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

FORM 10-Q

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

For the quarterly period ended September 30, 2023

☐ 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:

SPECTRAL AI, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**85-3987148**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2515 McKinney Avenue,
Suite 1000
Dallas, Texas 75201
(Address of principal executive offices)

(972) 499-4934
(Issuer's telephone number)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	MDAI	The Nasdaq Stock Market LLC
Redeemable warrants, each whole warrant exercisable for one share of Class A common stock at an exercise price of $11.50	MDAIW	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 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 elected 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 ☐

As of November 9, 2023, there were 16,254,935 shares of Common Stock, $0.0001 par value, issued and outstanding.

SPECTRAL AI, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2023

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PART I - FINANCIAL INFORMATION

Item 1. Interim Financial Statements

Spectral AI, Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 7,348	$ 14,174
Accounts receivable, net	1,312	2,294
Inventory	220	-
Unbilled revenue	127	618
Prepaid expenses	1,755	331
Other current assets	594	270
Total current assets	11,356	17,687
Non-current assets:		
Property and equipment, net	14	21
Right-of-use assets	961	1,008
Total Assets	$ 12,331	$ 18,716
Commitments and contingencies (Note 8)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,275	$ 2,759
Accrued expenses	3,983	2,631
Deferred revenue	795	-
Lease liabilities, short-term	813	680
Notes payable	632	175
Warrant liabilities	1,149	129
Total current liabilities	10,647	6,374
Lease liabilities, long-term	228	346
Total Liabilities	10,875	6,720
Stockholders' Equity		
Preferred stock ($0.0001 par value); 1,000,000 shares authorized; no shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock ($0.0001 par value); 80,000,000 shares authorized; 15,688,268 and 13,127,472 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	2	1
Additional paid-in capital	30,696	23,929
Accumulated deficit	(29,242)	(11,934)
Total stockholders' equity	1,456	11,996
Total Liabilities and Stockholders' Equity	$ 12,331	$ 18,716

See accompanying notes to the condensed consolidated financial statements

Spectral AI, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Research and development revenue	$ 3,440	$ 7,038	$ 12,769	$ 19,272
Cost of revenue	(1,968)	(3,811)	(7,325)	(10,943)
Gross profit	1,472	3,227	5,444	8,329
Operating costs and expenses:				
General and administrative	5,638	3,478	15,499	9,207
Total operating costs and expenses	5,638	3,478	15,499	9,207
Operating loss	(4,166)	(251)	(10,055)	(878)
Other income (expense):				
Net interest income	42	2	128	1
Change in fair value of warrant liability	1,069	22	1,004	50
Foreign exchange transaction loss, net	(24)	(51)	(11)	(255)
Transaction costs	(7,604)	-	(8,342)	-
Other expense	-	(17)	-	-
Total other expense, net	(6,517)	(44)	(7,221)	(204)
Loss before income taxes	(10,683)	(295)	(17,276)	(1,082)
Income tax benefit (provision)	54	(85)	(32)	(91)
Net loss	$ (10,629)	$ (380)	$ (17,308)	$ (1,173)
Net loss per share of common stock				
Basic and Diluted	$ (0.77)	$ (0.03)	$ (1.29)	$ (0.09)
Weighted average common shares outstanding				
Basic and Diluted	13,822,990	13,145,834	13,410,287	13,127,825

See accompanying notes to the condensed consolidated financial statements

Spectral AI, Inc.
Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2022	135,409,564	$ 135	$ 23,795	$ (11,934)	$ 11,996
Retroactive application of recapitalization	(122,282,092)	(134)	134	-	-
Balance at December 31, 2022, after effect of Business Combination	13,127,472	1	23,929	(11,934)	11,996
Stock-based compensation	54,558	-	300	-	300
Stock option exercises	10,129	-	-	-	-
Net loss	-	-	-	(3,609)	(3,609)
Balance at March 31, 2023	13,192,159	$ 1	$ 24,229	$ (15,543)	$ 8,687
Stock-based compensation	12,124	-	396	-	396
Stock option exercises	5,819	-	6	-	6
Net loss	-	-	-	(3,070)	(3,070)
Balance at June 30, 2023	13,210,102	$ 1	$ 24,631	$ (18,613)	$ 6,019
Issuance of common stock upon Business Combination	1,160,485	1	(2,375)	-	(2,374)
Issuance of common stock to settle accounts payable	33,333	-	150	-	150
Issuance of shares for transaction costs	400,000	-	1,800	-	1,800
Commitment to issue shares for transaction costs	-	-	2,550	-	2,550
Private placement equity issuance	744,667	-	3,351	-	3,351
Stock-based compensation	-	-	279	-	279
Stock option exercises	139,681	-	310	-	310
Net loss	-	-	-	(10,629)	(10,629)
Balance at September 30, 2023	15,688,268	$ 2	$ 30,696	$ (29,242)	$ 1,456

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2021	135,034,564	$ 135	$ 22,640	$ (9,022)	$ 13,753
Retroactive application of recapitalization	(121,937,160)	$ (134)	$ 134	$ -	$ -
Balance at December 31, 2021, after effect of Business Combination	13,097,404	1	22,774	(9,022)	13,753
Stock-based compensation	18,186	-	333	-	333
Net loss	-	-	-	(528)	(528)
Balance at March 31, 2022	13,115,590	1	23,107	(9,550)	13,558
Stock-based compensation	18,186	-	294	-	294
Net loss	-	-	-	(265)	(265)
Balance at June 30, 2022	13,133,776	$ 1	$ 23,401	$ (9,815)	$ 13,587
Stock-based compensation	12,124	-	247	-	247
Net loss	-	-	-	(380)	(380)
Balance at September 30, 2022	13,145,900	$ 1	$ 23,648	$ (10,195)	$ 13,454

See accompanying notes to the condensed consolidated financial statements

Spectral AI, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (17,308)	$ (1,173)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	7	6
Stock-based compensation	975	874
Amortization of right-of-use assets	530	377
Issuance of shares for transaction costs	1,800	-
Commitment to issue shares for transaction costs	2,550	-
Change in fair value of warrant liabilities	(1,004)	(50)
Changes in operating assets and liabilities:		
Accounts receivable	982	(317)
Inventory	(220)	-
Unbilled revenue	491	(1,502)
Prepaid expenses	(469)	753
Other assets	(197)	(188)
Accounts payable	(554)	886
Accrued expenses	1,225	(76)
Deferred revenue	795	-
Lease liabilities	(468)	(453)
Net cash used in operating activities	(10,865)	(863)
Cash flows from financing activities:		
Proceeds from issuance of common stock for Equity Raise	3,351	-
Cash received in Business Combination	660	-
Payments for notes payable	(288)	(651)
Stock option exercises	316	-
Net cash provided by (used in) financing activities	4,039	(651)
Net decrease in cash	(6,826)	(1,514)
Cash	14,174	16,121
Cash	$ 7,348	$ 14,607
Supplemental cash flow information:		
Cash paid for interest	$ 6	$ 19
Cash paid for taxes	$ 114	$ 53
Noncash operating and financing activities disclosure:		
Recognition of Right-of-use assets and related lease liabilities upon adoption of ASC 842	$ -	$ 624
Recognition of Right-of-use assets and related lease liabilities upon lease amendment	$ 483	$ -
Issuance of common stock for net liabilities upon Business Combination	$ 3,034	$ -
Prepaid asset acquired, net of cancellation, for debt and accounts payable	$ 955	$ 376
Issuance of common stock to settle accounts payable	$ 150	$ -

See accompanying notes to the condensed consolidated financial statements

1. ORGANIZATION, NATURE OF BUSINESS AND LIQUIDITY

Business Combination

Spectral AI, Inc., a Delaware corporation formerly known as Rosecliff Acquisition Corp I ("Spectral AI" or the "Company") was formed as a blank check company on November 17, 2020. The Company was formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses.

On September 11, 2023, the Company consummated a business combination (the "Business Combination"), pursuant to the business combination agreement dated April 11, 2023 (the "Business Combination Agreement") by and among the Company, Ghost Merger Sub I, a Delaware Corporation, Ghost Merger Sub II, a Delaware corporation and Spectral MD Holdings, Ltd., a Delaware corporation incorporated on March 9, 2009 and headquartered in Dallas, Texas ("Legacy Spectral"). Upon closing of the Business Combination (the "Closing"), in sequential order: (a) Ghost Merger Sub I merged with and into the Legacy Spectral, with Legacy Spectral continuing as the surviving company as a wholly owned subsidiary of the Company (the "Spectral Merger") and then, (b) Legacy Spectral merged with and into Ghost Merger Sub II (renamed Spectral MD Holdings LLC) (the "SPAC Merger", together with the Spectral Merger (the "Business Combination")), with Ghost Merger Sub II surviving the SPAC Merger as a direct wholly-owned subsidiary of the Company. See Note 3. Upon the Closing, the Company changed its name from Rosecliff Acquisition Corp I to Spectral AI, Inc.

In conjunction with the Business Combination, the Company cancelled the redeemable warrants that it issued to Rosecliff Acquisition Sponsor I LLC, a Delaware limited liability company (the "Sponsor"), in a private placement (the "Private Warrants") in connection with the Company's initial public offering on February 17, 2021 (the "Initial Public Offering") at Closing, but the 8,433,333 redeemable warrants issued to the public in the Initial Public Offering (the "Public Warrants") remain outstanding.

Prior to the Business Combination, Rosecliff had 280,485 shares of Class A common stock, par value $0.0001 per share, issued and outstanding and held by public shareholders (the "Public Shares") and 6,325,000 shares of Class B common stock, par value $0.0001 per share, issued and outstanding and held by the Sponsor (the "Sponsor Shares"). Upon the Closing, 5,445,000 of the Sponsor Shares were forfeited, in accordance with a letter agreement with the Sponsor, and the remaining 880,000 Sponsor Shares and 280,485 Public Shares, no longer designated Class A and Class B, were included in shares of the Company's common stock, par value $0.0001 per share (the "Company Common Stock").

Prior to the Business Combination, Legacy Spectral's shares of common stock, par value $0.001 per share ("Legacy Spectral Common Stock") were listed on the AIM market on the London Stock Exchange (delisted on September 7, 2023). In September 2023, prior to the Closing, Legacy Spectral issued 7,679,198 shares of Legacy Spectral Common Stock to certain investors in a private placement, in exchange for $3.4 million (the "Equity Raise").Upon the Closing, all of Legacy Spectral's issued and outstanding 145,380,871 shares of Legacy Spectral Common Stock, including the shares from the Equity Raise, were exchanged for 14,094,450 shares of Company Common Stock at an exchange ratio of 10.31 (the "Exchange Ratio"), meaning that the Company issued one share of Company Common Stock in exchange for 10.31 shares of Legacy Spectral Common Stock.

On September 12, 2023, the Company began trading the Company Common Stock and the Public Warrants on the NASDAQ Capital Market ("NASDAQ") under the symbols "MDAI" and "MDAIW", respectively. Prior to the Business Combination, the Company's shares of Company Common Stock and Public Warrants were listed on the NASDAQ under the symbols "RCLF" and "RCLFW", respectively.

Nature of Operations

Spectral AI is devoting substantially all of its efforts towards research and development of its DeepView® Wound Imaging System, currently focused on burn wounds and diabetic foot ulcer ("DFU") indications, specifically engineered to allow physicians to make a more accurate, timely and informed decision for treatment options. The Company has not generated any product revenue to date. The Company currently generates revenue from contract development and research services by providing such services to governmental agencies, primarily to the Biomedical Advanced Research and Development Authority ("BARDA") and under a contract with Medical Technology Enterprise Consortium ("MTEC").

In September 2023, the Company executed its third contract with BARDA for a multi-year Project BioShield ("PBS") contract, valued at up to approximately $149 million. This multi-year contract includes an initial award of nearly $55 million to support the clinical validation and FDA clearance of DeepView® for commercial marketing and distribution purposes. The Company is also completing the second contract with BARDA, referred to as BARDA Burn II, which was signed in July 2019 and is due to be completed in July 2024. Under this contract, the Company expects to further the DeepView System design, develop the AI algorithm, and take the necessary steps to obtain FDA approval for its DeepView GEN 3 System.

In April, 2023, the Company received a $4.0 million grant from MTEC for a project that is expected to be completed by April 2025 (the "MTEC Agreement"). The MTEC project is for the development of a handheld device for the DeepView System which is to be used to support military battlefield burn evaluation. The project has three phases, beginning with planning, design and testing, followed by development, design modification and buildout of the handheld device, and then the manufacturing of the handheld device.

The Company operates in one segment.

Liquidity

As of September 30, 2023 and December 31, 2022, the Company had approximately $7.3 million and $14.2 million, respectively, in cash, and an accumulated deficit of $29.2 million and $11.9 million, respectively. The Company has historically funded its operations through the issuance of notes and the sale of preferred stock and common stock. Together with the new PBS BARDA Contract, executed in September 2023, for a total value of up to $149 million, the Company's total potential support from BARDA is nearly $250 million if all future options are executed. The base phase of the PBS BARDA Contract, valued at $55 million, was exercised concurrently with the contract award in September 2023. To date, for the 2013 and 2019 BARDA contracts, the Company has committed funding of $101 million of which the Company has received $99 million. In April, 2023, we received a $4.0 million grant under the MTEC Agreement. See Research and Development Revenue below. With the PBS BARDA Contract and the MTEC Agreement, the Company believes it will have sufficient working capital to fund operations for at least one year beyond the release date of the condensed consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") as determined by the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC").

The Business Combination was accounted for as a reverse recapitalization in accordance with GAAP. Legacy Spectral was determined as the accounting acquirer and the Company as the acquired company for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination is treated as the equivalent of a capital transaction in which Legacy Spectral issued stock for the net assets of the Company. Upon the Closing, the net assets of the Company are stated at fair value, with no goodwill or other intangible assets recorded. See Note 3.

Legacy Spectral was determined to be the accounting acquiror based on evaluation of the following facts and circumstances:

(i) Legacy Spectral's former shareholders have a majority of the voting power of Spectral AI;

(ii) Legacy Spectral's senior management comprises all of the senior management of Spectral AI;

(iii) Legacy Spectral selected five of the six directors for the Board of Directors of Spectral AI;

(iv) Legacy Spectral's relative size of assets and operations compared to Rosecliff; and

(v) Legacy Spectral's operations comprise the ongoing operations of Spectral AI.

All historical financial information presented in the unaudited condensed consolidated financial statements represents the accounts of Legacy Spectral at their historical values as if Legacy Spectral is the predecessor to the Company. The unaudited condensed consolidated financial statements following the Closing reflect the results of the combined entity's operations.

All issued and outstanding shares of Legacy Spectral Common Stock and warrants, stock options, restricted stock units ("RSUs") and restricted stock awards ("RSAs") of Legacy Spectral and the per share amounts contained in the unaudited condensed consolidated financial statements for the periods presented prior to the Closing have been retroactively restated to reflect the Exchange Ratio (as defined in Note 3).

Unaudited Interim Condensed Financial Statements

The accompanying condensed consolidated balance sheet as of September 30, 2023, the condensed consolidated statements of operations and stockholders' equity for the three and nine months ended September 30, 2023 and 2022, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022 are unaudited. The interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in management's opinion, include all adjustments consisting of normal recurring adjustments necessary for the fair statement of the Company's financial position as of September 30, 2023 and its results of operations and cash flows for the three and nine months ended September 30, 2023 and 2022. The results of operations for the three and nine months ended September 30, 2023 and 2022 are not necessarily indicative of the results to be expected for the full fiscal year or any other period.

These interim condensed consolidated financial statements should be read in conjunction with Legacy Spectral's annual consolidated financial statements for the year ended December 31, 2022 included in the Company's Form S-4/A filed with the Securities and Exchange Commission ("SEC") on August 11, 2023.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Spectral MD Holdings LLC, Spectral MD Inc. and Spectral MD UK Ltd. ("Spectral MD UK"). Significant inter-company transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of these condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, revenue recognition, warrant liabilities, stock-based compensation expense, stock issued for transaction costs, the net realizable value of inventory, right-of-use assets and income tax valuation allowances. Actual results could differ from these estimates.

Cash

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash is held in US financial institutions.

Accounts Receivable, Net and Unbilled Revenue

Accounts receivable represent amounts due from US government agencies pursuant to research and development contracts associated with the Company's DeepView® Wound Imaging System.

The Company evaluates the collectability of its receivables based on a variety of factors, including the length of time the receivables are past due, the financial health of its customers and historical experience. Based upon the review of these factors, the Company recorded no allowance for doubtful accounts as of September 30, 2023 and December 31, 2022.

The Company records unbilled revenue when revenue is recognized prior to billing customers.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash and accounts receivable. Primarily all cash is held in US financial institutions which, at times, exceed federally insured limits. The Company has not recognized any losses from credit risks on such accounts. The Company believes it is not exposed to significant credit risk on cash.

Additional credit risk is related to the Company's concentration of receivables. As of September 30, 2023 and December 31, 2022, receivables were concentrated from one customer (which is a US. government agency) representing 87% and 96% of total net receivables, respectively. No allowance for doubtful accounts were recorded as of September 30, 2023 and December 31, 2022.

One customer (which is a U.S. government agency) accounted for 89% and 94% for the three and nine months ended September 30, 2023, respectively, and 98% for each of the three and nine months ended September 30, 2022 of the recognized research and development revenue.

Inventory

Inventory is comprised of finished goods, purchased from a third-party manufacturer, and is stated at the lower of cost (average cost) or net realizable value. For the three and nine months ended September 30, 2023, the Company did not have write-downs for obsolete inventory.

Fair Value

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1 - Unadjusted quoted prices in active markets that are assessable at the measurement date for identical, unrestricted assets or liabilities.

Level 2 - Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3 - Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

Foreign Currency

The reporting currency for the condensed consolidated financial statements of the Company is the US dollar. The functional currency of the Company and its wholly owned subsidiaries Spectral MD Holdings LLC and Spectral MD, Inc. is the US dollar. The functional currency of Spectral MD UK is its local currency, the British pound. The assets and liabilities of Spectral MD UK are translated into US. dollars at exchange rates in effect at the end of each reporting period, and the revenues and expenses are translated at average exchange rates in effect during the applicable period. Translation adjustments are included in accumulated other comprehensive income as a component of stockholders' equity. As of September 30, 2023 and December 31, 2022, the Company's translation adjustments are not material.

Monetary assets and liabilities denominated in currencies other than the functional currency are translated at exchange rates in effect at the balance sheet date. Resulting unrealized gains and losses are included in other income (expense), net in the condensed consolidated statements of operations. For the three and nine months ended September 30, 2023 the Company recorded approximately $24,000 and $11,000, respectively, of net foreign exchange transaction losses. For the three and nine months ended September 30, 2022, the Company recorded approximately $0.1 million and $0.3 million, respectively, of net foreign exchange transaction losses primarily related to the Company's bank account denominated in British Pounds and accounts payable denominated in British Pounds.

Leases

The Company accounts for its leases under ASC 842, Leases. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases. Operating leases are recorded in the condensed consolidated balance sheets as both a right-of-use asset and a lease liability, calculated by discounting fixed lease payments at the rate implicit in the lease or the Company's incremental borrowing rate factoring the term of the lease. The incremental borrowing rate used by the Company is an estimate of the interest rate the Company would incur to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease. Because the Company does not generally borrow on a collateralized basis, it uses the interest rate it pays on its noncollateralized borrowings as an input to deriving an appropriate incremental borrowing rate, adjusted for the amount of lease payments, the lease term and the effect on that rate of designating specific collateral with a value equal to the unpaid lease payments for that lease. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset results in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred. In calculating the right-of-use assets and lease liabilities, the Company has elected to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the requirement to capitalize right-of-use assets and liabilities as an accounting policy election.

During the three and nine months ended September 30, 2023 and 2022, the Company did not have any financing leases.

Warrant Liabilities

On September 11, 2023, in conjunction with the Business Combination, the Company assumed the Public Warrants which have an exercise price of $11.50 per share, are exercisable 30 days after the Business Combination and expire five years after the Business Combination or upon redemption. The Company may redeem the Public Warrants if the Company's common stock equals or exceeds $18.00 per share for 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which the Company sends the notice of redemption to the holders of Public Warrants. As of September 30, 2023, there are 8,433,333 Public Warrants Outstanding.

In September 2021, Legacy Spectral issued 73,978 warrants, with a strike price of $7.60 and a five-year life, to SP Angel Corporate Finance LLP ("SP Angel"), who acted as nominated adviser and broker to the Company for the purposes of the AIM Rules ("Angel Warrants"). In conjunction with the Business Combination, the Angel Warrants were converted into warrants to purchase Company Common Stock based on the Exchange Ratio. As of September 30, 2023, there are 73,978 warrants to purchase Company Common Stock outstanding.

The Company accounts for its Public Warrants and the Angel Warrants as derivative liabilities in accordance with ASC 815, Derivatives and Hedging ("ASC 815"). Accordingly, the Company recognizes the instruments as liabilities at fair value, determined using the closing price of the observable market quote in an active market (the NASDAQ) for the Public Warrants and the Black-Scholes option-pricing model for the Angel Warrants, and adjusts the instruments to fair value at the end of each reporting period. The liabilities are subject to re-measurement at each balance sheet date until exercised, redeemed or expired, and any change in fair value is recognized in the Company's condensed consolidated statements of operations within other income (expense).

Research and Development Revenue

The Company recognizes revenue when the Company's customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services by analyzing the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation.

The Company generates research and development revenue, primarily from the contracts with BARDA and MTEC. Each contract for BARDA and MTEC has a single performance obligation.

The contracts with BARDA are cost-plus-fee contracts associated with development of certain product candidates. Revenues from these reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee.

The MTEC Agreement provides for installment payments after the completion of milestone events. The installment payments are considered variable consideration as the entitlement depends on successful completion of research, however, the payments are not constrained from inclusion in the transaction price as it not probable that a significant reversal of cumulative revenue will be reversed when the underlying uncertainty is resolved. Revenue for the MTEC Agreement is recognized over time based upon the cost-to-cost measure of progress, using this input method to measure progress as the customer has the benefit of access to the development research under these projects and therefore benefits from the Company's performance incrementally as research and development activities occur under each project. The Company measures progress of performance by comparing the actual costs incurred to-date to the total estimated cost of the project. The Company will adjust the measure of progress at the end of each reporting period and reflect any changes to the estimated cost of the project on a prospective basis.

The Company elected the practical expedient not to adjust the transaction price for the effects of a significant financing component as the period between performance (satisfaction of a performance obligation) and payment is one year or less. Payments from customers are generally received within 30 days of when the invoice is sent.

The Company records deferred revenue when the customers have been billed prior to recognizing revenue.

Research and Development Expense

The Company expenses research and development costs as incurred. These expenses include salaries for research and development personnel, consulting fees, product development, pre-clinical studies, clinical trial costs, and other fees and costs related to the development of the technology. For the three months ended September 30, 2023 and 2022, research and development expense was $3.6 million and $4.3 million, respectively, of which $2.0 million and $3.8 million, respectively, is related to the BARDA and MTEC contracts and included in cost of revenue and $1.6 million and $0.5 million, respectively, is included in general and administrative expenses. For the nine months ended September 30, 2023 and 2022, research and development expense was $11.3 million and $12.2 million, respectively, of which $7.3 million and $10.9 million, respectively, is related to the BARDA and MTEC contracts and included in cost of revenue and $4.0 million and $1.3 million, respectively, is included in general and administrative expenses.

Stock-Based Compensation

The Company accounts for all stock-based payments to employees and non-employees, including grants of stock options, RSUs, RSAs and stock options with non-market performance conditions ("PSOs") based on their respective grant date fair values. The Company estimates the fair value of stock option grants and PSOs using the Black-Scholes option pricing model. The RSUs and RSAs are valued based on the fair value of the Company's common stock on the date of grant. The assumptions used in calculating the fair value of the Company's stock and stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company expenses stock-based compensation related to stock options, RSUs and RSAs over the requisite service period. As the PSOs have performance conditions, compensation expense is recognized for each award if and when the Company's management deems it probable that the performance conditions will be satisfied. Forfeitures are recorded as they occur. Compensation previously recorded for unvested equity awards that are forfeited is reversed upon forfeiture. The Company expenses stock-based compensation to employees over the requisite service period, on a straight-line basis, based on the estimated grant-date fair value of the awards.

Income Taxes

Income taxes are recorded in accordance with ASC 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the condensed consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company has no uncertain tax positions as of September 30, 2023 and December 31, 2022 that qualify for either recognition or disclosure in the condensed consolidated financial statements under this guidance.

The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the condensed consolidated statements of operations. The Company did not have any interest and penalties during the three and nine months ended September 30, 2023 and 2022 and did not have any interest or penalties accrued as of September 30, 2023.

Comprehensive Loss

Comprehensive loss is equal to net loss as presented in the condensed consolidated statements of operations, as the Company did not have any material other comprehensive income or loss for the periods presented.

Net Loss per Share of Common Stock

Basic net loss share of common stock is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock adjusts basic earnings per share for the potentially dilutive impact of unvested restricted stock, stock options and warrants. Securities having an anti-dilutive effect on diluted net earnings per share are excluded from the calculation. The dilutive effect of the unvested restricted stock and stock options is calculated using the treasury stock method. For warrants that are liability-classified, during periods when the impact is dilutive, the Company assumes share settlement of the instruments as of the beginning of the reporting period and adjusts the numerator to remove the change in fair value of the warrant liability and adjusts the denominator to include the dilutive shares calculated using the treasury stock method.

Recently Adopted Accounting Standards

In September 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments - Credit Losses, which was subsequently amended by ASU 2018-19 and ASU 2019-10. This standard requires the measurement of expected credit losses for financial instruments carried at amortized cost held at the reporting date based on historical experience, current conditions and reasonable forecasts. The updated guidance also amends the current other-than-temporary impairment model for available-for-sale debt securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security's amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The Company adopted this standard on January 1, 2023, with no impact on its condensed consolidated financial statements and related disclosures.

In September 2022, the FASB issued ASU 2022-03, ASC Subtopic 820, Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions. The FASB is issuing this update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. The amendments in this update are effective for the Company on January 1, 2025. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. The Company is still evaluating the impact of this pronouncement on the condensed consolidated financial statements.

3. RECAPITALIZATION

As discussed in Note 1, on September 11, 2023, the Company consummated the Business Combination, with Legacy Spectral surviving the merger as a wholly-owned subsidiary of the Company.

On the date of the Business Combination, the Company recorded net liabilities of $2.4 million, with an offsetting decrease to additional paid-in capital. The following table provides the elements of the Business Combination and reconciles these elements to the condensed consolidated statements of stockholders' equity and the condensed consolidated statements of cash flows for the nine months ended September 30, 2023:

Cash	$ 660
Other current assets	127
Accounts payable	(860)
Accrued expenses	(277)
Warrant liabilities	(2,024)
Net assets assumed in exchange for common stock	(2,374)
Less: Cash	(660)
Non-cash net assets assumed in exchange for common stock	$ (3,034)

Upon the Closing, the Company issued 33,333 shares of Company Common Stock, with a fair value of $0.2 million, to settle an assumed liability to the Sponsor as a payment for an administrative fee.

The Company recorded transaction costs, consisting of legal, accounting and other professional services incurred by Legacy Spectral related to the Business Combination, of $7.6 million (the "Transaction Costs"), in other income (expense) in the condensed consolidated statement of operations for the three and nine months ended September 30, 2023 and no costs were capitalized. As of September 30, 2023, $1.4 million and $1.0 million of the Transaction Costs are included accounts payable and accrued expenses, respectively. The remaining $5.2 million of Transaction Costs included $0.8 million in cash paid for transaction costs, the issuance of 400,000 shares of Company Common Stock with a fair value of $1.8 million and the commitment to issue 566,667 shares of Company Common Stock with an aggregate fair value of $2.6 million (the "Committed Stock"). See Note 15.

The commitments to issue shares in exchange for Committed Stock obligation is equity-classified in accordance with ASC 815 as they are freestanding contracts that will be settled in shares of Company Common Stock. Accordingly, the Company recorded the Committed Stock obligations based on the fair value of the Company Common Stock upon the Closing and will not remeasure this obligation at any reporting dates or upon issuance of the shares.

Prior to the Business Combination the Company incurred $0.7 million of transaction costs, included in other income (expense) in the condensed consolidated statement of operations for the nine months ended September 30, 2023, for professional services incurred by Legacy Spectral that were related to potential business combinations that did not occur.

Registration Rights Agreements

In accordance with the agreement with one of the Company's underwriters, for 166,667 shares of Committed Stock, the Company was required to file a registration statement with the SEC within 45 days of the Closing. The Company is required to use its commercially reasonable efforts to cause such registration to become effective, and in any event if such registration statement does not become effective, the Company has 30 days to cure such default or will be required to pay the obligation with $1.3 million of cash. In accordance with ASC 825, Financial Instruments, the Company has a registration right obligation, however, in accordance with ASC 450, Contingencies ("ASC 450"), the obligation is not probable as the Company has several options to provide registration rights pursuant to the agreement and thus no liability has been recorded.

In addition, the Company has an obligation to register 400,000 shares of Committed Stock pursuant to an effective registration statement with the SEC within 30 days of the Closing. The Company is required to use its best efforts to cause such registration to become effective within 45 days if the registration statement is not reviewed by the SEC and 60 days if the registration statement is reviewed by the SEC. If the registration statement is not effective by the specified time period or if the Company does not maintain effectiveness of the registration statement for two years, the Company has to pay the obligation with $3.0 million of cash. In accordance with ASC 825, Financial Instruments, the Company has a registration right obligation, however, in accordance with ASC 450 the obligation is not probable as the Company has several options to provide registration rights pursuant to the agreement and thus no liability has been recorded.

4. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial liabilities that are measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022, by level within the fair value hierarchy (in thousands):

	Fair value measured as of September 30, 2023			
	Fair value at September 30, 2023	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liabilities	$ 1,149	$ 1,096	$ -	$ 53

	Fair value measured as of December 31, 2023			
	Fair value at December 31, 2023	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liabilities	$ 129	$ -	$ -	$ 129

There were no transfers between Level 1, 2 or 3 during the three and nine months ended September 30, 2023 and 2022.

Fair values of cash, accounts receivable, accounts payable, accrued expenses and short-term debt are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of the Public Warrants, which trade in active markets, is based on quoted market prices and classified in Level 1 of the fair value hierarchy. The Angel Warrants are classified within Level 3 of the fair value hierarchy because their fair values are based on significant inputs that are unobservable in the market.

The following table presents changes in Level 3 liabilities measured at fair value for the three and nine months ended September 30, 2023 and 2022 (in thousands):

Balance - January 1, 2023	$ 129
Change in fair value	(16)
Balance - March 31, 2023	$ 113
Change in fair value	81
Balance - June 30, 2023	$ 194
Change in fair value	(141)
Balance - September 30, 2023	$ 53
Balance - January 1, 2022	$ 186
Change in fair value	(66)
Balance - March 31, 2022	$ 120
Change in fair value	38
Balance - June 30, 2022	$ 158
Change in fair value	(22)
Balance - September 30, 2022	$ 136

Both observable and unobservable inputs were used to determine the fair value of warrants that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long- dated volatilities) inputs.

The following table provides quantitative information regarding Level 3 fair value measurements inputs at their measurement:

	September 30, 2023	December 31, 2022
Strike price (per share)	$ 7.60	$ 7.60
Contractual term (years)	3.7	4.5
Volatility (annual)	70.0%	72.6%
Risk-free rate	4.5%	4.0%
Dividend yield (per share)	0.0%	0.0%

5. RESEARCH AND DEVELOPMENT REVENUE

For the three and nine months ended September 30, 2023 and 2022, the Company's revenues disaggregated by the major sources was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
BARDA	$ 3,055	$ 6,903	$ 12,018	$ 18,866
Other U.S governmental authorities	385	135	751	406
Total revenue	$ 3,440	$ 7,038	$ 12,769	$ 19,272

6. ACCRUED EXPENSES

Accrued expenses consist of the following as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Salary and wages	$ 1,403	$ 1,135
Transaction costs	1,000	-
Operating expenses	619	736
Benefits	803	650
Taxes	158	110
Total accrued expenses	$ 3,983	$ 2,631

7. NOTES PAYABLE

Insurance Note

The Company entered into financing arrangements for a portion of its insurance premiums, as follows (in thousands):

			Principal Repayments Nine Months Ended September 30,		Outstanding Balance	
	Amount Financed	Interest Rate	2023	2022	September 30, 2023	December 31, 2022
New 2023 Insurance Note	$ 632	8.6%	$ -	$ -	$ 632	$ -
2023 Insurance Note	151	9.7%	113	-	-	-
2022 Insurance Note	376	6.7%	175	67	-	175
2021 Insurance Note	474	5.7%	-	160	-	-
			$ 288	$ 227	$ 632	$ 175

In September 2023, in connection with the Business Combination, the Company cancelled the 2023 Insurance Note and replaced it with the New 2023 Insurance Note. Accordingly, the Company reversed the unpaid balance of approximately $38,000 from notes payable and prepaid expenses.

The Company determined that the carrying amounts of all of the insurance notes approximate fair value due to the short-term nature of borrowings and current market rates of interest.

PPP Loan

On April 13, 2020, the Company entered into a promissory note with JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program ("PPP") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") for $768,575 (the "PPP Loan"). The PPP Loan, which matured on April 13, 2022 and bears interest at 1% per annum. Beginning on September 13, 2021, the Company was required to make equal monthly payments of principal and interest until the loan maturity on April 13, 2022. The PPP Loan was subject to customary terms for payment defaults and breaches of representations and warranties. The Company did not request the PPP Loan to be forgiven. During the nine months ended September 30, 2022, the Company repaid the remaining $0.4 million of principal and interest for the PPP Loan. There was no outstanding balance for the PPP Loan as of December 31, 2022.

8. COMMITMENTS AND CONTINGENCIES

Legal Matters

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

9. LEASES

The Company leases office space for its principal office in Dallas, Texas, which was extended during 2022 to expire in May 2024. This lease was extended again in 2023 to expire in December 2024. During 2022, the Company entered into a lease for office space in the United Kingdom under a lease that expired in May 2023.

During 2023, the Company entered into a lease for office space in the United Kingdom for annual payments of $0.1 million under a lease that expires in March 2024. The lease has been excluded from the tables below as the term is twelve months.

The following table summarizes quantitative information about the Company's operating leases for the three and nine months ended September 30, 2023 and 2022 (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating cash flows from operating leases	$ 208	$ 159	$ 536	$ 472
Right-of-use assets exchanged for operating lease liabilities	$ -	$ -	$ 483	$ 624
Weighted average remaining lease term (in years)	1.3	0.4	1.3	0.4
Weighted average discount rate	8.5%	6.7%	8.5%	6.7%

The following table provides the components of the Company's lease cost included in general and administrative expense in the condensed consolidated statement of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating leases				
Operating lease cost	$ 205	$ 132	$ 597	$ 396
Variable lease cost	92	45	256	78
Operating lease expense	297	177	853	474
Short-term lease rent expense	41	-	69	-
Total rent expense	$ 338	$ 177	$ 922	$ 474

Variable lease cost is primarily attributable to amounts paid to lessors for utility charges, parking and property taxes under an office space lease.

As of September 30, 2023, future minimum payments under the non-cancelable operating leases under ASC 842 were as follows (in thousands):

Three months ending December 31, 2023	$ 208
Year ending December 31, 2024	894
Total	1,102
Less: imputed interest	(61)
Operating lease liabilities	$ 1,041

10. STOCKHOLDERS' EQUITY

In conjunction of the Closing, the Company's certificate of incorporation was amended and restated to authorize the issuance of 80,000,000 shares of Company Common Stock, $0.0001 par value and 1,000,000 shares of preferred stock, $0.0001 par value (the "Company Preferred Stock").

11. STOCK-BASED COMPENSATION

Each option and warrant to purchase common stock of Legacy Spectral was converted into an option and warrant, respectively, to purchase Spectral AI's common stock based on the Exchange Ratio, with corresponding adjustments to the exercise price. Accordingly, the options and warrants to purchase 46,592,862 and 762,712, respectively, shares of the common stock of Legacy Spectral were converted into options and warrants to purchase 4,519,191 and 73,978, respectively, shares of Spectral AI's common stock. Legacy Spectral's 600,000 RSUs were converted into 58,196 Spectral AI RSUs, based on the Exchange Ratio.

2018 Long Term Incentive Plan

On July 24, 2018, Legacy Spectral's Board of Directors adopted the 2018 Long Term Incentive Plan (the "2018 Plan") which permits granting of incentive stock options (they must meet all statutory requirements), non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, and other cash-based or stock-based awards. Pursuant to the 2018 Plan, stock options must expire within 10 years and must be granted with exercise prices of no less than the fair value of the common stock on the grant date, as determined by Legacy Spectral's Board of Directors. As of September 30, 2023, 3,720,089 shares of common stock were authorized for issuance under the 2018 Plan, of which 47,036 remain available for issuance. See Note 15.

2022 Long Term Incentive Plan

On September 27, 2022, Legacy Spectral's stockholders approved the adoption of the 2022 Long Term Incentive Plan (the "2022 Plan") which permits granting of incentive stock options (they must meet all statutory requirements), non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, and other cash-based or stock-based awards. Pursuant to the 2022 Plan, stock options must expire within 10 years and must be granted with exercise prices of no less than the fair value of the common stock on the grant date, as determined by Legacy Spectral's Board of Directors. As of September 30, 2023, 1,939,864 shares of common stock were authorized for issuance under the 2022 Plan, of which 1,792,918 remain available for issuance. See Note 15.

Restricted Stock Awards

The RSAs generally vest over four years. A summary of RSA activities for the nine months ended September 30, 2023 are presented below:

	Number of Shares	***Weighted Average Grant Date Fair Value per Share US$***
Nonvested as of January 1, 2023	30,318	$ 1.07
Vested	(30,318)	$ 1.07
Nonvested as of September 30, 2023	-	$ -

Restricted Stock Units

The RSUs generally vest over three years. A summary of RSU activities for the nine months ended September 30, 2023 are presented below:

	Number of Shares	***Weighted Average Grant Date Fair Value per Share US$***
Nonvested as of January 1, 2023	-	$ -
Granted	58,197	$ 4.65
Nonvested as of September 30, 2023	58,197	$ 4.65

Stock Options

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Legacy Spectral's stock became publicly traded on July 22, 2021 on the AIM, and lacks company-specific historical and implied volatility information. Therefore, Legacy Spectral estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Legacy Spectral's stock options for employees has been determined utilizing the simplified method by taking an average of the vesting periods and the original contractual terms for each award. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the US. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that Legacy Spectral has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

In applying the Black Scholes option pricing model, the Company used the following assumptions for stock options granted in the nine months ended September 30, 2023:

	Nine Months Ended September 30, 2023
Exercise price (per share)	$ 4.68
Expected term (years)	6.0
Volatility (annual)	72%
Risk-free rate	3.6%
Dividend yield (per share)	0%

A summary of stock options activity for the nine months ended September 30, 2023 is presented below:

	Stock Options	*Weighted Average Exercise Price US$*	*Weighted Average Remaining Contractual Life (in years)*	*Aggregate Intrinsic Value (in thousands)*
Outstanding at January 1, 2023	3,503,790	$ 2.06	7.3	$ 6,831
Options granted	253,250	$ 4.68		
Options forfeited	(15,844)	$ 3.68		
Options cancelled	(20,368)	$ 1.95		
Options exercised	(126,247)	$ 2.16		
Outstanding as of September 30, 2023	3,594,581	$ 2.22	6.8	$ 2,823
Options vested and exercisable as of September 30, 2023	2,847,580	$ 1.74	6.3	$ 2,752

The Company recorded stock-based compensation expense for stock options, RSUs and restricted stock awards of $0.3 million and $1.0 million for the three and nine months ended September 30, 2023, respectively, and $0.2 million and $0.9 million for the three and nine months ended September 30, 2022, respectively, in general and administrative expenses in the condensed consolidated statements of operations.

As of September 30, 2023, there was approximately $1.5 million and $0.2 million of unrecognized stock-based compensation related to stock option grants and restricted stock unit grants, respectively, that will be amortized over a weighted average period of 1.1 years and 1.2 years, respectively.

During the year ended December 31, 2018, the Company granted of 973,803 stock options to investors (the “Investor Options”) that were approved by the Board of Directors outside of the 2018 Plan, of which 939,024 Investor Options were outstanding as of December 31, 2022. During September 30, 2023, 34,779 of the Investor Options were exercised and the remaining 904,245 Investor Options are outstanding and will expire in November 2023. The Investor Options have an exercise price of $2.06 per share. As of September 30, 2023, there is no unrecognized stock-based compensation expense related to the Investor Options.

As of September 30, 2023, the Company has outstanding stock options, issued to an investor, to purchase 20,369 shares of the Company’s common stock (the “ASC 815 Options”) at a price of $1.96 per share that expire in December 2023. The ASC 815 Options have a grant date fair value of $2.17 per share and are equity-classified stock options in accordance with ASC 815.

12. INCOME TAXES

The Company recorded an income tax benefit of approximately $54,000 for the three months ended September 30, 2023 and an income tax provision of approximately $32,000 for the nine months ended September 30, 2023, and $85,000 and $91,000 for the three and nine months ended September 30, 2022, respectively. The effective tax rate was (0.5%) and 0.2% for the three and nine months ended September 30, 2023, respectively, and 28.8% and 8.4% for the three and nine months ended September 30, 2022, respectively.

The tax provision for interim periods is determined using an estimate of the Company's annual effective tax rate, adjusted for discrete items arising in that quarter. The Company's effective tax rate differs from the U.S. statutory tax rate in the three and nine months ended September 30, 2023 primarily due to changes in valuation allowances on deferred tax assets as it is more likely than not that the Company's deferred tax assets will not be realized.

The Company evaluates its tax positions on a quarterly basis and revises its estimate accordingly.

13. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share attributable to common stockholders are the same for the three and nine months ended September 30, 2023 and 2022, since the inclusion of all potential shares of common stock outstanding would have been anti-dilutive due to the Company's net loss.

The table below summarizes potentially dilutive securities that were excluded from the computation of net loss per common share as of the periods presented because including them would be anti-dilutive.

	2023	2022
Common stock options	4,519,195	4,418,871
Common stock warrants	8,507,311	73,978
Unvested restricted stock units	58,197	-
Unvested restricted stock	-	54,566
Potentially dilutive securities	13,084,703	4,547,415

14. RELATED PARTY TRANSACTIONS

For the three and nine months ended September 30, 2023 and 2022, the Company did not have any transactions with related parties.

15. SUBSEQUENT EVENTS

During October 2023, the Company filed a Form S-1 to register 8,433,231 shares of Company Common Stock issuable upon exercise of the Public Warrants and 10,069,748 shares of Company Common Stock (the "Registration"). In conjunction with the Registration, the Company issued 566,667 shares of Company Common Stock for the Committed Stock.

In November 2023, in connection with the Business Combination, the Company's Board of Directors adopted the 2023 Long Term Incentive Plan (the "2023 Plan") which permits granting of incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units, stock appreciation rights, bonus awards, dividend equivalents and other cash-based or stock-based awards to employees and non-employees. Pursuant to the 2023 Plan, 8,000,000 shares of common stock were authorized for issuance under the 2023 Plan. The awards issued under the Legacy Spectral's 2018 Plan and the 2022 Plan will be rolled into the 2023 Plan.

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

Unless otherwise indicated or the context otherwise requires, references in this section to "we," "our," "us" or other similar terms refer to the business and operations of Spectral AI, Inc., and its subsidiaries or Legacy Spectral, prior to its business combination with Spectral MD Holdings, Ltd. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited quarterly condensed financial statements and related notes included elsewhere in this Form 10-Q, as well as Legacy Spectral's audited annual consolidated financial statements and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" as of and for the years ended December 31, 2022 and 2021 included in our final prospectus, as amended, on Form S-4/A filed with the Securities and Exchange Commission ("SEC") on August 10, 2023 (the 'Prospectus"). In addition to historical data, this discussion contains forward-looking statements about our business, results of operations, cash flows, financial condition and prospects based on current expectations that involve risks, uncertainties and assumptions. Our actual results could differ materially from such forward-looking statements. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed in the sections titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" included in the Prospectus. Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are an AI company focused on predictive medical diagnostics. We operate in one segment. We are devoting substantially all of our efforts towards research and development of our DeepView System, an internally developed multi-spectral imaging ("MSI") device which has designated FDA breakthrough device designation ("BDD") status. Our DeepView System uses proprietary algorithms to distinguish between damaged and healthy human tissue invisible to the naked eye, providing "Day One" healing assessments. DeepView's output is specifically engineered to allow the physician to make a more accurate, timely and informed decision regarding the treatment of the patient's wound. Our focus from 2013 through 2021 was on the burn indication. In 2022 and 2023, we expanded our focus to include the diabetic foot ulcer ("DFU") indication.

In the case of DFUs, a non-healing assessment would provide the physician with an objective assessment to use an advanced wound care therapy on "Day One", in seconds, as opposed to the current approach that involves waiting up to 30 days to see how the wound develops before making such clinical assessment.

For burn wounds, a non-healing assessment could aid the clinician in making an immediate and objective determination for appropriate candidates for surgery, as well as determining what specific areas of the burn wound will require excision and skin grafting. DeepView's current accuracy for burn wounds is 92% for adults and 88% for pediatrics, compared with current physician accuracy of 50% to 75%, respectively, at best, according to industry literature.[1] In addition, in head-to-head clinical trial evaluations, our DeepView System provided higher accuracy to "ground truth" on burn wound analysis than the accuracy of burn specialists, reporting at 70-80% accuracy, or non-burn specialist physicians, reporting at 50-60% accuracy.[2] We have conducted three large clinical studies with multiple sites across the United States, enrolling 413 burn patients, including 329 adult and 84 pediatric patients. Through these studies, we were able to identify the burn assessment accuracy in both surgical and non-surgical treatment.

We have not generated any product revenue to date. We have received substantial support from the U.S. government for our DeepView System's application for burn wounds, including from agencies such as the Biomedical Advanced Research and Development Authority ("BARDA"), which is part of the HHS Office of the Assistant Secretary for Preparedness and Response in the United States, established to aid in securing the United States from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases. We have also received funding from the National Science Foundation (the "NSF"), the National Institute of Health (the "NIH") and the Defense Health Agency (the "DHA"). Since 2013, we have received approximately $279.0 million in funding commitments from government contracts, primarily from BARDA, which accounts for $271.9 million. This has allowed us to develop our technology and further our clinical trials.

1 Henk Hoeksema, Karlien Van de Sijpe, Thiery Tondu, Moustapha Hamdi, Koenraad Van Landuyt, Phillip Blondeel, Stan Monstrey, Accuracy of early burn depth assessment by laser Doppler imaging on different days post burn, Burns, Volume 35, Issue 1, 2009, Pages 36-45, ISSN 0305-4179. The above article was exploring laser doppler imaging as an objective technique to determine the depth of a burn wound and states "as has been demonstrated in several studies, a purely clinical, bedside evaluation of the burn depth in dermal burns is accurate only in about 50-75% of the cases."

2 Rise of the (Learning) Machines: An Interim Analysis Assessing Burn Wound Healing; Jeffrey E. Carter, MD, FACS, et.al., *https://clinicaltrials.gov/ct2/show/NCT05023135*.

In September 2023, we executed our third contract with BARDA for a multi-year Project BioShield (“PBS”) contract, valued at up to approximately $149 million (the “PBS BARDA Contract”). This multi-year contract includes our initial award of nearly $55.0 million to support the clinical validation and FDA clearance of DeepView® for commercial marketing and distribution purposes. We are also currently completing our second contract with BARDA, referred to as the BARDA Burn II contract, which was signed in July 2019 and is due to be completed in July 2024. Under this contract, we expect to further the DeepView System design, refine the AI algorithm, and take the necessary steps to obtain FDA approval for our DeepView GEN 3 System. However, approval from the FDA or other regulatory agencies, foreign or domestic, cannot be guaranteed and may take longer than planned. In August 2022, we also received the Option 1B extension of the BARDA Burn II contract, which is valued at an additional $8.2 million, bringing the total funding received from Option 1 of the BARDA Burn II contract to $47.6 million, since July 2021, under Option 1A and 1B (including modification), to execute the adult and pediatric multi-center clinical training study. This grant funding is non-dilutive to our shareholders, and we believe it validates the important nature of our mission and technology.

In April 2023, we received a $4.0 million grant award from the Medical Technology Enterprise Consortium (“MTEC”), which, building on prior awards from DHA, is to be used to support military battlefield burn evaluation via a handheld DeepView (the “MTEC Agreement”). The MTEC Agreement extends the DHA Phase II contract for the development of the handheld device of the DeepView System. Under the terms of the MTEC Agreement, MTEC will pay us a firm fixed fee based upon our achievement of certain milestones described in the agreement through April 5, 2025. The milestone payment schedule is based on a three phased approach to the development of our handheld device. Phase 1 of the MTEC Agreement began in April 2023 and is scheduled to extend through at least July 2023 and is focused on the planning, design and testing of the handheld device for its intended applications. Phase 1 has a funding budget of $1.2 million. Once Phase 1 is completed, Phase 2 is intended to run through October 2024 and encompasses the development, design modification and build-out of the handheld device to the U.S. government standards as identified in the design and commercialization plans for the device. Phase 2 has a funding budget of $1.6 million. Phase 3 of the MTEC Agreement addresses the complete manufacturing of the device, the process validation of the production and completion of up to thirty handheld devices. Phase 3 begins following completion of Phase 2 and is intended to run through April 2025 with a funding budget of approximately $1.2 million.

We anticipate that the DeepView System will have two revenue streams, a SaMD (software as a medical device) model, and an imaging device component. The SaMD model applies a SaaS (software as a service) treatment for the DeepView System which will feature a software licensing fee that includes maintenance, image hosting, and access to algorithm updates. The proprietary imaging device accesses artificial intelligence algorithms and is a universal platform to house multiple clinical applications. Pricing for these components will be evaluated and strategically set per country and site-of-service for heightened customer adoption.

Business Combination

On September 11, 2023, we consummated a business combination, pursuant to the business combination agreement dated April 11, 2023 (the “Business Combination Agreement”) by and among Spectral AI, Inc. (Previously, Rosecliff Acquisition Corp I (“Rosecliff”)), Ghost Merger Sub I (a wholly owned subsidiary of Rosecliff), Ghost Merger Sub II (a wholly owned subsidiary of Rosecliff) and Spectral MD Holdings, Ltd. (“Legacy Spectral”). Upon the closing of the Business Combination (the “Closing”), in sequential order: (a) Ghost Merger Sub I merged with and into Legacy Spectral, with Legacy Spectral continuing as the surviving company as our wholly owned subsidiary (the “Spectral Merger”) and then, (b) Legacy Spectral merged with and into Ghost Merger Sub II (the “SPAC Merger”, together with the Spectral Merger (the “Business Combination”)), with Ghost Merger Sub II (renamed Spectral MD Holdings LLC) surviving the SPAC Merger as our direct wholly-owned subsidiary. Upon the Closing, we changed our name from Rosecliff Acquisition Corp I to Spectral AI, Inc. (“Spectral AI”, the “Company” or the “Combined Company”). In addition, the Company cancelled the redeemable warrants that it issued to Rosecliff Acquisition Sponsor I LLC, a Delaware limited liability company (the “Sponsor”), in a private placement (the “Private Warrants”) in connection with the Company’s initial public offering on February 17, 2021 (the “Initial Public Offering”) at Closing, with the 8,433,333 redeemable warrants issued to the public in the Initial Public Offering (the “Public Warrants”) remaining outstanding.

Prior to the Business Combination, Rosecliff had 280,485 shares of Class A common stock, par value $0.0001 per share, issued and outstanding and held by public shareholders (the “Public Shares”) and 6,325,000 shares of Class B common stock, par value $0.0001 per share, issued and outstanding and held by the Sponsor (the “Sponsor Shares”). Upon the Closing, 5,445,000 of the Sponsor Shares were forfeited, in accordance with a letter agreement with the Sponsor, and the remaining 880,000 Sponsor Shares and 280,485 Public Shares, no longer designated Class A and Class B, were included in shares of the Company’s common stock, par value $0.0001 per share (the “Company Common Stock”).

Prior to the Business Combination, Legacy Spectral's shares of common stock, par value $0.001 per share (“Legacy Spectral Common Stock”) were listed on the AIM market on the London Stock Exchange (delisted on September 7, 2023). In September 2023, prior to the Closing, Legacy Spectral issued 7,679,198 shares of Legacy Spectral Common Stock to certain investors in a private placement, in exchange for $3.4 million (the “Equity Raise”).Upon the Closing, all of Legacy Spectral’s issued and outstanding 145,380,871 shares of Legacy Spectral Common Stock, including the shares from the Equity Raise, were exchanged for 14,094,450 shares of Company Common Stock at an exchange ratio of 10.31 (the “Exchange Ratio”), meaning that the Company issued one share of Company Common Stock in exchange for 10.31 shares of Legacy Spectral Common Stock.

On September 12, 2023, the Company began trading its shares of the Company Common Stock and the Public Warrants on the NASDAQ Capital Market (the “NASDAQ”) under the symbols “MDAI” and “MDAIW”, respectively. Prior to the Business Combination, the Company’s shares of Company Common Stock and Public Warrants were listed on the NASDAQ under the symbols “RCLF” and “RCLFW”, respectively.

In September 2023, prior to the Closing, Legacy Spectral issued 7,679,198 shares of Legacy Spectral Common Stock, which was converted to 744,667 shares of Company Common Stock based on the Exchange Ratio, for $3.4 million (the “Equity Raise”).

The Business Combination was accounted for as a reverse recapitalization in accordance with GAAP. Under the guidance in Accounting Standards Codification (“ASC”) 805, Business Combinations, Rosecliff, which is the legal acquirer, has been treated as the “acquired” company for financial reporting purposes and Legacy Spectral has been treated as the accounting acquirer. This determination was primarily based on the following:

(i) Legacy Spectral’s former shareholders has a majority of the voting power of Spectral AI;

(ii) Legacy Spectral’s senior management comprises all of the senior management of Spectral AI;

(iii) Legacy Spectral selected five of the six of the directors for the Board of Directors of Spectral AI;

(iv) Legacy Spectral's relative size of assets and operations compared to Rosecliff; and

(v) Legacy Spectral's operations comprised the ongoing operations of Spectral AI.

Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of a capital transaction in which Legacy Spectral issued stock for the net assets of Rosecliff prior to the Closing. Upon the Closing, the net assets of Rosecliff are stated at fair value, with no goodwill or other intangible assets recorded. All historical financial information presented in the unaudited condensed consolidated financial statements represents the accounts of Legacy Spectral at their historical cost as if Legacy Spectral is the predecessor to the Company. The unaudited condensed consolidated financial statements following the Closing reflect the results of the Combined Company's operations.

Public Company Costs

Upon consummation of the Business Combination, Spectral AI has continued as an SEC-registered and NASDAQ-listed company. We expect to hire additional staff and implement new processes and procedures to address public company requirements in anticipation of and following the completion of the Business Combination. We also expect to incur substantial additional expenses for, among other things, directors' and officers' liability insurance, director fees, internal control compliance, and additional costs for investor relations, accounting, audit, legal and other functions.

Key Operating and Financial Metrics

We regularly review a number of metrics, including the following key operating and financial metrics, to evaluate our business, measure our performance, identify trends in our business, prepare financial projections and make strategic decisions. We believe the operating and financial metrics presented are useful in evaluating our operating performance, as they are similar to measures by our public competitors and are regularly used by security analysts, institutional investors, and other interested parties in analyzing operating performance and prospects. Adjusted EBITDA is a non-GAAP measure, as it is not a financial measure calculated in accordance with GAAP and should not be considered as a substitute for net (loss) income, calculated in accordance with GAAP. See "Non-GAAP Financial Measures" for additional information on adopted non-GAAP financial measures and a reconciliation of these non-GAAP measures to the most comparable GAAP measures.

The following table sets forth these metrics for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Research and development revenue	$ 3,440	$ 7,038	$ 12,769	$ 19,272
Gross Profit	1,472	3,227	5,444	8,329
Gross margin	42.8%	45.9%	42.6%	43.2%
Operating loss	(4,166)	(251)	(10,055)	(878)
Net loss	(10,629)	(380)	(17,308)	(1,173)
Adjusted EBITDA	(3,885)	(4)	(9,073)	2

See "Non-GAAP Financial Measures" below for a reconciliation of net loss to Adjusted EBITDA.

Research and development revenue

We define research and development revenue as revenue generated from the research, testing and development of the DeepView System as utilized in connection with our burn indication. This research and development revenue reflects applied research and experimental development costs relating to our burn application as developed in connection with our BARDA, MTEC and DHA contracts.

Gross Profit and Gross Margin

We define gross profit as research and development revenue, less cost of revenue, and define gross margin, expressed as a percentage, as the ratio of gross profit to revenue. Gross profit and margin can be used to understand our financial performance and efficiency and as we begin commercialization, it will allow investors to evaluate our pricing strategy and compare against our competitors. Our management uses these metrics to make strategic decisions, pricing decisions, identifying areas for improvement, set targets for future performance and make informed decisions about how to allocate resources going forward.

Adjusted EBITDA

We define adjusted earnings before interest, tax, depreciation and amortization ("Adjusted EBITDA") as net loss excluding income taxes, depreciation of property and equipment, net interest income, stock compensation, transaction costs and any non-operating financial income and expense. See "— Non-GAAP Financial Measures" for a reconciliation of GAAP net loss to Adjusted EBITDA.

Key Factors that May Influence Future Results of Operations

Our financial results of operations may not be comparable from period to period due to several factors. Key factors affecting our results of operations are summarized below.

Revenue Sources. As a pre-commercialization company, we currently generate revenue almost exclusively from two U.S. governmental agencies. We are highly dependent upon the continuation of the existing U.S. governmental contract awards, as well as future governmental procurement or other awards. Our operating results may not be comparable between periods as the timing and amount of awards or procurements from the U.S. government may be inconsistent with the timing of prior awards, and due to the phasing of the development study schedules. Our revenues may continue to be almost exclusively dependent upon the terms of those awards.

Gross Margin. As we begin commercial sales of the DeepView System, we may need to determine lower pricing and incentives to accelerate adoption and implementation of the DeepView System, which may negatively impact future revenue and gross margin percentages.

Managing our Supply Chain. We are reliant on contract manufacturers and suppliers to produce our components. While we have not been subject to any disruptions in our current production, there remain global supply chain challenges and logistics constraints, including component shortages, which may cause delays in critical components and inventory, longer lead times, increased costs and delays in product shipments. Our ability to grow depends, in part, on the ability of our contract manufacturers and suppliers to provide high quality services and deliver components and finished products on time and at reasonable costs. While we do not maintain sole-source suppliers, there is a concentration of suppliers which could lead to supply shortages, long lead times for components and supply changes. In the event we are unable to mitigate the impact of delays and/or price increases in raw materials, electronic components and freight, it could delay the manufacturing and installation of our products, which would adversely impact our cash flows and results of operations, including revenue and gross margin.

Components of Consolidated Statements of Operations

Research and Development Revenue

Our primary source of revenue is research and development revenue. Currently, we are highly dependent upon the reimbursements from BARDA for the burn diagnostic testing of our DeepView System. Our research and development revenue is affected by the amount of research and development that is expended each month with respect to our contract with BARDA and other U.S. governmental contract awards. During 2023, we received a grant under the MTEC Agreement which we earn based on the achievement of milestones. Our revenue growth is dependent on a number of factors including expanding the research and development expense under the BARDA contract, research and development reimbursed expenses relating to other contract awards from U.S. governmental agencies and the intended future commercial sales of our DeepView System.

Cost of Revenue

Our cost of revenues consists primarily of direct and indirect costs associated with the research and development expenses relating to the BARDA and MTEC contracts. Our revenue costs are affected by the extent of research and development expenses as well as expansion of work on other U.S. governmental projects and the expanded applications for our DeepView System.

Gross Profit

Gross profit may vary from period-to-period and is primarily affected by the current reimbursement rates under the BARDA contract and other U.S. governmental contract awards, as well as the percentage of revenue related to the BARDA contract as compared to the MTEC project. These reimbursement rates are fixed under each contact award. Our gross profit represents this reimbursement rate plus a variable component relating to non-reimbursed expenses incurred in connection with the work completed on these contracts.

Operating Costs and Expenses

Operating costs and expenses consist of general and administrative expense. These expenses primarily relate to salaries and related costs of our organization's support and operations staff, consulting fees, rent, insurance and office expenses, and our non-revenue generating research and development expenses, primarily related to salaries and related costs and consulting fees.

Other income (expense)

Other income (expense) primarily consists of transaction costs, primarily related to the Business Combination, net interest income, change in fair value of warrant liabilities and foreign exchange transaction gains/losses. Historic foreign exchange transaction loss primarily relates to changes in the exchange rate between the U.S. dollar and the British pound sterling for our deposit accounts that are denominated in British pound sterling. In addition, this amount includes costs associated with buying British pound sterling for payment of our employees and vendors in the UK.

Results of Operations

The following table sets forth a summary of our consolidated statements of operations for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Research and development revenue	$ 3,440	$ 7,038	$ 12,769	$ 19,272
Cost of revenue	(1,968)	(3,811)	(7,325)	(10,943)
Gross profit	1,472	3,227	5,444	8,329
Operating costs and expenses:				
General and administrative	5,638	3,478	15,499	9,207
Total operating costs and expenses	5,638	3,478	15,499	9,207
Operating loss	(4,166)	(251)	(10,055)	(878)
Other income (expense):				
Net interest income	42	2	128	1
Change in fair value of warrant liability	1,069	22	1,004	50
Foreign exchange transaction loss	(24)	(51)	(11)	(255)
Transaction costs	(7,604)	-	(8,342)	-
Other income	-	(17)	-	-
Total other expense, net	(6,517)	(44)	(7,221)	(204)
Loss before income taxes	(10,683)	(295)	(17,276)	(1,082)
Income tax benefit (provision)	54	(85)	(32)	(91)
Net loss	$ (10,629)	$ (380)	$ (17,308)	$ (1,173)

Research and development revenue

	Three Months Ended September 30,		Change in		Nine Months Ended September 30,		Change in	
	2023	2022	$	%	2023	2022	$	%
	(In thousands, except percentages)							
Research and development revenue	$ 3,440	$ 7,038	$ (3,598)	(51.1)%	$ 12,769	$ 19,272	$ (6,503)	(33.7)%

Research and development revenue decreased by 51.1% and 33.7%, respectively, or approximately $3.6 million and $6.5 million, respectively, for the three and nine months ended September 30, 2023, as compared to the comparable periods in 2022, primarily due to decreased research and development work performed pursuant to the BARDA Burn II contract as clinical trials under this contract were nearing completion. New patient enrollments in our BARDA clinical study decreased in the three months ended September 30, 2023 compared to the three months ended September 30, 2022 as the Company is completing enrollment and transitioning to the closeout phase of the study.

For the three and nine months ended September 30, 2023 and 2022, the Company's revenues disaggregated by the major sources was as follows:

	Three Months Ended September 30,		Change in		Nine Months Ended September 30,		Change in	
	2023	2022	$	%	2023	2022	$	%
	(In thousands, except percentages)							
BARDA	$ 3,055	$ 6,903	$ (3,848)	(55.7)%	$ 12,018	$ 18,866	$ (6,848)	(36.3)%
Other U.S. governmental authorities	385	135	250	185.2%	751	406	345	85.0%
Total research and development revenue	$ 3,440	$ 7,038	$ (3,598)	(51.1)%	$ 12,769	$ 19,272	$ (6,503)	(33.7)%

Cost of Revenues and Gross Profit

	Three Months Ended September 30,		Change in		Nine Months Ended September 30,		Change in	
	2023	2022	$	%	2023	2022	$	%
	(In thousands, except percentages)							
Cost of revenue	$ 1,968	$ 3,811	$ (1,843)	(48.4)%	$ 7,325	$ 10,943	$ (3,618)	(33.1)%
Gross profit	1,472	3,227	(1,755)	(54.4)%	5,444	8,329	(2,885)	(34.6)%
Gross margin	42.8%	45.9%			42.6%	43.2%		

Cost of revenue for the three and nine months ended September 30, 2023 compared to the comparable periods in 2022 decreased by 48.4% and 33.1%, respectively, or approximately $1.8 million and $3.6 million, respectively, primarily due to decreased activity to fulfill our U.S. governmental contracts, which is consistent with decreased research and development revenue.

Gross margin for the three months ended September 30, 2023 decreased 3.1% as compared to the comparable period in 2022 primarily due to beginning the MTEC contract, which has a lower gross margin, during 2023. Gross margin was relatively consistent for nine months ended September 30, 2023, as compared to the comparable periods in 2022.

General and Administrative Expense

	Three Months Ended September 30,		Change in		Nine Months Ended September 30,		Change in	
	2023	2022	$	%	2023	2022	$	%
	(In thousands, except percentages)							
General and administrative expense	$ 5,638	$ 3,478	$ 2,160	62.1%	$ 15,499	$ 9,207	$ 6,292	68.3%

General and administrative expense increased by 62.1% and 68.3%, respectively, or approximately $2.2 million and $6.2 million, respectively, for the three and nine months ended September 30, 2023, as compared to the comparable periods in 2022. The increase was primarily due to an increase in our administrative staffing since 2022. Our headcount grew from 63 employees as of September 30, 2022 to 83 full-time employees as of September 30, 2023 resulting in an increase in general and administrative expense of approximately $0.7 million and $3.5 million, respectively, for the three and nine months ended September 30, 2023. Additionally, non-revenue generating research and development activities, primarily related to salaries and related costs and consulting fees, have increased by approximately $1.2 million and $2.8 million, respectively, in the three and nine months ended September 30, 2023 compared to the comparable periods in 2022.

Other income (expense)

	Three Months Ended September 30,		Change in	Nine Months Ended September 30,		Change in
	2023	2022	$	2023	2022	$
	(In thousands, except percentages)					
Net interest income	$ 42	$ 2	$ 40	$ 128	$ 1	$ 127
Change in fair value of warrant liability	1,069	22	1,047	1,004	50	954
Foreign exchange transaction loss	(24)	(51)	27	(11)	(255)	244
Transaction costs	(7,604)	-	(7,604)	(8,342)	-	(8,342)
Other income	-	(17)	17	-	-	-
Total other expense, net	$ (6,517)	$ (44)	$ (6,473)	$ (7,221)	$ (204)	$ (7,017)

Net interest income for the three and nine months ended September 30, 2023 primarily relates to cash interest received by us from our deposit accounts.

Change in fair value of warrant liability increased by approximately $1.0 million for each of the three and nine months ended September 30, 2023, as compared to the comparable period in 2022. The income during the three and nine months ended September 30, 2023, was primarily due to the decrease in the fair value of the Public Warrants from the closing of the Business Combination to September 30, 2023.

Foreign exchange transaction loss for the three and nine months ended September 30, 2022 relates to the decreased exchange rate between the U.S. dollar and the British pound sterling during the third quarter of 2022 for our deposit accounts that are denominated in British pound sterling. In addition, this amount includes costs associated with buying British pound sterling for payment of our employees and vendors in the UK. Foreign exchange transaction loss for the three and nine months ended September 30, 2023 is immaterial due to much lower balances in our deposit accounts and accounts payable denominated in British pound sterling and less fluctuation in the exchange rate between the U.S. dollar and the British pound sterling.

Transaction costs for the three and nine months ended September 30, 2023 primarily relate to non-recurring legal, accounting and consulting costs expended for the Business Combination.

Non-GAAP Financial Measures

We use Adjusted EBITDA as a non-GAAP metric when measuring performance, including when measuring current period results against prior periods' Adjusted EBITDA. This non-GAAP financial measure should be considered in addition to results prepared in accordance with GAAP and should not be considered as a substitute for, or superior to, GAAP results. In addition, Adjusted EBITDA should not be construed as an indicator of our operating performance, liquidity or cash flows generated by operating, investing and financing activities, as there may be significant factors or trends that it fails to address.

Because of their non-standardized definitions, non-GAAP measures (unlike GAAP measures) may not be comparable to the calculation of similar measures of other companies. We caution investors that non-GAAP financial information, by its nature, departs from traditional accounting conventions. Supplemental non-GAAP measures are presented solely to permit investors to more fully understand how Spectral AI's management assesses underlying performance.

Adjusted EBITDA

We define Adjusted EBITDA as net loss excluding income taxes, depreciation of property and equipment, net interest income, stock compensation, transaction costs and any non-operating financial income and expense.

The following table presents our Adjusted EBITDA for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Net loss	$ (10,629)	$ (380)	$ (17,308)	$ (1,173)
Adjust:				
Depreciation expense	2	-	7	6
Provision for income taxes	(54)	85	32	91
Net interest income	(42)	(2)	(128)	(1)
EBITDA	**(10,723)**	**(297)**	**(17,397)**	**(1,077)**
Additional adjustments:				
Stock-based compensation	279	247	975	874
Change in fair value of warrant liability	(1,069)	(22)	(1,004)	(50)
Foreign exchange transaction gain	24	51	11	255
Transaction costs	7,604	-	8,342	-
Other income	-	17	-	-
Adjusted EBITDA	**$ (3,885)**	**$ (4)**	**$ (9,073)**	**$ 2**

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2023 we had approximately $7.3 million in cash, and an accumulated deficit of approximately $29.2 million.

We have historically funded our operations through the issuance of notes and the sale of preferred stock and common stock. Together with the new PBS BARDA Contract, executed in September 2023, for a total value of up to $149 million, our total potential support from BARDA is nearly $250 million if all future options are executed. The base phase of the PBS BARDA Contract, valued at $55 million, was exercised concurrently with the contract award in September 2023. To date, for our 2013 and 2019 BARDA contracts, we have committed funding of $101 million of which we have received $99 million. In April 2023, we received a $4.0 million grant under the MTEC Agreement. See "*Research and Development Revenue*" above. With the PBS BARDA Contract and the MTEC Agreement, the Company believes it will have sufficient working capital to fund operations for at least one year beyond the release date of the condensed consolidated financial statements.

Our future capital requirements will depend on many factors, including the revenue growth rate, the success of future product development and capital investment required, and the timing and extent of spending to support further sales and marketing and research and development efforts. In addition, we expect to incur additional costs as a result of operating as a U.S. public company. There can be no assurance that we will be successful in raising any additional capital. If additional financing is required from outside sources, we cannot be sure that any additional financing will be available to us on acceptable terms, if at all. If we are unable to raise additional capital when desired, our business, operating results, and financial condition could be adversely affected.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	**2022**
	(In thousands)	
Net cash used in operating activities	$ (10,865)	$ (863)
Net cash provided by (used in) financing activities	4,039	(651)

Cash Flows Used in Operating Activities

Net cash used in operating activities increased by approximately $10.0 million for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022 primarily driven by (a) increased spending on general and administrative expenses of approximately $3.5 million for our increased staff and approximately $2.8 million for our higher non-revenue generating research and development costs, (b) decreased gross profit of approximately $2.9 million from less research and development work performed pursuant to the BARDA Burn II contract as clinical trials under this contract were nearing completion, partially offset by cash receipts in excess of cash payments, and (c) cash paid for transaction costs for the Business Combination of $1.0 million.

Cash Flows Provided by (Used in) Financing Activities

Net cash provided by (used in) financing activities increased approximately $4.7 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. This was primarily attributable to the proceeds of $3.4 million from the Equity Raise and operating cash received upon closing of the Business Combination of $0.7 million.

Current Indebtedness

In September 2023, we entered into a financing arrangement for a portion of our insurance premium for approximately $0.6 million (the “Note”). The Note bears interest at 8.6% per annum and is payable in equal monthly payments of principal and interest, maturing in June 2024. As of September 30, 2023, we owed $0.6 million for the Note.

Related Party Transactions

For the nine months ended September 30, 2023 and 2022, we did not have any transactions with related parties.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Critical Accounting Policies

There have been no material changes to the Company’s critical accounting policies and estimates discussed in Legacy Spectral’s Management’s Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies for the years ended December 31, 2022 and 2021 included in the Prospectus.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, of the notes to our condensed consolidated financial statements included elsewhere in this Form 10-Q for recently adopted accounting standards and recently issued accounting standards as of the dates of the statement of financial position included in this Form 10-Q.

Emerging Growth Company

We are an emerging growth company, as defined in the JOBS Act. The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period under the JOBS Act for the adoption of certain accounting standards until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply more promptly with new or revised accounting pronouncements as of public company effective dates.

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate, foreign exchange, credit and inflation risks.

Interest Rate Sensitivity

We maintain a large amount of our assets in cash. Our cash is held primarily in cash deposits. The fair value of our cash would not be significantly affected by either an increase or decrease in interest rates due mainly to the short-term nature of these instruments. Additionally, changes to interest rates will impact on the cost of any future borrowings. With respect to our current borrowings, the interest rate on the Note for insurance premiums is fixed. Changes in prevailing interest rates could have a material impact on our results of operations.

Foreign Currency Risk

Our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States and UK, with an insignificant portion of expenses incurred in our wholly owned subsidiaries in the UK and denominated in British pound sterling.

Credit Risk

Financial instruments that subject us to concentrations of credit risk consist primarily of cash and accounts receivable. The vast majority of our cash is held in U.S. financial institutions which, at times, exceed federally insured limits. We have not recognized any losses from credit risks on such accounts. We believe we are not exposed to significant credit risk on cash.

Additional credit risk is related to our concentration of receivables and revenues. One customer (which is a U.S. government agency) represents the majority of our research and development revenue and accounts receivable.

Inflation Risk

The recent increase in inflation partially contributed to the increase in the cost of our research and development as well as operating costs. If the cost of our products, employee costs, or other costs continue to be subject to significant inflationary pressures, such inflationary pressure may have an adverse effect on our ability to maintain current levels of gross margin and selling, general and administrative expense. As a result, our inability to quickly respond to inflation could harm our cash flows and results of operations in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on management's evaluation as of the quarter ended September 30, 2023, our Chief Executive Officer and Chief Financial Officer have concluded that, as a result of the material weaknesses in our internal control over financial reporting as described below and in Part II, Item 1A. Risk Factors, our disclosure controls and procedures were not effective as of September 30, 2023. In connection with the preparation of our consolidated financial statements for the quarter ended September 30, 2023, we identified material weaknesses in our internal control over financial reporting related to deficiencies in our controls over the accounting for complex equity arrangements, and in the design and operation of internal controls involving accruals and unbilled revenue.

Notwithstanding the identified material weaknesses, our management believes the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with U.S. GAAP

Remediation Plan for Material Weaknesses

Remediation generally requires making changes to how controls are designed and implemented and then adhering to those changes for a sufficient period of time such that the effectiveness of those changes is demonstrated with an appropriate amount of consistency. In response to the material weaknesses, we implemented, and are continuing to implement, measures designed to improve our internal control over financial reporting. These efforts include:

- engaging a professional accounting services firm to help us assess and commence documentation of our internal controls for complying with the Sarbanes-Oxley Act of 2002;

- strengthening, formalizing, documenting and testing accounting processes and internal controls, specifically regarding accrued expenses and contract reviews; and

- engaging consultants to provide additional technical accounting expertise.

The measures we are implementing are subject to continued management review supported by confirmation and testing, as well as audit committee oversight. Management and the Audit Committee remain committed to the implementation of remediation efforts to address the material weaknesses. We will continue to implement measures to remedy our internal control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. In addition, until remediation steps have been completed and are operated for a sufficient period of time, and subsequent evaluation of their effectiveness is completed, the material weaknesses previously disclosed, and as described above, will continue to exist.

Changes in Internal Control over Financial Reporting

Except for the remediation measures in connection with the material weaknesses described above, there were no other changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Factors that could cause our actual results to differ materially from those in this Quarterly Report include the risk factors described in our Annual Report on Form 10-K filed with the SEC on March 31, 2023 and in the Registration Statement on Form S-4 filed with the SEC on May 2, 2023, as amended. Any of those factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. As of the date of this Quarterly Report, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K filed with the SEC on March 31, 2023 and in the Registration Statement on Form S-4 filed with the SEC on May 2, 2023, as amended, except as listed below. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

Our internal controls over financial reporting currently do not meet all of the standards contemplated by Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("SOX"), and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of SOX could impair our ability to produce timely and accurate financial statements or comply with applicable regulations and have a material adverse effect on our business. In the future, our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we are subject to certain reporting requirements of the Exchange Act and have significant requirements for enhanced financial reporting and internal controls. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments, and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. If we are unable to maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis, result in material misstatements in our consolidated financial statements, and harm our operating results. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. In addition, we are required, pursuant to Section 404 of the Sarbanes–Oxley Act of 2002, as amended ("SOX"), to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. Testing and maintaining internal controls may divert management's attention from other matters that are important to our business. As an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until our annual report for any fiscal year following such date that we are no longer an emerging growth company. If we are not able to complete our initial assessment of our internal controls and otherwise implement the requirements of Section 404 of SOX in a timely manner or with adequate compliance, our independent registered public accounting firm may not be able to certify as to the adequacy of our internal controls over financial reporting. Additionally, when required, an independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. Matters impacting our internal controls may cause us to be unable to report our financial information on a timely basis and thereby subject us to adverse regulatory consequences, including sanctions by the SEC or violations of applicable stock exchange listing rules, which may result in a breach of the covenants under existing or future financing arrangements. There also could be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our consolidated financial statements. Confidence in the reliability of our consolidated financial statements also could suffer if we or our independent registered public accounting firm report a material weakness in our internal controls over financial reporting. In connection with the preparation of our consolidated financial statements for the quarter ended September 30, 2023, we identified material weaknesses in our internal control over financial reporting related to deficiencies in our controls over the accounting for complex equity arrangements, and in the design and operation of internal controls involving accruals and unbilled revenue.

We have implemented, and are continuing to implement, measures designed to improve our internal control over financial reporting to remediate these material weaknesses. These measures include formalizing our processes and internal control documentation, strengthening supervisory reviews by our financial management, and engaging financial consultants to enable the implementation of internal control over financial reporting. We expect to incur additional costs to remediate the control deficiencies identified, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by the National Association of Securities Dealers Automated Quotations ("NASDAQ"), the SEC or other regulatory authorities. Our internal resources and personnel may in the future be insufficient to avoid accounting errors and there can be no assurance that we will not have additional material weaknesses in the future. Any failure to develop or maintain effective controls or any difficulties encountered implementing required new or improved controls could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our consolidated financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls, procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on NASDAQ.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q:

No.	Description of Exhibit
2.1	Business Combination Agreement, dated as of April 11, 2023, by and among Rosecliff Acquisition Corp I, Ghost Merger Sub I Inc., Ghost Merger Sub II and Spectral MD Holdings Ltd. (incorporated by reference to the Company's Form 8-K, filed with the SEC on April 17, 2023).
10.1*	Agreement, dated September 27, 2023, by and between Spectral MD, Inc. and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services (certain portions of this exhibit have been omitted pursuant to Rule 601(b)(10 of Regulation S-K. The omitted information is (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed).
31.1*	Certification of Chief Executive Officer (Principal Executive Officer)
31.2*	Certification of Chief Financial Officer (Principal Financial and Accounting Officer)
32**	18 U.S.C. Section 1350 Certification
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

SPECTRAL AI, INC.

Date: November 14, 2023

By: /s/ Wensheng Fan
Name: Wensheng Fan
Title: Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2023

By: /s/ Nils Windler
Name: Nils Windler
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
			1 107

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
[***]	See Block 20C	OS320420

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

6. ADMINISTERED BY *(If other than Item 5)*	CODE	ASPR-BARDA
ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201 SCD-C		

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, country, State and ZIP Code)*	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT
SPECTRAL MD, INC. [***] BRANDYPIERRE;2515 MCKINNEY AVE STE 1000 2515 MCKINNEY AVE STE 1000 DALLAS TX 75201	☐ FOB ORIGIN ☒ OTHER *(See below)*	

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM
	G.5

CODE	[***]	FACILITY CODE	

11. SHIP TO/MARK FOR	CODE	OS
Office of the Secretary Office of the Secretary 200 Independence Ave. S.W. Washington DC 20201		

12. PAYMENT WILL BE MADE BY	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		

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 3304 (a) ( )	2023.1995361.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT ▶				[***]

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(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
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X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	4			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	10	X	J	LIST OF ATTACHMENTS	56
X	D	PACKAGING AND MARKING	12			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* _____ *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD (*Contractor is not required to sign this document.)* Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER
Wensheng Fan CEO	JONATHAN F. GONZALEZ

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
SPECTRAL MD, INC. 1178833 BY: /s/ Wensheng Fan *(Signature of person authorized to sign)*	09/27/2023	BY: /s/ Jonathan F. Gonzalez - S *(Signature of the Contracting Officer)*	9/27/2023

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STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

SPECTRAL MD, INC. [***]

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: [***] UEI: XYMKTFCE2XR3 OTA: N Delivery: [***] Appr. Yr.: 2023 CAN: 1995361 Object Class: 25106 Period of Performance: [***]				
1	ASPR-23-02537 Base period (CLIN1) funds to Spectral MD Inc for new Project BioShield award Obligated Amount: [***]				[***]
2	Option 1 - Procurement of DeepView Devices by [***] Amount: [***] (Option Line Item)				[***]
3	Option 2 - Follow-on Development Amount: [***] (Option Line Item)				[***]
4	Option 3 - Additional Procurement of DeepView Devices by [***] Amount: [***] (Option Line Item)				[***]
5	Option 4 - Additional Development Amount: [***] (Option Line Item)				[***]

CONTRACT TABLE OF CONTENTS

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SERVICES

The Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 established the Biomedical Advanced Research and Development Authority (BARDA) and was reauthorized under the PAHPA of 2013 and again in 2019 under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), Public Law No. 116-22, to support development and acquisition of medical countermeasure (MCMs) to prevent or treat the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza (PI), and emerging infectious diseases (EID). These MCMs include vaccines, therapeutics, diagnostics, and medical devices. Additionally, BARDA is entrusted to foster innovation of technologies that enable better manufacturing, testing, and utilization of these medical countermeasures.

This hybrid cost plus fixed fee, Firm Fixed Price and cost sharing contract with Spectral MD, Inc. is to support development of a novel burn wound imaging technology (BWIT).

The Government has determined a Bona Fide Need for each non-severable discrete work segment which will conclude upon the completion of a defined tasks that provide(s) independent merit and value to the Government. The Contractor's success in completing the required tasks under the work segments must be demonstrated through the Deliverables and Milestones specified under Article F of this contract. As set forth in Attachment J Statement of Work, the Go/No-Go, Deliverable, and/or Milestone will constitute the basis for the Government's decision, at its sole discretion, to exercise any follow-on option period(s).

The period of performance under CLIN 1 Phase A is time driven. The CLIN is fully funded for the period of performance and shall only be used for the scope of work covered in CLIN 1 Phase A. The period of performance is listed under Article B.2.1.

B.2. COST AND PERIOD OF PERFORMANCE

1. The government will not be responsible for any Contractor-incurred costs that exceed this amount unless a modification to the contract is signed by the Contracting Officer which expressly increases this amount.

2. The Contractor shall maintain records of all contract costs and such records shall be subject to FAR 52.215-2 (Oct 2010), Audit and Records-Negotiation, and Health and Human Services Acquisition Regulation (HHSAR) 352.242-74, Final Decisions on Audit Findings, incorporated by reference into this contract in SECTION I.

B.2.1 BASE PERIOD

1. The Base Period is a Cost-Plus Fixed Fee (CPFF) Contract Line Item Number (CLIN).

2. The total estimated cost of the base period of this contract is [***].

3. The fixed fee for CLIN 0001 is [***]. The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in Section I of this contract.

Table 1. Base Period Cost Reimbursement CLIN

CLIN	Period of Performance	Supplies/Services	Estimated Cost	Fixed Fee	Cost + Fixed Fee (CPFF)
0001	[***]	[***]	[***]	[***]	[***]

4. The amount currently obligated will cover base performance of the contract through [***], unless FAR Clause 52.217-8 is exercised. The period of performance may be adjusted with mutual agreement.

B.2.2. OPTIONS

a. The contract includes optional cost sharing CLINs 3 and 5. The Government may exercise Options in accordance with 52.217-7 Option for Increased Quantity – Separately Priced Line Item (March 1989), as set forth in Section I of the contract.

b. Unless the government exercises its option pursuant to the option clause contained in SECTION I, as well as successful completion of the "go criteria," the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in SECTION B.2 of the contract.

c. The Government may modify the contract bilaterally and require the contractor to provide supplies and services for Option Periods listed below, in accordance with 52.217-7.

d. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in Section I. The tentative time frame for period of performance is set forth below.

Table 2. Option Period Firm Fixed Price CLINs

CLIN	Period of Performance	Supplies/Services	Number of Units	Total Price
0002	[***]	Option 1 - Procurement of DeepView Devices [***]	[***]	[***]
0004	[***]	Option 3 – Additional Procurement of DeepView Devices [***]	[***]	[***]

Table 3. Option Period CLINs Cost Share

CLIN	Est. Period of Performance	Services	Government Cost Share	Contractor Cost Share	Total Estimated Cost
0003	[***]	Option 2 – Follow-on Development	[***]	[***]	[***]
0005	[***]	Option 4 – Additional Development	[***]	[***]	[***]

B.3. ESTIMATED COST - COST SHARING

This is a cost-sharing contract. The total estimated cost sharing for performing the work in the optional CLINs 0003 and 0005 is established in the above schedule, B.2 Table 4. For further provisions regarding the specific cost-sharing arrangement, see the ADVANCE UNDERSTANDINGS Article in SECTION B.5 of the Contract.

B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS

1. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses and unless authorized in writing by the Contracting Officer or set forth in the Statement of Work, the cost of the following items or activities shall be unallowable as direct costs:

a. Acquisition, by purchase or lease, of any interest in real property;

b. Special rearrangement or alteration of facilities;

c. Accountable Government Property (see the HHS Contracting Guide for Control for Government Property incorporated by Section G.9. of this contract);

Note: this includes the lease or purchase of <u>any</u> item of general-purpose office furniture or office equipment regardless of dollar value.

d. Purchase or lease of scientific instruments or equipment over $10,000 except for instruments and equipment specifically included in the Statement of Work;

e. Travel to attend general scientific meetings/conferences;

f. Promotional Items

g. Printing Costs (as defined in the Government Printing and Binding Regulations);

h. Overtime (premium) compensation;

i. Entering into certain types of subcontracting arrangements (See Section B.5(3) for specific obligations). Note that most consulting agreements require CO’s written consent;

j. Foreign Travel (see Subparagraph B.4.2(3));

k. Patient care costs (see Section J-List of Attachments);

l. Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer’s Representative (COR), with a copy to the Contracting Officer, at least six weeks in advance of the event and are subject to “HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications.” The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

2. Travel Costs

1) Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract during the Base Period shall not exceed [***] without the prior written approval of the Contracting Officer. The Contractor shall notify the Contracting Officer in writing when travel expenditures have exceeded 80% of the base period travel expenses. Costs must be consistent with Federal Acquisition Regulations (FAR) 52.247-63 – Preference for U.S. Air Flag carriers.

2) Subject to the dollar limitation specified under B.5.b.1. above, the Contactor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulation (FAR) 31.2 – Contracts with Commercial Organizations, Sub-Section 31.205- 46, Travel Costs.

3) If foreign travel is necessary, a Contracting Officer Authorization (COA) will be required. Expenditures for foreign travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed the amount specified in each approved COA, without the prior written approval of the Contracting Officer.

Requests for foreign travel must be submitted at least four weeks in advance and shall contain the following:

- Meeting(s) and place(s) to be visited, with costs and dates; name(s) and title(s) of Contractor personnel to travel and their functions in the contract project;
- Contract purposes to be served by the travel;
- How travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of BARDA contract funds;
- How such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and
- What additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

Contractor Consent to Go/No-Go Decision

The Government's discretion to exercise options for periods beyond the base period may only be exercised if Contractor and Government agree that the Milestones of the current base or option period(s) have been accomplished as detailed in GO/NO-GO DECISION POINTS. Following Contractor's notification to the COR that all Milestones of the current base or option period(s) have been achieved, the Government may, at its sole discretion, exercise its right to award the next option period.

B.5. ADVANCE UNDERSTANDINGS

1. Person-in-Plant

With seven 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.

2. Security

A security plan is required within 30 days of contract award.

3. 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, time-and-materials or labor-hour type or
- Is of the fixed price type and exceeds $250,000 or 5% of the contract

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.

4. Overtime Compensation

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

5. Sharing of contract deliverables within United States Government (USG)

Subject to the data rights provisions of FAR 52.227-14 and 52.227-14 Alt. II, in an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, BARDA may share technical deliverables and test results created in the performance of this Contract with the United States Government and entities within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial or technical information, technical deliverables, or any other data outside of the United States Government. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

6. Approval of Human and Animal Protocols

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the COR for review and approval prior to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government requires no fewer than ten (10) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

7. Rights in Data

The contract will incorporate the FAR Clause 52.227-14, Rights in Data—General. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

This notice shall be marked on any reproduction of these data, in whole or in part.

8. Cost Sharing

1. This is a cost-sharing contract for CLINs 0003 and 0005. Monies shall be provided for the total cost of performance from BARDA and Spectral MD.

2. BARDA shall provide monies in an amount not to exceed [***] for CLINs 0003 and 0005, if the options are exercised. The Contractor's share of CLINs 0003 and 0005 is estimated at [***].

3. The Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the Audit and Records- Negotiation and Final Decisions on Audit Findings clauses of the General Clauses.

4. Costs contributed by the Contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program). The Contractor shall report the organization's share of the costs expended by category, on the Financial Report of Individual Project/Contract as referenced in the CONTRACT FINANCIAL REPORT Article in SECTION G of this contract.

9. Determination On Execution Of Options

1. BARDA would have the sole discretion to make the determination on execution of options for additional device procurements [***].

2. [***].

3. [***].

B.6 ORGANIZATIONAL CONFLICT OF INTEREST

a. 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.

b. 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.

c. 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.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work attached to this contract as Attachment 1 (Section J-List of Attachments).

C.2. REPORTING REQUIREMENTS

Refer to Section F.2 for specific instructions regarding Reporting Requirements.

C.3. PROJECT MEETING CONFERENCE CALLS

A conference call between the Contracting Officer, the Contracting Officer's Representative (COR) and designees and the Contractor's Project Leader/delegate and designees shall occur bi-weekly or as otherwise mutually agreed upon by the Government and the Contractor or determined by the Contracting Officer. During this call the Contractor's Project Leader/delegate and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leader/delegate may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative. Electronic copy of conference call meeting minutes/summaries shall be provided via e-mail to the CO, COR, and uploaded into a new "Collaborator Portal" by the Contractor within five (5) business days after the conference call is held. The COR shall provide details and setup instructions for the portal once it is authorized for use.

C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the COR. These meetings may include virtual and/or face-to-face meetings with BARDA in Washington, D.C. and at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor confidential or proprietary data) and Government personnel as required by the COR in order to facilitate review of contract activities.

1. Kickoff Meeting

The Contractor and Government shall conduct a kickoff meeting within 45 calendar days after contract award to review HHS procedures, processes and expectations. Contractor shall provide an itinerary/agenda no later than five (5) business days before meeting. Minutes from the kickoff meeting must be provided within ten (10) business days of the event.

2. Quarterly and Ad-Hoc Meetings

At the discretion of the CO or COR, the Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may be conducted via virtual or face-to-face meetings in Washington, D.C. or at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor's confidential or proprietary data) and Government personnel as required by the Contracting Officer's Representative, giving reasonable prior notice of such requirement to Contractor, in order to facilitate review of contract activities.

Contractor shall provide itinerary/agenda at least two (2) business days in advance of meetings.

Contractor shall provide a meeting summary to the BARDA COR no later than five (5) business days after the meeting.

3. Project Review Meetings

The Contractor shall, at a time to be determined later, present a comprehensive review of contract progress to date in a virtual or face-to-face meeting in Washington, DC., or, alternatively upon agreement of the parties a virtual or remote meeting, including due to public health reasons. The Contractor will be responsible for updating the BARDA program on technical progress under the Statement of Work. Presentation must be delivered seven (7) business days prior to the scheduled meeting.

C.5 RISK MANAGEMENT

The Contractor shall establish and maintain an active, enterprise-wide risk management system as well as a specific risk management plan that includes the SOPs governing risk management, a description of the risk management activities required to oversee the project across its range of scope, and the processes for reviewing completed risk mitigations. The Contractor shall complete risk management documentation for the program as applicable, such as:

1. Preliminary hazard analyses as necessary for each product component

2. Design, user, and process FMEA plans

3. Risk control plans to verify the proposed mitigations

C.6 REGULATORY ACTIVITIES

The Contractor shall provide the COR the opportunity to review and comment upon any draft documents, including draft pre-submission packages, and meeting requests, to be submitted to the FDA or other regulatory agency. The Contractor shall provide the COR with fifteen (15) business days for review and comments. An acceptable version shall be provided to the COR prior to FDA submission.

The Contractor shall provide the COR initial draft minutes and final draft minutes of any - meeting with the FDA and other regulatory agencies.

The Contractor shall communicate the dates and times of any meeting with the FDA and other regulatory agencies to the COR and ensure participation for appropriate COR and BARDA SME staff to attend the meetings.

The Contractor shall forward Standard Operating Procedures (SOPs) upon request from Contracting Officer's Representative /Contracting Officer.

The Contractor shall work to support BARDA in development of FDA submissions and meeting for seeking a Pre-Emergency Use Authorization if deemed necessary by BARDA. The support may require the Contractor to develop unique deliverables other than the ones related to the SOW for submission to the FDA by BARDA.

The Contractor shall support FDA audits. Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, 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.

C.7 QUALITY

The Contractor shall establish and maintain a Quality Management System with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 210-211.

The Contractor shall establish routine internal reviews, documentation, and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 210-211.

The Contractor shall conduct an audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the Quality Audit Findings and resolutions to the Government. The audit shall be conducted by individuals who do not have direct responsibility for the matters being audited.

SECTION D – PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications and Section F. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition

Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following 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. Also, the full text of a clause may be accessed electronically at: https://www.acquisition.gov/FAR/

FAR Clause **Title and Date**

FAR 52.246-3, Inspection of Supplies – Cost-Reimbursement (May 2001)
FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)
FAR 52.246-8, Inspection of Research and Development – Cost-reimbursement (May 2001)
FAR 52.246-16, Responsibility for Supplies (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

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 a duly authorized representative. Delivery, technical inspection and acceptance will take place at a location designated by the Contracting Officer or the Contracting Officer Representative.

1. Site Visits and Inspections

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. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. 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:

a. 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.

b. COR and CO will review the report and provide a response to the Contractor within ten business days.

c. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the Base Period in Section B.2.1. If the Government exercises the Options Period(s) pursuant to the Option Clause in Section I.3 of the contract, the period of performance shall be increased as shown in the tables in Section B.2.2.

F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in the Statement of Work, set forth in Section J - List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the COR, of each of the deliverables described in Section C, Section F, and Section J.

All deliverables and reporting documents listed within this Section shall be delivered electronically (as defined in Section F.3 Electronic Submission) to the CO, CS, and the COR unless otherwise specified by the CO.

Unless otherwise specified by the CO, the deliverables identified in this Section F shall also be delivered electronically to the designated Collaborator Portal along with a concurrent email notification sent to the CO, CS, COR, and Alternate COR stating delivery has been made.

Electronic copies of documents/reports are preferred, however if a paper/hard copy documents/reports is to be submitted under this contract, it shall be printed or copied, double- sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b). The Contracting Officer or the Contracting Officer Representative shall provide the designated shipping address, as required.

Contract Data Requirements List (CDRLs)

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
01	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	● Within 45 calendar days after contract award. ● Materials: Contractor shall provide itinerary, slides, and agenda to CO and COR at least five (5) business days in advance of meeting. COR approves distributes itinerary and agenda within three (3) business days. ● Due out: Contractor provides meeting minutes to CO and COR within five (5) business days after the meeting. The CO and COR reviews, comments, and the COR approves minutes within ten (10) business days of the event.
02	Quarterly Meetings	At the discretion of the government, the Contractor shall hold recurring virtual or face-to- face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or subcontractors. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	● Materials: Contractor shall provide itinerary, slides, and agenda to CO and COR at least five (5) business days in advance of site visit. The COR approves and distributes itinerary and agenda within three (3) business days. ● Due out: Contractor provides meeting minutes to the CO and the COR within five (5) business days after the meeting. The CO and COR reviews, comments, and the COR approves minutes within ten (10) business days.
03	Biweekly Virtual Meetings	The Contractor shall participate in virtual meeting every two weeks with the CO and the COR to discuss the performance of the contract. The COR shall approve the virtual platform the meeting will be held on.	● Materials: Contractor provides agenda and slides to the CO and COR no later than two (2) business days in advance of meeting. The COR approves and distributes agenda prior to meeting. ● Due out: Contractor provides meeting minutes to the CO and COR within five (5) business days following the meeting. The CO and COR reviews, comments, and the COR approves minutes within ten (10) business days following the meeting.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
04 (Monthly) 05 (Annual)	Monthly & Annual Technical Progress Reports	The Monthly and Annual Technical Progress report shall address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), and Contract Performance Report (CPR). An Executive Summary highlighting the progress, issues and relevant manufacturing, non- clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2-3 pages. Progress in meeting contract milestones – broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining occurrences of any differences between the two and the corrective steps. The reports shall also include a three-month rolling forecast of the key planned activities, referencing the WBS/IMS. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps. Estimated and Actual Expenses. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.	• Due: Monthly Reports shall be submitted on the 25th day of the month after the end of each month with an Annual Report submitted on the 30th calendar day of the final month of each contract year for the previous twelve calendar months. • When the 15th or 30th falls on a weekend or a US Holiday, the reports will be due the next business day. • Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report are due. The CO and the COR will review the monthly reports and provide feedback within ten (10) business days of receiving the report. The COR approves acceptance of monthly and annual reports.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
06	Risk Management Plan	The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.	● Due: Within 90 days of contract award. ● Due out: Contractor provides updated Risk Management Plan in Monthly Progress Report. The COR shall provide Contractor with written comments in response submitted plan. Contractor must address, in writing, all commercially reasonable concerns raised by the COR within 20 business days of Contractor's receipt of COR's concerns for CO approval.
07	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule. Contractor shall notify BARDA of significant changes the IMS defined as increases in cost above 5% or schedule slippage of more than thirty (>30) days, which would require a PoP extension. Contractor shall provide a high- level management strategy for risk mitigation.	● Due: As needed and communicated by the COR/CO.
08	Go/No-Go In- Process Review (IPR) or Decision Gate Presentation	Contractor shall provide a presentation detailing technical progress made towards completion of Go/No-Go decision gate milestones using a mutually agreed upon template prior to the IPR.	● Materials: Contractor shall provide agenda and presentation materials to the CO and COR ten (10) business days prior to the In-Process Review (IPR). Contractor shall submit written justification of progress towards satisfying Go/No-Go criteria. After reviewing, the CO and COR will provide a written response within ten (10) business days.
09	Incident Report	Contractor shall communicate and document all critical programmatic concerns, risks, or potential risks with the CO and COR.	● Due: Within 48 hours of activity or incident or within 24 hours for a security activity or incident via email or telephone, with written follow-up to the CO and COR. Additional updates due within 48 hours of additional developments. ● Due out: Contractor shall submit, within five (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 the CO, within five (5) business days of receiving such concerns in writing.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
10	Draft and Final Reports for Clinical and Non-Clinical Studies	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to the CO and COR for review and comment.	● Draft - within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Subcontractor prepared Draft Final reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than five (5) business days after receipt by Contractor. The CO or COR shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies within fifteen (15) business days after the submission. ● Final - due 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies. If corrective action is recommended, Contractor must address, in writing, all reasonable concerns raised by the CO in writing. Contractor shall consider revising reports to address CO's recommendations prior to FDA submission. ● Final FDA submissions shall be provided to the CO and COR concurrently or no later than five (5) business days after submission to the FDA.
11	Standard Operating Procedures	The Contractor shall make internal and, to the extent possible, subcontractor Standard Operating Procedures (SOPs) available for review electronically.	Upon request from the CO.
12	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to the CO and COR. All documents shall be duly marked as either "Draft" or "Final".	● Due: Contractor shall provide written summary of any FDA correspondence within five (5) business days of correspondence.
13	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to the CO and COR and make arrangements for appropriate government staff to attend the FDA meetings. Government staff shall include up to a maximum of four (4) people (COR, CO and up to 2 subject matter experts).	● Contractor shall schedule upcoming FDA meetings, so at a minimum the CO, COR, and RQA persons from BARDA can attend. Additionally, a pre- meeting needs to be held with BARDA to review slides and discuss meeting strategies. ● Contractor shall notify the CO and COR of upcoming FDA meeting within 24 hours of scheduling. ● The Contractor shall forward initial Contractor and FDA- issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within five (5) business days of receipt. All documents shall be duly marked as either "Draft" or "Final".

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
14	FDA Submissions	The Contractor shall provide the CO and COR the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide the CO and COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final”.	● Due: Contractor shall submit draft FDA submissions to the CO and COR at least 15 business days prior to FDA submission. The CO and COR will provide feedback to Contractor within ten (10) business days of receipt. ● Due out: The Contractor shall consider revising their documents to address BARDA’s concerns and/or recommendations prior to FDA submission. If Contractor does not address CO/CORs recommendations, then the Contractor shall provide a justification/explanation why BARDA recommendation is rejected. ● Final FDA submissions shall be submitted to the CO and COR concurrently or no later than five (5) calendar day from its submission to FDA.
15	FDA Audits	In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the Government with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.	● Contractor shall notify the CO and COR within ten (10) business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice. ● Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within five (5) business days of receiving correspondence from the FDA or third party. ● Within ten (10) business days of audit report, Contractor shall provide CO and COR with a plan for addressing areas of nonconformance, if any are identified.
16	QA Audit Reports	BARDA Quality group and /or their qualified representatives reserves the right to participate in QA audits. 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 the CO and COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.	● Contractor shall notify the CO and COR ten (10) days in advance of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. ● Contractor shall notify the CO and COR within five (5) business days of report completion.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
17	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by the CO and COR. Contractor shall also accommodate any 'for cause' audit if and when there are potential issues identified in the program during the period of performance. Such issues include but are not limited to stability failures, GLP issues etc. If the CO, COR, 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 CO and COR.	● 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 ten (10) business days of the audit. ● Due out: The CO and COR 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.
18	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.	● Contractor shall provide technical document within ten (10) business days of COR's request. Contractor can request additional time on an as needed basis. ● If corrective action is recommended by the COR, the Contractor must address, in writing, concerns raised by the COR to the COR and CO in writing within five (5) business days.
19	Raw Data or Data Analysis	Contractor shall provide raw data and/or data analysis generated under this contract to the CO and COR upon request. Contractor shall address and adjudicate all concerns from BARDA review of the data/analysis and amend the reports as required.	● Contractor shall provide data or data analysis to the CO and COR within 20 business days of request. ● Contractor shall amend the reports if required and adjudicate all comments.
20	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to the CO and COR for review prior to submission.	● Contractor must submit all manuscript or scientific meeting abstract to the CO and COR within 30 days for manuscripts and 15 days for abstracts. ● Contractor must address in writing all concerns raised by the CO and COR in writing. ● Final submissions shall be submitted to the CO and COR concurrently or no later than five (5) calendar days after its submission.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
21	Press Releases	Any press release representing the work under this contract.	• The contractor shall accurately and factually represent the work conducted under this contract in all press releases. • With the exception of ad-hoc press releases required by applicable law or regulations, Contractor shall ensure that the CO and COR has received and approved an advanced copy of any draft press release to this contract not less than two (2) business days prior to the issuance of the press release. The CO/COR shall reply with comments within one (1) business day of receipt of the draft press release. Should no comments be forthcoming from the CO/COR by end of the 1st business day, Contractor is permitted to issue the press release • If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. • Any final press releases shall be submitted to the CO and COR no later than one (1) calendar day prior to its release.
22	Integrated Master Schedule (IMS)- Gantt	The Contractor shall provide an IMS including WBS, critical path, and milestones.	• Due: Contractor shall provide the draft IMS-Gantt within 90 days of contract award with final due 8 months after award and updated monthly as part of the Monthly Progress Report. • Contractor must address, in writing, all concerns raised by the COR in writing and provide response to the CO and COR.
23	Draft and Final Report	A Draft Final Technical Progress Report containing a summation of the work performed and the results obtained for the entire contract PoP. The draft report shall be duly marked as 'Draft'. The Final Technical Progress Report incorporating feedback received from the CO and COR and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final'.	• Due: Contractor shall provide a draft Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP. • Subcontractor prepared reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than five (5) business days after receipt by the Contractor. • Due out: the CO shall provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report. • Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
24	Draft and Final Study Protocols	Contractor shall provide all Draft and Final Study Protocols to the COR for evaluation	• The Contractor will submit all proposed protocols to the CO and COR at least ten (10) business days prior to study start. If corrective action is required, the Contractor must address in writing all concerns raised by the CO and COR to the satisfaction of the COR before study execution and provide the CO and COR a revised draft protocol that addresses the CO's comments and requested changes. • After receiving the revised Study Protocol that satisfies the COR, the CO will approve the revised Study Protocol and will provide a written approval to the Contractor that provides authorization to the Contractor to execute the specific study. • Contractor shall not proceed with any study protocol until the COR gives its approval and the Contractor has provided the CO and COR with a final and approved Study Protocol.
25	Non-proprietary Study Protocol	Upon request by the CO and COR.	• The Contractor shall provide a non-proprietary version of the study protocol for distribution within the US Government.
26	Clinical Study Status Update	Contractor shall provide COR with a status update of clinical studies that are actively enrolling patients to include by study site: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal. Contractor will provide proposed format for the COR's review and approval.	• Update will be submitted by e- mail or other electronic format to be provided by the COR by the end of the 15th business day of each new month. • When the 15th falls on a weekend or US Holiday, the update will be due the next business day. • Updates, to the extent they are available, will be presented during biweekly virtual. • If no changes have occurred since the prior update only a simple statement that there is no new data is required.
27	Manufacturing Campaign Reports	Contractor shall provide Manufacturing Campaign Reports to BARDA for review and comment prior to submission to FDA. The COR and CO reserve the right to request within the Period of Performance (PoP) a non-proprietary Manufacturing Campaign Report for distribution within the USG	• Contractor will submit to BARDA Manufacturing Campaign Reports at least ten (10) business days prior to FDA submission. • If corrective action is recommended, Contractor mush address, in writing, all concerns raised by BARDA withing five (5) business days. • Contractor shall consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission. • Final FDA submission shall be submitted to BARDA concurrently or no later than one (1) business day after submission to the FDA.

NOTE: Pursuant to federal law, no Government personnel shall publish, divulge, disclose, or otherwise make known to any non-Government entity any Contractor data marked according to FAR 52.227-14 and FAR 52.227-14 Alt. II, unless permitted to do so by law or regulation.

Detailed Description of Select Contract Deliverables

1. Monthly and Annual Progress Reports, and *Ad hoc* reporting requirements

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Section F of this contract, and in the Statement of Work, attached to this contract (see Section J- List of Attachments).

a. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing 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 Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this Section. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

The format should include:

- A cover page that includes 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;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.

- SECTION III: Estimated and Actual Expenses.

  a. This Section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.

  b. This Section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

  A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

b. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due. The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under Section F.2. of this contract. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;

- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.

- SECTION II: PROGRESS

- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.

- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).

- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Schedule. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

c. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the Deliverables Chart in Section F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the table ("Summary of Contract Deliverables") under SECTION F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.

2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in Section F.2. of the contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

d. Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary of salient results achieved during the performance of the contract.

e. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report and as related to activities funded under this contract.

f. Periodic Document Review

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the Government. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA in writing.

g. Risk Management Plan

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 90 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- The COR shall provide Contractor with a written list of concerns in response plan submitted

Contractor must address, in writing, all concerns raised by COR in writing within 20 business days of Contractor's receipt of COR's concerns.

2. Deliverables Arising from FDA Correspondence

a. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

b. FDA Submissions

The Contractor shall provide the COR all documents submitted to the FDA. Contractor shall provide the COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final."

- When draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt.
- When BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar days of their submission to FDA.

c. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of any potential FDA Form 483 and the Establishment Inspection Report (EIR) received within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.

- Contractor shall provide copies of any FDA Audit Findings report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.

- Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

d. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All documents shall be duly marked as either “Draft” or “Final.” Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

F.3. ELECTRONIC SUBMISSION

For electronic delivery, the Contractor shall upload documents the designated Government file sharing system. The Government shall provide two contractor representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the Government prior to gaining user access. A notification email should be sent to the CO and COR upon electronic delivery of any documents.

F.4. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b) (2) (ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

Reports and documentation submitted to the Contracting Officer shall be sent to the address set forth in Section G – Contract Administration Data.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause(s) 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. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FAR 52.242-15, Stop Work Order (August 1989), Alternate 1 (Aug 1989)

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Jonathan Gonzalez
Contracting Officer
Contract Management and Acquisition (CMA)
Biomedical Advanced Research & Development Authority (BARDA)
Administration for Strategic Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (DHHS)
Phone: 202-381-7248
Email: jonathan.gonzalez@hhs.gov

1. The Contracting Officer is the only individual who can legally commit 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.

2. The Contracting Officer is the only person with the 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 work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.

3. 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 US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.

4. The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

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 following Contracting Officer's Representative (COR) will represent the Government for this contract:

Name: Julio Barrera-Oro
U.S. Department of Health & Human Services
Administration for Strategic Preparedness and Response
Biomedical Advanced Research & Development Authority (BARDA)
Phone: (202)260-0393
Email: julio.barrera-oro@hhs.gov

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 Contracting Officer in interpreting the statement of work and any other technical performance requirements;

3. Performing technical evaluation as required;

4. Performing technical inspections and acceptances required by this contract; and

5. Assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title
[***]	[***]
[***]	[***]
[***]	[***]

The key personnel specified in this contract are considered to be essential to work performance. At least 30-days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications of the individual proposed as a substitute to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government. At a minimum, the key personnel should include the project manager, principal investigator, radiation biologist, quality control manager, quality assurance director, regulatory lead, and manufacturing lead.

G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated as a part of this contract and can be found under Section J entitled, “Financial Report of Individual Project/Contract,”.

f. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

g. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting, and be sent electronically through the IPP system.

h. The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states;

Limitation of Cost (Apr 1984)

- The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government’s share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government’s and the Contractor’s share of the cost.

- The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—

- The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

- The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

- As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.

- Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—

- The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and

- The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

- No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract’s estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.

- If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

- Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

- If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

h. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Jan 2017).

i. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.

2. Fringe Benefits - Cite rate and amount

3. Overhead - Cite rate and amount

4. Materials & Supplies - Include detailed breakdown when total amount is over $10,000

5. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car etc), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.

6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA

7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA

8. Equipment - Cite authorization and amount. Cite appropriate COA

9. Other Direct Costs - Include detailed breakdown when total amount is over $10,000.

10. G&A - Cite rate and amount.

11. Total Cost (and applicable cost-shared ratio)

12. Fixed Fee (if applicable)

13. Total Cost-Plus Fixed Fee

Additional instructions and an invoice template are provided in Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost- Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5. INVOICE SUBMISSION - HHSAR 352.232-71 Electronic submission of payment requests Electronic Submission of Payment Requests (Feb 2022)

(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)

G.5.1 INVOICE ELEMENTS

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

   i. Contractor's Name & Address

   ii. Contractor's Tax Identification Number (TIN)

   iii. Contract Number

   iv. Invoice Number

   v. Invoice Date

   vi. Contract Line Item Number (CLIN)

   vii. Requisition number associated with each CLIN

   viii. Quantity

   ix. Unit Price & Extended Amount for each line item

   x. Total Amount of Invoice

   xi. Name, title and telephone number of person to be notified in the event of a defective invoice

   xii. Payment Address

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

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

d. The Contractor shall include the following certification at the bottom of the payment request: "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."

G.5.2 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 ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

    - 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.

Additional Office of the Assistant Secretary for Preparedness and Response (ASPR) requirements:

(i) The contractor shall submit monthly invoices under this contract unless otherwise agreed upon by all parties. For indefinite delivery and blanket purchase agreement vehicles, separate invoices must be submitted for each order.

(ii) Invoices must break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract.

(iii) Invoices must include the Dun & Bradstreet Number (DUNS) of the Contractor.

(iv) Invoices that include time and materials or labor hours CLINS must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

(v) Invoices that include cost-reimbursement CLINs must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person’s name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;

- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;

- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;

- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;

- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;

- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and

- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

G.6. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

[***]

G.7. INDIRECT COST RATES

a. The following provisional rates are established and incorporated into the contract for interim reimbursement of indirect costs (include specific CLINS or Base period if needed) pending the establishment of final indirect cost rates in accordance with FAR 52.216-7. The provisional rates may be revised during contract performance by mutual agreement of the contracting officer and the contractor at either party's request, to prevent substantial overpayment or underpayment. Use of the provisional rates does not change any cost ceilings or specific obligations in the contract.

Rate Type	Ceiling Rate	Allocation Base
[***]	[***]	[***]
[***]	[***]	[***]

b. The above indirect cost rates are also established as ceiling rates in the contract. Accordingly, the Government will not be obligated to pay any additional amounts should the final indirect cost rates exceed the ceiling rates set forth above, and in the event the final indirect cost rates are less than the above established ceiling rates, the negotiated final rates will be reduced to conform to the lower rates.

c. In accordance with FAR Part 52.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer within the 6-months period following the end of its fiscal years during the period of contract performance.

G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://www.cpars.csd.disa.mil/cparsmain.htm

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

CPARS Point of Contact for Spectral MD *Contractor Populates*

Name: [***]
Title: [***]
Phone Number: [***]
Email Address: [***]

G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number from Page 1 of the contract.

G.10. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in Section I of this contract, the Contractor shall comply with the provisions of HHS Publication, “HHS Contracting Guide for Control of Government Property,” which is incorporated into this contract by reference. This document can be accessed at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Govt-Owned-Prop.pdf

Among other issues, this publication provides a summary of the Contractor’s responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Notwithstanding the provisions outlined in the HHS Publication, “HHS Contracting Guide for Control of Government Property,” which is incorporated in this contract in paragraph 1 above, the Contractor shall use the form entitled, “Report of Government Owned, Contractor Held Property” for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is attached to this contract (see Section J- List of Attachments). Title will vest in the Government for equipment purchased as a direct cost.

Section H – Special Contract Requirements

H.1 CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial *and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer's Representative (COR) for evaluation and comment.

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within ten (10) business days. The Contractor must address, in writing, all concerns (*e.g.* study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, the COR review shall occur before submission, pursuant to the terms set forth by Section F.2 of this contract. The Contractor shall revise their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by Section F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from the Government. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

The Government shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form to ensure the Government has the ability to review and distribute the deliverables as the Government deems necessary.

Important information regarding performing human subject research is available at https://www.niaid.nih.gov/research/clinical-research.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. Non-Clinical Terms of Award

This contract does not involve the use of animals.

2. Clinical Terms of Award

These Clinical Terms of Award detail an agreement between the Government and the Contractor; they apply to all grants and contracts that involve clinical research.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

a. Safety and Monitoring Issues

i. Institutional Review Board or Independent Ethics Committee Approval

Within 30 days of award and then with the annual progress report, the Contractor must submit to the COR a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols is reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the COR copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify the COR and CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research and not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102I).

Final decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the responsible BARDA Project Officer regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following.

- § **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

- § **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.

- § **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the COR before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with the CO and COR.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

iii. BARDA Protocol Review Process Before Patient Enrollment Begins

The COR has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.

- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.

- IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.

- Plans for the management of side effects.

- Procedures for assessing and reporting adverse events.

- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.

- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to the COR) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from the COR in accordance with this Section of this contract.

iv. Investigational New drug or Investigational Device Exemption Requirements

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted. The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

v. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible Contracting Officer's Representative (COR) as follows:

i. Expedited safety report of unexpected or life-threatening experience or death:

A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification.

ii. Expedited safety reports of serious and unexpected adverse experiences: A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification. For medical devices, adverse events should be reported under the MedWatch (MDR) program with reporting timelines of 5 days for serious adverse events or 30 days for reportable events.

iii. IDE reports of unanticipated adverse device effect:

A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the COR within 24 hours of FDA notification.

iv. Expedited safety reports: Sent to the COR concurrently with the report to FDA.

v. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

In case of problems or issues, the Contracting Officer's Representative will contact the Contractor within ten (10) business days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

vi. Safety reporting for research not performed under an IND or IDE.

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the Contracting Officer's Representative and the Contractor.

H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current federal wide Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FW' via designation as agents of the institution of via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf - PDF).

d. If at any time during the performance of this contract, the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP- approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

H.5. 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.6. 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.7. 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.8. 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.9. 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.10. 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.11. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.12. 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.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.14. 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 Contractor 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.15. 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.16. 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.

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 amounts 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; Office of the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. (to be inserted upon award).”

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 two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Administration for Strategic Preparedness and Response, 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; Office of the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No."

H.17. 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.18. 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.19. 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.20. 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.21. 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.22. 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.23. DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical Sections for which the contractor can assert a copyright under FAR Clause 52.227-14 I no information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer. In the event that the contractor seeks to publicize data through a scientific or technical Section, the contractor shall provide BARDA, through the COR, with a minimum of thirty (30) business days to review the Section prior to publication.

H.24. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency 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, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

H.25. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under Section F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR.

H.26. HUMAN SUBJECTS

The Contractor shall submit all human clinical protocols and informed consent documents to BARDA for review and comment prior to submission to another entity.

Research involving human subjects shall not be conducted under this contract until the study protocol has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

For any resultant award involving human subjects engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected or used, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service (PHS) Act (42 U.S.C. 241).

H.27. SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA- funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.28. 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.29. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Administration for Strategic Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

H.30. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site:
https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA- funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

H.31. 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 42.12 pertaining to Novation, specifically FAR section 42.1204. 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.32. CERTIFICATE OF CONFIDENTIALITY

Section 301(d) of the Public Health Service (PHS) Act (42 U.S.C. 241) provides authority to the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research by issuing Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected.

Effective July 17, 2023, BARDA will automatically issue a Certificate to all BARDA funded research commenced on or after July 17, 2023, that is within the scope of the BARDA Policy Notice No. BARDA-CoC-001-2023 – Issuing Certificates of Confidentiality (CoC). The Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the PHS Act as a term and condition of the contract. The certificate will not be issued as a separate document.

BARDA considers research in which identifiable, sensitive information is collected or used, to include:

☐ Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

☐ Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;

☐ Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or

☐ Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

☐ Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

☐ Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO as soon as practicable prior to disclosure.

☐ Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

☐ Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

☐ Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

☐ Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

The Contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

The recipient of CoCs shall ensure that any company/institution/individual not funded by BARDA who receives a copy of identifiable, sensitive information protected by a Certificate, understands that they must also comply with the requirements of subsection 301(d) of the Public Health Service Act. The Contractor shall ensure that Subcontractors who receive funds to carry out part of the BARDA award involving information protected by a Certificate understands that they are also required to comply with 301(d) of the Public Health Service Act and the BARDA Policy for Issuing CoCs.

PART II

SECTION I CONTRACT CLAUSES

To the extent applicable to the work performed by the Contractor under this Contract, this contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text.

I.1. FAR 52.2522, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following 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. The full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352.html

General Clauses for Cost-Reimbursement Research and Development Contract

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

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	52.203-6	Jun 2020	Restrictions on Subcontractor Sales to the Government
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	52.203-12	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	Jun 2020	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-10	Jun 2020	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.204-18	Aug 2020	Commercial and Government Entity Code Maintenance
FAR	52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
FAR	52.204-21	Nov 2021	Basic Safeguarding of Covered Contractor Information Systems
FAR	52.204-23	Nov 2021	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.204-25	Nov 2021	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
FAR	52.204-27	Jun 2023	Prohibition on a ByteDance Covered Application
FAR	52.209-6	Nov 2021	Protecting the Government’s Interests When Subcontracting With Offerors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Nov 2021	Market Research
FAR	52.215-2	Jun 2020	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data
FAR	52.215-11	Jun 2020	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
FAR	52.215-12	Jun 2020	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Jun 2020	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Nov 2021	Integrity of Unit Prices

FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Nov 2021	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications
FAR	52.215-23	Jun 2020	Limitations on Pass-Through Charges
FAR	52.216-7	Aug 2018	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Oct 2018	Utilization of Small Business Concerns
FAR	52.219-28	Sep 2021	Post-Award Small Business Program Representation
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-2	July 1990	Payment for Overtime Premiums
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Jun 2020	Equal Opportunity for Veterans
FAR	52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Jun 2020	Employment Reports on Veterans
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Nov 2021	Combating Trafficking in Persons
FAR	52.222-54	May 2022	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Jun 2020	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.224-1	Apr 1984	Privacy Act Notification
FAR	52.224-2	Apr 1984	Privacy Act
FAR	52.225-13	Feb 2021	Restrictions on Certain Foreign Purchases
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	June 2020	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data - General, Alternate II
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
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	Nov 2021	Providing Accelerated Payments to Small Business SubOfferors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-2	Apr 1991	Production Progress Reports
FAR	52.242-3	Sep 2021	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement Alternate V (Apr 1984).
FAR	52.243-6	Apr 1984	Change Order Accounting
FAR	52.243-7	Jan 2017	Notification of Changes
FAR	52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
FAR	52.244-5	Dec 1996	Competition in Subcontracting

FAR	52.244-6	Jan 2022	Subcontracts for Commercial Products and Commercial Services
FAR	52.245-1	Sep 2021	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.247-67	Feb 2006	Submission of Transportation Documents for Audit
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-2	Dec 2015	Conference Sponsorship Requests and Conference Materials Disclaimer
HHSAR	352.215-70	Dec 2015	Late Proposals and Revisions
HHSAR	352.216-70	Dec 2015	Additional Cost Principles
HHSAR	352.222-70	Dec 2015	Offeror Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2015	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.270-6	Dec 2015	Restriction on use of Human Subjects
HHSAR	352.270-9	Dec 2015	Non-Discrimination for Conscience

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

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 10 days of exercise of the option. 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.

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 10 days.

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days of the contract expiration date; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed ten years.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated August 31, 2023, 32 pages

2. Invoice Instructions for Cost Reimbursement Contracts, 6 pages

3. Financial Report of Individual Project/Contract, 1 page

4. Instructions for Completing Financial Report of Individual Project/Contract, 2 pages

5. Inclusion Enrollment Report

Inclusion Enrollment Report, 1 page.

6. Research Patient Care Costs

Research Patient Care Costs, 1 page.

7. BARDA Security Requirements, 6 pages

8. Report of Government Owned Contractor Held Property

Report of Government Owned Contractor Held Property, 1 page located at:
https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Govt-Owned-Prop.pdf

Burn Wound Imaging Technology
Statement of Work

Original Document
Solicitation Number: [***]
UEI Number: [***]
DUNS Number: [***]

Offeror: **[***]**

Technical Contact [***]

Administrative Contact [***]

Date of submission: August 31st, 2023

Government Notice for Handling Proposals:
This document contains information that is proprietary, privileged and/or confidential to Spectral MD, Inc.

Table of Contents

1. Statement of Work (SOW)

1.1. Preamble

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

1.2. Overall Objectives and Scope

The proposed project scope is aimed at redefining burn assessments in routine burn care and bolstering emergency preparedness for scenarios involving mass burn casualties. The project will propel AI technology for burn assessment into clinical use, expand manufacturing capabilities to ensure access to advanced burn care technology, and execute a comprehensive strategy for deploying DeepView systems and training users across various care scenarios. Post-market studies will generate evidence to support the acceptance and integration of DeepView into the clinical burn care settings, with the ultimate goal of establishing them as the gold standard in burn assessment. Continuous enhancements driven by user insights will further enrich system functionalities, while innovative procurement strategies, including lease agreements and service contracts, will secure their sustained presence in both initial response and definitive burn care settings. This holistic approach converges to reshape conventional burn care paradigms and enhance the nation's readiness for burn mass casualty incidents.

1.3. Expected Outcomes

- Completion of pivotal studies that meet requirements for and achievement of FDA clearance of AI- driven solutions that hold the potential to redefine burn diagnosis.
- Expansion of manufacturing capabilities to ensure seamless production of the DeepView systems at scale, thereby increasing access to advanced burn care technology.
- Strategic procurement through innovative payment models including DeepView system lease agreements, service contracts, and transition agreements, ensuring the sustained presence of our systems in both initial response and definitive burn care settings. Strategic deployment of [***] procured DeepView systems, coupled with a comprehensive end-user clinical training program, for users in both initial response and definitive care scenarios.
- Significant improvements to burn care outcomes demonstrated with post-market studies—driving market adoption in EDs and BCs and paving the way for the DeepView's eventual acceptance as the gold standard in burn assessment.
- Product enhancements especially in improved AI burn assessment and burn %TBSA burn wound size measurements that evolve with future clinical needs fortified by the invaluable insights gleaned from users.

1.4. Technical Tasks and Subtasks

The following sections provide the SOW for the proposed project scope with a detailed description of all the activities planned for all five CLINs.

[***]

The following two tables summarize the key product activities and clinical studies included in the SMD's SOW for all five CLINs (**Table 4** and **Table 5**).

Table 1. Summary of Product Activities By CLIN

Product Activities	Description	CLIN
[***]	[***]	CLIN 1
[***]	[***]	CLIN 1
DeepView HW & SW Enhancements	[***]	CLIN 1
DeepView Image Projection Proof-Of-Concept	[***]	CLIN 1
AI-Burns Improvements in ED and Special Populations	[***]	CLIN 3
[***]	[***]	CLIN 3 & CLIN 5
DeepView HW & SW Enhancements	[***]	CLIN 3
DeepView HW Enhancement	[***]	CLIN 5

Table 2. Summary of Clinical Study Activities By CLIN

Clinical Studies	Description	CLIN
AI-Burns Pivotal Study	[***]	CLIN 1
AI-Burns Enhancement Study	[***]	CLIN 3
Clinical Outcome Study	[***]	CLIN 3
[***] Pivotal Study	[***]	CLIN 5
Clinical Outcome Study	[***]	CLIN 5

1. Base Phase (CLIN 1): Late-stage Product Development and Initial Procurement for Placement in Clinical Sites

The Base Phase of the contract will permit SMD to enroll sufficient study subjects at multiple clinical sites to validate the algorithm that was optimized and selected in the previous BARDA contract. Development, validation, and regulatory clearance of 3D technology for accurate %TBSA measurements leveraging existing DeepView hardware (HW) will be completed. The validation data obtained during Base Phase will be submitted to the FDA for the final clearance process and commercial release of the AI-Burns software. The initial % TBSA burn size measurement software will also be released at the same time as the AI-Burns software. In addition, the final manufacturing process to produce DeepView systems for commercial sales will have been optimized specifically for the FDA-cleared product. Retrospective cost-benefit analysis, value proposition development and testing, new technology add-on payment (NTAP) preparation, FDA submission and clearance will all help prepare for future outcome studies. These studies will provide substantial health economic cost-benefit evidence for commercial sales and prepare SMD for Commercial release.

1.1. Program Management (WBS 1.1)

WBS	Milestone	Deliverable	Success Criteria	[***]
1.1.1	Integrated Master Schedule, IMS, Responsibilities Matrix	[***]	[***]	[***]
1.1.2	Risk Management Plan	[***]	[***]	[***]
1.1.3	Monthly Report, Direct Labor Invoice, and Invoice for all Other Costs.	[***]	[***]	[***]

1.1.1. Project Initiation and Planning (WBS 1.1.1)

SMD shall prepare and maintain a Work Breakdown Structure (WBS) agreed upon by the government for reporting on the contract. SMD shall expand and delineate the contract WBS to a level agreed upon by the government as part of their Integrated Master Plan for contract reporting. The WBS shall be discernable, consistent, and cross-linked with the Statement of Work (SOW). The Contract Officer (CO) may require SMD to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. SMD shall prepare and maintain a responsibility matrix outlining responsibility for key activities and deliverables defined in the agreed-upon SOW.

Within 90 calendar days of the effective date of the contract, SMD shall submit a first draft of an updated IMS to the CO and Contracting Officer's Representative (COR) for review and comment. The integrated master plan will be used to monitor the performance of the contract. SMD shall include the key milestones and Go/No-Go Decision Gates as defined in the agreed-upon SOW.

The SMD Project Manager (PM) will be the main liaison between SMD and BARDA, including the CO and COR. The PM shall schedule monthly teleconferences with the BARDA Project Coordinating Team (PCT) and provide any presentation materials and agenda to the BARDA CO/COR no later than two (2) business days before the meeting. Meeting minutes will be provided no later than 5 business days after the meeting.

The PM shall also schedule touch base teleconferences with BARDA CO/COR bi-weekly, which can be modified as needed. The PM shall also provide project task updates using BARDA CO/COR's template. SMD shall include the risk management plan on a quarterly basis at a minimum in the monthly Project Status Report. SMD shall also monitor and track day-to-day progress of all project activities, including subcontractor and consultant communications and timeline updates. When needed, SMD shall document project decisions and key takeaways in meeting minutes for record keeping, which can be shared with BARDA CO/COR upon request.

1.1.2. Risk Management Plan (WBS 1.1.2)

SMD shall develop a risk management plan within 90 days of contract award date, highlighting 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 should reference relevant WBS elements where appropriate. Updates to this plan shall be included on a quarterly basis (every three months) at a minimum in the monthly Project Status Report. The Senior Project Manager shall maintain and manage the risk management plan to minimize project risks per approved project scope by BARDA and proposes mitigation plan for each risk. The Senior PM will also send an updated risk management plan once every three months.

1.1.3. Federal Reporting (WBS 1.1.3)

All contractual documentation and BARDA requests for information and regular project status updates shall be submitted by the Project Manager by email to the CO and COR as well as uploaded in BARDA Digital Resource (BDR) Site. The Project Manager will maintain the Integrated Master Plan and WBS to ensure it reflects the scope and timeline as agreed by BARDA. The Integrated Master Plan shall include key milestones with "Go/No-Go" decision criteria (entrance and exit criteria for each of the project). The project plan should include, but are not limited to, milestones in manufacturing, non-clinical and clinical studies, and regulatory submissions.

During the contract, SMD shall submit a Deviation Report for needed changes for IMS activities as baselined. This report shall request a change in the agreed upon IMS and timelines. This report shall include: (i) discussion of the rationale/justification for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget. The Project Manager shall prepare and submit contract modification requests when necessary. Upon BARDA approval, the Project Manager shall update the SOW to ensure that it reflects the project scope as agreed upon with BARDA.

The Project Manager shall maintain and manage the risk management plan to ensure it includes project risks per approved project scope by BARDA and proposes mitigation plan for each risk.

SMD shall deliver one invoice monthly to include all costs and a Project Status Report. The monthly reports shall address the items below cross referenced to the SOW, WBS, IMS, and other Project Management Plan tool(s):

i. Executive summary highlighting the progress, issues, and relevant manufacturing, non- clinical, clinical, and regulatory activities;

ii. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, which explains any differences between the two and corrective steps;

iii. Updated IMS;

iv. Updated Risk Management Plan (every three months);

v. Three-month rolling forecast of planned activities;

vi. Progress of regulatory submissions; and

vii. Estimated and actual expenses.

SMD shall participate in regular meetings to coordinate and oversee the contract effort in coordination with the CO and COR. Such meetings may include, but are not limited to, meeting of SMD and subcontractors to discuss clinical manufacturing progress, product development, scale-up manufacturing development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by SMD estimated and actual expenses.

The SMD Project Manager shall coordinate monthly teleconferences with the BARDA Project Coordinating Team (PCT) to occur once a month, which can be adjusted as necessary. The Senior Project Manager shall be responsible for providing any presentation materials and agenda to the BARDA CO/COR no later than two (2) business days before the meeting. In addition, the SMD Senior Project Manager shall be responsible for providing meeting minutes to the BARDA CO/COR no later than 5 business days after the meeting.

The SMD Project Manager shall be responsible for holding "touch base" teleconferences with the BARDA CO/COR to occur bi-weekly at a minimum, which can be adjusted as necessary. The SMD Senior Project Manager shall provide project task updates using the template to be provided by the BARDA COR/CO (Meeting summary can be provided by the Senior Project Manager via email as needed and formal meeting minutes may not be required unless specified by the BARDA COR).

1.2. Regulatory and Quality (WBS 1.2)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.2.1	Updated DeepView SnapShot regulatory documentation	[***]	[***]	[***]
1.2.2	DeepView AI- *Burns de novo marketing application submission*	[***]	[***]	[***]

1.2.1. Regulatory Plan Update and Regulatory/Quality Support (WBS 1.2.1)

Following discussions planned with the FDA in [***], the regulatory team will work with SMD's quality, clinical, software, and hardware teams to ensure all final clinical and non-clinical verification and validation test plans are aligned with FDA's expectations. The final phase of testing will support the FDA marketing application planned for submission in [***]. Regulatory plans will be updated to ensure alignment with the DeepView Target Product Profile (TPP) and FDA feedback.

SMD has registered as a medical device manufacturer and listed the DeepView SnapShot, the Class I imaging device with the FDA-CDRH in August 2023. The DeepView SnapShot device will run the DeepView AI-Burns software after AI-burns receives marketing clearance. Regulatory Affairs (RA)/ Quality Assurance (QA) will ensure DeepView Snapshot's design history file is updated as HW and SW changes are implemented and all aspects of SMD's product development process, e.g., design, implementation, verification, and validation, are completed and released to SMD's Quality Management System (QMS).

SMD passed ISO 13485 audit and received certification on August 9th, 2023. Internal and Surveillance audits will be conducted annually.

RA/QA will support SMD's cross functional team to ensure plans for oversight of critical compliance areas, including good machine learning practices (GMLP), HIPAA, and cybersecurity including DeepView device EHR interconnectivity features are up to date. According to the plan SMD will work with independent consultants or companies to conduct audits of these areas.

The CRO subcontractor, [***], will be tasked with independently ensuring clinical studies sponsored by SMD are in compliance with the Health Insurance Portability and Accountability Act (HIPAA). This includes databases used for storing information collected from study participants. RA/QA will be responsible for ensuring SMD databases are HIPAA compliant.

1.2.2. DeepView AI-Burns Regulatory Submission (WBS 1.2.2)

SMD will prepare a marketing application package to the FDA-CDRH for the DeepView AI-Burns Software. [***].

1.3. Product Development (WBS 1.3)

1.3.1. DeepView AI-Burns Pivotal Study (WBS 1.3.1)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.3.1.1	Pivotal study ready	[***]	[***]	[***]
1.3.1 .2	Pivotal study BC and ED enrollment complete	[***]	[***]	[***]
1.3.1.3	DeepView AI- Burns meets pivotal study endpoints	[***]	[***]	[***]

Clinical study preparation will be conducted to prepare sites to enroll subjects in the pivotal study. This will involve [***].

Execution of the pivotal study is currently estimated to enroll up to [***] subjects from study site EDs and enrollment of up to an additional [***] subjects from study site BCs, including both adult and pediatrics. [***].

Data analysis for the Pivotal study will be conducted by analyzing each endpoint described in the study protocol and all tables, listings and figures created based on the SAP. A Clinical Study Report (CSR) will be authored to report the conduct of the study, results of the study, and the analysis of results. An external party (e.g., the biostatistics group of our CRO subcontractor) will verify all results by reproducing the analysis independently in their own statistical software environment. The CSR will be reviewed by BARDA prior to completion. [***].

1.3.2. Hardware and Software—Late-stage Product Development (WBS 1.3.2)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.3.2.1	Software verification and validation for DeepView AI-Burns and % TBSA	[***]	[***]	[***]
1.3.2.2	Planned Change Control Procedure for AI	[***]	[***]	[***]
1.3.2.3	Human factors validation report	[***]	[***]	[***]

Late-stage product development encompasses the final activities for preparation of the DeepView SnapShot device and DeepView AI-Burns software prior to commercialization other than the pivotal clinical study.

[***]

1.3.3 Direct EHR Connectivity (WBS 1.3.3)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.3.3	Direct EHR connection	[***]	[***]	[***]

The software team will develop an improvement to its EHR connectivity module for the DeepView AI- Burns that can directly connect to hospital IT systems, eliminating third-party applications for EHR connectivity. [***].

1.4. Manufacturing—Initial Procurement for Pivotal Study & Support (WBS 1.4)

WBS	Milestones	Deliverable	Success Criteria	Timing
1.4.1	Deployment of [***] DeepView systems to [***] pivotal Study sites	[***]	[***]	[***]
1.4.2	VMI system established	[***]	[***]	[***]
1.4.3	Support of DeepView systems in the pivotal study complete	[***]	[***]	[***]

1.4.1. Device Manufacturing (WBS 1.4.1)

SMD will produce [***] DeepView commercial systems through its CM. DeepView systems will be transferred and stored in a warehouse managed by SMD until they are shipped to pivotal clinical study sites.

1.4.2. VMI system established (WBS 1.4.2)

To accommodate storage of DeepView systems before they are shipped to the pivotal study clinical sites and to prepare for commercialization, SMD will develop a Vendor Managed Inventory (VMI) system. [***].

1.4.3. DeepView System Support for Pivotal Study (WBS 1.4.3)

During CLIN 1, SMD will continue to support all the DeepView systems participating in the AI-Burns pivotal study ensuring that all systems are functioning properly, and all clinical site questions are addressed timely with the goal of every DeepView system at each clinical study site completing patient enrollment and data collection successfully.

1.5. HEOR Database Analysis (WBS 1.5)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.5.1	Clinician interviews and [***] database analysis complete	[***]	[***]	[***]

SMD will partner with a health economics research organization, [***], to develop a cost- effectiveness and budget impact model to initiate efforts in health economics and outcomes research for DeepView. [***].

1.6. Program Management (WBS 1.6)

See SOW section **1.1 Program Management** for program management activities to occur.

WBS	Milestone	Deliverable	Success Criteria	Timing
1.6.1	Monthly Report, Direct Labor Invoice, and Invoice for all Other Costs.	[***]	[***]	[***]
1.6.2	Summary of current phase and plan for next phase complete	[***]	[***]	[***]

1.6.1. Federal Reporting

See SOW section 1.1 Program Management for Federal Reporting activities to occur.

1.6.2. Next Phase Planning (WBS 1.6.2)

Upon completion of all deliverables and scope under the Base funding period, SMD shall prepare a technical progress report to summarize results achieved during this period, including challenges and lessons learned. Upon approval of the report by BARDA, SMD will prepare slides to be presented during an In-Process-Review (IPR) or Programmatic Review with BARDA. These meetings will be attended by BARDA, SMD, and other parties as necessary and take place either in person or via teleconference as determined by BARDA. Upon IPR or Programmatic Review approval, BARDA will issue directions to proceed. In accordance with such directions, SMD will prepare a plan for the next phase and provide all justifications as requested by the government.

1.7. Regulatory and Quality (WBS 1.7)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.7.1	DeepView AI- Burns Market clearance	[***]	[***]	[***]
1.7.2	Cloud-based quality/product development lifecycle management system	[***]	[***]	[***]

1.7.1. DeepView AI-Burns Regulatory Clearance (WBS 1.7.1)

[***].

1.7.2. Cloud-based quality/product development lifecycle management system (WBS 1.7.2)

[***].

1.8. Product Development (WBS 1.8)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.8.1	[***]	[***]	[***]	[***]
1.8.2	[***]	[***]	[***]	[***]

1.8.1. [***] (WBS 1.8.1)

[***].

1.8.2. [***] (WBS 1.8.2)

[***].

1.9. Manufacturing - Sustaining Engineering (WBS 1.9)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.9.1	DeepView sustaining engineering activities complete	[***]	[***]	[***]

1.9.1. DeepView Sustaining Engineering (WBS 1.9.2)

SMD will address all sustaining engineering activities required to keep the DeepView system up to date, including [***].

1.10. Commercialization (WBS 1.10)

WBS	Milestone	Deliverable	Success Criteria	Timing
1.10.1	US HEOR BEACON model developed	[***]	[***]	[***]
1.10.2	Customer-based validation of value proposition	[***]	[***]	[***]
1.10.3	Reimbursement strategy developed	[***]	[***]	[***]
1.10.4	Market awareness and adoption activities complete	[***]	[***]	[***]

1.10.1. HEOR—BEACON Model Development (WBS 1.10.1)

SMD will partner with a health economics research organization, [***], to develop a cost- effectiveness and budget impact model. [***].

1.10.2. DeepView Value Proposition User-Based Validation (WBS 1.10.2)

SMD will contract an experienced market research firm to refine and validate the current value proposition for market acceptance, understandability, believability, and intent to purchase. [***].

1.10.3. Reimbursement—Strategy Development (WBS 1.10.3)

SMD will investigate reimbursement opportunities to create a reimbursement recommendation report that will contain SMD's reimbursement strategy. [***].

1.10.4. Market Awareness and Adoption (WBS 1.10.4)

[***].

2. Option [***] (CLIN 2): Post-Approval Procurement

2.1. Procurement (WBS 2.1)

WBS	Milestone	Deliverable	Success Criteria	Timing
2.1.1	[***] commercial DeepView systems built	[***]	[***]	[***]
2.1.2	[***] DeepView systems deployed	[***]	[***]	[***]
2.1.3	System Service, Maintenance, Warranty, End-User Training and Support Readiness	[***]	[***]	[***]
2.1.4	[***] Agreements Ready for Procurement	[***]	[***]	[***]

2.1.1. Manufacturing of [***] Units (WBS 2.1.1)

[***].

2.1.2. Deployment of [***] Units (WBS 2.1.2)

[***].

2.1.3. System Service, Maintenance, Warranty, End-User Training and Support (WBS 2.1.3)

SMD will hire resources to establish its field clinical/service and customer support teams including [***].

2.1.4. [***] Agreements (WBS 2.1.4)

SMD will develop and complete [***] agreements to be used for the procurement of up to [***] systems in CLIN2. [***].

3. Option [***] (CLIN 3): Post-Marketing Commitments and/or Requirements

3.1. Program Management (WBS 3.1)

See SOW section **1.1 & 1.6 Program Management** for program management activities to occur in CLIN 3.

3.2. Regulatory and Quality (WBS 3.2)

WBS	Milestone	Deliverable	Success Criteria	Timing
3.2.1	Regulatory and Quality support complete	[***]	[***]	[***]
3.2.2.1	Pre-submission package for enhancements [***]	[***]	[***]	[***]
3.2.2.2	Submission of 510(k) for enhancements to [***]	[***]	[***]	[***]
3.2.2.3	Clearance of 510(k) for enhancements to [***]	[***]	[***]	[***]

3.2.1. Regulatory and Quality Support (WBS 3.2.1)

SMD's Quality and Regulatory staff will provide post-market surveillance to monitor the safety and performance of DeepView systems deployed to the market. [***].

3.2.2. DeepView FDA 510(k) Submission and Clearance (WBS 3.2.2)

[***].

[***].

3.3. Product Development (WBS 3.3)

WBS	Milestone	Deliverable	Success Criteria	Timing
3.3.1	AI-Burns algorithm enhanced performance per PCCP complete	[***]	[***]	[***]
3.3.2	AI-Burns enhanced training data collection complete	[***]	[***]	[***]
3.3.3	[***] AI algorithm “lock-down”	[***]	[***]	[***]
3.3.4	DeepView SnapShot device hardware and software enhancements complete	[***]	[***]	[***]

3.3.1. AI-Burns Enhancements (WBS 3.3.1)

SMD’s Software and Data Science teams will execute AI improvements outlined in the PCCP, [***].

3.3.2. AI-Burns Enhancement ED and Special Populations Clinical Study (WBS 3.3.2)

SMD will conduct a subsequent clinical study called [***].

3.3.3. [***] (WBS 3.3.3)

[***].

3.3.4. Hardware & Software Enhancement—Portability and Manufacturability (WBS 3.3.4)

[***].

3.4. Manufacturing, Sustaining Engineering and Study System Support (WBS 3.4)

WBS	Milestone	Deliverable	Success Criteria	Timing
3.4.1	Support of DeepView systems in the AI-Burns Enhancement Study complete	[***]	[***]	[***]
3.4.2	DeepView sustaining engineering activities complete	[***]	[***]	[***]

3.4.1 DeepView System Support for AI-Burns Enhancement Study (WBS 3.4.1)

[***].

3.4.2 DeepView Sustaining Engineering (WBS 3.4.4)

SMD will address all sustaining engineering activities required to keep the DeepView system up to date, [***].

3.5. Commercialization (WBS 3.5)

WBS	Milestone	Deliverable	Success Criteria	Timing
3.5.1	HEOR-BEACON model updated	[***]	[***]	[***]
3.5.2.1	Prospective clinical outcomes study preparation ready	[***]	[***]	[***]
3.5.2.2	Prospective clinical outcomes study enrollment complete	[***]	[***]	[***]
3.5.2.3	Prospective clinical outcomes study analysis complete	[***]	[***]	[***]
3.5.3.1	NTAP submission	[***]	[***]	[***]
3.5.3.2	NTAP granted	[***]	[***]	[***]
3.5.3.3	CMS approval of EDP for TCET	[***]	[***]	[***]
			[***]	
3.5.3.4	NCD submission under TCET	[***]	[***]	[***]
3.5.4.1	BC and ED KOL panels formation	[***]	[***]	[***]
3.5.4.2	Commercial team, market awareness and adoption activities complete	[***]	[***]	[***]

3.5.1. HEOR—BEACON Model Expansion (WBS 3.5.1)

[***].

3.5.2. Clinical Outcomes Study (WBS 3.5.2)

A prospective outcomes study will be conducted to quantify cost impact and confirm the value proposition of incorporating DeepView into the clinical burn workflow. [***].

3.5.3. Market Access – Reimbursement (WBS 3.5.3)

[***].

3.5.4. Market Awareness and Adoption (WBS 3.5.4)

SMD will ensure the commercial team supporting the [***] DeepView systems [***] is in place, fully trained and ready.

SMD will continue efforts to advance clinical adoption. [***].

4. Option [***] (CLIN 4): Additional Procurement

4.1. Procurement (WBS 4.1)

WBS	Milestone	Deliverable	Success Criteria	Timing
4.1.1	[***] commercial DeepView systems built	[***]	[***]	[***]
4.1.2	[***] DeepView systems deployed	[***]	[***]	[***]
4.1.3	System Service, Maintenance and End- User Training Support Readiness	[***]	[***]	[***]

4.1.1. Manufacturing of [***] Units (WBS 4.1.1)

[***].

4.1.2. Deploy [***] Units (WBS 4.1.2)

[***].

4.1.3. System Service, Maintenance and End-User Training and Support (WBS 4.1.3)

[***].

5. Option [***] (CLIN 5): Additional Development

5.1. Program Management (WBS 5.1)

See SOW section **1.1 & 1.6 Program Management** for program management activities to occur in CLIN 5.

5.2. Regulatory and Quality (WBS 5.2)

WBS	Milestone	Deliverable	Success Criteria	Timing
5.2.1	Regulatory and Quality support complete	[***]	[***]	[***]
5.2.2.1	Pre-submission meeting for [***]	[***]	[***]	[***]
5.2.2.2	Submission of 510(k) for [***] functionality	[***]	[***]	[***]
5.2.2.3	Clearance of 510(k) for [***]	[***]	[***]	[***]

5.2.1. Regulatory and Quality Support (WBS 5.2.1)

SMD's Quality and Regulatory team will provide post-market surveillance to monitor the safety and performance of DeepView systems deployed to the market. [***].

5.2.2. DeepView [***] FDA 510(k) Submission and Clearance (WBS 5.2.2)

[***].

5.3. Product Development (WBS 5.3)

5.3.1. [***] Pivotal Study (WBS 5.3.1)

WBS	Milestone	Deliverable	Success Criteria	Timing
5.3.1.1	Pivotal study ready to start	[***]	[***]	[***]
5.3.1.2	Pivotal study enrollment complete	[***]	[***]	[***]
5.3.1.3	Clinical validation of [***] software complete	[***]	[***]	[***]

A pivotal clinical study will be conducted in CLIN 5 for [***].

5.3.2. Hardware and Software Enhancements—Portability (WBS 5.3.2)

WBS	Milestone	Deliverable	Success Criteria	Timing
5.3.2	Hardware and software enhancements	[***]	[***]	[***]

[***].

5.3.3. AI Enhancements (WBS 5.3.3)

WBS	Milestone	Deliverable	Success Criteria	Timing
5.3.3	AI-Burns models optimized to maximize clinical benefit	[***]	[***]	[***]

SMD's Software and Data Science teams will continue working toward AI improvements outlined in the PCCP, using data newly acquired from clinical outcomes studies. [***].

5.4. Manufacturing, Supply Chain and Contract Manufacturing de-risking, Design Transfer and Sustaining Engineering Activities (WBS 5.4)

WBS	Milestone	Deliverable	Success Criteria	Timing
5.4.1	Support of DeepView systems in the clinical outcomes rural study	[***]	[***]	[***]
5.4.2	DeepView sustaining engineering activities complete	[***]	[***]	[***]
5.4.3	DeepView design transfer activities complete	[***]	[***]	[***]
5.4.4	[***] CM Setup & DeepView design transfer complete	[***]	[***]	[***]

5.4.1. DeepView System Support for Clinical Outcomes Rural Study (WBS 5.4.1)

During CLIN 5, SMD will continue to support all the DeepView systems participating in the clinical outcomes rural study ensuring that all systems are functioning properly, and all clinical site questions are addressed timely with the goal of every DeepView system at each clinical study site completing patient enrollment and data collection successfully.

5.4.2. DeepView Sustaining Engineering (WBS 5.4.2)

Furthermore, SMD will address all sustaining engineering activities required to keep the DeepView system up to date, [***].

5.4.3. DeepView Design Transfer (WBS 5.4.3)

[***].

5.4.4. 2nd CM Set-up & Design Transfer (WBS 5.4.4)

[***].

5.5 Commercialization (WBS 5.5)

WBS	Milestone	Deliverable	Success Criteria	Timing
5.5.1	HEOR-BEACON model updated	[***]	[***]	[***]
5.5.2.1	Clinical outcomes study ready to start	[***]	[***]	[***]
5.5.2.2	Rural ED transfer clinical study enrollment complete	[***]	[***]	[***]
5.5.2.3	Clinical outcomes study analysis	[***]	[***]	[***]
5.5.3	NCD granted	[***]	[***]	[***]
5.5.4	Commercial team, market awareness and adoption activities complete	[***]	[***]	[***]

5.5.1 HEOR—BEACON Model Expansion (WBS 5.5.1)

[***].

5.5.2 Clinical Outcomes Study (WBS 5.5.2)

[***].

5.5.3 Market Access - Reimbursement (WBS 5.5.3)

[***].

5.5.4 Market Awareness and Adoption (WBS 5.5.4)

SMD will ensure the commercial team supporting the [***] DeepView systems [***] is in place, fully trained and ready.

[***].

6 Milestones and Deliverables Table

WBS	Milestone	Deliverable	Success Criteria	Timing	Option
1.1.1	[***]	[***]	[***]	[***]	[***]
1.1.2	[***]	[***]	[***]	[***]	[***]
1.1.3	[***]	[***]	[***]	[***]	[***]
1.2.1	[***]	[***]	[***]	[***]	[***]
1.2.2	[***]	[***]	[***]	[***]	[***]
1.3.1.1	[***]	[***]	[***]	[***]	[***]
1.3.1.2	[***]	[***]	[***]	[***]	[***]
1.3.1.3	[***]	[***]	[***]	[***]	[***]
1.3.2.1	[***]	[***]	[***]	[***]	[***]
1.3.2.2	[***]	[***]	[***]	[***]	[***]
1.3.2.3	[***]	[***]	[***]	[***]	[***]
1.3.3	[***]	[***]	[***]	[***]	[***]
1.4.1	[***]	[***]	[***]	[***]	[***]
1.4.2	[***]	[***]	[***]	[***]	[***]
1.4.3	[***]	[***]	[***]	[***]	[***]
1.5.1	[***]	[***]	[***]	[***]	[***]
1.6.1	[***]	[***]	[***]	[***]	[***]
1.6.2	[***]	[***]	[***]	[***]	[***]
1.7.1	[***]	[***]	[***]	[***]	[***]
1.7.2	[***]	[***]	[***]	**[***]**	**[***]**
1.8.1	[***]	[***]	[***]	**[***]**	**[***]**
1.8.2	[***]	[***]	[***]	**[***]**	**[***]**
1.9.1	[***]	[***]	[***]	[***]	**[***]**
1.10.1	[***]	[***]	[***]	**[***]**	**[***]**
1.10.2	[***]	[***]	[***]	**[***]**	**[***]**
1.10.3	[***]	**[***]**	[***]	**[***]**	**[***]**
1.10.4	**[***]**	[***]	[***]	**[***]**	**[***]**
2.1.1	[***]	[***]	[***]	[***]	[***]
2.1.2	[***]	[***]	[***]	[***]	[***]
2.1.3	[***]	[***]	[***]	**[***]**	**[***]**
2.1.4	[***]	[***]	[***]	**[***]**	[***]
3.1.1	[***]	[***]	[***]	[***]	[***]
3.1.2	[***]	[***]	[***]	[***]	[***]
3.1.3	[***]	[***]	[***]	**[***]**	[***]
3.1.4	[***]	**[***]**	[***]	**[***]**	[***]
3.2.1	[***]	**[***]**	[***]	**[***]**	[***]
3.2.2.1	[***]	[***]	[***]	**[***]**	[***]
3.2.2.2	[***]	[***]	[***]	**[***]**	[***]
3.2.2.3	[***]	[***]	[***]	**[***]**	[***]
3.3.1	[***]	**[***]**	[***]	**[***]**	[***]
3.3.2	[***]	[***]	[***]	[***]	[***]
3.3.3	[***]	[***]	[***]	**[***]**	[***]

WBS	Milestone	Deliverable	Success Criteria	Timing	Option
3.3.4	[***]	[***]	[***]	**[***]**	**[***]**
3.4.1	[***]	**[***]**	[***]	**[***]**	**[***]**
3.4.2	[***]	[***]	[***]	[***]	[***]
3.5.1	[***]	[***]	[***]	**[***]**	[***]
3.5.2.1	[***]	[***]	[***]	**[***]**	[***]
3.5.2.2	[***]	[***]	[***]	**[***]**	[***]
3.5.2.3	[***]	[***]	[***]	**[***]**	[***]
3.5.3.1	[***]	[***]	[***]	[***]	[***]
3.5.3.2	[***]	[***]	[***]	[***]	[***]
3.5.3.3	[***]	**[***]**	[***]	**[***]**	[***]
3.5.3.4	**[***]**	[***]	**[***]**	**[***]**	[***]
3.5.4.1	[***]	[***]	[***]	[***]	[***]
3.5.4.2	**[***]**	[***]	[***]	**[***]**	**[***]**
4.1.1	[***]	[***]	[***]	[***]	[***]
4.1.2	[***]	[***]	[***]	**[***]**	[***]
4.1.3	[***]	[***]	[***]	**[***]**	[***]
5.1.1	[***]	[***]	[***]	[***]	[***]
5.1.2	[***]	[***]	[***]	[***]	[***]
5.1.3	[***]	[***]	[***]	**[***]**	[***]
5.1.4	[***]	**[***]**	[***]	**[***]**	[***]
5.2.1	[***]	**[***]**	[***]	**[***]**	[***]
5.2.2.1	[***]	[***]	[***]	[***]	[***]
5.2.2.2	[***]	**[***]**	[***]	**[***]**	[***]
5.2.2.3	[***]	[***]	[***]	[***]	[***]
5.3.1.1	**[***]**	[***]	[***]	**[***]**	**[***]**
5.3.1.2	[***]	[***]	[***]	**[***]**	[***]
5.3.1.3	**[***]**	[***]	[***]	**[***]**	**[***]**
5.3.2	[***]	[***]	[***]	**[***]**	[***]
5.3.3	[***]	[***]	[***]	**[***]**	[***]
5.4.1	[***]	[***]	[***]	**[***]**	[***]
5.4.2	[***]	[***]	[***]	**[***]**	[***]
5.4.3	[***]	[***]	[***]	**[***]**	[***]
5.4.4	[***]	[***]	[***]	[***]	[***]
		[***]			
5.5.1	**[***]**	[***]	[***]	**[***]**	**[***]**
5.5.2.1	[***]	[***]	[***]	**[***]**	[***]
5.5.2.2	[***]	[***]	[***]	**[***]**	[***]
5.5.2.3	[***]	[***]	[***]	**[***]**	[***]
5.5.3	[***]	[***]	[***]	[***]	[***]
5.5.4	**[***]**	[***]	**[***]**	**[***]**	**[***]**

7 High-level Timeline

[***]

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A)

UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Wensheng Fan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Spectral AI, 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 period presented in this report;

4. The registrant's other certifying officer(s) 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 my 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; and

    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 my 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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(s) 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 the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ Wensheng Fan

Wensheng Fan
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A)

UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nils Windler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Spectral AI, 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 period presented in this report;

4. The registrant's other certifying officer(s) 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 my 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; and

    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 my 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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(s) 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 the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ Nils Windler

Nils Windler
Chief Financial Officer
(Principal Financial 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 Spectral AI, Inc. (the "Company"), does hereby certify, to such officer's knowledge, that:

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

Dated: November 14, 2023

/s/ Wensheng Fan

Name: Wensheng Fan
Title: Chief Executive Officer
(Principal Executive Officer)

Dated: November 14, 2023

/s/ Nils Windler

Name: Nils Windler
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.