive Order Number 14292 titled Improving the Safety and Security of Biological Research (the "Order") and any applicable regulations is material to the Government's payment decisions for purposes of 31 U.S.C. § 3729(b)(4), consistent with existing laws and regulations.

H.30. CERTIFICATION REGARDING RESEARCH ACTIVITIES

By executing this contract, Contractor certifies that it does not operate, participate in, or fund any dangerous gain-of-function research or other life-science research conducted in foreign countries that could cause significant societal consequences or generate unnecessary national security risks, and that all such activities, if any, are in full compliance with the Order and the policies set forth therein.

H.31. INSTITUTIONAL RESPONSIBILITY FOR VIOLATIONS

The Contractor acknowledges and agrees that any individual who commits a violation of The Order or applicable regulations, that violation may be deemed a violation by the recipient's employer or affiliated institution.

H.32. CONSEQUENCES OF NONCOMPLIANCE

The Contractor further acknowledges that any recipient, employer, or institution found to be in violation of the Order or applicable regulations may be subject to immediate revocation of ongoing Federal funding and may be rendered ineligible for Federal life-sciences grant funds offered by the Department of Health and Human Services and other relevant agencies for a period of up to five (5) years.

H.33. Compliance with Executive Order Number 14292:

1. Material Compliance Requirement

Contractor agrees that full compliance with the terms of Executive Order Number 14292 titled Improving the Safety and Security of Biological Research (the "Order") and any applicable regulations is material to the Government's payment decisions for purposes of 31 U.S.C. § 3729(b)(4), consistent with existing laws and regulations.

2. Certification Regarding Research Activities

By executing this contract, Contractor certifies that it does not operate, participate in, or fund any dangerous gain-of-function research or other life-science research conducted in foreign countries that could cause significant societal consequences or generate unnecessary national security risks, and that all such activities, if any, are in full compliance with the Order and the policies set forth therein.

3. Institutional Responsibility for Violations

The Contractor acknowledges and agrees that any individual who commits a violation of The Order or applicable regulations, that violation may be deemed a violation by the recipient's employer or affiliated institution.

4. Consequences of Noncompliance

The Contractor further acknowledges that any recipient, employer, or institution found to be in violation of the Order or applicable regulations may be subject to immediate revocation of ongoing Federal funding and may be rendered ineligible for Federal life-sciences grant funds offered by the Department of Health and Human Services and other relevant agencies for a period of up to five (5) years.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at:
https://www.acquisition.gov/far-overhaul/far-part-deviationn-guide

System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations, including 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation, and paragraph (t) of 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services. Agencies will not consider or use these representations. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jun 2020	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-7	Jun 2020	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-11	Sep 2024	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions
FAR	52.203-12	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Nov 2021	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Nov 2021	Display of Hotline Poster(s)
FAR	52.203-17	Nov 2023	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-18	Jan 2017	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation.
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-5	Oct 2014	Women-Owned Business (Other than Small Business)
FAR	52.204-7	Nov 2025	System for Award Management
FAR	52.204-10	Nov 2025	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Nov 2025	System for Award Management Maintenance
FAR	52.204-14	Nov 2025	Service Contract Reporting Requirements
FAR	52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
FAR	52.209-5	Nov 2025	Certification Regarding Responsibility Matters
FAR	52.209-6	Nov 2025	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Nov 2025	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2025	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Nov 2025	Market Research
FAR	52.215-2	Nov 2025	Audit and Records – Negotiation
FAR	52.215-8	Nov 2025	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Nov 2025	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.

FAR	52.215-12	Nov 2025	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Nov 2025	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Nov 2025	Integrity of Unit Prices
FAR	52.215-15	Nov 2025	Pension Adjustments and Asset Reversions
FAR	52.215-18	Nov 2025	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Nov 2025	Notification of Ownership Changes
FAR	52.215-21	Nov 2025	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications
FAR	52.215-22	Nov 2025	Limitations on Pass-Through Charges-Identification of Subcontract Effort
FAR	52.215-23	Nov 2025	Limitations on Pass-Through Charges
FAR	52.216-4	Jan 2017	Economic Price Adjustment-Labor and Material
FAR	52.216-7	Nov 2025	Allowable Cost and Payment
FAR	52.217-2	Oct 1997	Cancellation Under Multi-year Contracts
FAR	52.217-8	Nov 1999	Option to Extend Services
FAR	52.217-9	Mar 2000	Option to Extend the Term of the Contract
FAR	52.219-8	Nov 2025	Utilization of Small Business Concerns
FAR	52.219-9	Nov 2025	Small Business Subcontracting Plan
FAR	52.219-16	Nov 2025	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	Nov 2025	Post-Award Small Business Program Rerepresentation
FAR	52.222-3	Nov 2025	Convict Labor
FAR	52.222-35	Nov 2025	Equal Opportunity for Veterans
FAR	52.222-36	Nov 2025	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Nov 2025	Employment Reports on Veterans
FAR	52.222-40	Nov 2025	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-41	Nov 2025	Service Contract Labor Standards
FAR	52.222-43	Nov 2025	Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts)
FAR	52.222-50	Nov 2025	Combating Trafficking in Persons
FAR	52.222-54	Nov 2025	Employment Eligibility Verification
FAR	52.223-23	Nov 2025	Sustainable Products and Services
FAR	52.225-5	Nov 2023	Trade Agreements
FAR	52.226-7	May 2024	Drug-Free Workplace
FAR	52.226-8	May 2024	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.227-1	Jun 2020	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
FAR	52.227-16	Jun 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.230-2	Nov 2025	Cost Accounting Standards
FAR	52.230-6	Jun 2020	Administration of Cost Accounting Standards
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Nov 2025	Limitation of Cost
FAR	52.232-22	Nov 2025	Limitation of Funds
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-32	Apr 2012	Performance-Based Payments
FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Mar 2023	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	Nov 2025	Disputes

FAR	52.233-3	Nov 2025	Protest After Award
FAR	52.233-4	Nov 2025	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	Nov 2025	Penalties for Unallowable Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.242-15	Aug 1989	Stop-Work Order
FAR	52.243-1	Nov 2025	Changes - Fixed-Price Alternate V (Apr 1984).
FAR	52.243-6	Nov 2025	Change Order Accounting
FAR	52.243-7	Nov 2025	Notification of Changes
FAR	52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
FAR	52.244-5	Aug 2024	Competition in Subcontracting
FAR	52.244-6	Nov 2025	Subcontracts for Commercial Items
FAR	52.245-1	Sep 2021	Government Property
FAR	52.246-2	Aug 1996	Inspection of Supplies – Fixed Price
FAR	52.246-4	Aug 1996	Inspection of Services – Fixed Price
FAR	52.246-16	Apr 1994	Responsibility for Supplies
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.247-30	Feb 2006	F.O.B. Origin, Contractor's Facility
FAR	52.247-34	Jan 1991	F.O.B. Destination
FAR	52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
FAR	52.249-4	Apr 1984	Termination for Convenience of the Government (Services) (Short Form)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Nov 2025	Computer Generated Forms

"System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations.

I.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES

Full text of the HHSAR clauses can be found at https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Feb 2026	Printing and Duplication
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Feb 2024	Privacy Act
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.231-70	Feb 2026	Salary Rate Limitation
HHSAR	352.232-71	Feb 2022	Electronic Submission of Payment Requests
HHSAR	352.237-75	Dec 2015	Key Personnel

I.3. ADDITIONAL CONTRACT CLAUSES

I.3.1. Additional Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses – In Full Text

52.212-4 Terms and Conditions—Commercial Products and Commercial Services.

As prescribed in 12.205(b)(3), insert the following clause:

TERMS AND CONDITIONS—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (DEVIATION DATE)

(a) *Definitions*. The clause at Federal Acquisition Regulation (FAR) 52.202-1, Definitions, is incorporated by reference.

(b) *Inspection/Acceptance*. The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post acceptance rights—

(1) Within a reasonable time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(c) *Assignment*. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (*e.g.,* use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(d) *Changes*. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(e) *Disputes*. This contract is subject to 41 U.S.C. chapter 71, Contract Disputes. Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal, or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause FAR 52.233-1, Disputes, which is incorporated in this contract by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(f) *Excusable delays*. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence. Examples of occurrences include acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. When an excusable delay occurs, the Contractor shall—

(1) Notify the Contracting Officer in writing as soon as possible;

(2) Remedy the delay as quickly as possible; and

(3) Notify the Contracting Officer when the occurrence is over.

(g) Invoice. The Government will handle invoices according to the Prompt Payment Act (31 U.S.C. 3903) and 5 CFR part 1315. The Contractor shall submit invoices to the address designated in the contract to receive invoices. An invoice must include the information required by 5 CFR part 1315.9(b).

(h) *Patent indemnity*. The Contractor shall indemnify the Government and its officers, employees, and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark, or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) *Payment*—

(1) *Items accepted*. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) *Prompt payment*. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.

(3) *Discount*. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date that appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(4) *Overpayments*. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—

(A) Circumstances of the overpayment (*e.g.*, duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected line item or subline item, if applicable;

(D) Contractor point of contact; and

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(5) *Interest*.

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) *Final decisions*. The Contracting Officer will issue a final decision as required by FAR part 33 if–

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see FAR part 32).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a termination for cause.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on-

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures for interest credits prescribed in FAR part 32 in effect on the date of this contract.

(j) *Risk of loss*. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon—

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) *Taxes*. The contract price includes all applicable Federal, State, and local taxes and duties.

(l) *Termination for the Government's convenience*. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) *Termination for cause*. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. The Government will send a cure notice to the Contractor, unless the reason for the termination is late delivery. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) *Title*. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) *Warranty*. The Contractor warrants and implies that the items delivered under this contract are merchantable and fit for use for the particular purpose described in this contract.

(p) *Limitation of liability*. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) *Compliance with laws unique to Government contracts*. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 49 U.S.C. 40118, Government-financed air transportation; and 41 U.S.C. chapter 21 relating to procurement integrity.

(r) *Order of precedence*. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services;

(2) The Disputes, Payments, Invoice, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause;

(3) Other contract clauses incorporated in the solicitation or contract;

(4) Addenda to this solicitation or contract;

(5) Solicitation provisions incorporated in the solicitation;

(6) Other paragraphs of this clause;

(7) Other documents, exhibits, and attachments; and

(8) The specification.

(s) *Unauthorized obligations*.

(1) Except as stated in paragraph (s)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government-authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an “I agree” click box or other comparable mechanism (e.g., “click-wrap” or “browse-wrap” agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (s)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(t) *Comptroller General examination of record*. This paragraph applies if this contract was awarded using other than sealed bid procedures and is in excess of the simplified acquisition threshold on the date of award of this contract.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor’s directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices, at all reasonable times, the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR part 4, longer period required by statute, or periods specified in other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after

any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This clause does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(u) *Incorporation by reference*. The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of clause)

FAR 52.216-2 Economic Price Adjustment—Standard Supplies (Nov 2021)

(a) The Contractor warrants that the unit price stated in the Schedule for _____[offeror insert Schedule line item number] is not in excess of the Contractor's applicable established price in effect on the contract date for like quantities of the same item. The term "unit price" excludes any part of the price directly resulting from requirements for preservation, packaging, or packing beyond standard commercial practice. The term "established price" means a price that-

(1) Is an established catalog or market price for a commercial product sold in substantial quantities to the general public; and

(2) Is the net price after applying any standard trade discounts offered by the Contractor.

(b) The Contractor shall promptly notify the Contracting Officer of the amount and effective date of each decrease in any applicable established price. Each corresponding contract unit price shall be decreased by the same percentage that the established price is decreased. The decrease shall apply to those items delivered on and after the effective date of the decrease in the Contractor's established price, and this contract shall be modified accordingly.

(c) If the Contractor's applicable established price is increased after the contract date, the corresponding contract unit price shall be increased, upon the Contractor's written request to the Contracting Officer, by the same percentage that the established price is increased, and the contract shall be modified accordingly, subject to the following limitations:

(1) The aggregate of the increases in any contract unit price under this clause shall not exceed 10 percent of the original contract unit price.

(2) The increased contract unit price shall be effective-

(i) On the effective date of the increase in the applicable established price if the Contracting Officer receives the Contractor's written request within 10 days thereafter; or

(ii) If the written request is received later, on the date the Contracting Officer receives the request.

(3) The increased contract unit price shall not apply to quantities scheduled under the contract for delivery before the effective date of the increased contract unit price, unless failure to deliver before that date results from causes beyond the control and without the fault or negligence of the Contractor, within the meaning of the Default clause.

(4) No modification increasing a contract unit price shall be executed under this paragraph (c) until the Contracting Officer verifies the increase in the applicable established price.

(5) Within 30 days after receipt of the Contractor's written request, the Contracting Officer may cancel, without liability to either party, any undelivered portion of the contract items affected by the requested increase.

(d) During the time allowed for the cancellation provided for in paragraph (c)(5) of this clause, and thereafter if there is no cancellation, the Contractor shall continue deliveries according to the contract delivery schedule, and the Government shall pay for such deliveries at the contract unit price, increased to the extent provided by paragraph (c) of this clause.

(End of clause)

FAR 52.217-2 Cancellation Under Multi-year Contracts

CANCELLATION UNDER MULTI-YEAR CONTRACTS (OCT 1997)

(a) "Cancellation," as used in this clause, means that the Government is canceling its requirements for all supplies or services in program years subsequent to that in which notice of cancellation is provided. Cancellation shall occur by the date or within the time period specified in the Schedule, unless a later date is agreed to, if the Contracting Officer-

(1) Notifies the Contractor that funds are not available for contract performance for any subsequent program year; or

(2) Fails to notify the Contractor that funds are available for performance of the succeeding program year requirement.

(b) Except for cancellation under this clause or termination under the Default clause, any reduction by the Contracting Officer in the requirements of this contract shall be considered a termination under the Termination for Convenience of the Government clause.

(c) If cancellation under this clause occurs, the Contractor will be paid a cancellation charge not over the cancellation ceiling specified in the Schedule as applicable at the time of cancellation.

(d) The cancellation charge will cover only-

(1) Costs-

(i) Incurred by the Contractor and/or subcontractor;

(ii) Reasonably necessary for performance of the contract; and

(iii) That would have been equitably amortized over the entire multi-year contract period but, because of the cancellation, are not so amortized; and

(2) A reasonable profit or fee on the costs.

(e) The cancellation charge shall be computed and the claim made for it as if the claim were being made under the Termination for Convenience of the Government clause of this contract. The Contractor shall submit the claim promptly but no later than 1 year from the date-

(1) Of notification of the nonavailability of funds; or

(2) Specified in the Schedule by which notification of the availability of additional funds for the next succeeding program year is required to be issued, whichever is earlier, unless extensions in writing are granted by the Contracting Officer.

(f) The Contractor's claim may include-

(1) Reasonable nonrecurring costs (see subpart 15.4 of the Federal Acquisition Regulation) which are applicable to and normally would have been amortized in all supplies or services which are multi-year requirements;

(2) Allocable portions of the costs of facilities acquired or established for the conduct of the work, to the extent that it is impracticable for the Contractor to use the facilities in its commercial work, and if the costs are not charged to the contract through overhead or otherwise depreciated;

(3) Costs incurred for the assembly, training, and transportation to and from the job site of a specialized work force; and

(4) Costs not amortized solely because the cancellation had precluded anticipated benefits of Contractor or subcontractor learning.

(g) The claim shall not include-

(1) Labor, material, or other expenses incurred by the Contractor or subcontractors for performance of the canceled work;

(2) Any cost already paid to the Contractor;

(3) Anticipated profit or unearned fee on the canceled work; or

(4) For service contracts, the remaining useful commercial life of facilities. "Useful commercial life" means the commercial utility of the facilities rather than their physical life with due consideration given to such factors as location of facilities, their specialized nature, and obsolescence.

(h) This contract may include an Option clause with the period for exercising the option limited to the date in the contract for notification that funds are available for the next succeeding program year. If so, the Contractor agrees not to include in option quantities any costs of a startup or nonrecurring nature that have been fully set forth in the contract. The Contractor further agrees that the option quantities will reflect only those recurring costs and a reasonable profit or fee necessary to furnish the additional option quantities.

(i) Quantities added to the original contract through the Option clause of this contract shall be included in the quantity canceled for the purpose of computing allowable cancellation charges.

(End of clause)

FAR 52.217-6 Option for Increased Quantity (Mar 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 15-days. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of clause)

PART III – ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following Attachments are provided with this Solicitation:

1. Attachment 1 - Statement of Work
2. Attachment 2 - Miscellaneous Payment Enrollment Form
3. Attachment 3 - Sample Invoice/Payment Request And Contract Financial Report
4. Attachment 4 - Disclosure Of Lobbying Activities, With Instructions
5. Attachment 5 - Risk Mitigation Plan/Matrix Template
6. Attachment 6 - BARDA Security Requirements
7. Attachment 7- Security Plan Template With Instructions

Attachment #1 Statement of Work (SOW)

FDA-Approved Autograft Sparing Device for National Preparedness

1. Introduction

This Statement of Work (SOW) defines the tasks, deliverables, service levels, and acceptance criteria for AVITA Medical's provision of FDA-approved RECELL® devices under an Access-Maintenance model for national preparedness. The SOW is organized by Contract Line Item Number (CLIN) and aligns with the structure and pricing described in Volume III – Business Proposal. Unless otherwise directed by the Contracting Officer (CO), this SOW governs the execution of work under the awarded contract.

See Appendix A (Past Performance & Utilization) and Appendix B (Sales Velocity) for supporting data.

2. Background and Objectives

AVITA Medical will maintain, rotate, and deploy RECELL devices for rapid response to burn mass casualty incidents and surge scenarios. Objectives include: maintaining [***] units; providing 24-hour deployment readiness; conducting mock deployments; and scaling manufacturing capacity to meet surge procurement as directed by the USG.

3. Definitions and Acronyms

Access-Maintenance: Commercially held inventory designated for USG right-of-first-access and immediate procurement.

BARDA: Center for the Biomedical Advanced Research and Development Authority.

CO/COR: Contracting Officer / Contracting Officer's Representative.

QMS/QSR: Quality Management System / 21 CFR 820 Quality System Regulation.

RECELL Devices: FDA-approved RECELL systems and kits offered under this contract (e.g., RECELL GO, GO Mini, Ease-of-Use).

4. Place of Performance

AVITA Medical manufacturing and warehousing sites (Ventura, CA) and other qualified facilities as necessary to perform packaging and shipment. Deployments will be shipped to USG-designated receiving sites.

5. Reporting Requirements

AVITA Medical shall provide the following reports, unless otherwise directed by the CO/COR:

- Monthly inventory reports (SKU, description, quantity, expiration dates) for Access-Maintenance units.
- Annual inventory report.
- Risk mitigation plan/matrix (initial and updates as required).
- Security plan/report and quality management plan.
- Manufacturing plan and surge readiness updates.
- Incident notifications within one (1) business day for any event affecting deployment readiness or product quality.

6. Quality, Compliance, and Security

AVITA shall maintain an ISO 13485-compliant Quality Management System aligned with 21 CFR 820. All activities covered by this SOW shall follow cGMP and GDP practices, validated processes, and change control. Electronic systems impacting quality data shall remain validated and compliant. AVITA shall maintain physical security and cybersecurity controls consistent with its Security Plan (e.g., access control, CCTV, ISO 27001-aligned IT controls).

7. Cross-CLIN Assumptions and Dependencies

Emergency shelf-life: For deployments under CLIN 003 and CLIN 005, all devices shipped to the USG will have at least three (3) months of remaining shelf-life at time of shipment.

8. CLIN 001 — Initial Procurement of Maintained Product (up to [***] units)

8.1. Scope:

Provide immediate procurement access to up to [***] RECELL devices held in AVITA's Access-Maintenance inventory.

8.2. Tasks

1) Maintain [***] units designated for USG right-of-first-access.
2) Rotate lots using FIFO/FEFO.
3) Provide monthly inventory reports (SKU, quantity, expiration).
4) Prepare units for shipment within 24 hours of written USG request.

8.3. Deliverables & Acceptance

- D1: Monthly inventory report.
- D2: Shipment acknowledgement and tracking information within 24 hours of notice.

Acceptance: USG acceptance upon verification of report completeness and confirmed receipt at designated site(s).

8.4. Service Level Agreements (SLAs)

Not applicable.

9. CLIN 002 — Access‑Maintenance Inventory Holding Fee

9.1. Scope

Hold, rotate, and report on [***] Access‑Maintenance units; sustain validated packaging and shipping readiness; maintain 24/7 emergency contact availability; and support mock deployment exercises and audits.

9.2. Tasks

1) Maintain inventory and lot rotation for [***] units.
2) Provide monthly inventory reporting and an annual inventory summary.
3) Maintain validated packaging and shipping methods for ambient shipments.
4) Provide 24/7 contact list for emergency deployment.
5) Conduct up to three (3) synchronized mock deployments across the PoP.
6) Maintain QMS documents, audit readiness, and change control per QSR/ISO 13485.

9.3. Deliverables & Acceptance

- D1: Monthly/annual inventory reports.
- D2: Updated contact list and deployment SOPs.
- D3: Mock deployment after-action reports.

Acceptance: USG acceptance of reports and completion of exercises per the schedule.

9.4. SLAs
Not applicable.

10. CLIN 003 — Emergency Deployment Readiness (Initial [***] units)

10.1. Scope
See Appendix A (Past Performance & Utilization) and Appendix B (Sales Velocity) for supporting data.
Packaging and shipment readiness for the initial [***] units, including execution of up to three (3) mock deployment exercises over the PoP. Upon USG activation, package and ship to designated sites within 24 hours.

10.2. Tasks
1) Maintain deployment kits and materials for ambient shipping.
2) Upon activation, prepare shipping documents, labels, and palletization as applicable. (Reference Work Instruction 7.18.9 “USG Communication Procedure” & Work Instruction 7.2.1 “Product Shipping”)
3) Handoff to commercial carrier for next-day air/ground, or stage for SNS/USG pick-up.
4) Provide real-time tracking and delivery confirmation.
5) Conduct three (3) mock deployments during the contract and provide after-action reports.

10.3. Deliverables & Acceptance
- D1: Shipment tracking details within 24 hours of activation.
- D2: Proof of delivery confirmation.
- D3: Mock deployment after-action reports.

Acceptance: USG acceptance upon delivery confirmation and receipt of required reports.

10.4. SLAs
- Packaging and shipment handoff within 24 hours of written activation.
- Provide delivery confirmation within one (1) business day of receipt at destination.
- Minimum remaining shelf-life at emergency shipment: ≥ 3months.

10.5. Notes — Packaging vs. Shipping Cost Assumptions
- Costs are separated for transparency and invoicing: Packaging ([***] units): $[***]; Shipping ([***] units): $[***] (flat-rate scenario).
- Packaging includes cartons/inserts, tamper-evident seals, labels, documentation, labor for kitting, palletization, and staging.
- Shipping includes commercial air/ground freight, accessories, fuel surcharges, and carrier handling; modeled as a cross-country air scenario for all [***] units.
- Units are packed in 1- or 3-packs and palletized based on total volume; real-time tracking and proof of delivery are provided.
- If SNS/USG elects to pick up at AVITA Ventura, only Packaging will be invoiced; no Shipping will be charged.

11. CLIN 004 — Surge Manufacturing Ramp‑Up (up to[***] Units)

11.1. Scope
See Appendix A (Past Performance & Utilization) and Appendix B (Sales Velocity) for supporting data.
Upon USG surge procurement, AVITA will ramp manufacturing, packaging, sterilization, and QA release for up to [***] additional units. A delivery schedule will be provided within five (5) business days of the surge order.

11.2. Tasks

1) Coordinate suppliers and outside sterilization/testing to meet accelerated timelines.
2) Build and release lots in waves per the agreed ramp schedule.
3) Maintain validated packaging and shipping readiness for all ramp-up units.
4) Provide weekly production status updates to CO/COR during ramp intervals.

11.3. Deliverables & Acceptance

- D1: Surge delivery schedule within five (5) business days of order.
- D2: Weekly status updates during ramp-up; final lot-release documentation. Acceptance: USG acceptance upon verification against the surge schedule and receipt of release docs.

11.4. SLAs

- Provide initial schedule within 5 business days of surge order.
- Meet mutually agreed wave-by-wave delivery dates.
- Maintain quality release and shipment readiness upon lot completion.

12. CLIN 005 — Emergency Deployment for Ramp-Up Units

12.1. Scope

See Appendix A (Past Performance & Utilization) and Appendix B (Sales Velocity) for supporting data.

Ambient-condition packaging and shipment (or staging for SNS pick-up) of surge units produced under CLIN 004. Upon USG activation, package and handoff per the agreed deployment plan.

12.2. Tasks

1) Package ramp-up units for air/ground shipment or SNS pick-up. (Reference Work Instruction 7.18.9 “USG Communication Procedure” & Work Instruction 7.2.1 “Product Shipping”)
2) Coordinate carrier booking, palletization, and loading for bulk shipments.
3) Provide tracking and delivery confirmation for all shipments.

12.3. Deliverables & Acceptance

- D1: Shipment tracking details for each wave of ramp-up units.
- D2: Proof of delivery confirmation for each destination site. Acceptance: USG acceptance upon delivery confirmation.

12.4. SLAs

- Shipment handoff timelines per surge deployment plan.
- Delivery confirmation within one (1) business day of site receipt.
- Minimum remaining shelf-life at emergency shipment: ≥ 3 months.

12.5. Notes — Packaging vs. Shipping Cost Assumptions

- Costs are separated for transparency and invoicing: Packaging ([***] units): $[***]; Shipping ([***] units): $[***] (flat-rate scenario).
- Packaging includes cartons/inserts, tamper-evident seals, labels, documentation, labor for kitting, palletization, and staging.
- Shipping includes commercial air/ground freight, accessorial, fuel surcharges, and carrier handling; modeled as a cross-country air scenario for all [***] units.
- Units are packed in 1- or 3-packs and palletized based on total volume; real-time tracking and proof of delivery are provided.
- If SNS/USG elects to pick up at AVITA Ventura, only Packaging will be invoiced; no Shipping will be charged.

13. Invoicing and Data Requirements
AVITA shall invoice by CLIN in accordance with the executed contract and CO/COR direction. For deployment CLINs, invoices shall clearly separate packaging and shipping
when required, and identify any USG/SNS pick-up scenarios where only packaging is invoiced.

14. Change Management
Changes to scope, deliverables, or SLAs shall be effected only via written contract modification or CO-approved change request. AVITA shall maintain internal change control per QMS procedures for any process or documentation updates relevant to this SOW.

15. Acceptance of the SOW
The Parties acknowledge that this SOW aligns with the Business Proposal CLIN structure and shall be updated if the USG directs changes during negotiations, award, or performance. AVITA will incorporate any CO-directed adjustments.

Appendix A — Past Performance & Utilization (Summary)
This appendix summarizes AVITA's historical training and utilization of RECELL across burn and full-thickness skin defect (FTSD) indications. Active users performed ≥1 procedure within the calendar year. Trained personnel include attendings, fellows, residents, nurses, and OR staff.

Metric	2019	2020	2021	2022	2023	2024
Certified Accounts	[***]	[***]	[***]	[***]	[***]	[***]
Certified Surgeons & Staff	[***]	[***]	[***]	[***]	[***]	[***]
Active Accounts	[***]	[***]	[***]	[***]	[***]	[***]
Active Surgeons & Staff	[***]	[***]	[***]	[***]	[***]	[***]

Notes: Figures reflect cumulative certified and actively using sites and personnel by calendar year.

Appendix B — Sales Velocity (Calendar Year 2024)
The following table summarizes the number of RECELL kits sold by quarter in 2024.

Q1 2024	Q2 2024	Q3 2024	Q4 2024
[***]	[***]	[***]	[***]

Change from Q1 to Q4: +[***]%.

ATTACHMENT #2

MISCELLANEOUS PAYMENT ENROLLMENT FORM

Payment Information Form
The information requested on this form concerns your financial institution, your account at that institution, and personal information which needs to verified and completed.

Privacy Act Statement
The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 USC 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to your financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

Check one of the following:

☐ Federal Employee: ☐ Contractor: ☐ Vendor:

Name: _____

Business Address: _____

_____

Remit To
(If same as above, leave blank. Must match address on invoice for internal control purposes.)
Address: _____

_____

Taxpayer Identification # (TIN): _____
(If you are an individual, this may be your Social Security number)
1. Payee's Telephone Number: (_____) _____

The following information must be completed by your financial institution representative:

2. Name of Financial Institution: _____

3. Address of Financial Institution:

_____

_____

_____

4. Financial Institution's 9-digit ABA Routing Number for

Transfer of Funds: _____
5. Depositor Account Title: _____

6. Depositor Account Number:														

7. Type of Account: Ch king ☐ Savings ☐

8. Signature and Title of Authorized Official of Financial Institution:

_____

Telephone Number: (_____) _____Date: _____

********** The following must be signed by the payee**********

I have verified the information on this form.

_____ _____
Signature Date

ATTACHMENT #3
SAMPLE INVOICE/PAYMENT REQUEST – TABLE 1

Standard Form 1034 Revised October 1967 Department of the Treasury 1 TFM 4-2000 1034-121	**PUBLIC VOUCHER FOR PURCHASES AND SERVICES OTHER THAN PERSONAL**	VOUCHER NO. (invoice number)

U.S. DEPARTMENT, BUREAU, OR ESTABLISHMENT AND LOCATION	DATE VOUCHER PREPARED	SCHEDULE NO.
DHHS/ASPR/BARDA/CMA Attn: R. Anthony Hall, Contracting Officer US Dept of Health & Human Services Administration of Strategic Preparedness & Response Division of Contract Management & Acquisitions Constitution Center Washington, D.C. 20024	Ending date of work (not prior to) CONTRACT NUMBER AND DATE Block 2 & 3 on SF 26 of Base Contract REQUISITION NUMBER AND DATE Block 4 on SF 26 of Base Contract	PAID BY

PAYEE'S NAME AND ADDRESS
Contractor's Name
Street Address and Suite City/Town, State, Zip Code

Name, Title, Phone Number, and Email Address of person to notify in event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent.

DATE INVOICE RECEIVED

DISCOUNT TERMS

PAYEE'S ACCOUNT NUMBER

SHIPPED FROM | TO | WEIGHT | GOVERNMENT B/L NUMBER

NUMBER AND DATE OF ORDER	DATE OF DELIVERY OR SERVICE	ARTICLES OR SERVICES *(Enter description, item number of contract or Federal supply schedule, and other information deemed necessary)*	QUANTITY	UNIT PRICE COST	UNIT PRICE PER	AMOUNT (1)
(Use continuation sheet(s) if necessary)		**(Payee must NOT use the space below)**			**TOTAL**	

PAYMENT:	APPROVED FOR	EXCHANGE RATE	DIFFERENCES	
☐ PROVISIONAL	=$	=$1.00		
☐ COMPLETE	BY [2]			
☐ PARTIAL				
☐ FINAL			Amount verified; correct for payment	
☐ PROGRESS	TITLE		*(Signature or initials)*	
☐ ADVANCE				

"I hereby certify that the salaries billed in this payment request are in compliance with the current HHS Salary Rate Limitation Provisions in Section I of the contract."
Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment.

(Date) *(Authorized Certifying Officer)* *(Title)*

ACCOUNTING CLASSIFICATION

NOTE: Invoices will not be accepted before the service has been provided. If your voucher is received prior to the dates of service, it will be returned to you.

PAID BY				
	CHECK NUMBER	ON TREASURER OF THE UNITED STATES	CHECK NUMBER	ON *(Name of bank)*
	CASH $	DATE	PAYEE [3]	

1. When stated in foreign currency, insert name of currency.
2. If the ability to certify and authority to approve are combined in one person, one signature only is necessary; otherwise, the approving officer will sign in the space provided over his official title.
3. When a voucher is receipted in the name of a company or corporation, the name of the person writing the company or corporate name, as well as the capacity in which he signs, must appear. For example: "John Doe Company, per John Smith, Secretary", or "Treasurer", as the case may be.

FOR

TITLE

Previous edition usable NSN 7540-00-900-2234

PRIVACY ACT STATEMENT

The information requested on this form is required under the provisions of 31 U.S.C. 82b and 82c, for the purpose of disbursing Federal money. The information requested is to identify the particular creditor and the amounts to be paid. Failure to furnish this information will hinder discharge of the payment obligation.

SAMPLE INVOICE/PAYMENT REQUEST - TABLE 2

CLIN	Requisition Number	Mod #	Total Funds Obligated	Cumulative Spend to Date	Remaining Funds	Spend Current Invoice
CLIN XXXX	OS#XXXXXX	#	$	$	$	$

Please use Table 2 under Table 1 in the submission of invoices to track spending.

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT Note: Complete this Form in Accordance with Accompanying Instructions.	**Project Task:**	**Contract No.:**	**Date of Report:**
	Reporting Period:	**Contractor Name and Address:**	

CLIN	Incurred Total – Current Period	Cumulative Total to Date	Negotiated Contract Amount
A	B	C	D

ATTACHMENT #4

DISCLOSURE OF LOBBYING ACTIVITIES, WITH INSTRUCTIONS

Please complete form available here:
https://www.gsa.gov/forms-library/disclosure-lobbying-activities

Copy and paste the above link into your browser.

ATTACHMENT #5

RISK MITIGATION PLAN/MATRIX TEMPLATE

Offeror's Name Risk Mitigation Matrix Risks Identified from XXXX (Contract # or Specific Document) Date											
Prior to Risk Mitigations Strategy						Post Risk Mitigations					
Risks	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to Schedule	Risk to Tech Performanc e	Risk Mitigation effort	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to Schedule	Risk to Tech Performance

ATTACHMENT #6

BARDA SECURITY REQUIREMENTS

The following table outlines the minimum-security requirements for any partner facility receiving a BARDA contract under which the USG purchases products or technologies.

1. Security Administration	
Security Program	The partner facility shall have a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities associated with fulfilling the BARDA requirement. The proposal submitted shall include a security plan which establishes security practices and procedures that demonstrate how the Offeror will meet and adhere to the security requirements outlined below by time of contract award. The Offeror shall also ensure that other entities (sub-contractors, consultants, etc.) performing work on behalf of the Offeror establishes and manages a security program that complies with BARDA security requirements.
2. Facility Security Plan	
As part of the partner facility's overall security program, they shall submit a written security plan with their proposal to BARDA for review and approval by the BARDA PPO. Performance of work under the BARDA contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	Organization and responsibilities; security risk assessment for site; threat levels identification matrix; security procedures during elevated threats; liaison with law enforcement; security education and training
Personnel Security Policies and Procedures	Candidate recruitment process; background investigations; employment suitability policy; access determination; rules of behavior/ conduct; termination procedures; non-disclosure agreements.
Physical Security Policies and Procedures	Internal/external access control; protective services; identification/badging; visitor access controls; parking areas and access control; perimeter fencing/barriers; shipping, receiving and transport; security lighting; restricted areas; signage; intrusion detection systems; alarm monitoring/response; closed circuit television; product storage security; other control measures.
Information Security	Identification of sensitive information; access control; storage of information; document control; retention/ destruction requirements.
Information Technology/Cyber Security Policies and Procedures	Intrusion detection and prevention systems; threat identification; employee training; encryption systems; identification of sensitive information/media; password policy; removable media policy; laptop policy; access control and determination; system document control; system backup; system disaster recovery; incident response; system audit procedures; property accountability.

3. Site Security Master Plan	
The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; bio-containment laboratories	
4. Site Threat / Vulnerability / Risk Assessment	
The partner facility shall provide a written risk assessment for the facility addressing: criminal threat; terrorist threat; industrial espionage; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies.	
5. Physical Security	
Closed Circuit Television (CCTV) Monitoring	Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. CCTV coverage should include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup.
Facility Lighting	Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. Lighting must have emergency power backup. Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	Should have CCTV coverage and an electronic access control system. Should have procedures in place to control access and movement of drivers picking up or delivering shipments. Must identify drivers picking up BARDA products by government issued photo identification.
Access Control	Should have an electronic intrusion detection system with centralized monitoring. Responses to alarms must be immediate and documented in writing. Employ an electronic system (i.e. card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. Should have procedures to prevent employee piggybacking. Access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. Should have a manual key accountability and inventory process. Physical access controls should present a layered approach to critical assets within the facility.

Employee/Visitor Identification	Should issue company photo identification to all employees. Photo identification should be displayed above the waist anytime the employee is on company property.
	Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program and the potential threat environment.
Protective Security Forces	Requirements for a security force will be determined by the criticality of the program and the potential threat environment.
6. Security Operations	
Information Sharing	Establish formal liaison with law enforcement and implement procedures for receiving and disseminating threat information.
Training	Conduct new employee security awareness training. Conduct and maintain records of annual security awareness training.
Security Management	Designate a knowledgeable security professional to manage security of the facility. Ensure subcontractor compliance with BARDA security requirements.
7. Personnel Security	
Records Checks	Verification of date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, and local / national criminal history search.
Hiring and Retention Standards	Policies and procedures concerning hiring, and retention of employees to include employee conduct expectations.
8. Information Security	
Physical Document Control	Applicable documents shall be identified and marked as procurement sensitive, proprietary or with appropriate government markings. Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet / desk or other storage device and not be left unattended. Access to sensitive information should be restricted to those with a need to know.

Document Destruction	Documents shall be destroyed using approved destruction measures (i.e. shredders / approved third party vendors / pulverizing / incinerating).
9. Information Technology & Cybersecurity	
Access Control	Limit information systems access to authorized users. Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. Limit physical access to information systems, equipment, and server rooms with electronic access controls.
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	Create, protect, and retain information system audit records to the extent to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Ensure the actions of individual information system users can be uniquely traced to those users.
Configuration Management	Establish and enforce security configuration settings.
Contingency Planning	Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents.
Media and Information Protection	Protect information system media, both paper and digital. Limit access to information on information systems media to authorized users Sanitize and destroy media no longer in use. Control the use of removable media through technology or policy.
Physical and Environmental Protection	Limit access to information systems, equipment, and the respective operating environments to authorized individuals. Protect the physical and support infrastructure for all information systems. Protect information systems against environmental hazards.
Network Protection	Employ intrusion prevention and detection technology.

10. Transportation Security	
Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	Drivers should be vetted in accordance with BARDA Personnel Security Requirements. Drivers should be trained on specific security and emergency procedures. Drivers should be equipped with backup communications. Driver identity should be 100 percent confirmed before pick-up of any BARDA product. Drivers should never leave BARDA product unattended and two drivers may be required for longer transport routes or critical products during times of emergency.
Transport Routes	Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. Transport routes should be continuously evaluated based upon new threats, large planned events, weather, and other situations that may delay or disrupt transport.
Product Security	BARDA products should be secured with tamper resistant seals during transport and the transport trailer should be locked and sealed. Tamper resistant seals should be verified as “secure” after the product is placed in the transport vehicle. BARDA product should be continually monitored by GPS technology while in transport and any deviations from planned routes should be investigated and documented. Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
11. Security Reporting Requirements	
The partner facility shall immediately report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
12. Security Audits	
The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub locations.	

ATTACHMENT #7

SECURITY PLAN TEMPLATE WITH INSTRUCTIONS

COMPANY SECURITY PLAN TEMPLATE

Prepared by:
Program Protection Office

Office of Biomedical Advanced Research and Development Authority

Preface

The intent of this document is to provide possible practices and procedures that entities may use to assist them in developing and implementing the written security plan required by the Office of Biomedical Advanced Research and Development Authority (BARDA). The ideas and suggestions provided in this document do not constitute or establish minimum standards but are provided as general guidance. Each security program will be assessed in its totality. This document was prepared as a reference guide and template to assist entities in the development of a site-specific security plan. Additionally, a BARDA Audit Checklist is provided at Appendix B.

A good security plan model could be to organize into the following sections: Physical Security, Personnel Security, Information Security, Security Awareness Training, Information Technology Security, and Transportation Security (shipping). For each section, we recommend that you provide a complete description of the relevant specific security measures you will use to reduce your vulnerabilities. You shall also discuss personnel roles and responsibilities for implementing each measure. There is set formula for what an acceptable security plan looks like. Sometimes very simple changes in procedures can achieve the same result as a much more costly equipment-based solution.

A layered approach to security is recommended when designing an overall security strategy. Security protective measures developed in unison are more cost effective and successful. Each layer alone may be capable of stopping an incident but in combination, their security value is multiplied, creating a much stronger, formidable system. A potential terrorist, criminal, or unauthorized person who has to overcome multiple security layers in order to carry out an attack is more likely to be pre-empted, deterred, or to fail during the attempt. The below illustration depicts the concept of layered security.

General Outline of Security Plan Topics

I. Organization and Responsibilities
II. Site- Specific Risk Assessment
    a. Statement of Threats
        i. Industrial Espionage
        ii. Criminal
        iii. Terrorism
        iv. Natural Disasters
    b. Vulnerability + Consequence of Loss=Risk
III. Threat Levels
    a. Low – Protective Measures
    b. Medium – Protective Measures
    c. High – Protective Measures
IV. Physical Security
    a. General Description
    b. Access Control
        i. Perimeter
        ii. Internal
        iii. Badge Policy
            1. Permanent employees
            2. Visitors
            3. Others
    c. Parking Areas
    d. Security Lighting
    e. Other Building Features
    f. Signage
    g. Designation of Restricted Areas
        i. Entry Points
        ii. Electronic Access Control
        iii. Electronic Intrusion Detection
        iv. Closed Circuit Television
        v. Other Control Measures
V. Personnel Security Program
    a. General Description
    b. Recruitment of New Employees
        i. Interview process
        ii. Background Checks
        iii. Suitability / Adjudication Guidelines
        iv. Non-Disclosure Agreements
        v. Rules of Behavior
        vi. Access Determination/Badge System
    c. Temporary Employees
        i. Interview
        ii. Background Checks
        iii. Non-Disclosure Agreements
        iv. Access Determination/Badge System
    d. Contractor Support
    e. Termination
        i. Denial of Access
        ii. Post Employee Interview
        iii. Non-Disclosure Agreements

VI. Information Security
- a. General Description
- b. Identification of Sensitive Information
- c. Physical Document Control
  - i. Marking
  - ii. Secure Storage
  - iii. Destruction Policy
- d. Information Technology Security
  - i. General Description
  - ii. Media Control
    1. Media Protection
    2. Sanitization and Disposal of Information
    3. Input/Output Controls
  - iii. Equipment
    1. Workstations
    2. Laptops and Other Portable Computing Devices
  - iv. Personally Owned Equipment and Software
  - v. IT Disaster Recovery
    1. Backup Data.
    2. Store Backup Data

VII. Security Awareness Training and Reporting Requirements
- a. Training
  - i. New Employees
  - ii. Annual
- b. Security Reporting
  - i. Reporting of Compromise
  - ii. Reporting of Incidents

VIII. Transportation Security

I. Organization and Responsibilities – Provide an overview of key company personnel with security responsibilities. Include an organization chart, key personnel, contact numbers, and areas of expertise.

II. Site Specific Risk Assessment - Provide an assessment of the threat environment and discuss potential hazards that could undermine or hinder completion of the contract. Threats, such as terrorism, industrial espionage/sabotage, may appear to pose a minimal risk to company operations but the possibility of their occurrence and its impact on operations cannot be ignored. Additionally, an all-hazards approach shall be considered when developing a security strategy. Loss of power, severe weather, and other natural or manmade disasters can be mitigated by thoughtful security and contingency planning. With limited security dollars, each company will design the countermeasures to vulnerabilities to meet its primary security objectives while addressing identified risks.

III. Threat Levels – Institute a graduated Threat Advisory System to advise employees of potential increased threats and to implement a set of corresponding protective measures which would further reduce vulnerability and increase response capability during periods of heightened alert. Threat levels can be as simple as: Low; Medium; High; or something that corresponds with local, state, or federal government procedures. During periods of heightened alert, entities shall consider the following no cost / low cost measures:

- Increase the visible security personnel presence wherever possible.
- Rearrange exterior vehicle barriers (if available) to alter traffic patterns near facilities.
- Institute a vehicle inspection program.
- Institute/increase vehicle, foot, and roving security patrols.
- Implement random security guard shift changes.
- Arrange for law enforcement vehicles to be parked randomly near entrances and exits.

- Approach all illegally parked vehicles in and around facilities, question drivers and direct them to move immediately, if owner cannot be identified, have vehicle towed by law enforcement.
- Report any suspicious activity immediately to law enforcement.
- Limit the number of access points and strictly enforce access control procedures.
- Implement stringent identification procedures to include conducting 100% "hands on" checks of security badges for all personnel if badges are required.
- Remind personnel to properly display badges, if applicable, and enforce visibility.
- Require two forms of photo identification for all visitors.
- X-ray packages and inspect handbags and briefcases at entry if possible.
- Validate vendor lists for all routine deliveries and repair services.

IV. Personnel Security – Provide a detailed description of your Personnel Security Program that includes hiring practices, determination of suitability for employment, termination for cause processes, and individual training goals. Personnel Security focuses on verifying the identity and credentials of a candidate and assessing their trustworthiness based on past behavior. Examples of Personnel Security measures include:

- Conduct national and local criminal history check;
- Confirm past employment (five years);
- Verify education;
- Perform reference checks;
- Perform credit check;
- Confirm Citizenship and Social Security number;
- Conduct drug and alcohol testing;
- Sign non-disclosures agreements.

Entities shall also provide a description of methods and practices used to determine suitability for employment. Suitability refers to identifiable character traits and conduct sufficient to decide whether an individual is likely or not likely to be able to carry out the duties of a job with appropriate integrity, efficiency, and effectiveness. When adjudicating suitability, the process shall carefully weigh reliable information about the person, past and present, favorable and unfavorable, before reaching a final determination. Consideration shall also be given to the following when evaluating a potential employee's suitability:

- Nature, extent and seriousness of the conduct
- Circumstances surrounding the conduct, to include knowledgeable participation
- Frequency of the conduct
- Individual's age and maturity at the time of the conduct
- Extent to which participation was voluntary
- Presence or absence of rehabilitation and other permanent behavioral changes
- Motivation for the conduct
- Potential for pressure, coercion, exploitation, or duress
- Likelihood of continuation or recurrence.

V. Physical Security – Provide a detailed description of your Physical Security Program designed to prevent or deter attackers from accessing a facility, resource, or information. Physical Security program uses a coordinated approach using obstacles, barriers, equipment, and policies to limit access to company property to only those with a need.

a. Obstacles and barriers provide the ability to prevent, discourage, or delay entry into the protected space at its outer boundaries. Some examples of physical security techniques (in escalating order) include:

- Install a fence around the site;
- Fenced sites shall have a "clear zone" inside and outside the fence for unobstructed observation;

- Fenced-in sites shall have the capability to have locked, secure gates;
- Installation of a security alarm system;
- Sufficient lighting in and around the site;
- Random checks of lighting and fencing in and around the site;
- Increase testing the security alarm systems;
- Increase testing the site alarm system with local law enforcement; and
- Locking hardware for gates shall be case-hardened chain and high-security padlocks;
- Employ additional portable lighting in and around the site for critical assets, and
- Employ obstacles or barriers in addition to standard fencing. Examples would be using concertina or razor wire to provide a double fence, or placing Jersey barriers to restrict vehicular traffic. While the concertina wire or Jersey barriers would have to already be on site, they can be put in place very quickly.

b. Badge System - An access badge system is an effective method to control entry to the company facilities, offices, and restricted areas other places that have access controlled entry points. Entry points may be doors, turnstiles, parking gates or other controlled entry points. Access badges use various technologies to identify the holder of the badge to the access control system. The most common technologies are magnetic stripe, proximity, barcode, smart cards and various biometric devices. The access badge contains information in digital form that is decoded by a card reader. The information is transmitted to the access control system. The access control system is a computer running access control software that makes access control decisions based on information about the holder of the access badge. If the credential has the proper privilege the access control system unlocks the controlled access point. Simultaneously, information about the transaction is stored in the access control system for later retrieval. Reports can be generated that will reveal who entered what portal at what time. Considerations for a badge system include:

- Establish a control and custody process for the identification badge program;
- Enforce display of badge for employees while at work and for visitors;
- Require photo identification badges for permanent employees and long-term visitors;
- Limit site access to one entrance and exit for visitors;

c. Intrusion Detection - Use of alarms, lightning, and locks provide enhanced security for protected space and improve the reliability of traditional physical security tactics, such as employee training, guards, and fencing. Each improvement is designed to restrict access to authorized personnel. Additional security measures that directly enhance the physical protection of property include:

- Training for employees to recognize unauthorized people inside the facility;
- Institute periodic roving patrols of the facility perimeter by guard force;
- Install a property alarm system;
- Integrate alarm systems with security force and regularly exercise and check for reliability;
- Tie site alarm system into local law-enforcement department;
- Have a video camera monitor areas not under direct observation;
- Employ explosive detection devices; and
- Use metal detectors/x-ray machines to screen personnel, visitors, and bags.

d. Personnel Protection – Unfortunately, the threat of violence in the workplace is a variable which you may choose to address as part of your security plan. The first step in protecting the work force from physical threats is educating the individual to recognize threatening situations. This must also be supported by systems and infrastructure that provide the capability for a proper response. Robust communications, particularly the ability to communicate as well as function under duress, are an essential consideration. The response capability shall be described in terms of timing, capability, and quantity. Any response that can disrupt or otherwise degrade a potential attack scenario, without placing additional

people at risk or otherwise raising the potential target value, may be considered as a security measure. For example:

- Determine if the organization has personnel deemed as critical and more likely to be targeted, if so, establish procedures for the protection of personnel deemed critical;
- Identify and assess potential safe havens within buildings to use in emergencies (safe havens are areas that are more survivable than other areas in buildings-basements, hallways, inner rooms, or stairwells-and that generally offer a significant barrier to an intruder);
- Inform employees about buildings that contain safe havens;
- Have an emergency evacuation plan;
- Ensure the emergency evacuation plan has escape routes, emergency lighting, and exits; and
- Establish emergency lockdown/shelter-in-place procedures, then;
    - Conduct drills moving employees to designated safe havens; and
    - Periodically run drills to test the emergency evacuation plan;
    - Establish procedures for retaining essential employees on site.

VI. Information Security – Provide a detailed description of your Information Security Program designed to protect information systems against unauthorized access to or modification of information, whether in storage, processing or transit, and against the denial of service to authorized users or the provision of service to unauthorized users, including those measures necessary to detect, document, and counter such threats. This program shall address physical and electronic media.

a. Identifying physically marking and then protecting sensitive program information are the lynchpins of an effective information security program. BARDA contracts are unclassified but information within the program can be designated as proprietary, company confidential, Critical Infrastructure Program information, sensitive but unclassified, and other handling designations. By identifying sensitive information and using appropriate markings warns and informs the recipient of the degree of protection required. Examples of information security for the protection of physical media include:

- Identify information that shall be considered sensitive (proposed listing at Appendix A)
- Institute security training program on the marking, handling, dissemination, and destruction of physical and electronic media containing sensitive information.
- Develop a destruction policy using approved methods (burning or shredding)
- Establish destruction or turn-in policies for computer equipment.

b. The use of systems can enhance security and allows for the rapid dissemination of information. However, these systems must be secure or protected to prevent intrusion. Once again, some security measures are listed below. Develop one or more primary objectives and then use the measures below, or others you think of, to satisfy each primary objective. Examples of IT Systems security techniques include:

- Install a computer-intrusion-detection system;
- Monitor Internet activity in your organization;
- Periodically test back-up power for communication systems;
- Hire consultants to attempt to penetrate your system and/or assess your vulnerability to outside hackers;
- Do not disseminate sensitive program information over the unsecured internet connection;
- Develop policies limiting downloading capabilities from company computer systems; and
- Identify specific sanitized laptops for use by company personnel on travel.

VII. Security Awareness Program – Describe in detail your Security Awareness Program which educates your personnel of company security policies and the need to protect the physical and, especially, information assets of your company. An effective Security Awareness Program gains the trust of its personnel and continually re-enforces practical security responsibilities throughout the service of each employee. Examples of security awareness programs include:

- Security education training as part of new employee indoctrination;
- Post reminders in the workplace that includes Security points of contact for questions and to report violations;
- Annual security education training, highlighting the need for continued vigilance and improvements made in the company security strategies and policies;
- Host outside guest speakers to discuss the importance of security, threats, and personal protection;
- Conduct after hour inspections to ensure compliance with company policies;
- Provide incentives for recognized excellence in security awareness.

VIII. Transportation Security - Describe in detail your Transportation Security Program which protects materials while in transit from theft, destruction, manipulation, or damage.

a. A vehicle or shipment in transit represents not just a moving target, but a critical space in constant exposure to an uncontrolled environment harboring a diversity of threats. When defining primary objectives, it is important to remember that the cargo is the prime source of consequential damage. Security measures that do not, in some way, link directly to the covered materials, but just the vehicle, may be of limited value. Examples of transportation security considerations include:

- Plan for primary (phone/cell phone), secondary (radio), and tertiary (satellite tracking) means of communications;
- Install by-pass and shutdown mechanisms;
- Install panic-button option in vehicles;
- Install theft-protection devices to disable fuel, hydraulics, and/or electrical systems;
- Seal trailers/containers;
- Driver shall always have a communication device readily available
- Institute a two-person rule
- Inspect cargo manifest and match with cargo;
- See that all tractor/trailer access panels/doors are locked, and seals remain intact/undamaged;
- Implement a search plan for tractors and trailers on the site;
- Routinely check truck transits to ensure routing plan is on file prior to departure
- Coordinate routes with law enforcement authorities
- Devise an Incident Management Plan
- Arrange with consignee to notify shipper and carrier if the cargo does not reach its destination, and
- Purchase all other necessary technology devices to be installed.

b. Tracking Systems - satellite systems and other technologies are excellent examples of graduated security capabilities. The frequency of location and status checks can be varied with alert levels and tailored to specific materials, reflecting the threat environment and potential consequences.

c. Cargo Status and Seals - Cargo seals, tamper-proof locks, and other technology may be utilized. Some cargo seals are designed to show signs of physical tampering, while others are electronic and can provide wireless notification if breached by an unauthorized individual. However, a basic locking system may be all that is necessary to deter theft. Of course, seals are not appropriate in all circumstances. For example, it would be counterproductive to use seals for bulk shipments which require multiple pickups or drops (unloading). Check paperwork to ensure it is complete and accurate.

Exhibit 10.3

SIXTH AMENDMENT TO LEASE

28159 Avenue Stanford Properties, LLC
10919 Vanowen Street
North Hollywood, CA 91605

Date: June 3, 2026

Avita Medical Americas, LLC
Attn: Mr. David O'Toole, CFO
28159 Avenue Stanford, Suites 200/220
Valencia, CA 91355

Re: Amendment of Standard Multi-Tenant Office Lease - Gross dated October 3, 2016 ("Office Lease"), between RIF III – Avenue Stanford, LLC, a California limited liability company, predecessor-in-interest to 28159 Avenue Stanford Properties, LLC, a California limited liability company ("Landlord") and Avita Medical Americas, LLC, a Delaware limited liability company ("Tenant"), concerning Suite 220 ("Original Premises") in the building located at 28159 Avenue Stanford, Valencia, CA 91355 ("Building"); as amended by that certain First Amendment to Lease dated December 14, 2016, between Landlord and Tenant ("First Amendment"); as further amended by that certain Second Amendment to Lease dated December 4, 2017 ("Second Amendment") between Landlord and Tenant concerning the Original Premises and Suite 220 ("Expansion Premises") (the Original Premises and Expansion Premises shall be collectively known as the "Premises"); as further amended by that certain Third Amendment to Lease dated November 17, 2020 ("Third Amendment") between Landlord and Tenant concerning the Premises; as further amended by that certain Fourth Amendment to Lease dated August 25, 2021 ("Fourth Amendment"); and as further amended between Landlord and Tenant Fifty Amendment to Lease dated January 26, 2023 ("Fifth Amendment") between Landlord and Tenant concerning the Premises. The Original Lease, First Amendment, Second Amendment, Third Amendment, Fourth Amendment and Fifth Amendment shall be collectively known as the "Lease".

Mr. David O'Toole:

As additional consideration for Tenant having entered into the Lease with Landlord and for other good and valuable consideration, the receipt of which is hereby acknowledged, Landlord agrees to and does amend the Lease in the following respects.

1. Extension of Term. Notwithstanding anything to the contrary contained in the Lease, the Term shall be extended for six (6) months and expire on April 30, 2027. The monthly Base Rent due for the period November 1, 2026 through April

30, 2027 shall be equal to Thirty-Nine Thousand Six Hundred Twenty-Two and 84/100 Dollars ($39,622.84).

2. Option to Extend Term Further. Provided that Tenant is not then in Default, Tenant shall have the right to extend the Term to expire on October 31, 2027 by providing written notice ("Extension Notice") to be received by Landlord on or before July 31, 2027. Provided that Tenant is not then in Default and Tenant timely delivers the Extension Notice, then the Term shall expire on October 31, 2027 and the monthly Base Rent due for the period May 1, 2027 through October 31, 2027 shall be equal to Forty-Thousand Eight Hundred Eleven and 53/100 Dollars ($40,811.53)

3. Broker. Tenant represents and warrants that is has dealt with no broker, agent or other person in connection with this transaction other than Savills. Tenant agrees to indemnify and hold Landlord harmless from and against any claims made by any other broker, agent or other persons claiming a commission or other form of compensation by virtue of having dealt with tenant with regard to this leasing transaction. Landlord shall pay Savills a market commission equal to two (2%) percent of the gross aggregate rental due for the Extension Term. Payment shall be due on the mutual execution of this Amendment. Savills shall also be entitled to a commission in the event Tenant exercises the Option to Extend Term Further. The commission due shall be equal to two (2%) percent of the aggregate rental due during said extension period and shall be paid to Savills by May 1, 2027.

Except as explicitly set forth in this Sixth Amendment to Lease, all capitalized terms herein shall have the respective meanings as set forth in the Lease and the terms and provisions of the Lease shall be and remain in full force and effect.

[Signatures on Next Page]

Very truly yours,

"Landlord":

28159 Avenue Stanford Properties, LLC,
a California limited liability company

By: FREDMORE, LLC,
a California limited liability company

By: The Rosenthal Revocable Trust
dated 6/3/03, its sole member

By: _____
Name: Fredrick Jay Rosenthal
Title: Trustee

The Foregoing Is Accepted And
Agreed To:

"Tenant":

Avita Medical Americas, LLC,
a Delaware limited liability company

By: _____
Name: David O'Toole, CFO

Date: _____

Exhibit 31.1

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

I, Cary Vance, 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

    d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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: August 6, 2026

/s/ Cary Vance

Name: Cary G. Vance
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, David O'Toole, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of AVITA Medical, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

    d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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: August 6, 2026

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

Exhibit 32

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

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

The Quarterly Report on Form 10-Q for the period ended June 30, 2026 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: August 6, 2026

/s/ Cary Vance

Name: Cary G. Vance
Title: Chief Executive Officer
(Principal Executive Officer)

Dated: August 6, 2026

/s/ David O'Toole

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

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