# 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 June 30, 2024

OR

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

For the transition period from \_\_\_\_\_to \_\_\_\_

Commission file number: 001-35285

Vaxart, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

(650) 550-3500

170 Harbor Way, Suite 300, South San Francisco, CA 94080 (Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code)

N/A

(Former Name, Former Address and Former Fiscal Year,

if Changed Since Last Report)

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

Title of each class	Trading symbol	Name of each exchange on which
		registered
Common Stock, \$0.0001 par value	VXRT	The Nasdaq Capital Market

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  $\square$  No  $\square$ 

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  $\square$  No  $\square$ 

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

Large accelerated filer  $\Box$ Non-accelerated filer  $\Box$ Emerging growth company  $\Box$  Accelerated filer  $\Box$ Smaller reporting company  $\blacksquare$ 

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.  $\Box$ 

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

The Registrant had 227,439,293 shares of common stock, \$0.0001 par value, outstanding as of August 1, 2024.

59-1212264 Employer Identification No

# FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2024 TABLE OF CONTENTS

Part I	FINANCIAL	INFORMATION	Page <u>1</u>
	Item 1.	Financial Statements (Unaudited)	<u>1</u>
		Condensed Consolidated Balance Sheets as of June 30, 2024 and December 31, 2023	<u>1</u>
		Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2024 and 2023	<u>2</u>
		Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2024 and 2023	<u>3</u>
		Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2024 and 2023	<u>5</u>
		Notes to the Condensed Consolidated Financial Statements	<u>6</u>
	Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>18</u>
	Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>27</u>
	Item 4.	Controls and Procedures	<u>28</u>
Part II	OTHER INFO	<u>DRMATION</u>	<u>29</u>
	Item 1.	Legal Proceedings	<u>29</u>
	Item 1A.	Risk Factors	<u>29</u>
	Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	<u>30</u>
	Item 3.	Defaults Upon Senior Securities	<u>30</u>
	Item 4.	Mine Safety Disclosures	<u>30</u>
	Item 5.	Other Information	<u>30</u>
	Item 6.	Exhibits	<u>31</u>
SIGNATURE	<u>S</u>		<u>33</u>

## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") for the quarterly period ended June 30, 2024, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections, concerning our business, operations, and financial performance and condition as well as our plans, objectives, and expectations for business operations and financial performance and condition. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as "anticipate," "assume," "believe," "could," "estimate," "expect," "intend," "may," "plan," "should," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to, those risks and uncertainties described herein under "Item 1A. Risk Factors." and those described in our Annual Report on Form 10-K for the year ended December 31, 2023, under "Item 1A. Risk Factors." You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the filing date of this Quarterly Report. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the risk factors we describe in the reports we will file from time to time with the Securities and Exchange Commission (the "SEC") after the date of this Quarterly Report.

This Quarterly Report also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may harm our business, results of operations, financial condition and the market price of our common stock.

## PART I FINANCIAL INFORMATION

# Item 1. Financial Statements

# VAXART, INC.

## Condensed Consolidated Balance Sheets (In thousands, except share and per share amounts) (Unaudited)

	Ju	ne 30, 2024	Decem	ber 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	\$	43,285	\$	34,755
Short-term investments		19,308		4,958
Accounts receivable		1,088		3,008
Unbilled receivable from government contracts		3,689		
Prepaid expenses and other current assets		4,165		2,815
Total current assets		71,535		45,536
Property and equipment, net		10,280		11,731
Right-of-use assets, net		22,652		24,840
Intangible assets, net		3,923		4,289
Goodwill		4,508		4,508
Other long-term assets		851		926
Total assets	\$	113,749	\$	91,830
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	3,587	\$	1,584
Other accrued current liabilities		6,611		5,634
Current portion of operating lease liability		2,872		2,703
Current portion of liability related to sale of future royalties		2,686		3,803
Total current liabilities		15,756		13,724
Operating lease liability, net of current portion		15,983		17,385
Liability related to sale of future royalties, net of current portion		1,591		2,623
Other long-term liabilities		405		293
Total liabilities		33,735		34,025
Commitments and contingencies (Note 8)				
Stockholders' equity:				
Preferred stock: \$0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of June 30, 2024 and December 31, 2023		_		_
Common stock: \$0.0001 par value; 350,000,000 shares authorized as of June 30, 2024 and 250,000,000 shares authorized as of December 31, 2023; 228,119,936 shares issued and 227,431,605 shares outstanding as of June 30, 2024 and 153,959,853 shares issued and 153,452,833 shares outstanding as of				
December 31, 2023		23		15
Additional paid-in capital		531,029		467,731
Treasury stock at cost, 688,331 shares as of June 30, 2024 and 507,020 shares as of December 31, 2023		(565)		(366)
Accumulated deficit		(450,457)		(409,574)
Accumulated other comprehensive loss		(16)		(1)
		00.014		57,805
Total stockholders' equity		80,014		57,005

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## Condensed Consolidated Statements of Operations and Comprehensive Loss (In thousands, except share and per share amounts) (Unaudited)

	Т	Three Months	Ende	ed June 30,	5	Six Months E	nde	d June 30,
		2024		2023		2024		2023
Revenue:								
Non-cash royalty revenue related to sale of future royalties	\$	37	\$	30	\$	622	\$	308
Revenue from government contracts		6,364		—		7,960		—
Grant revenue				1,328				1,725
Total revenue		6,401		1,358		8,582		2,033
Operating expenses:								
Research and development		17,480		18,813		36,493		38,435
General and administrative		5,177		5,598		12,415		12,223
Total operating expenses		22,657		24,411		48,908		50,658
Operating loss		(16,256)		(23,053)		(40,326)		(48,625)
Other income (expense):								
Interest income		416		711		919		1,353
Non-cash interest expense related to sale of future royalties		(610)		(188)		(1,414)		(366)
Other income (expense), net		5		(1)	_	4		(4)
Loss before income taxes		(16,445)		(22,531)		(40,817)		(47,642)
Provision for income taxes		21		19		66		48
Net loss	\$	(16,466)	\$	(22,550)	\$	(40,883)	\$	(47,690)
Net loss per share - basic and diluted	\$	(0.09)	\$	(0.16)	\$	(0.23)	\$	(0.35)
Shares used to compute net loss per share - basic and diluted	_	184,703,003		139,594,238		176,757,049		137,403,416
Comprehensive loss:								
Net loss	\$	(16,466)	\$	(22,550)	\$	(40,883)	\$	(47,690)
Unrealized (loss) gain on available-for-sale investments, net of tax		(6)		46		(15)		275
Comprehensive loss	\$	(16,472)	\$	(22,504)	\$	(40,898)	\$	(47,415)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## Condensed Consolidated Statements of Stockholders' Equity For the Three and Six Months Ended June 30, 2024 (In thousands, except share amounts) (Unaudited)

		Paid-in Accumulated			Accumulated Other Comprehensive	Total Stockholders' Equity						
Three Months Ended June 30, 2024	Shares	Amo	ount	Shares	Amoun	t	Capital		Deficit	Loss	Equi	ty
Balances as of March 31, 2024	177,187,965	\$	18	(664,923)	\$ (	548)	\$ 490,221	\$	(433,991)	\$ (10)	\$ 5	55,690
Issuance of common stock under the September 2021 ATM, net of offering costs of \$21	314,969		_	_		_	377		_	_		377
Issuance of common stock under the 2024 Securities Purchase Agreement, net of offering costs of \$55	_		_	_			_		_	_		_
Issuance of common stock under the June 2024 Offering, net of offering costs of \$2,445	50,000,000		5	_			37,550		_	_	3	37,555
Issuance of common stock upon exercise of stock options	18,115		_	_		_	14		_	_		14
Issuance of common stock under ESPP	502,423		—	—		—	312		—	—		312
Release of common stock for vested restricted stock units	96,464		_	_		_	_		_	_		
Repurchase of common stock to satisfy tax withholding	_		_	(23,408)		(17)	_		_	_		(17)
Stock-based compensation	_		—	—		—	2,555		—	_		2,555
Unrealized gain on available-for-sale investments	_		_	_		_	_		_	(6)		(6)
Net loss	_		_	_		_	_		(16,466)	_	(1	6,466)
Balances as of June 30, 2024	228,119,936	\$	23	(688,331)	\$ (	565)	\$ 531,029	\$	(450,457)	\$ (16)	\$ 8	30,014
											<u>.</u>	
Six Months Ended June 30, 2024 Balances as of December 31, 2023	153,959,853	\$	15	(507,020)	\$ (	366)	\$ 467,731	\$	(409,574)	\$ (1)	\$ 5	57,805
Issuance of common stock under the September 2021 ATM, net of offering costs of \$248	7,719,641		1	_			8,801		_	_		8,802
Issuance of common stock under the 2024 Securities Purchase Agreement, net of offering costs of \$55	15,384,615		2	_			9,943		_	_		9,945
Issuance of common stock under the June 2024 Offering, net of offering costs of \$2,445	50,000,000		5	_			37,550		_	_	3	37,555
Issuance of common stock upon exercise of stock options	26,980		_	_		_	21		_	_		21
Issuance of common stock under ESPP	502,423		—	—		_	312		—	—		312
Stock-based compensation	—		_	_		_	6,671		_	—		6,671
Release of common stock for vested restricted stock units	526,424		_	_			_		_	_		_
Repurchase of common stock to satisfy tax withholding	_		_	(181,311)	(	199)	_		_	_		(199)
Unrealized gains on available-for-sale investments										(15)		(15)

Net loss		 		 	 	 (40,883)	 	 (40,883)
Balances as of June 30, 2024	228,119,936	\$ 23	(688,331)	\$ (565)	\$ 531,029	\$ (450,457)	\$ (16)	\$ 80,014

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## Condensed Consolidated Statements of Stockholders' Equity For the Three and Six Months Ended June 30, 2023 (In thousands, except share amounts) (Unaudited)

		on Stock	Treasury	y Stock	Paid-i	Additional Paid-in Accumulate Capital Deficit		Accumulated Other Comprehensive	Total Stockholders'
Three Months Ended June 30, 2023	Shares	Amount	Shares	Amount	Capita	<u> </u>	Deficit	(Loss) Gain	Equity
Balances as of March 31, 2023	135,610,869	\$ 14	(13,553)	\$ (10	) \$ 442	.,068	\$ (352,249)	\$ (70)	\$ 89,753
Issuance of common stock under 2023 Shelf Registration, net of offering costs of \$284	16,000,000	1	_	_	- 13	,602	_	_	13,603
Issuance of common stock upon exercise of stock options	54,720	_	_	_		17	_	_	17
Issuance of common stock under ESPP	301,061	_	_	_		298	_	_	298
Stock-based compensation	—	—	—		. 3	,927	—	—	3,927
Release of common stock for vested restricted stock units	49,588	_	_	_		_	_	_	
Repurchase of common stock to satisfy tax withholding	_	_	(19,693)	(21	)	_	_	_	(21)
Unrealized gain on available-for- sale investments	_	_	_	_		_	_	46	46
Net loss							(22,550)		(22,550)
Balances as of June 30, 2023	152,016,238	<u>\$ 15</u>	(33,246)	<u>\$ (31</u>	) <u>\$ 459</u>	,912 .	\$ (374,799)	<u>\$ (24)</u>	\$ 85,073
Six Months Ended June 30, 2023									
Balances as of December 31, 2022	134,199,429	\$ 13	—	\$ -	\$ 437	,992 S	\$ (327,109)	\$ (299)	\$ 110,597
Issuance of common stock under September 2021 ATM, net of offering costs of \$103	1,362,220	1	_	_	. ]	,429	_	_	1,430
Issuance of common stock under 2023 Shelf Registration, net of offering costs of \$284	16,000,000	1			13	,602			13,603
Issuance of common stock upon exercise of stock options	54,720	_	_	_		17		_	17
Issuance of common stock under ESPP	301,061	_	_	_		298	_	_	298
Stock-based compensation	—	_	_		. (	,574	—	—	6,574
Release of common stock for vested restricted stock units	98,808	_	_	_		_	_	_	_
Repurchase of common stock to satisfy tax withholding	_	_	(33,246)	(31	)	_	_	_	(31)
Unrealized gain on available-for- sale investments	_	_	_	_		_	_	275	275
Net loss					<u> </u>		(47,690)		(47,690)
Balances as of June 30, 2023	152,016,238	<u>\$ 15</u>	(33,246)	<u>\$ (31</u>	) <u>\$ 459</u>	912	\$ <u>(374,799</u> )	<u>\$ (24)</u>	<u>\$ 85,073</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## Condensed Consolidated Statements of Cash Flows (In thousands) (Unaudited)

	Six Months Ended June 30,					
		2024		2023		
Cash flows from operating activities:						
Net loss	\$	(40,883)	\$	(47,690)		
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization		4,390		4,228		
Amortization of discount on investments, net		(178)		(220)		
Stock-based compensation		6,671		6,574		
Non-cash interest expense related to sale of future royalties		1,414		370		
Non-cash revenue related to sale of future royalties		(3,563)		(288)		
Change in operating assets and liabilities:		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		()		
Accounts receivable		1,920		(9)		
Unbilled receivable from government contracts		(3,689)		(*)		
Prepaid expenses and other assets		(1,275)		2,447		
Accounts payable		2,083		105		
Deferred grant revenue		2,005		(1,725)		
Other accrued liabilities		(108)		(5,723)		
Other accrued habilities		(100)		(3,723)		
Net cash used in operating activities		(33,218)		(41,931)		
Cash flows from investing activities:						
Purchases of property and equipment		(501)		(1,693)		
Purchases of investments		(29,187)		(22,629)		
Proceeds from maturities of investments		15,000		48,200		
Net cash (used in) provided by investing activities		(14,688)		23,878		
Cash flows from financing activities:						
Net proceeds from issuance of common stock in the June 2024 Offering		37,555				
Net proceeds from issuance of securities in registered direct offering		51,555		13,603		
Net proceeds from issuance of securities in registered direct onering		8,802		1,430		
Net proceeds from issuance of common stock through the 2024 Securities Purchase Agreement		9,945		1,450		
Proceeds from issuance of common stock through the 2024 Sectimes Futenase Agreement Proceeds from issuance of common stock upon exercise of stock options		21		17		
Shares acquired to settle employee tax withholding liabilities		(199)		(31)		
Proceeds from issuance of common stock under the employee stock purchase plan		312		298		
Net cash provided by financing activities		56,436	_	15,317		
Net increase (decrease) in cash, cash equivalents and restricted cash		8,530		(2,736)		
Cash, cash equivalents and restricted cash at beginning of the period		34,755		46,013		
Cash, cash equivalents and restricted cash at end of the period	\$	43,285	\$	43,277		
Supplemental reconciliation of cash, cash equivalents and restricted cash in the condensed consolidated balance sheets:	\$	43,285	\$	43,002		
Cash and cash equivalents	¢	45,265	<u>р</u>	43,002		
Restricted cash			_	275		
Cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	¢	42 295	¢	42 277		
at the end of the period	\$	43,285	\$	43,277		
Supplemental disclosure of non-cash investing and financing activity:						
Operating lease liabilities arising from obtaining right-of-use assets	\$	_	\$	296		
	\$	35	\$	281		
Acquisition of property and equipment included in accounts payable and accrued expenses	Ψ		Ψ	201		

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## NOTE 1. Organization and Nature of Business

## General

Vaxart Biosciences, Inc. was originally incorporated in California in March 2004, under the name West Coast Biologicals, Inc. The Company changed its name to Vaxart, Inc. ("Private Vaxart") in July 2007, and reincorporated in the state of Delaware. In February 2018, Private Vaxart completed a business combination with Aviragen Therapeutics, Inc. ("Aviragen"), pursuant to which Aviragen merged with Private Vaxart, with Private Vaxart surviving as a wholly-owned subsidiary of Aviragen (the "Merger"). Pursuant to the terms of the Merger, Aviragen changed its name to Vaxart, Inc. (together with its subsidiaries, the "Company" or "Vaxart") and Private Vaxart changed its name to Vaxart Biosciences, Inc.

In June 2024, the Company entered into an underwriting agreement with Oppenheimer & Co. Inc., relating to the issuance and sale by the Company in an underwritten registered direct offering of 50,000,000 shares of the Company's common stock, at a price of \$0.80 per share. The gross proceeds to the Company from such offering were \$40.0 million, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company, the net proceeds were \$37.6 million.

In January 2024, the Company entered into a securities purchase agreement (the "2024 Securities Purchase Agreement") with RA Capital Healthcare Fund, L.P. pursuant to which 15,384,615 shares of the Company's common stock were sold to RA Capital Healthcare Fund, L.P. at an offering price of \$0.65 per share pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-270671) (the "2023 Shelf Registration"). The gross proceeds from the 2024 Securities Purchase Agreement were \$10.0 million and, after deducting offering expenses, the net proceeds were \$9.9 million.

In September 2021, the Company entered into a Controlled Equity Offering Sales Agreement (the "September 2021 ATM"), pursuant to which it may offer and sell, from time to time through sales agents, shares of its common stock having an aggregate offering price of up to \$100 million. The Company filed a prospectus supplement with the SEC on September 16, 2021, a subsequent prospectus supplement with the SEC on May 9, 2023 and will pay sales commissions of up to 3.0% of gross proceeds from the sale of shares. In the six months ended June 30, 2024, 7,719,641 shares were issued and sold under the September 2021 ATM for gross proceeds of \$9.1 million, which, after deducting sales commissions and expenses incurred to date, resulted in net proceeds of \$8.8 million. Since June 30, 2024, we have not raised any additional capital under the September 2021 ATM.

The Company's principal operations are based in South San Francisco, California, and it operates in one reportable segment, which is the discovery and development of oral recombinant protein vaccines, based on its proprietary oral vaccine platform.

## **NOTE 2.** Summary of Significant Accounting Policies

**Basis of Presentation, Liquidity and Going Concern** – The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the accounting and disclosure rules and regulations of the SEC assuming the Company will continue as a going concern.

The Company is a clinical-stage biotechnology company with no product sales. Its primary source of capital is from the sale and issuance of common stock and common stock warrants as well as funding from the Biomedical Advanced Research and Development Authority ("HHS BARDA"), a division of the Administration for Strategic Preparedness and Response ("ASPR") within the United States ("U.S.") Department of Health and Human Services. As of June 30, 2024, the Company had cash, cash equivalents and investments of \$62.6 million.

Based on management's current plan, the Company expects to have cash runway into 2026. The Company will be dependent upon raising additional capital through placement of its common stock, notes or other securities, borrowings, or entering into a partnership with a strategic party in order to implement its business plan. There can be no assurance that the Company will be successful raising additional capital in order to continue as a going concern.

The condensed consolidated balance sheet as of December 31, 2023, included in this filing, was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. Certain information and footnote disclosures normally included in consolidated financial statements have been condensed or omitted pursuant to these rules and regulations. These condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and footnotes related thereto for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2024 (the "Annual Report"). Unless noted below, there have been no material changes to the Company's significant accounting policies described in Note 2 to the consolidated financial statements included in the Annual Report. In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the Company's financial position and the results of its operations and cash flows. The results of operations for such interim periods are not necessarily indicative of the results to be expected for the full year or any future periods.

**Basis of Consolidation** – The unaudited condensed consolidated financial statements include the financial statements of Vaxart, Inc. and its subsidiaries. All significant transactions and balances between Vaxart, Inc. and its subsidiaries have been eliminated in consolidation.

Use of Estimates – The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Actual results and outcomes could differ from these estimates and assumptions.

**Concentration of Credit Risk** – Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, available-for-sale investments and accounts receivable. The Company places its cash, cash equivalents and available-for-sale investments at financial institutions that management believes are of high credit quality. The Company is exposed to credit risk in the event of default by the financial institutions holding the cash and cash equivalents to the extent such amounts are in excess of the federally insured limits. Losses incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

The primary focus of the Company's investment strategy is to preserve capital and meet liquidity requirements. The Company's investment policy addresses the level of credit exposure by limiting the concentration in any one corporate issuer or sector and establishing a minimum allowable credit rating.

## **Revenue Recognition**

## Revenue from Government Contracts

Under firm fixed-price milestone contracts, the Company recognizes the firm fixed-price revenue as the milestones are substantially complete and the firm fixed-price for the milestone is earned ("firm fixed-price milestone"). Under cost reimbursable contracts, the Company recognizes revenue as allowable costs are incurred and the fixed fee is earned ("cost-plus-fixed-fee"). Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and approved overhead and indirect costs. Fixed fees under cost reimbursable contracts are earned in proportion to the allowable costs incurred in performance of the work relative to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed.

Payments to the Company under cost reimbursable contracts are provisional payments subject to adjustment upon annual audit by the government. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

#### **Recent Accounting Pronouncements**

The Company has reviewed all significant newly-issued accounting pronouncements that are not yet effective and concluded that they are either not applicable to its operations or their adoption is not expected to have a material impact on its financial position or results of operations.

## NOTE 3. Fair Value of Financial Instruments

Fair value accounting is applied for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the condensed consolidated financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities that approximate fair value due to their relatively short maturities.

Assets and liabilities recorded at fair value on a recurring basis in the condensed consolidated balance sheets are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

- Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2 Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level 3 Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The following table sets forth the fair value of the Company's financial assets that are measured on a recurring basis as of June 30, 2024 and December 31, 2023 (in thousands):

	I	Level 1	Level 2	Level 3	Total
June 30, 2024					
Financial assets:					
Money market funds	\$	38,000	\$ 	\$ _	\$ 38,000
U.S. Treasury securities			 19,308	 _	 19,308
Total assets	\$	38,000	\$ 19,308	\$ 	\$ 57,308
	]	Level 1	Level 2	Level 3	Total
December 31, 2023	]	Level 1	 Level 2	 Level 3	 Total
December 31, 2023 Financial assets:	]	Level 1	 Level 2	 Level 3	 Total
*	<u> </u>	Level 1 31,403	\$ Level 2	\$ Level 3	\$ <b>Total</b> 31,403
Financial assets:			\$ Level 2 	\$ Level 3	\$

The Company held no financial liabilities measured on a recurring basis as of June 30, 2024 or December 31, 2023.



## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## **NOTE 4. Balance Sheet Components**

## (a) Cash, Cash Equivalents and Investments

Cash, cash equivalents and investments consisted of the following (in thousands):

	Am	ortized	_	Gross U	nrea	lized	E	stimated	(	Cash and Cash	S	hort-Term
		Cost		Gains Losses		Losses	Fair Value		Equivalents		In	vestments
June 30, 2024												
Cash at banks	\$	5,285	\$		\$		\$	5,285	\$	5,285	\$	—
Money market funds		38,000						38,000		38,000		
U.S. Treasury securities		19,324		—		(16)		19,308		—		19,308
Total	\$	62,609	\$	_	\$	(16)	\$	62,593	\$	43,285	\$	19,308

	An	ortized	Gross Ui	nrea	lized	I	Estimated	(	Cash and Cash	SI	hort-Term
		Cost	 Gains		Losses	F	Fair Value	Ec	quivalents	In	vestments
December 31, 2023											
Cash at banks	\$	3,352	\$ 	\$	_	\$	3,352	\$	3,352	\$	_
Money market funds		31,403					31,403		31,403		_
U.S. Treasury securities		4,959			(1)		4,958				4,958
Total	\$	39,714	\$ 	\$	(1)	\$	39,713	\$	34,755	\$	4,958

As of June 30, 2024 and December 31, 2023, all investments were available-for-sale debt securities with remaining maturities of 12 months or less.

### (b) Accounts Receivable

Accounts receivable consists of \$1.053 million of government contract receivables from HHS BARDA, and \$35,000 royalty receivable totaling \$1.088 million as of June 30, 2024 and a total of \$3.0 million of accounts receivable for royalties as of December 31, 2023.

An allowance for expected credit losses over the life of the receivables is reserved for based on a combination of historical experience, aging analysis, current economic trends and information on specific accounts, with related amounts recorded as a reserve against revenue recognized. The reserve is re-evaluated on a regular basis and adjusted as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the reserve. The Company has provided no allowance for credit losses as of June 30, 2024 and December 31, 2023.

## (c) Unbilled Receivable from Government Contracts

Unbilled receivable which was earned and not yet billed, consists of government contracts from HHS BARDA of \$3.7 million and zero as of June 30, 2024 and December 31, 2023, respectively.

## (d) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consists of the following (in thousands):

	June	e 30, 2024	Decem	ber 31, 2023
Prepaid clinical and manufacturing expenses	\$	2,218	\$	984
Prepaid insurance		734		258
Prepaid rent				488
Other prepaid		885		752
Other current assets		328		333
Prepaid expenses and other current assets	\$	4,165	\$	2,815

## (e) Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	June 30, 2	024	December 31, 2023		
Laboratory equipment	\$	13,554	\$	13,448	
Office and computer equipment		1,120		1,105	
Leasehold improvements		4,078		3,985	
Construction in progress		191		24	
Total property and equipment		18,943		18,562	
Less: accumulated depreciation		(8,663)		(6,831)	
Property and equipment, net	\$	10,280	\$	11,731	

Depreciation expense was \$0.9 million for each of the three months ended June 30, 2024 and 2023, and \$1.8 million for each of the six months ended June 30, 2024 and 2023. There were no impairments of the Company's property and equipment recorded in the three and six months ended June 30, 2024 or 2023.

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## (f) Right-of-Use Assets, Net

Right-of-use assets, net comprises facilities of \$22.7 million and \$24.8 million as of June 30, 2024 and December 31, 2023, respectively. The right-of-use of additional leased premises in California commenced in 2023, resulting in an additional \$3.1 million right-of-use assets recorded in the year ended December 31, 2023.

## (g) Intangible Assets, Net

Intangible assets comprise developed technology and intellectual property. Intangible assets are carried at cost less accumulated amortization. As of June 30, 2024, developed technology and intellectual property had remaining lives of 5.4 years and 3.5 years, respectively. As of June 30, 2024, there have been no indicators of impairment. Intangible assets consist of the following (in thousands):

	June 30, 202			mber 31, 2023	
Developed technology	\$	5,000	\$	5,000	
Intellectual property		80		80	
Total cost		5,080		5,080	
Less: accumulated amortization		(1,157)		(791)	
Intangible assets, net	\$	3,923	\$	4,289	

Intangible asset amortization expense was \$0.2 million for each of the three months ended June 30, 2024 and 2023, and \$0.4 million for each of the six months ended June 30, 2024 and 2023.

As of June 30, 2024, the estimated future amortization expense by year is as follows (in thousands):

Year Ending December 31,	 Amount
2024 (six months remaining)	\$ 365
2025	732
2026	731
2027	731
2028	727
Thereafter	637
Total	\$ 3,923

## (h) Goodwill

Goodwill, which represents the excess of the purchase price over the fair value of assets acquired, comprises \$4.5 million as of both June 30, 2024 and December 31, 2023. As of June 30, 2024, there have been no indicators of impairment.

## (i) Other Accrued Current Liabilities

Other accrued current liabilities consist of the following (in thousands):

	June 3	30, 2024	Decem	ber 31, 2023
Accrued compensation	\$	3,704	\$	4,576
Accrued clinical and manufacturing expenses		1,591		312
Accrued professional and consulting services		522		211
Other liabilities, current portion		794		535
Total	\$	6,611	\$	5,634

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## NOTE 5. Revenue

## Royalty Revenue Related to Sale of Future Royalties

The Company generates royalty revenue from the sale of Inavir in Japan, pursuant to a collaboration and license agreement that Aviragen entered into with Daiichi Sankyo Company, Limited ("Daiichi Sankyo") in 2009. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza in adults and children, which Daiichi Sankyo markets as Inavir. Under the agreement, the Company currently receives a 4% royalty on net sales of Inavir in Japan. Based on information provided by Daiichi Sankyo, the Company believes the expiration of the last patent related to Inavir is in August 2036, at which time royalty revenue will cease. The Company's royalty revenue is seasonal, in line with the flu season, so the majority of the Company's royalty revenue and non-cash royalty revenue related to the sale of future royalties are earned in the first and fourth fiscal quarters. The royalty revenue related to Inavir recognized for the six months ended June 30, 2024 and 2023, was zero. The Company recognized non-cash royalty revenue related to sale of future royalties of \$37,000 and \$30,000 for the three months ended June 30, 2024 and 2023, respectively, and \$0.6 million and \$0.3 million for the six months ended June 30, 2024 and 2023, respectively, and \$0.6 million and \$0.2024 and 2023, respectively, and \$31,000 and \$15,000 for the six months ended June 30, 2024 and 2023, respectively, further detailed to the sale of future royalties are subject to a 5% withholding tax in Japan, for which \$2,000 and \$1,000 was included in income tax expense for the three months ended June 30, 2024 and 2023, respectively, further detailed in <u>Note 6</u>.

## Revenue from Government Contracts

The Company recognized revenue from government contracts of \$6.4 million and \$8.0 million for the three and six months ended June 30, 2024, respectively, consisting of revenues from the 2024 ASPR-BARDA Contract (as defined below) and the 2024 ATI-RRPV Contract (as defined below) described in more detail below. Unbilled receivable from government contracts consists of government fixed fee revenue from HHS BARDA, which was earned and not yet billed. As of June 30, 2024, the amount of unbilled receivable was \$3.7 million.

### 2024 ATI-RRPV Contract

In June 2024, the Company entered into an agreement (the "2024 ATI-RRPV Contract") with Advanced Technology International, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by HHS BARDA. Pursuant to the 2024 ATI-RRPV Contract, the Company will receive funding of up to \$452.9 million to conduct a Phase 2b comparative study evaluating the Company's oral pill XBB COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the U.S. Food and Drug Administration. The 2024 ATI-RRPV Contract provides for an initial award in the aggregate amount of up to \$65.7 million, consisting of a fixed fee of \$64.7 million and reimbursement of costs incurred in trial preparation activities. The 2024 ATI-RRPV Contract further contemplates additional funding up to \$387.2 million if the Company and HHS BARDA decide to continue with the Phase 2b comparative study. The Company accounts for the 2024 ATI-RRPV Contract under Accounting Standards Codification 958-605 and recognizes revenue as the firm fixed-price milestone is earned and allowable cost-plus-fixed-fees are incurred. Reimbursable costs under the 2024 ATI-RRPV Contract primarily include direct labor, subcontract costs, materials, travel, and approved overhead and indirect costs. The 2024 ATI-RRPV Contract contains terms and conditions that are customary for contracts with HHS BARDA of this nature, including the U.S. government having the right to terminate the contract for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work. Revenue from government contracts recognized on the 2024 ATI-RRPV Contract was \$0.2 million for the three and six months ended June 30, 2024, based on costs incurred under the 2024 ATI-RRPV Contract.

Management believes that if the 2024 ATI-RRPV Contract were to be terminated prior to completion of the Phase 2b comparative study, the costs incurred through the effective date of such termination and any settlement costs resulting from such termination would be allowable costs. Cost reimbursement payments to the Company are provisional payments subject to adjustment upon annual audit by the government. Management believes that revenue for periods not yet audited will be recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

## 2024 ASPR-BARDA Contract

In January 2024, the Company was awarded a contract (the "2024 ASPR-BARDA Contract") by HHS BARDA with a base and all options value of \$9.3 million. Under the 2024 ASPR-BARDA Contract, the Company received an award to support clinical trial planning activities for a Phase 2b clinical trial that would compare the Company's XBB vaccine candidate to an mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events. The 2024 ASPR-BARDA Contract originally had a term that was set to expire in July 2024, but the Company entered into an amendment in July 2024 that extended the expiration date into October 2024. The Company accounts for the 2024 ASPR-BARDA Contract under Accounting Standards Codification 958-605 and recognizes revenue as donor-imposed conditions are met. Revenue from government contracts recognized on the 2024 ASPR-BARDA Contract was \$6.2 million and \$7.8 million for the three and six months ended June 30, 2024, respectively, based on the achievement of certain milestones under the 2024 ASPR-BARDA Contract.

## Grant Revenue

In November 2022, the Company accepted a \$3.5 million grant to perform research and development work for the Bill & Melinda Gates Foundation (the "BMGF Grant") and received \$2.0 million in advance that was recorded as restricted cash and deferred revenue. The Company received an additional \$1.5 million in July 2023 upon completion of certain milestones. The Company recognizes revenue under research contracts only when a contract is executed and the contract price is fixed or determinable. Revenue from the BMGF Grant was recognized in the period during which the related costs were incurred and the related services rendered, as the applicable conditions under the contract were met. Costs of contract revenue were recorded as a component of operating expenses in the condensed consolidated statements of operations and comprehensive loss. The Company recognized revenue from the BMGF Grant of zero and \$1.3 million for the three months ended June 30, 2024 and 2023, respectively, and zero and \$1.7 million for the six months ended June 30, 2024 and 2023, respectively. The Company fully recognized revenue from the BMGF Grant during the year ended December 31, 2023.

#### Notes to the Condensed Consolidated Financial Statements (Unaudited)

#### NOTE 6. Liabilities Related to Sale of Future Royalties

In April 2016, Aviragen entered into a Royalty Interest Acquisition Agreement (the "RIAA") with HealthCare Royalty Partners III, L.P. ("HCRP"). Under the RIAA, HCRP made a \$20.0 million cash payment to Aviragen in consideration for acquiring certain royalty rights ("Royalty Rights") related to the approved product Inavir in the Japanese market. The Royalty Rights were obtained pursuant to the collaboration and license agreements (the "License Agreement") and a commercialization agreement that the Company entered into with Daiichi Sankyo. Per the terms of the RIAA, during the first royalty interest period of April 1, 2016 through March 31, 2025, HCRP is entitled to the first \$3.0 million and any cumulative remaining shortfall amount plus 15% of the next \$1.0 million in royalties earned in each year commencing on April 1, with any excess revenue being retained by the Company. Further, during the second royalty interest period beginning April 1, 2025 and ending on December 24, 2029, HCRP is entitled to the first \$2.7 million and any cumulative remaining shortfall amount, plus 15% of the next \$1.0 million in royalties, with any excess revenue being retained by the Company. A shortfall occurs when, during an annual period ending on March 31st, for the first royalty interest period of April 1, 2016 through March 31, 2025, the first royalty interest period of April 1, 2025, the Company's royalty payments fall below \$3.0 million; and \$2.7 million for the second royalty interest period of April 1, 2025 and ending on December 24, 2025 and ending on December 24, 2029, excluding the period of April 1, 2028 through December 24, 2029. In the event there shall remain any cumulative remaining shortfall amount as of December 24, 2029, any royalties received from Daiichi Sankyo subsequently by the Company would be payable to HCRP until the cumulative remaining shortfall amount has been paid.

For avoidance of doubt, the RIAA states, in the event there is a remaining cumulative remaining shortfall amount as of December 24, 2029, the Company shall not be obligated to pay HCRP any royalty payment beyond what the Company is paid from Daiichi Sankyo. The cumulative remaining shortfall amount is the aggregate amount of the remaining shortfall for each annual period, which was \$6.0 million and \$7.0 million as of June 30, 2024 and December 31, 2023, respectively.

Under the relevant accounting guidance, due to a limit on the amount of royalties that HCRP can earn under the RIAA, this transaction was accounted for as a liability that is being amortized using the effective interest method over the life of the arrangement. The Company has no obligation to pay any amounts to HCRP other than to pass through to HCRP its share of royalties as they are received from Daiichi Sankyo. To record the amortization of the liability, the Company is required to estimate the total amount of future royalty payments to be received under the License Agreement and the payments that will be passed through to HCRP over the life of this agreement. Consequently, the Company imputes interest on the unamortized portion of the liability and records non-cash interest expense using an estimated effective interest rate. The royalties earned in each period that will be passed through to HCRP are recorded as non-cash royalty revenue related to sale of future royalties, with any excess not subject to pass-through being recorded as royalty revenue. When the pass-through royalties are paid to HCRP in the following quarter, the imputed liability related to sale of future royalties is commensurately reduced. The Company periodically assesses the expected royalty payments, and to the extent such payments are greater or less than the initial estimate, the Company adjusts the amortization of the liability and interest rate. As a result of this accounting, even though the Company does not retain HCRP's share of the royalties, it will continue to record non-cash revenue related to those royalties until the amount of the associated liability, including the related interest, is fully amortized.

The following table shows the activity within the liability account during the six months ended June 30, 2024 (in thousands):

Total liability related to sale of future royalties, start of period	\$ 6,426
Non-cash royalty revenue paid to HCRP	(3,563)
Non-cash interest expense recognized	1,414
Total liability related to sale of future royalties, end of period	4,277
Current portion	(2,686)
Long-term portion	\$ 1,591

#### Notes to the Condensed Consolidated Financial Statements (Unaudited)

#### NOTE 7. Leases

The Company has obtained the right of use for office and manufacturing facilities under six operating lease agreements with initial terms exceeding one year. The lease term at the commencement date is determined by considering whether renewal options and termination options are reasonably assured of exercise.

In September 2021, the Company executed a lease for a facility in South San Francisco, California, with an initial term expiring on March 31, 2029. This lease has two separate components, one commenced in the third quarter of 2022 and the other in the first quarter of 2023, resulting in an additional right of use asset of \$15.0 million and \$3.1 million, respectively.

As of June 30, 2024, the weighted average discount rate for operating leases with initial terms of more than one year was 9.8% and the weighted average remaining term of these leases was 4.7 years. Discount rates were determined using the Company's marginal rate of borrowing at the time each lease was executed or extended.

The following table summarizes the Company's undiscounted cash payment obligations for its operating lease liabilities with initial terms of more than 12 months as of June 30, 2024 (in thousands):

Year Ending December 31,	
2024 (six months remaining)	\$ 2,209
2025	4,511
2026	5,031
2027	5,207
2028	5,389
Thereafter	1,348
Undiscounted total	23,695
Less: imputed interest	(4,840)
Present value of future minimum payments	18,855
Current portion of operating lease liability	(2,872)
Operating lease liability, net of current portion	\$ 15,983

The Company is also required to pay for operating expenses related to the leased space. The operating expenses are incurred separately and were not included in the present value of lease payments. Operating lease expenses for the three and six months ended June 30, 2024 and 2023, are summarized as follows (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,				
	 2024		2023		2024		2023	
Lease cost								
Operating lease cost	\$ 1,553	\$	1,553	\$	3,107	\$	3,063	
Short-term lease cost	7		10		19		31	
Variable lease cost	381		431		885		942	
Sublease income	(20)		—		(34)		-	
Total lease cost	\$ 1,921	\$	1,994	\$	3,977	\$	4,036	
	12							

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## **NOTE 8.** Commitments and Contingencies

## (a) Purchase Commitments

As of June 30, 2024, the Company had approximately \$3.2 million of non-cancelable purchase commitments, principally for contract manufacturing and clinical services which are expected to be paid within the next year. In addition, the Company has operating lease commitments as detailed in <u>Note 7</u>.

## (b) Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has also entered into indemnification agreements with certain officers and directors which provide, among other things, that the Company will indemnify and advance expenses incurred in connection with certain actions, suits or proceedings to such officer or director, under the circumstances and to the extent provided for therein, for expenses, judgments, fines and settlements he or she may be required to pay in actions or proceedings which he or she is or may be made a party by reason of his or her position as a director, officer or other agent of the Company, and otherwise to the fullest extent permitted under Delaware law and the Company's Bylaws. The Company currently has directors' insurance.

## (c) Litigation

From time to time the Company may be involved in legal proceedings arising in connection with its business. Based on information currently available, the Company believes that the amount, or range, of reasonably possible losses in connection with any pending actions against it in excess of established reserves, in the aggregate, is indeterminable to its consolidated financial condition or cash flows. However, any current or future dispute resolution or legal proceeding, regardless of the merits of any such proceeding, could result in substantial costs and a diversion of management's attention and resources that are needed to run the Company successfully, and could have a material adverse impact on its business, financial condition and results of operations.

In August and September 2020, two substantially similar securities class actions were filed in the U.S. District Court for the Northern District of California. The first action, titled <u>Himmelberg v. Vaxart, Inc. et al.</u> was filed on August 24, 2020. The second action, titled <u>Hovhannisyan v. Vaxart, Inc. et al.</u> was filed on September 1, 2020 (together, the "Putative Class Action"). By Order dated September 17, 2020, the two actions were deemed related. On December 9, 2020, the court appointed lead plaintiffs' counsel.

On January 29, 2021, lead plaintiffs filed their consolidated amended complaint. On July 8, 2021, all defendants moved to dismiss the consolidated amended complaint. On May 14, 2021, the court granted lead plaintiffs' request to amend the consolidated amended complaint and denied defendants' motions to dismiss as moot. On June 10, 2021, lead plaintiffs filed a first amended consolidated complaint, and on August 9, 2021, lead plaintiffs filed a corrected first amended consolidated complaint. The first amended consolidated complaint, as corrected, named certain of Vaxart's current and former executive officers and directors, as well as Armistice Capital, LLC ("Armistice"), as defendants. It claimed three violations of federal civil securities laws; violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5, as against the Company and all individual defendants; violation of Section 20(a) of the Exchange Act, as against Armistice and all individual defendants; and violation of Section 20A of the Exchange Act against Armistice. The first amended consolidated complaint, as corrected, alleged that the defendants violated securities laws by misstating and/or omitting information regarding the Company's development of a norovirus vaccine, the vaccine manufacturing capabilities of a business counterparty, and the Company's involvement with Operation Warp Speed ("OWS"); and by engaging in a scheme to inflate Vaxart's stock price. The first amended consolidated complaint sought certification as a class action for similarly situated shareholders and sought, among other things, an unspecified amount of damages and attorneys' fees and costs. On July 8, 2021, all defendants moved to dismiss the first amended consolidated complaint. By Order dated December 22, 2021, the court granted the motion to dismiss by Armistice with leave to amend and otherwise denied the motions to dismiss. On July 27, 2022, lead plaintiffs filed a notice announcing that they had reached a partial settlement (the "Partial Settlement") to resolve all claims against the Company and its current or former officers and/or directors in their capacity as officers and/or directors of the Company (the "Settling Defendants"). Pursuant to the Partial Settlement, the Company agreed to a settlement amount of \$12.0 million with \$2.0 million to be paid by the Company and the remainder to be paid by the Company's insurers. On November 2, 2022, the Company paid the \$2.0 million settlement amount with respect to the Putative Class Action pursuant to the terms of the settlement agreement reached in that case. On November 14, 2022, lead plaintiffs filed a second amended consolidated class action complaint that purported to include new allegations to support claims against Armistice. By Orders dated January 25, 2023, the court approved the Partial Settlement and entered judgment dismissing with prejudice all claims asserted in the Putative Class Action against the Settling Defendants.

On October 23, 2020, a complaint was filed in the U.S. District Court for the Southern District of New York, entitled <u>Roth v. Armistice Capital LLC, et</u> <u>al.</u> The complaint names Armistice and certain Armistice-related parties as defendants, asserting a violation of Exchange Act Section 16(b) and seeking the disgorgement of short-swing profits. The complaint purports to bring the lawsuit on behalf of and for the benefit of the Company and names the Company as a "nominal defendant" for whose benefit damages are sought. Following discovery, a motion for summary judgment was filed by Armistice and the Armistice-related party defendants to dismiss the complaint. On March 27, 2024, the court granted the motion for summary judgment and dismissed all claims in the complaint in their entirety. On April 11, 2024, the Plaintiff timely filed a notice of appeal of the court's decision to the Second Circuit Court of Appeals, commencing appellate proceedings. In June 2024, Plaintiff filed a motion to the court of appeals to stay the appeal pending efforts to re-instate the complaint in the district court, which was granted by the court of appeals. In July 2024, Plaintiff filed a motion with the district court seeking to set aside the judgment and to re-instate the complaint, which is currently under consideration by that court.

On January 8, 2021, a purported shareholder, Phillip Chan, commenced a *pro se* lawsuit in the U.S. District Court for the Northern District of California titled <u>Chan v. Vaxart, Inc. et al.</u> (the "Opt-Out Action"), opting out of the consolidated Himmelberg v. Vaxart, Inc. et al. and Hovhannisyan v. Vaxart, Inc. et al. class actions, (together, the "Putative Class Action"). Because this complaint is nearly identical to an earlier version of a complaint filed in the Putative Class Action, the Opt-Out Action has been stayed while the Putative Class Action is pending.

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## NOTE 9. Stockholders' Equity

## (a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock, \$0.0001 par value per share. The Company's board of directors may, without further action by the stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 5,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deterring or preventing a change of control or other corporate action. No shares of preferred stock are currently outstanding, and the Company has no present plan to issue any shares of preferred stock.

## (b) Common Stock

As of June 30, 2024, the Company was authorized to issue 350,000,000 shares of common stock, \$0.0001 par value per share, which includes an increase of 100,000,000 on June 11, 2024, when the Company's stockholders approved an amendment to the Company's certificate of incorporation to increase the number of authorized shares of common stock from 250,000,000 to 350,000,000 shares. Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of common stock possess all voting power for the election of the Company's directors and all other matters requiring stockholder action. Holders of common stock are entitled to one vote per share on matters to be voted on by stockholders. Holders of common stock are entitled to receive such dividends, if any, as may be declared from time to time by the Company's board of directors at its discretion out of funds legally available therefor. In no event will any stock dividends or stock splits or combinations of stock be declared or made on common stock unless the shares of common stock at the time outstanding are treated equally and identically. As of June 30, 2024, no dividends had been declared by the board of directors.

In June 2024, the Company entered into an underwriting agreement with Oppenheimer & Co. Inc., relating to the issuance and sale by the Company in an underwritten registered direct offering of 50,000,000 shares of the Company's common stock, at a price of \$0.80 per share. The gross proceeds to the Company from such offering were \$40.0 million, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company, the net proceeds were \$37.6 million.

In January 2024, the Company entered into the 2024 Securities Purchase Agreement with RA Capital Healthcare Fund, L.P. pursuant to which 15,384,615 shares of the Company's common stock were sold to RA Capital Healthcare Fund, L.P. at an offering price of \$0.65 per share pursuant to the Company's 2023 Shelf Registration. The gross proceeds from the 2024 Securities Purchase Agreement were \$10.0 million and, after deducting offering expenses, the net proceeds were \$9.9 million.

In the event of the Company's voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of the common stock will be entitled to receive an equal amount per share of all the Company's assets of whatever kind available for distribution to stockholders, after the rights of the holders of the preferred stock have been satisfied. There are no sinking fund provisions applicable to the common stock.

The Company had shares of common stock reserved for issuance as follows:

	June 30, 2024	December 31, 2023
Options issued and outstanding	21,699,803	17,938,726
RSUs issued and outstanding	3,135,958	2,126,373
2019 Equity Incentive Plan available for future grant	16,621,469	5,685,806
2024 Inducement Award Plan available for future grant	1,727,500	—
Common stock warrants	140,596	227,434
2022 Employee Stock Purchase Plan	2,362,902	1,065,325
Total	45,688,228	27,043,664

The approved increase of reserved common stock for 2019 Equity Incentive Plan and 2022 Employee Stock Purchase Plan is detailed in Note 10.

## (c) Treasury Stock

The Company generally withholds shares of its common stock to cover employees' portion of required tax withholdings when employee equity awards are issued or vest. These shares are valued at cost, which equals the market price of the common stock on the date of issuance or vesting. The Company had 688,331 and 507,020 treasury shares as of June 30, 2024 and December 31, 2023, respectively.

## (d) Warrants

In April 2024, 70,663 of the warrants outstanding as of March 31, 2024, expired unexercised. The following warrants were outstanding as of June 30, 2024, all of which contain standard anti-dilution protections in the event of subsequent rights offerings, stock splits, stock dividends or other extraordinary dividends, or other similar changes in the Company's common stock or capital structure, and none of which have any participating rights for any losses:

Securities into which warrants are convertible	Warrants Outstanding	 Exercise Price	Expiration Date
Common Stock	29,150	\$ 2.50	March 2025
Common Stock	100,532	\$ 3.125	February 2025
Common Stock	10,914	\$ 22.99	December 2026

140,596

In the event of a Fundamental Transaction (a transfer of ownership of the Company as defined in the warrant) within the Company's control, the holders of the unexercised common stock warrants exercisable for \$2.50 and those exercisable for \$3.125 shall be entitled to receive cash consideration equal to a Black-Scholes valuation, as defined in the warrant. If such Fundamental Transaction is not within the Company's control, the warrant holders would only be entitled to receive the same form of consideration (and in the same proportion) as the holders of the Company's common stock, hence these warrants are classified as a component of permanent equity.

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## **NOTE 10. Equity Incentive Plans**

On April 23, 2019, the Company's stockholders approved the adoption of the 2019 Equity Incentive Plan (the "2019 Plan"), under which the Company is authorized to issue incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units ("RSUs"), other stock awards and performance awards that may be settled in cash, stock, or other property. The 2019 Plan is designed to secure and retain the services of employees, directors and consultants, provide incentives for the Company's employees, directors and consultants to exert maximum efforts for the success of the Company and its affiliates, and provide a means by which employees, directors and consultants may be given an opportunity to benefit from increases in the value of the Company's common stock. Following adoption of the 2019 Plan, all previous plans were frozen, and on forfeiture, cancellation and expiration, awards under those plans are not assumed by the 2019 Plan.

The aggregate number of shares of common stock authorized for issuance under the 2019 Plan was initially 1,600,000 shares, which was increased through an amendment to the 2019 Plan adopted by the Company's stockholders (a "Plan Amendment") on June 8, 2020, to 8,000,000, by a Plan Amendment on June 16, 2021, to 16,900,000, by a Plan Amendment on August 4, 2022, to 28,900,000, and by a Plan Amendment on June 11, 2024, to 43,900,000. Further amendments to the 2019 Plan to increase the share reserve would require stockholder approval. Awards that are forfeited or canceled generally become available for issuance again under the 2019 Plan. Awards have a maximum term of ten years from the grant date and may vest over varying periods, as specified by the Company's board of directors for each grant.

On February 27, 2024, the Company's board of directors adopted the Vaxart, Inc. 2024 Inducement Award Plan (the "2024 Inducement Plan"). The 2024 Inducement Plan was adopted without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4) and is administered by the Compensation Committee of the board of directors or the independent members of the board of directors. The board of directors reserved 3,000,000 shares of the Company's common stock for issuance under the 2024 Inducement Plan, subject to adjustment as provided in the plan document. The terms of the 2024 Inducement Plan are substantially similar to the terms of the 2019 Plan, with the exception that incentive stock options may not be issued under the 2024 Inducement Plan and equity awards under the 2024 Inducement Plan (including nonqualified stock options, restricted stock, restricted stock units, and other stock-based awards) may be issued only to an employee who is commencing employment with the Company or any subsidiary or who is being rehired following a bona fide interruption of employment by the Company or any subsidiary, in either case if he or she is granted such award in connection with his or her commencement of employment and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary.

A summary of stock option and RSU transactions in the six months ended June 30, 2024, is as follows:

			Weighted Option		W	Veighted
	Shares Available For Grant	Number of Options Outstanding	 Average Exercise Price	Unvested RSU Shares Outstanding	Gı	U Average rant Date air Value
Balance as of January 1, 2024	5,685,806	17,938,726	\$ 2.90	2,126,373	\$	1.37
Authorized under 2024 Inducement Plan	3,000,000					
Authorized under 2019 Plan	15,000,000					
Granted	(7,135,230)	5,226,937	\$ 1.12	1,908,293	\$	1.14
Exercised		(26,980)	\$ 0.78			
Released				(526,424)	\$	1.39
Forfeited	1,659,141	(1,286,857)	\$ 2.20	(372,284)	\$	1.49
Canceled	139,252	(152,023)	\$ 5.20			
Balance as of June 30, 2024	18,348,969	21,699,803	\$ 2.50	3,135,958	\$	1.21

As of June 30, 2024, there were 21,699,803 options outstanding with a weighted average exercise price of \$2.50, a weighted average remaining term of 7.09 years, and an aggregate intrinsic value of \$35,000. Of these options, 12,175,103 were vested, with a weighted average exercise price of \$2.98, a weighted average remaining term of 5.55 years, and an aggregate intrinsic value of \$35,000.

The Company received \$21,000 for the 26,980 options exercised during the six months ended June 30, 2024, which had an intrinsic value of \$6,000, and received \$17,000 for the 54,720 options exercised during the six months ended June 30, 2023, which had an intrinsic value of \$31,000. The aggregate intrinsic value represents the total pre-tax value (i.e., the difference between the Company's stock price and the exercise price) of stock options outstanding as of June 30, 2024, based on the Company's common stock closing price of \$0.67 on June 28, 2024, the prior business day, which would have been received by the option holders had all their in-the-money options been exercised as of that date.

The weighted average grant date fair value of options awarded in the six months ended June 30, 2024 and 2023, was \$1.01 and \$0.78, respectively. Their fair values were estimated using the following assumptions:

	Six Months End	ed June 30,
	2024	2023
Risk-free interest rate	4.4%	3.5% - 3.9%
Expected term (in years)	6.00	6.00
Expected volatility	128.9% - 129.3%	127.8% - 129.5%
Dividend yield	%	%

#### Notes to the Condensed Consolidated Financial Statements (Unaudited)

The Company measures the fair value of all stock-based awards on the grant date and records the fair value of these awards, net of estimated forfeitures, to compensation expense over the service period. Total stock-based compensation recognized for options, RSUs and ESPP was as follows (in thousands):

	Three Months Ended June 30,					Six Months Ended June 30,			
		2024 2023		2023	2024			2023	
Research and development	\$	1,868	\$	2,366	\$	3,675	\$	3,738	
General and administrative		687		1,561		2,996		2,836	
Total stock-based compensation	\$	2,555	\$	3,927	\$	6,671	\$	6,574	

As of June 30, 2024, the unrecognized stock-based compensation cost related to outstanding unvested stock options and RSUs expected to vest was \$18.7 million, which the Company expects to recognize over an estimated weighted average period of 2.4 years.

On August 4, 2022, the 2022 Employee Stock Purchase Plan (the "2022 ESPP") was approved by the Company's stockholders. The Company initially reserved 1,800,000 shares of the Company's common stock for purchase under the 2022 ESPP, which was increased by 1,800,000 shares through an amendment to the 2022 ESPP adopted by the Company's stockholders on June 11, 2024, to 3,600,000 shares. The 2022 ESPP generally has a six-month offering period comprised of one purchase period. In May 2024, the 2022 ESPP had a one-time modification following the end of the six-month offering period ended May 31, 2024, to commence the follow-on offering period on July 1, 2024 for a five-month offering period. The purchase price of the stock is equal to 85% of the lesser of the market value of such shares at the beginning of the six-month offering period or the end of such offering period. During the six months ended June 30, 2024 the Company received \$0.3 million and issued 502,423 shares under the 2022 ESPP. As of June 30, 2024, 2,362,902 shares are available and reserved for future issuance under the 2022 ESPP.

The estimated fair value used for the six-month offering period beginning December 1, 2023 and ending May 31, 2024, was \$0.27 per share. The estimated fair value used for the six-month offering period beginning June 1, 2023 and ending November 30, 2023 was \$0.54 per share. The estimated fair value used for the six-month offering period beginning December 1, 2022 and ending May 31, 2023 was \$0.46 per share. As of June 30, 2024, there was no unrecognized stock-based compensation cost due to the one-time modification which changed the following offering period to begin on July 1, 2024. The fair value of the 2022 ESPP shares was estimated using the Black-Scholes option pricing model using the following assumptions:

	Six-Month Offering Period Ending May 31, 2024	Six-Month Offering Period Ending Nov 30, 2023	Six-Month Offering Period Ending May 31, 2023		
Risk-free interest rate	5.3%	5.4%	4.6%		
Expected term (in years)	0.50	0.50	0.50		
Expected volatility	75.2%	98.6%	84.7%		
Dividend yield	%	%	%		

## NOTE 11. Net Loss Per Share Attributable to Common Stockholders

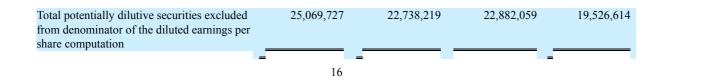
The following table presents the calculation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended June 30,					Six Months Ended June 3			
	2024			2023	2024			2023	
Net loss	\$	(16,466)	\$	(22,550)	\$	(40,883)	\$	(47,690)	
Shares used to compute net loss per share – basic and diluted	1	84,703,003		139,594,238		176,757,049		137,403,416	
Net loss per share – basic and diluted	\$	(0.09)	\$	(0.16)	\$	(0.23)	\$	(0.35)	

No adjustment has been made to the net loss in the three and six months ended June 30, 2024 and 2023, as the effect would be anti-dilutive due to the net loss.

The following potentially dilutive weighted average securities were excluded from the computation of weighted average shares outstanding because they would have been antidilutive:

	Three Months En	ded June 30,	Six Months Ended June 30,					
-	2024	2023	2024	2023				
Options to purchase common stock	21,705,187	18,469,856	19,869,813	16,452,951				
options to purchase common stock	21,705,167	10,409,050	17,007,015	10,452,951				
Restricted stock units to purchase common								
stock	3,223,944	3,672,594	2,600,499	2,445,397				
<b>TT</b> 7 ( ) <b>1</b> ( <b>1</b>	140 50 (	207 424	175.000	207 424				
Warrants to purchase common stock	140,596	227,434	175,928	227,434				
Employee Stock Purchase Plan	_	368,335	235,819	400,832				



## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## **NOTE 12. Subsequent Events**

On July 2, 2024, the Company received a written notice (the "Notice") from the Listing Qualifications Department of The Nasdaq Stock Market indicating that the Company is not in compliance with the \$1.00 Minimum Bid Price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market (the "Bid Price Requirement").

The Notice does not result in the immediate delisting of the Company's common stock from The Nasdaq Capital Market.

The Nasdaq Listing Rules require listed securities to maintain a minimum bid price of \$1.00 per share, and, based upon the closing bid price of the Company's common stock for the 30 consecutive business days for the period of May 17, 2024 through July 1, 2024, the Company no longer meets this requirement.

The Company intends to actively monitor the closing bid price of its common stock and is considering its options to regain compliance with the Bid Price Requirement. There can be no assurance that the Company will be able to regain compliance with the Bid Price Requirement or that the Company will otherwise remain in compliance with the other listing standards for The Nasdaq Capital Market.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and with our audited consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on March 14, 2024. This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "goal," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions intended to identify forward-looking statements and reflect our beliefs and opinions on the relevant subject. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and in this Quarterly Report on Form 10-Q. The forward-looking statements included in this Quarterly Report on Form 10-Q are made only as of the date hereof. These statements are based upon information available to us as of the filing date of this Quarterly Report on Form 10-O, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and we caution investors against unduly relying upon these statements. In all events, we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, change in circumstances, future events or otherwise, and you are advised to consult any additional disclosures that we may make directly to you or through reports that we, in the future, may file with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K.

### **Company Overview and Background**

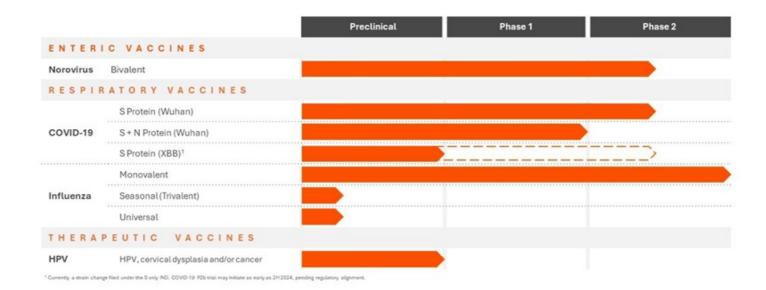
We are a clinical-stage biotechnology company primarily focused on the development of oral recombinant vaccines based on our Vector-Adjuvant-Antigen Standardized Technology ("VAAST") proprietary oral vaccine platform. We are developing prophylactic vaccine candidates that target a range of infectious diseases, including norovirus (a widespread cause of acute gastroenteritis), coronavirus including SARS-CoV-2 (the virus that causes coronavirus disease 2019 ("COVID-19")), and influenza. In addition, we have generated preclinical data for our first therapeutic vaccine candidate targeting cervical cancer and dysplasia caused by human papillomavirus ("HPV"). Our oral vaccines are designed to generate broad and durable immune responses that may protect against a wide range of infectious diseases and may be useful for the treatment of chronic viral infections and cancer. Our investigational vaccines are administered using a room temperature-stable tablet, rather than by injection.

Vaxart Biosciences, Inc. was originally incorporated in California under the name West Coast Biologicals, Inc. in March 2004 and changed its name to Vaxart, Inc. ("Private Vaxart") in July 2007, when it reincorporated in the state of Delaware. On February 13, 2018, Private Vaxart completed a reverse merger (the "Merger") with Aviragen Therapeutics, Inc. ("Aviragen"), pursuant to which Private Vaxart survived as a wholly owned subsidiary of Aviragen. Under the terms of the Merger, Aviragen changed its name to Vaxart, Inc. and Private Vaxart changed its name to Vaxart Biosciences, Inc.

#### Table of Contents

## **Our Product Pipeline**

Figure 1. The following table outlines the status of our oral vaccine development programs:



We are developing the following tablet vaccine candidates, which are all based on our proprietary platform:

• Norovirus Vaccine. Norovirus is the leading cause of acute gastroenteritis symptoms, such as vomiting and diarrhea, among people of all ages in the United States. Each year, on average in the United States, norovirus causes 19 to 21 million cases of acute gastroenteritis and contributes to 109,000 hospitalizations and 900 deaths, mostly among young children and older adults. Virtually all norovirus disease is caused by norovirus GI and GII genotypes, and we are developing a bivalent vaccine candidate designed to protect against both.

In September 2023, we announced that our Phase 2 GI.1 norovirus challenge study evaluating the safety, immunogenicity, and clinical efficacy of the GI.1 component of our bivalent norovirus vaccine candidate met five of six primary endpoints based on preliminary topline data. The study achieved its primary endpoints of a statistically significant 29% relative reduction in the rate of norovirus infection between the vaccinated and placebo arms, a strong induction of norovirus-specific immunoglobulin A (IgA) and immunoglobulin G (IgG) antibodies, and other immune response endpoints. Vaccination also led to a 21% relative reduction in norovirus acute gastroenteritis in the vaccine arm compared to placebo, but this was not statistically significant. In prespecified analyses, the study also showed an 85% relative decrease in viral shedding in the vaccine arm compared with placebo and no statistically significant difference in disease severity in the vaccinated cohort compared with placebo. The vaccine candidate was also safe and well tolerated with no vaccine-related serious adverse events.

In July 2023, we announced our Phase 2 placebo-controlled dose-ranging trial evaluating the safety and immunogenicity of our bivalent norovirus vaccine candidate met all primary endpoints and our bivalent norovirus vaccine candidate was well-tolerated with robust immunogenicity based on preliminary topline data. Preliminary results showed robust increases in serum antibody responses across both doses at Day 29 relative to Day 1. Placebo subjects did not have a measurable increase in the antibody response. The vaccine candidate also had a favorable safety profile that included no vaccine-related serious adverse events and no dose limiting toxicity. Adverse event rates for both doses were similar to placebo.

In July 2024, we received constructive feedback from the Food and Drug Administration ("FDA") on our data for potential correlates of protection and next steps for our norovirus program. The FDA also requested additional information that we expect will lead to further discussion and feedback. We are in the process of submitting the information and will determine next steps once we have finished our discussions with the FDA, such as potentially conducting a Phase 2b study and/or a GII.4 challenge study. We expect the Phase 2b study would generate sufficient safety data to enable us to have an end of Phase 2 meeting with the FDA. The end of Phase 2 meeting will allow us to gain concurrence on the scope and design of the Phase 3 pivotal efficacy study in adults over 18 years of age.

In the Fall of 2022, we announced a Phase 1 study that would receive significant funding and support from the Bill and Melinda Gates Foundation to evaluate whether our bivalent norovirus vaccine candidate induces antibodies in the breast milk of lactating mothers and whether infants up to six months of age can acquire those antibodies by breastfeeding. Passive transfer of antibodies from mother to infant that are induced in milk may protect breastfeeding infants from infectious pathogens. We initiated this study in the fourth quarter of 2023 and announced positive top line results in April 2024. Top line results showed antibodies rose in lactating mothers who received the high dose of our bivalent vaccine candidate. Specifically, serum antibodies to norovirus rose on average 5.6 fold in response to the GI.1 virus strain and 4.4 fold in response to the GII.4 virus strain and breast milk antibodies to norovirus rose on average 4.0 fold in response to the GI.1 virus strain and 6.0 fold in response to the GII.4 virus strain. The vaccine was well tolerated with no vaccine-related serious adverse events and no dose-limiting pharmacotoxicity. As a grant recipient from the Bill and Melinda Gates Foundation, Vaxart has agreed to a global access commitment for use of its bivalent norovirus vaccine candidate, if proven effective and approved, in breastfeeding mothers from low- and middle-income countries.

We have also created additional norovirus GI.1 and GII.4 constructs that may be more potent than the constructs being evaluated in clinical trials. Regulatory feedback from the FDA, along with the clinical data on current constructs, and preclinical data generated on new constructs will assist us in determining the best way to progress our norovirus program.

• Coronavirus Vaccine. COVID-19, a severe respiratory tract infection caused by the virus SARS-CoV-2, is a major cause of hospitalization and death in the U.S. and worldwide. According to the CDC, an outbreak of COVID-19 began in Wuhan, China, in late 2019 and rapidly spread worldwide. While most COVID-19 restrictions, such as stay-at-home orders, have been lifted, COVID-19 continues to spread and remains a public health threat, not least due to the continuing emergence of new variants.

In September 2022, we announced the results from the first part of a two-part Phase 2 clinical study evaluating the safety and immunogenicity of our oral COVID-19 (spike ("S") protein only) vaccine candidate VXA-CoV2-1.1-S met both its primary and secondary endpoints based on topline data. VXA-CoV2-1.1-S was able to boost the serum antibody responses for volunteers that previously received an mRNA vaccine (either Pfizer/BioNTech or Moderna). Serum neutralizing antibody responses to SARS-CoV-2 (Wuhan), a recognized correlate of protection, were boosted in this population from a geometric mean of 481 to 778, a fold rise of 1.6. Volunteers that had lower starting titers had larger increases than subjects that had higher titers. There were also substantial increases in the neutralizing antibody responses to the SARS-CoV-2 Omicron BA4/5 in these volunteers as measured by sVNT assay. Increases in the mucosal IgA antibody response to SARS-CoV-2 Wuhan S had an increase in IgA responses to other coronaviruses including SARS-CoV-2 Omicron BA4/5, SARS-CoV-1, and MERS-CoV, demonstrating the cross-reactive nature of these immune readouts. We are not proceeding with the second part of the study.

In February 2021, we announced our Phase 1 study evaluating the safety and immunogenicity of our oral COVID-19 (S and nucleocapsid ("N") proteins) vaccine candidate VXA-CoV2-1 met both its primary and secondary endpoints based on preliminary data. Initial results showing cross-reactive mucosal antibody responses were published in *Science Translational Medicine*. Additional detailed study results and mucosal durability data were reported in *medRxiv* in July 2022.

We have made a COVID-19 vaccine candidate that expresses only the S protein from the SARS-CoV-2 XBB strain. Based on preclinical data, our XBB COVID-19 vaccine candidate is more potent than our prior COVID-19 vaccine constructs. In January 2024, we were awarded a contract (the "2024 ASPR-BARDA Contract") by the Biomedical Advanced Research and Development Authority ("HHS BARDA"), a division of the Administration for Strategic Preparedness and Response ("ASPR") within the U.S. Department of Health and Human Services, in an amount of \$9.3 million to fund preparation for a Phase 2b clinical study involving 10,000 patients. In June 2024, we entered into an agreement (the "2024 ATI-RRPV Contract") with Advanced Technology International, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by HHS BARDA. Pursuant to the 2024 ATI-RRPV Contract, we will receive funding of up to \$452.9 million to conduct the Phase 2b study.

The Phase 2b study is a double-blind, multi-center, randomized, comparator-controlled study to determine the relative efficacy, safety, and immunogenicity of Vaxart's oral pill COVID-19 vaccine candidate against an approved mRNA COVID-19 injectable vaccine in adults previously immunized against COVID-19 infection. The study design anticipates enrolling approximately 10,000 healthy adults 18 years and older in the United States with 5,000 receiving our COVID-19 vaccine candidate and 5,000 receiving an approved mRNA comparator. At least 25% of the participants should be at least 65 years old.

The Phase 2b study will measure efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and the incidence of adverse events. The primary endpoint is relative efficacy of Vaxart's COVID-19 vaccine candidate compared to an approved mRNA comparator for the prevention of symptomatic disease. Primary efficacy analysis will be performed when all participants have either discontinued or completed a study visit 12 months post-vaccination. An interim analysis for vaccine efficacy compared to an approved mRNA comparator may be performed when 255 events have been reached.

We expect to initiate the Phase 2b clinical trial as early as the second half of 2024.

• Influenza Vaccine. Flu is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and sometimes the lungs. An estimated one billion cases of seasonal influenza occur annually worldwide, of which three to five million cases are considered severe, causing 290,000 to 650,000 deaths per year. In the United States, between 9,000,000 to 41,000,000 people catch influenza annually, between 140,000 and 710,000 people are hospitalized with complications of influenza, and between 12,000 and 52,000 people die from influenza and its complications each year.

In 2018, we completed a Phase 2 challenge study of our H1N1 flu vaccine candidate, which was funded through a \$15.7 million contract with HHS BARDA. We announced that, in healthy volunteers immunized and then experimentally infected with H1 influenza, our H1 influenza oral tablet vaccine candidate reduced clinical disease by 39% relative to placebo. Fluzone, the market-leading injectable quadrivalent influenza vaccine, reduced clinical disease by 27%. Our tablet vaccine candidate also showed a favorable safety profile, indistinguishable from placebo.

We also presented data from the study demonstrating that our vaccine candidate elicited a significant expansion of mucosal homing receptor plasmablasts to approximately 60% of all activated B cells. We believe these mucosal plasmablasts are a key indicator of a protective mucosal immune response and a unique feature of our vaccine candidates.

We have also initiated early-stage development on novel vaccine constructs containing our own antigens to develop a universal influenza vaccine candidate. We had previously produced a non-GMP oral vaccine candidate containing certain proprietary antigens from Janssen Vaccines & Prevention B.V. ("Janssen") and tested the candidate in a preclinical challenge model. The preclinical study has been completed and we have submitted a report to Janssen. In August 2023, Janssen announced it would exit all vaccine and infectious disease R&D programs aside from an E. coli preventive vaccine and continuing to provide access to marketed HIV products.

The Company intends to work with governments around the world to create pandemic monovalent influenza vaccines for emergency use or stockpiling, if requested. We are also continuing development of our preclinical seasonal and universal influenza vaccine candidates.

• *HPV Therapeutic Vaccine*. Cervical cancer is the fourth most common cancer in women worldwide and in the United States with about 13,000 new cases diagnosed annually in the United States according to the National Cervical Cancer Coalition. Our first therapeutic oral vaccine candidate targets HPV 16 and HPV 18, the two strains responsible for 70% of cervical cancers and precancerous cervical dysplasia.

We have tested our HPV 16 vaccine candidate in two different HPV 16 solid tumor models in mice. The HPV 16 vaccine candidate elicited T cell responses and promoted migration of the activated T cells into the tumors, leading to tumor cell killing. Mice that received our HPV 16 vaccine candidate showed a significant reduction in volume of their established tumors.

In October 2018, we filed a pre-IND meeting request with the FDA for our first therapeutic vaccine candidate targeting HPV 16 and HPV 18 and we subsequently submitted our pre-IND briefing package. We received feedback from the FDA in January 2019 to support submission of an IND application to support initiation of clinical testing.

The Company remains engaged in discussions with regulatory agencies, governments, non-governmental organizations and other potential strategic parties to determine the best way to progress its HPV program.

## Antivirals

- Through the Merger, we acquired two royalty earning products, Relenza and Inavir. We also acquired three Phase 2 clinical stage antiviral compounds and subsequently discontinued independent development of these compounds. However, for one of these, Vapendavir, we entered into an exclusive worldwide license agreement with Altesa Biosciences, Inc. ("Altesa") in July 2021, permitting Altesa to develop and commercialize this capsid-binding broad-spectrum antiviral. Altesa is conducting a double-blind, randomized, placebo-controlled trial in participants with chronic obstructive pulmonary disease to evaluate the impact of Vapendavir on the development of lower respiratory tract symptoms following rhinovirus challenge.
- Relenza and Inavir are antivirals for the treatment of influenza, marketed by GlaxoSmithKline, plc ("GSK") and Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), respectively. We have earned royalties on the net sales of Relenza and Inavir in Japan. The last patent for Relenza expired in July 2019 and the last patent for Inavir expires in August 2036. Sales of these antivirals vary significantly by quarter, because influenza virus activity displays strong seasonal cycles, and by year depending on the intensity and duration of the flu season, the impact COVID-19 has had, and may continue to have, on seasonal influenza, and competition from other antivirals such as Tamiflu and Xofluza.

## **Financial Operations Overview**

### Revenue

## Non-Cash Royalty Revenue Related to Sale of Future Royalties

In April 2016, Aviragen sold certain royalty rights related to Inavir in the Japanese market for \$20.0 million to HealthCare Royalty Partners III, L.P. ("HCRP"). Under the terms of our agreement with HCRP, during the first royalty interest period of April 1, 2016 through March 31, 2025, HCRP is entitled to the first \$3.0 million and any cumulative remaining shortfall amount plus 15% of the next \$1.0 million in royalties earned in each year commencing on April 1, with any excess revenue being retained by us. Further, during the second royalty interest period beginning April 1, 2025 and ending on December 24, 2029, HCRP is entitled to the first \$2.7 million and any cumulative remaining shortfall amount plus 15% of the next \$1.0 million in royalties, with any excess revenue being retained by us. A shortfall occurs when, during an annual period ending on March 31, 2025, royalty interest fall below \$3.0 million; and \$2.7 million for the second royalty interest period of April 1, 2016 through March 31, 2025, royalty payments fall below \$3.0 million; and \$2.7 million for the second royalty interest period of April 1, 2025 and ending on December 24, 2029, excluding the period of April 1, 2028 through December 24, 2029. In the event there is a remaining cumulative remaining shortfall amount as of December 24, 2029, then, for so long as the Company continues to receive royalties from Daiichi Sankyo Company Limited ("Daiichi Sankyo"), the sum of those royalties will be paid to HCRP until the cumulative remaining shortfall amount has been paid in full.

For avoidance of doubt, we are not obligated to pay HCRP any royalty payment beyond what we are paid by Daiichi Sankyo. The cumulative remaining shortfall amount is the aggregate amount of the shortfall for each annual period, which was \$6.0 million as of June 30, 2024.

## Revenue from Government Contracts

In January 2024, we were awarded the 2024 ASPR-BARDA Contract by HHS BARDA, with a base and all options value of \$9.3 million. Under the 2024 ASPR-BARDA Contract, we received an award to support clinical trial planning activities for a Phase 2b clinical trial that would compare our XBB vaccine candidate to an mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events. Revenue from government contracts recognized on the 2024 ASPR-BARDA Contract was \$6.2 million and \$7.8 million for the three and six months ended June 30, 2024, based on the achievement of certain milestones under the 2024 ASPR-BARDA Contract.

In June 2024, we entered into the 2024 ATI-RRPV Contract. Pursuant to the 2024 ATI-RRPV Contract, we will receive funding of up to \$452.9 million to conduct a Phase 2b comparative study evaluating our oral pill XBB COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the U.S. Food and Drug Administration. The 2024 ATI-RRPV Contract provides for an initial award in the aggregate amount of up to \$65.7 million, consisting of a fixed fee of \$64.7 million and reimbursement of costs incurred in trial preparation activities. The 2024 ATI-RRPV Contract further contemplates additional funding up to \$387.2 million if we and HHS BARDA decide to continue with the Phase 2b comparative study. Revenue from government contracts recognized on the 2024 ATI-RRPV Contract was \$0.2 million for the three and six months ended June 30, 2024, based on costs incurred under the 2024 ATI-RRPV Contract. In July 2024, the Company received payment for the \$64.7 million fixed fee portion of the initial award.

### Grant Revenue

In November 2022, we accepted a grant of \$3.5 million to perform research and development work for the Bill & Melinda Gates Foundation (the "BMGF Grant") and received \$2.0 million in advance that was recorded as restricted cash and deferred revenue. We received an additional \$1.5 million in July 2023 upon completion of certain milestones. We recognize revenue under research contracts only when a contract is executed and the contract price is fixed or determinable. Revenue from the BMGF Grant was recognized in the period during which the related costs were incurred and the related services rendered, as the applicable conditions under the contract were met. Costs of contract revenue were recorded as a component of operating expenses in the condensed consolidated statements of operations and comprehensive loss. We fully recognized revenue from the BMGF Grant during the year ended December 31, 2023.

#### **Research and Development Expenses**

Research and development expenses represent costs incurred on conducting research, such as developing our tablet vaccine platform, and supporting preclinical and clinical development activities of our tablet vaccine candidates. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with contract research organizations ("CROs"), that conduct clinical trials on our behalf;
- expenses incurred under agreements with contract manufacturing organizations ("CMOs"), that manufacture product used in the clinical trials;
- expenses incurred in procuring materials and for analytical and release testing services required to produce vaccine candidates used in clinical trials;
- process development expenses incurred internally and externally to improve the efficiency and yield of the bulk vaccine and tablet manufacturing activities
- laboratory supplies and vendor expenses related to preclinical research activities;
- consultant expenses for services supporting our clinical, regulatory and manufacturing activities; and
- facilities, depreciation and allocated overhead expenses.

We do not allocate our internal expenses to specific programs. Our employees and other internal resources are not directly tied to any one research program and are typically deployed across multiple projects. Internal research and development expenses are presented as one total.

We have incurred significant external costs for CROs that conduct clinical trials on our behalf, and for CMOs that manufacture our tablet vaccine candidates, although these costs have decreased since 2022 since we now perform the majority of our manufacturing activities in-house. We have captured these external costs for each vaccine program. We do not allocate external costs incurred on preclinical research or process development to specific programs.

## Table of Contents

The following table shows our period-over-period research and development expenses, identifying external costs that were incurred in each of our vaccine programs and, separately, on preclinical research and process development for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Т	hree Months	End	ed June 30,	Six Months Ended June 30,					
	2024			2023		2024		2023		
External program costs:										
Norovirus program	\$	737	\$	4,713	\$	1,739	\$	7,417		
COVID-19 program		3,373		314		6,336		1,992		
Other programs		14				14		_		
Preclinical research		657		165		1,380		630		
Process development		48		264		83		784		
Total external costs		4,829		5,456		9,552		10,823		
Internal costs		12,651		13,357		26,941		27,612		
Total research and development	\$	17,480	\$	18,813	\$	36,493	\$	38,435		

We expect to incur significant research and development expenses in 2024 and beyond as we advance our tablet vaccine candidates into and through clinical trials, pursue regulatory approval of our tablet vaccine candidates and prepare for a possible commercial launch, all of which will also require a significant investment in manufacturing and inventory related costs. To the extent that we enter into licensing, partnering or collaboration agreements, a significant portion of such costs may be borne by third parties.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our tablet vaccine candidates. The probability of successful commercialization of our tablet vaccine candidates may be affected by numerous factors, including clinical data obtained in future trials, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our tablet vaccine candidates.

### General and Administrative Expense

General and administrative expenses consist of personnel costs, insurance, allocated expenses and expenses for outside professional services, including legal, audit, accounting, public relations, market research and other consulting services. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of rent, depreciation and other facilities related expenses.

## **Results of Operations**

The following table presents period-over-period changes in selected items in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2024 and 2023 (in thousands, except percentages):

	Three Months Ended June 30,						Six Months Ended June 30,						
		2024		2023	% Change	_	2024		2023	% Change			
Revenue	\$	6,401	\$	1,358	*	\$	8,582	\$	2,033	*			
Operating expenses		22,657		24,411	(7)%	)	48,908		50,658	(3)%			
Operating loss		(16,256)		(23,053)	(29)%	)	(40,326)		(48,625)	(17)%			
Net non-operating income (expense)		(189)		522	*		(491)		983	*			
Loss before income taxes		(16,445)		(22,531)	(27)%	)	(40,817)		(47,642)	(14)%			
Provision for income taxes		21		19	11%		66		48	38%			
Net loss	\$	(16,466)	\$	(22,550)	(27)%	5 \$	(40,883)	\$	(47,690)	(14)%			

\* Percentages greater than 100% or not meaningful



## Table of Contents

## **Total Revenue**

The following table summarizes the period-over-period changes in our revenues for the three months and six months ended June 30, 2024 and 2023 (in thousands, except percentages):

		Three	nths Ended Ju	ne 30,		Six Months Ended June 30,					
		2024 2023		% Change		2024		2023	% Change		
Non-cash royalty revenue related to sale of	of										
future royalties	\$	37	\$	30	23%	\$	622	\$	308	*	
Revenue from government contracts		6,364		_	100%		7,960		_	100%	
Grant revenue				1,328	(100)%	, D	_		1,725	(100)	
Total revenue	\$	6,401	\$	1,358	*	\$	8,582	\$	2,033	*	

\* Percentages greater than 100% or not meaningful

### Non-cash Royalty Revenue Related to Sale of Future Royalties

For the three months ended June 30, 2024 and 2023, non-cash royalty revenue related to sale of future royalties from Daiichi Sankyo was \$37,000 and \$30,000, respectively, and for the six months ended June 30, 2024 and 2023, was \$0.6 million and \$0.3 million, respectively. We continue to have non-cash royalty revenue as all royalties received for the three and six months ended June 30, 2024 and 2023, were required to be paid to HCRP.

#### Revenue from Government Contracts

For the three months ended June 30, 2024 and 2023, revenue from government contracts was \$6.4 million and zero, respectively, and for the six months ended June 30, 2024 and 2023, was \$8.0 million and zero, respectively. The revenue from government contracts consists of the 2024 ASPR-BARDA Contract awarded to us in January 2024, which was \$6.2 million for the three months ended June 30, 2024 and \$7.8 million for the six months ended June 30, 2024 from government contracts for the 2024 ATI-RRPV Contract awarded in June 2024.

## Grant Revenue

We recognized revenue from the BMGF Grant of zero and \$1.3 million for the three months ended June 30, 2024 and 2023, respectively, and zero and \$1.7 million for the six months ended June 30, 2024 and 2023, respectively. All research and development work under the BMGF Grant was completed during the year ended December 31, 2023.

## **Total Operating Expenses**

The following table summarizes the period-over-period changes in our operating expenses for the three and six months ended June 30, 2024 and 2023 (in thousands, except percentages):

	Three Months Ended June 30,						Six Months Ended June 30,					
	 2024		2023	% Change		2024		2023	% Change			
Research and development	\$ 17,480	\$	18,813	(7)%	\$	36,493	\$	38,435	(5)%			
General and administrative	5,177		5,598	(8)%		12,415		12,223	2%			
Total operating expenses	\$ 22,657	\$	24,411	(7)%	\$	48,908	\$	50,658	(3)%			

#### Research and Development

For the three months ended June 30, 2024, research and development expenses decreased by \$1.3 million, or 7%, compared to the three months ended June 30, 2023. The decrease was primarily due to decreases in clinical trial expenses related to our norovirus vaccine candidate, stock-based compensation expense and personnel-related costs, partially offset by increases in clinical trial expenses, and pre-clinical expenses related to our COVID-19 vaccine candidate.

For the six months ended June 30, 2024, research and development expenses decreased by \$1.9 million, or 5%, compared to the six months ended June 30, 2023. The decrease was primarily due to decreases in personnel-related costs and clinical trial expenses related to our norovirus vaccine candidate, partially offset by increases in clinical trial expenses, manufacturing costs and pre-clinical expenses related to our COVID-19 vaccine candidate, and general manufacturing supplies.

#### General and Administrative

For the three months ended June 30, 2024, general and administrative expenses decreased by \$0.4 million, or 8%, compared to the three months ended June 30, 2023. The decrease was primarily due to decreases in stock-based compensation expense and personnel-related costs and directors' and officers' insurance costs, partially offset by increases in legal and professional fees.

For the six months ended June 30, 2024, general and administrative expenses increased by \$0.2 million, or 2%, compared to the six months ended June 30, 2023. The increase was primarily due to increased severance and legal and professional fees, partially offset by decreased personnel-related costs and directors' and officers' insurance costs.

# Non-Operating Income (Expense)

The following table summarizes the period-over-period changes in our non-operating income for the three and six months ended June 30, 2024 and 2023 (in thousands, except percentages):

		Three Months Ended June 30,					Six Months Ended June 30,				
		2024		2023	% Change		2024		2023	% Change	
Interest income	\$	416	\$	711	(41)%	6\$	919	\$	1,353	(32)%	
Non-cash interest expense related to sale of	f										
future royalties		(610)		(188)	*		(1,414)		(366)	*	
Other expense, net		5		(1)	*		4		(4)	*	
Net non-operating income (expense)	\$	(189)	\$	522	*	\$	(491)	\$	983	*	

\* Percentages greater than 100% or not meaningful

For the three months ended June 30,2024, we recorded interest income of \$0.4 million, a 41% decrease from the \$0.7 million interest income recorded in the three months ended June 30,2023. For the six months ended June 30, 2024, we recorded interest income of \$0.9 million, a 32% decrease from the \$1.4 million interest income recorded in the six months ended June 30, 2023. The decrease is primarily due to the decrease in our cash, cash equivalents and investments balance.

Non-cash interest expense related to sale of future royalties representing imputed interest on the unamortized portion of the sale of future royalties liability, increased to \$0.6 million for the three months ended June 30, 2024, from the \$0.2 million for the three months ended June 30, 2023, and to \$1.4 million for the six months ended June 30, 2024, from the \$0.4 million for the six months ended June 30, 2023, due to an increase in non-cash royalty revenue payable to HCRP.

# **Provision for Income Taxes**

The following table summarizes the period-over-period changes in our provision for income taxes for the three and six months ended June 30, 2024 and 2023 (in thousands, except percentages):

	Three Months Ended June 30,					Six Months Ended June 30,			
		2024		2023	% Change	2024		2023	% Change
Foreign withholding tax on royalty revenue	\$	2	\$	1	100%	\$ 31	\$	15	*
Foreign taxes payable on intercompany									
interest		16		15	7%	32		30	7%
State income taxes		3		3	%	3		3	%
Provision for income taxes	\$	21	\$	19	11%	\$ 66	\$	48	38%

\* Percentages greater than 100% or not meaningful

The provision for income taxes was \$21,000 and \$19,000 for the three months ended June 30, 2024 and 2023, respectively, and \$66,000 and \$48,000 for the six months ended June 30, 2024 and 2023, respectively. The tax charge relates to interest on an intercompany loan from a foreign subsidiary and a 5% withholding tax on royalty revenue earned on sales of Inavir in Japan, which is potentially recoverable as a foreign tax credit but expensed because we record a 100% valuation allowance against our deferred tax assets. The amount of income tax expense recorded is directly proportional to Inavir royalties, including the portion that we pass through to HCRP.

# Liquidity and Capital Resources

Our primary source of financing is from the sale and issuance of common stock in public offerings as well as funding from HHS BARDA. In the past, we have also obtained funds from the issuance of common stock warrants, secured debt and preferred stock and from collaboration agreements.

In September 2021, we entered into a Controlled Equity Offering Sales Agreement (the "September 2021 ATM"), under which we may offer and sell, from time to time through sales agents, shares of our common stock having an aggregate offering price of up to \$100 million. We incur direct expenses and pay sales commissions of up to 3.0% of gross proceeds from the sale of shares under the September 2021 ATM. In the six months ended June 30, 2024, 7,719,641 shares were issued and sold under the September 2021 ATM for gross proceeds of \$9.1 million, which, after deducting sales commissions and expenses incurred to date, resulted in net proceeds of \$8.8 million. As of June 30, 2024, there was approximately \$69.3 million in net proceeds still available to us under the September 2021 ATM.

In June 2024, we entered into the 2024 ATI-RRPV Contract. Pursuant to the 2024 ATI-RRPV Contract, we will receive funding of up to \$452.9 million to conduct a Phase 2b comparative study evaluating our oral pill XBB COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the U.S. Food and Drug Administration. As of June 30, 2024, we received no cash payments under the 2024 ATI-RRPV Contract. Subsequent to June 30, 2024, through the filing date of this Quarterly Report on Form 10-Q, we have received \$64.7 million under the 2024 ATI-RRPV Contract.

In June 2024, we entered into an underwriting agreement (the "Underwriting Agreement") with Oppenheimer & Co. Inc., relating to the issuance and sale by us in an underwritten registered direct offering of 50,000,000 shares of our common stock at a price of \$0.80 per share. The gross proceeds to us from such offering was \$40.0 million, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, the net proceeds were \$37.6 million.

In January 2024, we entered into a securities purchase agreement (the "2024 Securities Purchase Agreement") with RA Capital Healthcare Fund, L.P. pursuant to which 15,384,615 shares of our common stock were sold to RA Capital Healthcare Fund, L.P. at an offering price of \$0.65 per share. The gross proceeds from the 2024 Securities Purchase Agreement were \$10.0 million and, after deducting offering expenses, the net proceeds were \$9.9 million.

In January 2024, we were awarded the 2024 ASPR-BARDA Contract with a base and all options value of \$9.3 million. Under the 2024 ASPR-BARDA Contract, we received an award to support clinical trial planning activities for a Phase 2b clinical trial that would compare our XBB vaccine candidate to an

mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events. The 2024 ASPR-BARDA Contract originally had a term that was set to expire in July 2024, but we entered into an amendment in July 2024 that extended the expiration date into October 2024. As of June 30, 2024, we received approximately \$3.2 million of cash payments under the 2024 ASPR-BARDA Contract. Subsequent to June 30, 2024, through the filing date of this Quarterly Report on Form 10-Q, we have received \$4.0 million under the 2024 ASPR-BARDA Contract.

As of June 30, 2024, we had approximately \$62.6 million of cash, cash equivalents and investments. We believe our existing funds are sufficient to fund us for at least one year from the date of issuance of this Quarterly Report. To continue operations thereafter, we expect that we will need to raise further capital, through the sale of additional securities or otherwise. Our future capital requirements and the adequacy of our available funds will depend on many factors, most notably our ability to successfully commercialize our products and services.

We may fund a significant portion of our ongoing operations through partnering and collaboration agreements which, while reducing our risks and extending our cash runway, will also reduce our share of eventual revenues, if any, from our vaccine candidates. We may be able to fund certain activities with assistance from government programs. We may also fund our operations through debt financing, which would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations.

However, due to several factors, including those outside management's control, there can be no assurance that we will be able to complete additional financing transactions. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, management's plans include further reducing or delaying operating expenses.

Our future funding requirements will depend on many factors, including the following:

- the timing and costs of our planned preclinical studies for our product candidates;
- the timing and costs of our planned clinical trials of our product candidates;
- our manufacturing capabilities, including the availability of contract manufacturing organizations to supply our product candidates at reasonable cost;
- the amount and timing of royalties received on sales of Inavir;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- revenue received from commercial sales of our future products, which will be subject to receipt of regulatory approval;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may enter into;
- the amount and timing of any payments that may be required in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights;
- our ability to stay listed on The Nasdaq Capital Market; and
- the extent to which we in-license or acquire other products and technologies.

## **Cash Flows**

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

	Six Months Ended June 30,			
	 2024		2023	
Net cash used in operating activities	\$ (33,218)	\$	(41,931)	
Net cash (used in) provided by investing activities	(14,688)		23,878	
Net cash provided by financing activities	56,436		15,317	
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 8,530	\$	(2,736)	

#### Net Cash Used in Operating Activities

We experienced negative cash flow from operating activities for the six months ended June 30, 2024 and 2023, in the amounts of \$33.2 million and \$41.9 million, respectively. The cash used in operating activities in the six months ended June 30, 2024, was due to cash used to fund a net loss of \$40.9 million and a decrease in working capital of \$1.1 million, partially offset by adjustments for net non-cash income related to depreciation and amortization, amortization of discount on investments, net, stock-based compensation, non-cash interest expense related to sale of future royalties totaling \$8.7 million. The cash used in operating activities in the six months ended June 30, 2023, was due to cash used to fund a net loss of \$47.7 million and a decrease in working capital of \$4.9 million, partially offset by adjustments for net non-cash income related to depreciation and a mortization, amortization, amortization of (discount) premium on investments, stock-based compensation, non-cash interest expense related to sale of future royalties totaling \$10.7 million.

## Net Cash Provided by (Used in) Investing Activities

In the six months ended June 30, 2024, we used \$29.2 million of cash to purchase investments, net of maturities, used \$0.5 million of cash to purchase property and equipment, and we received \$15.0 million from maturities of marketable securities. In the six months ended June 30, 2023, we received \$25.6 million from maturities of marketable securities, and used \$1.7 million of cash to purchase property and equipment.

## Net Cash Provided by Financing Activities

In the six months ended June 30, 2024, we received net proceeds of \$37.6 million from the sale of our common stock under the June 2024 Offering, net proceeds of \$8.8 million from the sale of our common stock under the September 2021 ATM and net proceeds of \$9.9 million from the sale of our common stock under the 2024 Securities Purchase Agreement, partially offset by \$0.2 million from common stock acquired to settle employee tax withholding liabilities. In the six months ended June 30, 2023, we received net proceeds of \$13.6 million from the sale of 16,000,000 shares of our common stock and \$1.4 million from the sale of common stock under the September 2021 ATM.

## **Contractual Obligations and Commercial Commitments**

We have the following contractual obligations and commercial commitments as of June 30, 2024 (in thousands):

Contractual Obligation	 Total	 <1 Year	1 - 3 Years	3	3 - 5 Years	 > 5 Years
Long Term Debt, HCRP	\$ 21,547	\$ 62	\$ 5,494	\$	5,520	\$ 10,471
Operating Leases	23,695	2,209	9,542		10,596	1,348
Purchase Obligations	3,205	3,205				
Total	\$ 48,447	\$ 5,476	\$ 15,036	\$	16,116	\$ 11,819

*Long Term Debt, HCRP.* Under an agreement executed in 2016, during the first royalty interest period of April 1, 2016 through March 31, 2025, we are obligated to pay HCRP the first \$3.0 million and any cumulative remaining shortfall amount plus 15% of the next \$1.0 million in royalties earned in each year commencing on April 1, with any excess revenue being retained by us. Further, during the second royalty interest period beginning April 1, 2025 and ending on December 24, 2029, HCRP is entitled to the first \$2.7 million and any cumulative remaining shortfall amount plus 15% of the next \$1.0 million in royalties, with any excess revenue being retained by us. See <u>Note 6</u> to the Condensed Consolidated Financial Statements in Part I, Item 1 for further details.

*Operating leases.* Operating lease amounts include future minimum lease payments under all our non-cancellable operating leases with an initial term in excess of one year. See <u>Note 7</u> to the Condensed Consolidated Financial Statements in Part I, Item 1 for further details of leases.

*Purchase obligations.* These amounts include an estimate of all open purchase orders and contractual obligations in the ordinary course of business, including commitments with contract manufacturers and suppliers for which we have not received the goods or services. We consider all open purchase orders, which are generally enforceable and legally binding, to be commitments, although the terms may afford us the option to cancel based on our business needs prior to the delivery of goods or performance of services.

Share-based payment arrangements. Beginning in 2022, we shifted from awarding only options to issuing a mixture of options and restricted stock units ("RSUs") to our employees. As of June 30, 2024, the unrecognized stock-based compensation cost related to outstanding unvested stock options and RSUs expected to vest was \$18.7 million, which we expect to recognize over an estimated weighted average period of 2.4 years. See <u>Note 10</u> to the Condensed Consolidated Financial Statements in Part I, Item 1 for further details on stock-based compensation expense recognized.

## **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

## Accrued Research and Development Expenses

We record accrued expenses for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided and include the costs incurred but not yet invoiced within other accrued liabilities in the condensed consolidated balance sheets and within research and development expense in the condensed consolidated statements of operations and comprehensive loss. These costs can be a significant component of our research and development expenses.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

# Intangible Assets

Intangible assets acquired in the Merger were initially recorded at their estimated fair values of \$20.3 million for developed technology related to Inavir which was, until it was revalued, being amortized on a straight-line basis over the estimated period of future royalties of 11.75 years. The developed technology related to Inavir was revalued at \$5.0 million as of December 31, 2022, resulting in an impairment loss of \$4.3 million being recorded. These valuations were prepared with the assistance of an independent third party based on discounted cash flows of estimated future revenue streams, which are highly subjective. The fair value as of June 30, 2024, is being amortized on a straight-line basis over the remaining period of 5.4 years.

### **Revenue from Government Contracts**

Under firm fixed-price milestone contracts, we recognize the firm fixed-price revenue as the milestones are substantially complete and the firm fixed-price for the milestone is earned ("firm fixed-price milestone"). Under cost reimbursable contracts, we recognize revenue as allowable costs are incurred and the fixed fee is earned ("cost-plus-fixed-fee"). Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and approved overhead and indirect costs. Fixed fees under cost reimbursable contracts are earned in proportion to the allowable costs incurred in performance of the work relative to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed.

Payments to us under cost reimbursable contracts are provisional payments subject to adjustment upon annual audit by the government. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

#### Stock-Based Compensation

We measure the fair value of all stock option awards to employees, non-executive directors and consultants on the grant date, and record the fair value of these awards, net of estimated forfeitures, as compensation expense over the service period. The fair value of options is estimated using the Black-Scholes valuation model and the expense recorded is affected by subjective assumptions regarding a number of variables, as follows:

Expected term – This represents the period that our stock-based awards granted are expected to be outstanding and is determined using the simplified method (the arithmetic average of its original contractual term and its average vesting term). We have very limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock-based awards. Based on the weighted average applied to options awarded in six months ended June 30, 2024, a notional 10% decrease in expected term would have reduced the fair value and the related compensation expense by approximately 2.1%.

Expected volatility – This is a measure of the amount by which our common stock price has fluctuated or is expected to fluctuate. Since the beginning of 2020, we have measured volatility based on the historical volatility of our own stock over the retrospective period corresponding to the expected term of the options on the measurement date. Based on the weighted average applied to options awarded in six months ended June 30, 2024, a notional 10% decrease in expected volatility (from 129.1% to 116.2%) would have reduced the fair value and the related compensation expense by approximately 4.0%.

<u>Risk-free interest rate</u> – This is based on the U.S. Treasury yield curve on the measurement date corresponding with the expected term of the stock-based awards.

Expected dividend – We have not made any dividend payments and do not plan to pay dividends in the foreseeable future. Therefore, we use an expected dividend yield of zero.

<u>Forfeiture rate</u> – This is a measure of the number of awards that are expected to not vest and is reassessed quarterly. An increase in the estimated forfeiture rate will cause a small decrease in the related compensation expense early in the service period, but since the final expense recorded for each award is the number of options vested times their grant date fair value, it has no impact on the total expense recorded.

## **Recent Accounting Pronouncements**

See the "Recent Accounting Pronouncements" in <u>Note 2</u> to the Condensed Consolidated Financial Statements in Part I, Item 1 for information related to the issuance of new accounting standards in the first six months of 2024, which are either not applicable to its operations or their adoption is not expected to have a material impact on our condensed consolidated financial statements.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

#### **Interest Rate Sensitivity**

Our exposure to market risk for changes in interest rates relates primarily to our investments in marketable debt securities. The primary objective of our investment activities is to preserve principal, maintain liquidity that is sufficient to meet cash needs and maximize total return without significantly increasing risk. To achieve this goal, we maintain our excess cash and cash equivalents in money market funds and marketable debt securities. We do not enter into investments for trading or speculative purposes and we hold no equity securities. We presently have no borrowings or lines of credit.

Specifically, as of June 30, 2024, we had cash, cash equivalents and investments of approximately \$62.6 million, which consist of bank deposits, money market funds and U.S. government securities. All of our investments must satisfy high credit rating requirements at the time of purchase. Such interestearning instruments carry a degree of interest rate risk, however, because our investments are rated highly and mostly short-term, we believe that our exposure to risk of loss due to interest rate changes is not significant.

#### **Exchange Rate Sensitivity**

Our royalty revenue, which is calculated in U.S. dollars, is based on sales in Japanese yen, so a 1% increase in the strength of the U.S. dollar against the yen would lead to a 1% reduction in royalty revenue and related accounts receivable. All our other revenue and substantially all of our expenses, assets and

liabilities are denominated in U.S. dollars and, as a result, we have not experienced significant foreign exchange gains or losses recently and do not anticipate that foreign exchange gains or losses will be significant in the near future.

# Item 4. Controls and Procedures

# **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal accounting and 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) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our management has concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of June 30, 2024.

# Changes in Internal Control over Financial Reporting

There was no material change in our internal control over financial reporting that occurred during the quarter ended June 30, 2024, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal accounting and financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Vaxart have been detected.

## PART II OTHER INFORMATION

## **Item 1. Legal Proceedings**

The information included in "Note 8. Commitments and Contingencies—(c) Litigation" to the Condensed Consolidated Financial Statements in Part I, Item 1 is incorporated by reference into this Item.

We may also from time to time be involved in legal proceedings arising in connection with our business. Based on information currently available, we believe that the amount, or range, of reasonably possible losses in connection with any pending actions against us in excess of established reserves, in the aggregate, is not material to our condensed consolidated financial condition or cash flows. However, any current or future dispute resolution or legal proceeding, regardless of the merits of any such proceeding, could result in substantial costs and a diversion of management's attention and resources that are needed to run our business successfully, and could have a material adverse impact on our business, financial condition and results of operations.

## Item 1A. Risk Factors

You should consider the risks and uncertainties described under Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which we filed with the Securities and Exchange Commission on March 14, 2024, together with all other information contained or incorporated by reference in this Quarterly Report on Form 10-Q, when evaluating our business and our prospects. There are no material changes to the risk factors set forth in Part I, Item 1A, in our Annual Report on Form 10-K for the year ended December 31, 2023, except as described below.

A significant portion of the funding to further develop our XBB COVID-19 vaccine candidate is currently expected to come from HHS BARDA funds. If HHS BARDA were to eliminate, reduce, delay, or object to funding available to us under either the 2024 ASPR-BARDA Contract or the 2024 ATI-RRPV Contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate or obtain alternative sources of funding.

In January 2024, we were awarded the 2024 ASPR-BARDA Contract to fund preparation for a Phase 2b clinical study involving 10,000 patients. This study will evaluate our XBB COVID-19 vaccine candidate compared to an approved mRNA vaccine comparator to measure efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events. As of June 30, 2024, we have recognized \$7.8 million in revenue pursuant to the 2024 ASPR-BARDA Contract based on the achievement of certain milestones.

In addition, in June 2024, we entered into the 2024 ATI-RRPV Contract with Advanced Technology International, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by HHS BARDA. The 2024 ATI-RRPV Contract provides for an initial award in the aggregate amount of up to approximately \$65.7 million, consisting of a fixed fee of approximately \$64.7 million and reimbursement of costs incurred in trial preparation activities. The 2024 ATI-RRPV Contract further contemplates additional funding up to approximately \$387.2 million if the Company and HHS BARDA decide to continue with the related study. As of June 30, 2024, we have recognized \$0.2 million in revenue pursuant to the 2024 ATI-RRPV Contract based on costs incurred.

We anticipate that a significant portion of the funding to further develop our XBB COVID-19 vaccine candidate will come from the remaining amounts to be received under the 2024 ASPR-BARDA Contract and the 2024 ATI-RRPV Contract. HHS BARDA is entitled to terminate the 2024 ASPR-BARDA Contract for convenience at any time, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. The 2024 ATI-RRPV Contract provides that the government has the right to determine whether to fund the continued performance of the study after the initial funding. If either the 2024 ASPR-BARDA Contract or the 2024 ATI-RRPV Contract or suspended, or if there is any government decision not to continue funding or reduction or delay in funding under the 2024 ASPR-BARDA Contract or the 2024 ATI-RRPV Contract, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on no-dilutive terms, terms favorable to us, or at all.

## Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

Our common stock is listed on The Nasdaq Capital Market, which imposes, among other requirements, a 1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). Our common stock traded for less than 1.00 for 30 consecutive trading days, and we received notice of this from the Listing Qualifications Department of The Nasdaq Stock Market on July 2, 2024. Under Nasdaq Listing Rule 5810(c)(3)(A), we were granted a 180-calendar day grace period, or until December 30, 2024, to regain compliance with the minimum bid price requirement. The minimum bid price requirement would be met if our common stock had a minimum closing bid price of at least 1.00 per share for a minimum of ten consecutive business days during the 180-calendar day grace period. If at any time during this 180-calendar day period the bid price of the Company's common stock closes at or above 1.00 per share for a minimum of ten consecutive business days, the Nasdaq staff stated that it will provide the Company with a written confirmation of compliance and the matter will be closed. However, under Nasdaq Listing Rule 5810(c)(3)(A), the Nasdaq staff may exercise its discretion to extend this ten-day period as discussed in Rule 5810(c)(3)(H).

Alternatively, if we fail to regain compliance with Rule 5550(a)(2) prior to the expiration of the initial 180-calendar day period, we may be eligible for an additional 180-calendar day compliance period, provided (i) we meet the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market (except for the \$1.00 minimum bid price requirement) and (ii) we provide written notice to Nasdaq of our intention to cure this deficiency during the second compliance period by effecting a reverse stock split, if necessary. In the event we do not regain compliance with Rule 5550(a)(2) prior to the expiration of the initial 180-calendar day period, and if it appears to the Staff that we will not be able to cure the deficiency, or if we are not otherwise eligible, the Staff stated that it will provide us with written notice that our securities are subject to delisting from The Nasdaq Capital Market. At that time, we may appeal the delisting determination to a Hearings Panel. There can be no assurance that we will be able to regain compliance or that Nasdaq will grant us a further extension of time to regain compliance, if necessary.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future, or at all. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when they wish to do so. Further, if our common stock were to be delisted from The Nasdaq Capital Market, our common stock would cease to be recognized as a covered security and we would be subject to additional regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the Nasdaq minimum bid requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the Nasdaq minimum bid price required for continued listing again, or prevent future non-compliance with Nasdaq's listing requirements.

There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, or other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

# Unless our common stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

If we are unable to maintain the listing of our common stock on Nasdaq or another national securities exchange, our common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than \$5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than \$5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and "accredited investors" as defined by relevant SEC rules. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. This means that if we are unable to maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

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

None.

## Item 3. Defaults Upon Senior Securities

Not applicable.

## Item 4. Mine Safety Disclosures

Not applicable.

# Item 5. Other Information

During the quarter ended June 30, 2024, no director or officer, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement," or a "non-Rule 10b5-1 trading arrangement," each as defined in Item 408 of Regulation S-K.

# Item 6. Exhibits

	-	Incorporated by Reference						
Exhibit Number	Description of Document	Schedule/Form	File Number	Exhibit	Filing Date			
3.1	Restated Certificate of Incorporation of Aviragen Therapeutics, Inc.	Form 10-K	001-35285	3.1	September 13, 2016			
3.2	Certificate of Amendment to Restated Certificate of Incorporation of Aviragen Therapeutics, Inc.	Form 8-K	001-35285	3.1	February 20, 2018			
3.3	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	Form 8-K	001-35285	3.2	February 20, 2018			
3.4	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	Form 8-K	001-35285	3.1	April 24, 2019			
3.5	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	Form 8-K	001-35285	3.1	June 9, 2020			
3.6	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	Form 10-Q	001-35285	3.3	August 8, 2022			
3.7	Amended and Restated Bylaws of Vaxart, Inc., effective as of October 18, 2023	Form 8-K	001-35285	3.1	October 23, 2023			
3.8	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	Form 8-K	001-35285	3.1	June 13, 2024			
10.1 *#	<u>Non-Employee Director Compensation Program,</u> <u>effective as of April 1, 2024</u>							
10.2 *^	ATI-RRPV Base Agreement, dated May 6, 2024, between Vaxart Biosciences Inc. and Advanced Technology International (RRPV Consortium Management Firm)							
10.3 *^	ATI-RRPV Project Award Agreement No. 001, dated June 13, 2024, between Vaxart Biosciences Inc. and Advanced Technology International (RRPV Consortium Management Firm)							
10.4 #	2019 Equity Incentive Plan	Form 8-K	001-35285	10.1	June 13, 2024			
10.5 #	2022 Employee Stock Purchase Plan	Form 8-K	001-35285	10.2	June 13, 2024			
10.6	<u>Underwriting Agreement, dated June 13, 2024,</u> <u>between Vaxart, Inc. and Oppenheimer &amp; Co. Inc.</u>	Form 8-K	001-35285	1.1	June 14, 2024			

31.1 *	Certification of Principal Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002
31.2 *	Certification of Principal Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002
32.1 §	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a- 14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS *	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH *	Inline XBRL Taxonomy Extension Schema Document
101.CAL *	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF *	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB *	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE *	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

- \* Filed herewith.
- # Management contract or compensation plan or arrangement.
- § In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certification furnished in Exhibit 32.1 hereto is deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.
- <sup>^</sup> Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted as (i) the Company has determined the omitted information is not material and (ii) the Company customarily and actually treats the omitted information as private or confidential.

## 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.

Dated: August 8, 2024

Dated: August 8, 2024

VAXART, INC.

By: /s/ STEVEN LO Steven Lo President and Chief Executive Officer (Principal Executive Officer)

By: /s/ PHILLIP LEE Phillip Lee Chief Financial Officer (Principal Financial and Accounting Officer)

## VAXART, INC. NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the "<u>Board</u>") of Vaxart, Inc. (the "<u>Company</u>") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "<u>Program</u>"). This Program has been adopted under the Company's 2019 Equity Incentive Plan or its successor (the "<u>Equity Plan</u>") and shall be effective as of April 1, 2024 (the "<u>Effective Date</u>"). Except as provided in Section 3(b) below, the cash and equity compensation described in this Program shall be paid or be granted, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company and (each, a "<u>Non-Employee Director</u>"), unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion.

1. Compensation Philosophy. The Program is designed to enhance the Company's ability to attract and retain highly qualified Non-Employee Directors. The Program includes a cash component, which is designed to compensate Non-Employee Directors for their service on the Board and an equity component, which is designed to align the interests of Non-Employee Directors and stockholders. To enhance the alignment with stockholders, the Board generally attempts to structure the cash compensation for Non-Employee Directors at approximately the 25th to 50th percentile of the market data of the Company's compensation peer group and equity awards at approximately the 50th to 75th percentile of the market data. The Board, however, retains discretion to adjust specific compensation elements and levels above or below these guidelines to respond to market conditions, change in time commitments or other circumstances.

# 2. Cash Compensation.

(a) <u>Annual Retainers</u>. Each Non-Employee Director shall receive an annual cash retainer of \$40,000 for service on the Board.

(b) Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following additional annual cash retainers, as applicable:

(i) *Chairperson of the Board*. A Non-Employee Director serving as Chairperson of the Board shall receive an additional annual retainer of \$30,000 for such service.

(ii) *Audit Committee*. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$20,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual retainer of \$10,000 for such service.

(iii) *Compensation Committee*. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of \$12,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of \$6,000 for such service.

(iv) Science and Technology Committee. A Non-Employee Director serving as Chairperson of the Science and Technology Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member of the Science and Technology Committee (other than the Chairperson) shall receive an additional annual retainer of \$7,500 for such service.

(v) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual retainer of \$5,000 for such service.

(c) <u>Payment of Retainers</u>. The annual retainers described in Sections 2(a) and 2(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 2(b), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter during which he or she actually served as a Non-Employee Director, or in such position, as applicable.

3. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. The equity awards described below shall be granted under and shall be subject to the terms and provisions of the Equity Plan and shall be granted subject to the execution and delivery of award agreements in substantially the forms previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of equity awards hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement.

(a) <u>Initial Awards</u>. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall automatically be granted on the day of such first election or appointment, without further action of the Board: (i) a stock option to purchase 190,800 shares of the Company's common stock, and (ii) a restricted stock unit award covering 32,000 shares of the Company's common stock. The awards described in this Section 3(a) shall be referred to as "<u>Initial Awards</u>". No Non-Employee Director shall be granted more than one Initial Award.

(b) <u>Annual Awards</u>. Except as provided below, a Non-Employee Director who is serving on the Board as of the date of any annual meeting of the Company's stockholders after the Effective Date, and who will continue to serve as a Non-Employee Director immediately following such meeting, shall automatically be granted on the date of such annual meeting, without further action of the Board: (i) a stock option to purchase 95,400 shares of the Company's common stock, and (ii) a restricted stock unit award covering 16,000 shares of the Company's common stock. The awards described in this Section 3(b) shall be referred to as "<u>Annual Awards</u>". For the avoidance of doubt, a Non-Employee Director who is elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election and shall not receive any Annual Award on the date of such meeting for purposes of this clause (b) shall be the date on which all the business to be conducted at the annual meeting is concluded. If a Non-Employee Director is initially elected or appointed to the Board other than at an annual meeting of the Company's stockholders, then the Annual Award for his or her initial term and partial Service Period (as defined below) shall be reduced proportionately, such that the fixed share numbers set forth in Sections 3(b)(i) and (ii) above will be multiplied by a fraction, the numerator of which is the number of days during the period commencing on (and including) the date of the initial election or appointment and ending on (and including) the last day of the applicable Service Period, and the denominator of which is the total number of days in the Service Period (with any resulting fractional shares rounded down to the nearest

whole share). For this purpose, the term "Service Period" means the period commencing on (and including) the date of the annual meeting of the Company's stockholders that occurred immediately prior to the date that the Non-Employee Director was initially elected or appointed to the Board and ending on (and including) the date immediately prior to the date of the next occurring annual meeting of the Company's stockholders.

(c) <u>Termination of Employment of Employee Directors</u>. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 3(a) above, but to the extent that they are otherwise entitled, will receive, after termination from employment with the Company and any parent or subsidiary of the Company and any parent or subsidiary of the Company, Annual Awards as described in Section 3(b) above, determined as if they were initially elected or appointed to the Board as of the date of termination of employment.

## (d) <u>Terms of Awards Granted to Non-Employee Directors</u>

(i) *Exercise Price*. The per share exercise price of each stock option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of common stock on the date the option is granted.

(ii) Vesting. Each Initial Award shall vest and become exercisable in substantially equal installments on each of the first three anniversaries of the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting date. Each Annual Award shall vest and become exercisable on the earlier of (A) the first anniversary of the date of grant, or (B) the date immediately prior to the next annual meeting of the Company's stockholders following the date of grant, subject to the Non-Employee Director continuing in service on the Board through such vesting date. Unless the Board otherwise determines, no portion of an Initial Award or Annual Award which is unvested at the time of a Non-Employee Director's termination of service on the Board shall become vested thereafter. Upon a Change in Control, all outstanding equity awards granted under the Equity Plan that are held by a Non-Employee Director shall become fully vested and exercisable, irrespective of any other provisions of the Plan or any award agreement.

granted.

(iii)

Term. The term of each stock option granted to a Non-Employee Director shall be ten years from the date the option is

4. Compensation Limits. Notwithstanding anything to the contrary in this Program, all compensation payable under this Program will be subject to any limits on the maximum amount of Non-Employee Director compensation set forth in the Equity Plan, as in effect from time to time.

5. Insider Trading Policy. Each Non-Employee Director will be subject to the Insider Trading and Securities Law Compliance Policy of Vaxart, Inc. ("Insider Trading Policy"), and any transactions involving Company securities will be subject to the Insider Trading Policy and applicable securities laws and regulations.

\* \* \* \* \*

SPECIFIC TERMS IN THIS EXHIBIT HAVE BEEN REDACTED BECAUSE SUCH TERMS ARE BOTH NOT MATERIAL AND ARE THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. THESE REDACTED TERMS HAVE BEEN MARKED IN THIS EXHIBIT WITH THREE ASTERISKS AS [\*\*\*].

RRPV BASE AGREEMENT BETWEEN

ADVANCED TECHNOLOGY INTERNATIONAL 315 SIGMA DRIVE SUMMERVILLE, SC 29486

AND

RRPV Member Organization VAXART BIOSCIENCES INC 170 Harbor WAY STE 300 South San Francisco, California 94080-6102 UEI: WS6UMD1QTBC9

RRPV Base Agreement No: 2024-606 Authority: RRPV Other Transaction Agreement 75A50123D00005 and 42 USC § 247d–7e(c)(5).

Page 1 of 37

October 2023

This Agreement is entered into between Advanced Technology International, hereinafter referred to as the "Consortium Management Firm (CMF)" and Vaxart Biosciences Inc, hereinafter referred to as "RRPV Member" or "Project Awardee". This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent date duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance of this Agreement shall be governed by the laws of the state of South Carolina, excluding its choice of laws rules.

Vaxart Biosciences Inc	Advanced Technology Internation	onal
By: /s/[***]	By: <u>/s/[***]</u>	
Name:[***]	Name:[***]	
Title: [***]	Title: [***]	
Date: 05/03/2024	Date: 05/06/2024	
	Page 2 of 37	October 2023

ARTICLE 1. PREAMBLE	4
ARTICLE 2. DEFINITIONS	5
ARTICLE 3. TECHNICAL FOCUS AREAS	8
ARTICLE 4. REPORTS	8
ARTICLE 5. FUNDING OBLIGATIONS AND PAYMENTS	9
ARTICLE 6. ADMINISTRATION	13
ARTICLE 7. PROPRIETARY INFORMATION	17
ARTICLE 8. RIGHTS IN DATA	19
ARTICLE 9. INVENTIONS	22
ARTICLE 10. FOREIGN ACCESS TO TECHNOLOGY	27
ARTICLE 11. PUBLICATION AND PUBLICITY	28
ARTICLE 12. TERM OF AGREEMENT AND TERMINATION	29
ARTICLE 13. CONSORTIUM MEMBERSHIP TERMS AND PROJECT AWARDS	29
ARTICLE 14. REPRESENTATIONS AND WARRANTIES	33
ARTICLE 15. LIABILITY OF THE PARTIES	33
ARTICLE 16. DISPUTES	34
ARTICLE 17. REGULATORY TERMS	35
ARTICLE 18. GENERAL PROVISIONS	40
	2
	3

# **ARTICLE 1. PREAMBLE**

**1.1.** The Biomedical Advanced Research and Development Authority (BARDA) has entered into an Other Transaction Agreement (OTA) with Advanced Technology International (ATI) to form the Rapid Response Partnership Vehicle (RRPV) Consortium. The RRPV is a multiple-purpose acquisition vehicle designed to facilitate research and development (R&D) of future medical countermeasure (MCM) products, from early-stage development, through advanced development, procurement, sustainment, and commercialization, including manufacturing infrastructure development.

**1.2.** Under the RRPV OTA, the Government has partnered with the Consortium Management Firm (CMF), ATI, to establish and manage a consortium of pharmaceutical, medical, scientific, biomanufacturing, technology, and other related organizations working toward successful initiation and delivery of MCM materials and products to improve BARDA's preparedness and response capabilities for future pandemics. The CMF facilitates cooperative partnerships with industry to ensure that the product and materials will be available to produce or be procured in advance of and during a public health incident (PHI) such that MCMs will be readily available to civilian populations.

**1.3.** The scope of the RRPV OTA collaborative effort includes:

**1.3.1.** Overseeing establishment and a new dynamic BARDA partnership vehicle centered around establishing a consortium built for the speed of response, leveraged for preparedness, and appropriately staffed;

**1.3.2.** Providing a vehicle to conduct projects for research & development (R&D), testing, related work, procurement, maintenance and improvement of domestic manufacturing surge capacity and capabilities, and any other activity BARDA is authorized to support, and

**1.3.3.** Providing comprehensive services to help rapidly advance BARDA mission-relevant technologies to address unmet needs and priorities from both the USG and entrepreneurial community.

**1.4.** The RRPV OTA is an Other Transaction Agreement as defined in 42 USC § 247d-7e(c)(5). The Federal Acquisition Regulations ("FAR") does not apply to the OTA or this Agreement unless noted otherwise within this Agreement. The Parties agree that the principal purpose of this Agreement is to support all advancement of technology that falls within scope of the BARDA Mission and may result in projects to include any activity BARDA authorized under BARDA's OT Authority.<sup>1</sup>

**1.5.** The applicable provisions of the OTA have been incorporated by the CMF into this Agreement and any forthcoming Project Awards with RRPV Members whose proposals have been selected by the Government for a Project Award.

**1.6.** In consideration of the foregoing, the Government, the CMF, and the Project Awardee agree to the mutual covenants and promises contained in this Agreement.<sup>1</sup>

<sup>1</sup>See 42 USC § 247d–7e(c)(5); 42 U.S.C. 247d-7e(c)(4)(D); 42 USC § 247d-7e(c)(4)(F)

## **ARTICLE 2. DEFINITIONS**

2.1 When used in this Agreement, the following terms, whether used in the singular or plural, shall have the meanings set forth herein.

**2.2** "Agreement" or "Base Agreement" means the agreement between the RRPV CMF and RRPV member that serves as the baseline agreement for all future funded Project Awards and flows down applicable terms and conditions from the Other Transaction Agreement between the Government and the CMF.

**2.3** "BARDA Mission" means technology or action which BARDA is authorized by law<sup>2</sup> to support. The BARDA Mission generally includes technologies which support the acceleration of countermeasures and advanced research and development against a broad array of public health threats, whether natural or intentional in origin. Specific detail of the BARDA Mission at the time of Agreement execution can be found in BARDA's Strategic Plan (2022-2026), National Health Security Strategy (2023-2026), National Biodefense Strategy (2018), and the PHEMCE Strategy and Implementation Plan (2022), and by working directly with BARDA for specific information. The BARDA Mission is subject to change as laws, regulations and authorizations shift. Any statutory or regulatory updates to this authority are considered to be automatically incorporated into this Agreement.

2.4 "Cash Contribution" means the Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Project Award. The cash contribution may be derived from the Project Awardee (or a Project Awardees' subawards) funds, outside sources, nonfederal contract or grant revenues, or from profit or fee on a federal procurement contract. A Project Awardee's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent (committed after Project Award) IR&D funds may be utilized as a cash contribution provided those funds identified by the Project Awardee will be spent on performance of the Statement of Work (SOW) of a Project Award or specific tasks identified within the SOW of a Project Award. Prior (committed before Project Awardee's cash or in- kind contributions, nor will prospective fees be considered on a Project Awardee's cost sharing portion. Cash contributions include the funds a Project Awardee will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Project Award, and restocking the parts and material consumed.

**2.5** "Consortium" means the consortium established by the CMF and Government, comprised of a group of organizations collaborating to accomplish the objectives of the OTA, whose members represent industry, academia, for-profit organizations, non-profit organizations, and other entities.

**2.6** "Consortium Management Firm" (CMF) means the organization funded by the Government to execute and administer the efforts under the OTA for this program between the Government and the CMF.

2.7 "Consortium Member" or "Consortium Members" means the individual organizations that are members of the RRPV and signatories to the Consortium Member Agreement.

**2.8** "Consortium Member Agreement" (CMA) means the document signed by the Consortium members and CMF governing the rights and obligations of the Consortium Members as they relate to the Consortium and each other.

2See 42 USC § 247d-7e

- 2.9 "Days" means calendar days unless otherwise noted.
- **2.10** "Effective Date" means the date of last signature.
- 2.11 "Field" means any work performed that relates to or falls within the scope of this Agreement or the BARDA mission.

2.12 "Government" means the United States of America herein represented by BARDA to include all BARDA personnel, both federal and non-federal.

2.13 "Government Fiscal Year" ("FY") means the period commencing on October 1 and ending September 30 of the following calendar year.

2.14 "Government Purpose Rights" means the right by the Government to—

2.14.1 Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

**2.14.2** Release or disclose technical data outside the Government and authorize persons to whom release, or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

2.15 "Independent Research and Development (IR&D)" means a Project Awardee's cost relative to projects falling within the four following areas: (a) basic research, (b) applied research, (c) development, and (d) system and other concept formulation studies. The term does not include the cost of effort sponsored by a grant or required in the performance of a contract. IR&D effort shall not include technical effort expended in developing and preparing technical data specifically to support submitting a bid and proposal.

**2.16** "In-Kind Contribution" means the Project Awardees' non-financial resources expended by the Project Awardees to perform a Project Award such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

2.17 "Limited Rights" mean the rights to use, modify, reproduce, perform, display, or disclose data in whole or in part, within the Government. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of the Project Awardee, release or disclose the data outside the Government, use the data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the data to be used by another party. The Parties shall maintain the confidentiality of all data subject to or designated as falling within Limited Rights.

**2.18** "Other Transaction Agreement" or "OTA" refers to the 42 USC § 247d–7e(c)(5) Other Transaction Agreement between the Government and, Advanced Technology International (ATI) for the Rapid Response Partnership Vehicle, Agreement No. 75A50123D00005.

**2.19** "Other Transaction Agreements Officer" (OTAO) means the person identified by the Government in the OTA authorized to (1) obligate the Government under the OTA and any Project Award issued hereunder, and (2) modify the OTA and any Project Award issued hereunder.

**2.20** "Other Transaction Technical Representative" (OTTR) means the person designated by BARDA to be responsible for managing the scientific and technical aspects of the OTA and assisting with agreement administration.

2.21 "Other Transaction Agreements Specialist" (OTAS) means technical representative identified by the Government to assist the OTAO on the OTA.

2.22 "Parties" means the RRPV member and the CMF collectively.

2.23 "Principal Investigator" mean the individual, provided by the Project Awardee, responsible for the conduct of the project.

**2.24** "Project Approval Letter" (PAL) means the Project Awardee selection decision from BARDA to the CMF and authorizes the CMF to execute a Project Award. A PAL will include approved Statement of Work, award value, current funding, specific key Project Award considerations, and designated Project Award Representative (PAR). A PAL may be used for a modification to an existing Project Award.

2.25 "Project Awardee" means the RRPV consortium member that is issued a Project Award by the CMF.

**2.26** "Project Award" means an agreement between the CMF and Project Awardee, as authorized by the Government, whose proposal is evaluated and selected by the Government for funding, establishing the scope of work, terms and conditions for the RRPV member's performance and payment under the Government funded project. All Project Awards will be issued by the CMF. These awards may be of any appropriate type to include, but not limited to, fixed price, expenditure- based, cost share, milestone based, prize payments, etc.

2.27 "Project Award Representative" (PAR) means the individual designated by the Government on a per project basis to monitor all technical aspects and assist in agreement administration of a Project Award.

**2.28** "Project OTAO" means the person identified by the Government in the OTA authorized to (1) obligate the Government under the respective Task Order and any Project Award issued thereunder, and (2) modify the subject Task Order and any Project Award issued thereunder. This may or may not be the same person as the OTAO for the OTA.

**2.29** "Project Proposal" means a proposal submitted by the RRPV Member, through the CMF, to the Government for consideration for a Project Award by the Government Request for Project Proposal.

**2.30** "Request for Project Proposal" means the Government's request for proposals issued by the CMF to RRPV members, based on the focus areas or other mission requirements determined by the Government. Such request will include the technical, management, and cost factors as appropriate that will be used as the Government's basis for award selection.

2.31 "Subject Invention" means any Invention conceived or first actually reduced to practice in the performance of work under a Project Award.

**2.32** "Subject Matter Expert ("SME")" means members of the Government RRPV team who provide technical insights into development activities being undertaken by Project Awardees to satisfy the terms of the OTA. BARDA enters into agreements with outside entities for the technical services of SMEs. As non-federal personnel, SMEs are subject to non-disclosure agreements as determined by each contract or agreement that they support.

2.33 "Task Order" or "OT Task Order" means an award issued under the OTA from the Government to the CMF which provides funding and scope for Project Awards.

2.34 "Unlimited Rights" means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

## **ARTICLE 3. TECHNICAL FOCUS AREAS**

**3.1 General**. Under the Other Transaction Agreement, the CMF supports the Government in executing the dynamic needs of distinct and equally important technical focus areas. This approach is designed to enable targeted product development expertise and to ensure that, during a response event, sufficient dedicated resources are available to meet bold timelines, and avoid one technical focus area diverting resources from another. The initial focus areas are identified as follows:

3.1.1 Medical Technology (MedTech). MedTech refers to tools, equipment, and devices to diagnose and treat patients.

**3.1.2** Vaccines and Therapeutics (Vx/Tx). Vx refers to a biological preparation that is used to stimulate the body's immune response against viruses or diseases. Tx refers to medical intervention intended to treat a health issue, viruses, or disease.

**3.2** Revision of Focus Areas. The Focus Areas will be provided by the Government to the CMF, and the CMF will post the Focus Areas on its website for RRPV Consortium Members. The Government may revise or add Focus Areas at any time and will provide the RRPV CMF any such updates which will be posted on its website for RRPV members.

# **ARTICLE 4. REPORTS**

**4.1** Reports will be provided at the Project Award level.

**4.2** The Government, at its discretion, will have access to and the right to examine records of the CMF per normal course of the Agreement. BARDA may periodically request information from the CMF, including information from Consortium Members and Project Awardees, that include technology, financial, and IP progress in order to track impact, performance, and progress. These updates and reports will be considered confidential and shared on a need-to-know basis within USG.

**4.3** The Project Awardees shall submit documentation as prescribed by individual Project Awards. The documentation described below is the minimum reporting requirements that the CMF must include in each award:

**4.3.1** Quarterly/Monthly<sup>3</sup> and Annual Reports: One (1) copy shall be submitted or otherwise provided to the PAR and the CMF. The report will have two (2) major sections:

• Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues, major developments, and the status of external collaborations during the reporting period. Business Status Report. The business status report shall provide summarized details of the resource status of the Project Award, including the status of Project Awardee contributions. This report will include a quarterly accounting of current expenditures (or total amount of paid milestones, if FFP).

**4.3.2** Final Report: One (1) copy shall be submitted or otherwise provided to the PAR and the CMF. Unless otherwise directed, any format may be used for the final report will have two (2) major sections:

• Final Technical Report. The Project Awardee shall submit or otherwise provide a Final Report making full disclosure of all major developments by Project Awardee upon completion of the Project Award or within [\*\*\*] of termination of the Project Award. With the approval of the PAR, reprints of published articles may be attached to the Final Report. One (1) copy shall be submitted or otherwise provided to the PAR.

• Final Business Status Report. The final business status report shall summarize details of the resource status of the Project Award, including the status of the contributions by all participants. This report will include a final accounting of incurred expenditures (or total amount of paid milestones, if FFP).

# **ARTICLE 5. FUNDING OBLIGATIONS AND PAYMENTS**

**5.1 Project Award Invoicing.** Each Project Award shall identify the Payment Method for that project. The Project Awardee shall submit an invoice with the required level of detail, as well as the latest progress report to the CMF, who shall review and submit payment requests to the Project Award OTAO and PAR for the relevant work. After the PAR reviews the invoice and report, they will approve the invoice via signature and return to the CMF, allowing the CMF to issue payment to the Project Awardee.

**5.2** Invoicing Instructions. Invoices may be submitted no more than monthly, unless Firm Fixed Price. The Project Awardee shall submit invoices and any necessary supporting documentation via email to RRPV-invoices@ati.org.

**5.3** Payment Method Types:

a. *Fixed Price Milestone Payment Method*: Payments shall be made in accordance with the Payable Milestone Schedule of each Project Award, provided the designated PAR has verified compliance with the Statement of Work and accomplishment of the stated effort. An acceptable invoice for fixed price milestone payments is one that:

i. is addressed to the CMF and contains the CMF's address:

Advanced Technology International 315 Sigma Drive Summerville, SC 29486

<sup>3</sup>The decision to require progress reports at quarterly or monthly intervals will be determined by the PAR during RPP and project development phases.

- ii. contains the date of invoice, invoice number, and the Base Agreement number and Project Award number (20XX-XXX #X);
- iii. identifies the milestone number and description for any milestone(s) that are complete; and
- iv. lists the milestone cost negotiated and contained in the Project Award

b. *Expenditure-Based Milestone Payment Method (with not to exceed ceiling)*: Payment shall be made based on actual expenditures in completing milestones up to the total maximum amount allowable under the applicable Project Award, provided the designated PAR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (iii) below, a progress report identifying associated progress toward completion of each technical milestone is required with the invoice. An acceptable invoice for expenditure-based payment is one that:

i. is addressed to the CMF and contains the CMF's address:

Advanced Technology International 315 Sigma Drive Summerville, SC 29486

- ii. contains the date of invoice, invoice number, and the Base Agreement number and Project Award number (20XX-XXX #X);
- iii. identifies any associated technical milestones and the progress toward completion of each technical milestone;
- iv. includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;
- v. indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and
- vi. contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received." Authorized Signature

c. *Expenditure-Based with Fixed Fee Milestone Payment Method (with not to exceed ceiling)*: Payment shall be made based on actual expenditures in completing milestones up to the total maximum amount allowable under the applicable Project Award, provided the designated PAR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (iii) below, a progress report identifying associated progress toward completion of each technical milestone is required with the invoice. An acceptable invoice for expenditure-based payment is one that:

- i. is addressed to the CMF and contains the CMF's address:
  - Advanced Technology International
    - 315 Sigma Drive

Summerville, SC 29486

- ii. contains the date of invoice, invoice number, and the Base Agreement number and Project Award number (20XX-XXX #X);
- iii. identifies any associated technical milestones and the progress toward completion of each technical milestone;
- iv. includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, fixed fee and extended totals;

- v. indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and
- vi. contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

# Authorized Signature

## d. Expenditure-Based, Cost Sharing Milestone Payment Method (with not to exceed ceiling):

Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Award, provided the designated PAR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (iii) below, a progress report identifying associated the progress toward completion of each technical milestone is required with the invoice. An acceptable invoice for expenditure-based payment is one that:

- i. is addressed to the CMF and contains the CMF's address:
  - Advanced Technology International
    - 315 Sigma Drive
    - Summerville, SC 29486
- ii. contains the date of invoice, invoice number, and the Base Agreement number and Project Award number (20XX-XXX #X);
- iii. identifies any associated technical milestones and the progress toward completion of each technical milestone;
- iv. includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if the Project Awardee's practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CMF;
- v. includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;
- vi. indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and
- vii. contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received." Authorized Signature\_\_\_\_\_

**5.4 Final Invoices.** The Project Awardee's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed in accordance with the Project Award reporting requirements.

**5.5** Limitation of Funds. In no case shall the Government's or the CMF's or Consortium Members' financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or in-kind Contribution by the CMF or a Consortium Member under the Project Award. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist. In no event is the Government obligated to reimburse the recipient for expenditures in excess of the total funds allotted by the Government under a Project Award, regardless of any language to the contrary in any Termination clause herein or in any Project Award.

**5.6 Payment Terms.** Payment terms are [\*\*\*] after CMF's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in Section 5.3 Payment Method Types and approved by the PAR.

## **ARTICLE 6. ADMINISTRATION**

**6.1 Financial Records and Audit Access.** The costs incurred under any expenditure-based Project Award shall be those costs that are reasonable and prudent. Actual costs under expenditure-based Project Awards, including those direct costs associated with the research project as well as any indirect costs, are reimbursable to the extent they have a significant relationship to providing the goods or service under the Project Award.

The Project Awardee shall ensure that, for each Project Award, the Project Awardee's relevant financial records are available and subject to examination or audit on behalf of the Government for a period not to exceed [\*\*\*] after final payment of the Project Award.

Unless otherwise notified by the OTAO, these records are also subject to examination or audit by the Government's General Accountability Office (GAO). Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited Party. Any audit required during the course of this Agreement may be conducted by the Government using Government auditors or, at the request of the Project Awardee, by the Project Awardee's external CPA accounting firm at the expense of the Project Awardee. The terms of this paragraph shall be included in all sub-agreements to the Project Award.

**6.2** Accounting System. The Project Awardee shall have and maintain an established accounting system, which complies with Generally Accepted Accounting Principles, or comparable approved standards, and shall ensure that appropriate arrangements have been made for receiving, distributing, and accounting for federal funds. An adequate accounting system for an expenditure-based Project Award is normally accomplished through a job order cost accounting system, whereby the books and records segregate direct costs by agreement and includes an established allocation method for the equitable allocation of indirect costs among agreements/contracts.

6.3 Administrative Matters. Administrative matters under this Agreement shall be referred to the following representatives:

# **RRPV** Member Organization:

[\*\*\*] [\*\*\*] Vaxart, Inc. 170 Harbor Way, Suite 300 South San Francisco, CA 94080 [\*\*\*] [\*\*\*]

RRPV Consortium Management Firm: [\*\*\*] [\*\*\*] Advanced Technology International 315 Sigma Drive Summerville, SC 29486 [\*\*\*] [\*\*\*]

## 6.4 **Technical Matters.** Technical matters under this Agreement shall be referred to the following representative:

## **RRPV** Member Organization:

[\*\*\*] [\*\*\*] Vaxart, Inc. 170 Harbor Way, Suite 300 South San Francisco, CA 94080 [\*\*\*] [\*\*\*]

## RRPV Consortium Management Firm: [\*\*\*] [\*\*\*] Advanced Technology International 315 Sigma Drive Summerville, SC 29486

[\*\*\*] [\*\*\*]

A Project Award Representative (PAR) will be identified on each Project Award.

**6.5** System for Award Management (SAM). The RRPV member will be required to obtain a Unique Entity Identifier (UEI) from SAM.gov prior to award of a Project Award. A full SAM.gov registration is not required. See <u>www.sam.gov</u> for more information.

6.6 **Invoicing.** All invoice submissions are to be in accordance with Article 5.

6.7 Management of Project Awards. Performance of the work on Project Awards is subject to the technical oversight of the PAR designated in the Project Award.

6.7.1 For the purposes of this clause, technical oversight includes the following:

a. Direction to the Project Awardee, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;

b. Guidelines to the Project Awardee that assists in the interpretation of drawings, specifications or technical portions of work description.

c. Review and, where required by the Project Award, approval of technical reports, drawings, specifications, or technical information to be delivered by the Project Awardee under the Project Award.

The PAR shall monitor the Project Awardee's performance with respect to compliance with the technical requirements of the Project Award.

**6.7.2** Technical direction must be within the general scope of work stated in the Project Award. Technical direction may not be used to:

a. Assign additional work under the Project Award;

b. Increase or decrease the estimated Project Award cost, fee (if any), or the time required for the project period of performance;

c. Change any of the terms, conditions or specifications of the Project Award; or

d. Accept non-conforming work.

**6.7.3** As such, no verbal or written request, notice, authorization, direction or order received by the Project Awardee shall be binding upon the CMF or Government, or serve as the basis for a change in the Project Award cost or any other provision of the Project Award, unless issued (or confirmed) in writing by the CMF.

**6.7.4** The Project Awardee shall immediately notify the Project Award CMF Contractual Representative whenever a verbal or written change notification has been received from anyone other than the CMF, which would affect any of the terms, conditions, cost, schedules, etc. of the Project Award, and the Project Awardee is not to perform any work or make any changes in response to any such notification or make any claim on the CMF or Government, unless the CMF directs the Project Awardee, in writing, to implement such change notification.

**6.8 Modifications.** The only method by which this Agreement or Project Award may be modified is by a formal, written modification signed by the CMF, and, if necessary, additionally by the Project Awardee.

**6.8.1** Bilateral Modifications. Project Awardees may propose modifications to any Project Award in which they are involved, including justifications to support any proposed changes, by submitting a written request through the CMF to the Government. The modification request shall detail the technical, chronological, and financial impact of the proposed change to the Project Award.

**6.8.2** Unilateral Modifications. The CMF may unilaterally issue minor or administrative modifications, which do not materially change the obligations of the CMF or Project Awardee, such as incremental funding increases, or changes to personnel identified in the Agreement or Project Award. Unilateral modifications will be signed by only the CMF.

**6.8.3** Modification Communications. No other communications, whether oral or in writing, that purport to change this Agreement or a Project Award are valid.

6.9 **Pre-Award Costs.** Pre-Award costs supporting a Project Award are impermissible unless a written approval is authorized by the OTAO, through the CMF, or contained in the RPP.

6.10 **Project Subaward Approval.** Subawards that are proposed and agreed to during negotiations for a Project Award are considered as having OTAO approval. Modifications to approved subawards and/or new subawards, under a Project Award that will significantly impact the teaming arrangement and/or technical approach proposed and accepted require OTAO, through the CMF, approval prior to being executed.

**6.11 Title and Disposition of Property.** In this paragraph, "property" means any tangible personal property other than consumable property, which is not consumed during the execution of effort under a Project Award (e.g., equipment).

6.11.1 Title to Property, General. Title to property under Project Awards shall be determined per the below guidance.

**6.11.2** Title to Property: Fixed Price Project Awards. Project Awardee retains title to all property acquired as necessary to execute the work under the Project Award, unless otherwise dictated in the Project Award.

**6.11.3** Title to Property: Expenditure-Based (and other) Project Awards. Items of property with an acquisition value equal to or less than \$[\*\*\*] vest with the Project Awardee upon acquisition. For items greater than \$[\*\*\*], the Project Awardee must obtain approval from the OTAO, through the CMF, prior to purchasing property using Government funds in order to retain title. Property listed in the cost proposal is considered as having received OTAO approval. For those items of real property or nonexpendable personal property having a unit acquisition cost of \$[\*\*\*] or more, which will be acquired with Government funds received through the CMF, the Government reserves the right to transfer the title to the Federal Government or to a third Party named by the Government. If a Project Award includes the use of real property or equipment that is purchased with non-federal funds or that is donated by a third party to meet a portion of any required cost sharing or matching, the Government will have a financial interest in the property equal to the Federal funding in the project and such property shall be subject to this Article.

**6.11.4** Disposition of Property. At the completion of Project Awards containing property in which title does not vest with the Project Awardee, property shall be disposed of in the following manner:

**6.11.4.1** Purchased by the Project Awardee at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned as a credit to the Government; or,

**6.11.4.2** Transferred to a Government research facility with title and ownership being transferred to the Government or to an eligible third party; or

**6.11.4.3** Any other Government approved disposition procedures as approved by the Project OTAO, through the CMF. The Government shall provide disposition procedures within [\*\*\*] of being requested by the CMF to provide disposition.

# **ARTICLE 7. PROPRIETARY INFORMATION**

#### 7.1 Definitions for Article 7.

**7.1.1.** "Disclosing Party" means the CMF, a Consortium Member, Project Awardee, or the Government which discloses Proprietary Information as contemplated by the subsequent paragraphs.

**7.1.2.** "Receiving Party" means the CMF, a Consortium Member, Project Awardee, or the Government which receives Proprietary Information disclosed by a Disclosing Party.

7.1.3. "Proprietary Information" means information and materials of a Disclosing Party which are designated as Proprietary Information or as a Trade Secret or subject to export control in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information that are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Proprietary Information or a Trade Secret or be subject to export control if such Disclosing Party, within [\*\*\*] after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is proprietary or a Trade Secret or subject to export control. Any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Article.

**7.1.4.** "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if,

7.1.4.1. The owner thereof has taken reasonable measures to keep such information secret; and

**7.1.4.2.** The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

**7.2** Exchange of Information. Consortium Members may from time to time disclose Trade Secrets to the Government or to other Consortium Member(s) in connection with the Projects Awards. Neither the Government, nor the CMF, nor any Consortium Member, nor any Project Awardee, shall be obligated to transfer Proprietary Information or Trade Secrets independently developed unless a condition of the Project Award.

**7.3 Confidentiality and Authorized Disclosure**. The Receiving Party agrees, to the extent permitted by law, that Proprietary Information and Trade Secrets shall remain the property of the Disclosing Party (no one shall disclose such information unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Proprietary Information and Trade Secrets shall not be disclosed, divulged, or otherwise communicated by the Receiving Party to third parties (including without limitation, other Consortium Members) or used by the Receiving Party for any purposes other than in connection with the Project Awards and the licenses granted via this Agreement; provided that the terms "Proprietary Information "and "Trade Secrets" shall exclude materials or information that:

7.3.1 Are received or become available without restriction to the Receiving Party under separate agreement;

- 7.3.2 Are not identified with a suitable notice or legend prescribed under this Agreement;
- 7.3.3 Are in possession of the Receiving Party at the time of disclosure thereof as demonstrated by prior written records;
- 7.3.4 Are or later become part of the public domain through no fault of the Receiving Party;

7.3.5 Are received by the Receiving Party from a third Party having no obligation of confidentiality to the Disclosing Party that made the disclosure;

7.3.6 Are developed independently by the Receiving Party without use of Proprietary Information or Trade Secrets as evidenced by written records;

**7.3.7** Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

**7.4** Term. The obligations of the Receiving Party under this Article shall continue for a period of [\*\*\*] after the expiration or termination of this Agreement.

**7.5** Flow down. The Project Awardee shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all other forms of lower tier awards, regardless of tier. The Government will be a third party in interest for purposes of this Article in any agreement where flow down of rights and obligations is required.

# **ARTICLE 8. RIGHTS IN DATA**

**8.1** General. The Data Rights in this Article are specifically tailored for this Agreement to address respective rights of the Government and the Project Awardees to be included in Project Award Agreements to such Data as is owned, developed, to be developed or used by an actual or prospective Project Awardee (1) as identified in a Project Proposal submitted to the Government through the CMF in response to a Request for Proposals, and (2) when such proposal is selected by the Government for funded performance and the Project Award is issued by the CMF to that Project Awardee for performance of such Project Award.

## 8.2 Allocation of Principal Rights.

8.2.1 The Government shall have Unlimited Rights for use in the Field in:

**8.2.1.1** Preexisting data funded by the Government. For clarity, Government rights in any preexisting data produced by Project Awardee and funded by the Government under a separate agreement shall be governed by such separate agreement, and this Agreement shall not alter any Government rights in such data produced outside of this Agreement;

**8.2.1.2** Data first produced in the performance of this Agreement exclusively with Government funds;

8.2.1.3 Form, fit, and function data delivered under this Agreement; and

**8.2.1.4** Data delivered under this Agreement (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this Agreement.

**8.2.2** The Government shall have Government Purpose Rights to all data produced in performance of this Agreement that was funded jointly by both parties under a cost sharing arrangement. The Government also reserves the right to negotiate for Government Purpose Rights for data described in 8.2.1.

**8.2.3** The Government shall have Limited Rights to (a) all data, other than restricted computer software, that embody trade secrets or are commercial or financial and confidential or privileged, that pertains to items, components, or processes developed at private expense in the performance of this Agreement, and (b) data contained in a disclosure of a Subject Invention provided to the agency prior to the filing of a patent application.

# 8.3 Parties' Obligations Regarding Data.

**8.3.1** The Project Awardee agrees to retain and maintain in good condition all data necessary to achieve Practical Application of any Subject Invention in accordance with the Project Awardee's established record retention practices. In the event of exercise of the Compulsory Licensing Rights as set forth under this Agreement, Project Awardee agrees, upon written request from the Government, to deliver, as mutually agreed between the Parties, all existing Data necessary to achieve Practical Application of the relevant Subject Invention within [\*\*\*] from the date of the written request. Unless otherwise negotiated, the Government shall obtain Government Purpose Rights to this delivered Data, except for Data subject to Limited Rights as identified herein.

**8.3.2** The Project Awardee's right to use Data includes the right under Project Awardee's established business policies to make public research data (especially human research data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis. Project Awardee's publication of Data disclosing any Subject Invention shall trigger Project Awardee's obligation to file an application for a patent to such Subject Invention under this Agreement.

## 8.4 Marking of Data.

8.4.1 The Project Awardee will mark any Data delivered under a Project Award with Limited Rights with the following legend:

#### "LIMITED RIGHTS"

These data are submitted with limited rights under Agreement No. 75A50123D00005. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the CMF, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for purposes defined in the Project Award, if any, provided that the Government makes such disclosure subject to prohibition against further use and disclosure.

**8.4.2** Identification and Disposition of Data. The Project Awardee shall keep copies of all Data required by the FDA relevant to the Project Award for the time specified by the FDA. In addition, the Project Awardee shall provide regulatory data to the OTTR and OTAS (through the CMF) in accordance with the deliverable schedules in the Project Award's Statement of Work. The Government reserves the right to review any other data determined by the Government to be relevant to this Agreement. The Government further acknowledges that Project Awardee holds the commercialization rights for all products developed under the Project Award and will be responsible for their registration with the FDA.

**8.5** Negotiating Other Rights. Notwithstanding the paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual Project Award on a case-by-case basis as memorialized in the Project Award.

8.6 Survival Rights. Provisions of this Article will survive termination of this Agreement.

## 8.7 Copyright

**8.7.1** The Project Awardee, reserves the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual Project Awardee. The Project Awardee hereby grants to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this Agreement, and to authorize others to do so.

**8.7.2** In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.

**8.7.3** Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use and treated in accordance with such license rights legend markings restricting its use.

**8.7.4** The Project Awardee is responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.

8.7.5 The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

#### **ARTICLE 9. INVENTIONS**

#### 9.1 Allocation of Principal Rights and Obligations.

**9.1.1** Ownership. The Project Awardee shall retain ownership of each Subject Invention throughout the world, unless (i) Project Awardee shall have notified the OTAO, through the CMF, that Project Awardee does not intend to retain ownership of such Subject Invention in accordance with of this Article, (ii) Project Awardee fails to disclose such Subject Invention to the OTAO, through the CMF, in accordance with terms defined herein, or (iii) Project Awardee fails to file a patent application for such Subject Invention in accordance with the terms of this Agreement, in which case ownership shall vest with the Government.

**9.1.2** License to Government for Subject Inventions to Which Project Awardee Retains Ownership. With respect to any Subject Invention made under a Project Award in which the Project Awardee retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. For clarity, this license does not include the right to use or allow others to use the Subject Invention for commercial purposes.

# 9.2 **Project Awardee's Obligations.**

**9.2.1** The Project Awardee shall disclose in writing each Subject Invention to the OTAO, through the CMF, within [\*\*\*] after the inventor discloses it in writing to Recipient personnel responsible for patent matters. The disclosure shall identify the inventor(s) and the Project Award under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The parties agree that the information contained in the disclosure shall qualify as limited rights data as defined under this Agreement and is not subject to further disclosure without mutual agreement. Parties agree that such disclosure remains confidential pending filing of a patent application as detailed below.

**9.2.2** The Project Awardee shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTAO, through the CMF, within [\*\*\*] of disclosure to the agency. In the event that the Project Awardee's publication or use of the data has initiated the one-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than [\*\*\*].

**9.2.3** The Project Awardee shall file either a provisional or a non-provisional patent application on an elected Subject Invention within [\*\*\*] after election. If the Project Awardee files a provisional application, it shall file a non-provisional application within [\*\*\*] of the filing of the provisional application. The Project Awardee shall file patent applications in additional countries (or international patent offices within either [\*\*\*] of the first filed patent application or [\*\*\*] from the date permission is granted by the Commissioner of Patents to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

9.2.4 The Project Awardee may request extensions of time for disclosure, election, or filing under this Article.

**9.3** Conditions When the Government May Obtain Title. Upon the Government's written request, the Project Awardee shall convey title to any Subject Invention to the Government under any of the following conditions:

9.3.1 If the Project Awardee fails to disclose or elects not to retain title to the Subject Invention within the times specified under this Article.

**9.3.2** In those countries in which the Project Awardee fails to file patent applications within the times specified in this Article; provided, that if Project Awardee has filed a patent application in a country after the times specified in this Article, but prior to its receipt of the written request by the Government, Project Awardee shall continue to retain title in that country; or

**9.3.3** In any country in which the Project Awardee decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

9.3.4 License to Project Awardee for Subject Inventions to which the Project Awardee Does Not Elect to Retain Ownership.

**9.3.4.1** In the event that the Project Awardee does not elect to retain ownership in a Subject Invention pursuant to this Article, the Project Awardee shall retain a nonexclusive royalty-free license throughout the world in such Subject Invention to which the Government obtains title pursuant to 9.3 of this Article, unless the Project Awardee fails to disclose the invention within the times specified in this Article. The Project Awardee's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Project Awardee is a part and includes the right to grant sublicenses to the extent the Project Awardee was legally obligated to do so at award of the Project Award. The license is transferable only with the written approval of the Government, except when transferred to the successor of that part of the Recipient's business to which the invention pertains. The Government approval for license transfer shall not be unreasonably withheld.

**9.3.4.2** The Project Awardee's license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention in a particular country in accordance with the procedures outlined under this Agreement.

# 9.3.5 Third Party Application.

**9.3.5.1** In response to a third party's proper application for an exclusive license, the Project Awardee's domestic license may be revoked or modified to the extent necessary to achieve expeditious practical application of the Subject Invention. The application shall be submitted in accordance with the applicable provisions in 37 CFR part 404 and agency licensing regulations. The Project Awardee's license will not be revoked in that field of use or the geographical areas in which the Project Awardee has achieved practical application and continues to make the benefits of the Subject Invention reasonably accessible to the public. The license in any foreign country may be revoked or modified to the extent the Project Awardee, its licensees, or its domestic subsidiaries or affiliates have failed to achieve practical application in that country.

**9.3.5.2** Revocation or modification of the Project Awardee's minimum rights. Before revoking or modifying the Project Awardee's license in accordance this Article, the OTAO, through the CMF, shall furnish the Project Awardee a written notice of intention to revoke or modify the license. The Government shall allow the Project Awardee at least [\*\*\*] (or another time as may be authorized for good cause by the OTAO) after the notice to show cause why the license should not be revoked or modified. The Project Awardee has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and agency licensing regulations, any decisions concerning the revocation or modification.

**9.3.6** License to the Project Awardee for Subject Inventions to Which the Project Awardee Has Elected to Retain Ownership but Does Not File a Patent Application or does Not Prosecute a Patent Application.

**9.3.6.1** In the event that Project Awardee has elected to retain ownership of a Subject Invention but subsequently elects not to file a patent application for the Subject Invention or elects not to prosecute a patent application for the Subject Invention, the Project Awardee shall retain a fully paid up, sub- licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if the Project Awardee fails to disclose the Subject Invention within the times specified in this Article. The Project Awardee's license extends to the Project Awardee's subsidiaries and Affiliates, if any, within the corporate structure of which the Project Awardee is a party and includes the right to grant licenses of the same scope to the extent that the Project Awardee was legally obligated or permitted to do so at the time the Project Award was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of the Project Awardee's business to which the Subject Invention pertains. The Government approval for license transfer shall not be unreasonably withheld.

**9.3.6.2** The Project Awardee's license under this Paragraph may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. The Project Awardee's license shall not be revoked in that field of use or the geographical areas in which the Project Awardee has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

**9.3.6.3** Before revocation or modification of the Project Awardee's license under this Paragraph, the Government shall furnish the Project Awardee with a written notice of its intention to revoke or modify the license, and the Project Awardee shall be allowed [\*\*\*] (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

**9.4** Actions to Protect the Government's Interests. The Project Awardee agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which the Project Awardee elects to retain title and (ii) convey title to the Government when requested pursuant to this Article and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

**9.4.1** The Project Awardee shall require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Project Awardee, each Subject Invention made under this Agreement so the Project Awardee can comply with the disclosure provisions of this Article. The Project Awardee shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars. The Project Awardee shall also instruct all employees, in accordance with its regular business practices, on the need to maintain confidentiality of any information covered by the disclosure under this Article.

**9.4.2** The Project Awardee shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than [\*\*\*] before the expiration of the response period required by the relevant patent office.

**9.4.3** The Project Awardee shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement <u>75A50123D00005</u> awarded by The Department of Health and Human Services. The Government has certain rights in the invention."

# 9.5 Reporting on Utilization of Subject Inventions.

**9.5.1** Upon Government request, the Project Awardee agrees to submit, during the Term of the Project Award, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by the Project Awardee or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. The Project Awardee also agrees to provide additional reports as may be requested by the Government in connection with any compulsory licensing proceedings undertaken by the Government in accordance with this Article. The Government agrees it shall not disclose such information to persons outside of the Government, and non-federal Government personnel, and the CMF, without permission of the Project Awardee.

9.5.2 All required reports shall be submitted to the OTAS, OTAO (through the CMF), and PAR.

**9.6 Compulsory Licensing Rights.** The Project Awardee agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require the Project Awardee through the CMF, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Project Awardee refuses such a request, the Government has the right to grant such a license within the Field itself only if the Government determines that:

**9.6.1** Such action is necessary because the Project Awardee or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the subject invention; or

9.6.2 Such action is necessary to alleviate health or safety needs, which are not reasonably satisfied by the Project Awardee, assignee, or their licensees; or

**9.6.3** Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the CMF, assignee, or licensees; or

**9.6.4** Such action is necessary because the agreement required by 35 U.S. Code § 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 35 U.S. Code § 204.

9.7 Differing Patent Rights. Notwithstanding the paragraphs of this Article, differing patent rights may be negotiated among the Parties to each individual Project Award on a case-by-case basis as memorialized in the Project Award.

# ARTICLE 10. FOREIGN ACCESS TO TECHNOLOGY

**10.1** Foreign Access to Technology. The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national security, and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by foreign firms or institutions must be carefully controlled. The controls contemplated in this Article are in addition to, and are not intended to change or supersede, existing law or regulation.

**10.2 Restrictions on Sale or Transfer of Technology to Foreign Firms or Institutions.** In order to promote the national security and economic interests of the United States and to effectuate the policies that underlie the regulations cited above, the procedures stated in this Article below shall apply to any transfer of technology. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology.

**10.2.1** Transfers do not include:

**10.2.1.1** Sales of products or components;

**10.2.1.2** Licenses of software or documentation related to sales of products or components;

10.2.1.3 Transfer to foreign subsidiaries for purposes related to this Agreement; or

**10.2.1.4** Transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the conduct of research under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

**10.2.2** The Project Awardee shall provide timely notice to HHS of any proposed transfers from the Project Awardee of Technology developed under this Agreement to Foreign Firms or Institutions. If HHS determines that the transfer may have adverse consequences to the national security interests of the United States, HHS shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer, but which provide substantially equivalent benefits.

**10.2.3** In any event, Project Awardee shall provide written notice to the CMF of any proposed transfer from a Project Awardee to a foreign firm or institution at least [\*\*\*] prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within [\*\*\*] of receipt of written notification, the OTAO shall advise CMF whether it consents to the proposed transfer. No transfer shall take place until a decision is rendered.

**10.2.4** In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by HHS takes place, Project Awardee shall (a) refund to HHS funds paid pursuant to the Project Agreement for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of the Project Agreement. Upon request of the Government, the Project Awardee shall provide written confirmation of such licenses.

# ARTICLE 11. PUBLICATION AND PUBLICITY

**11.1 Review of Press Releases.** All Parties agree to accurately and factually represent the work conducted under this Agreement in all press releases. Misrepresenting results or releasing information that is injurious to the integrity of a Party may be construed as improper conduct. Press releases shall be defined as the public release of information via any medium, excluding peer- reviewed scientific publications. The Project Awardee agrees to provide the Government and the CMF with an advance copy of any press release related to this Agreement for review and approval not less than [\*\*\*] prior to the issuance of the press release. The PAR or OTAO will provide approval. The review time may be expedited for press releases issued to address safety concerns or issues of significant internal importance to the Project Awardee, when possible. Federal funds received through support shall be acknowledged in all such press releases substantially as follows:

"This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: <u>75A50123D00005</u>."

**11.2 Publication of Data**. No Data or other information obtained, delivered, or produced under this Agreement or Project Award shall be released or publicized without concurrence from the Government. For purposes of this Agreement, "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 Agreement, or Project Award, must be submitted to the CMF and the Government for review and comment no less than [\*\*\*] before submission of any manuscript for public presentation or publication, and no less than [\*\*\*] before submission of any abstract for public presentation or publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: <u>75A50123D00005</u>."

# ARTICLE 12. TERM OF AGREEMENT AND TERMINATION

**12.1 Term of the Agreement**. The Agreement is effective upon the Effective Date, which is the date of last signature, to [\*\*\*]. The term of each project will be as stated in each individual Project Award. The terms of individual Project Awards may extend beyond the term of this Agreement.

**12.2 Termination of This Agreement by Mutual Agreement**. This Agreement shall terminate by written agreement of the CMF and the Project Awardee or upon completion of all Project Awards. Rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government and the CMF and the Project Awardee shall survive any such mutual termination agreement unless otherwise agreed to in writing.

# ARTICLE 13. CONSORTIUM MEMBERSHIP TERMS AND PROJECT AWARDS

#### 13.1 Membership.

**13.1.1** Addition of Members to the Consortium. The consortium shall operate as an open model with a continuous membership application and approval process. Membership applications will be received by the CMF and subsequently submitted to the Government who will make the final decision if applicants will be permitted to join the consortium. OTAO will provide Government approval.

**13.1.2** Minimum Requirements to Join the Consortium.

**13.1.2.1** Organization shall possess a technology relevant to the RRPV mission of advancing medical countermeasures.

**13.1.2.2** Organization shall not be suspended or barred from conducting business with or receiving funds from the USG.

**13.1.3** Withdrawal of Consortium Members. Any consortium member may voluntarily withdraw from the Consortium at any time by providing notice to the CMF of this decision at least [\*\*\*] in advance. The Government reserves the right to unilaterally remove any member from the consortium if it determines their removal to be in the best of interest of the Government and provides the member with [\*\*\*] notice of its decision. The CMF will immediately notify the Government of any member's withdrawal from the consortium.

**13.1.4** Rights of a Consortium Member Following Withdrawal. Except for rights and obligations specified at the individual Project Award level, such as specific property or IP rights, from and after the effective withdrawal date, the former consortium member shall cease to have any rights or obligations as a consortium member under the RRPV. In the event of a withdrawal, in which the consortium member is currently executing any Project Award, the consortium member's obligation shall continue in accordance with the previously agreed-to schedule until its completion or the Government and consortium member come to an agreement to terminate the task, whichever is first.

**13.2** Term. The term of the Project Awards will be as stated in the terms and conditions of each individual Project Award.

# 13.3 Stop Work.

**13.3.1** As directed by the OTAO, the CMF may, at any time, by written order to the Project Awardee, require the Project Awardee to stop all, or any part, of the work called for under any Project Award for a period directed by the OTAO after the written order is delivered to the Project Awardee. The order shall be specifically identified as a stop-work order issued under this Article. Upon receipt of the order, the Project Awardee shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of [\*\*\*] after a stop-work is delivered to the Project Awardee, or within any extension of that period to which the Parties shall have agreed, the Government shall direct the RRPV CMF to either:

13.3.1.1 Cancel the stop-work order; or

**13.3.1.2** Terminate the work covered by the Project Award.

**13.3.2** If a stop work order issued under this Article is canceled, the Project Awardee shall resume work. The Government through the RRPV CMF shall make an equitable adjustment in the delivery schedule or Project Award estimated cost/price, or both, and the Government's share of the Project Award shall be modified, in writing, accordingly, if—

**13.3.2.1** The stop-work order results in an increase in the time required for, or in the Project Awardee's cost properly allocable to, the performance of any part of the Project Award; and

**13.3.2.2** The Project Awardee asserts its right to the adjustment within [\*\*\*] after the end of the period of work stoppage; provided that, if the Government decides the facts justify the action, the Government through the CMF may receive and act upon a proposal submitted at any time before final payment under the Project Award.

**13.3.3** If a stop work order is not canceled and the work covered by the Project Award is terminated in accordance with this article, at the direction of the OTAO, the CMF shall work with the Project Awardee to negotiate an equitable reimbursement.

13.4 Termination of Project Award. Any Project Award awarded pursuant to this Agreement may be terminated in whole or in part as set forth below:

**13.4.1** By the OTAO unilaterally, should insufficient funds be available to accomplish the goals or intent of the Project Award or for other convenience to the Government. Such termination will be effective immediately upon written notice notwithstanding any prior notice requirement of this Agreement. In any event, [\*\*\*] prior written notice will be provided to the maximum extent practicable;

**13.4.2** By the OTAO, with the consent of the Project Awardee through the CMF, based on an agreement by the Government and Project Awardee that the Project Award will not produce beneficial results commensurate with the expenditure of resources;

**13.4.3** By the OTAO, with the consent of the Project Awardee through the CMF. In this case, the Parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

**13.4.4** By the Project Awardee, upon sending the OTAO through the RRPV CMF, a written notification, setting forth the reasons for such termination, the effective date and, in the case of partial termination, the portion to be terminated. The notice shall also include the total costs incurred or committed to date as well as projected costs for closeout. The Project Awardee must provide such notice at least [\*\*\*] prior to the effective date of the termination. No costs shall be incurred beyond those listed in the termination notice, unless otherwise agreed to by the OTAO. Upon receipt of the termination notice, the OTAO in consultation with the OTTR and PAR, will determine the appropriate path forward, which may include a full or partial transfer of tasks to another Project Awardee or Government entity, full or partial termination of the Project Award, or other mutual agreement between the Parties. If the OTAO determines, in the case of partial termination, that the reduced or modified portion of the Project Award will not accomplish the purposes for which the Project Award was awarded, the OTAO, through the CMF, may terminate the Project Award in its entirety.

**13.5** Termination Caused by Material Breach by the Project Awardee. If the Project Awardee materially fails to comply with the provisions of a Project Award, the Project OTAO, after issuance of a notice through the RRPV CMF and failure of the Project Awardee to cure the defect within [\*\*\*] or the time allowed by the AO after receipt of the notice, may take one or more of the following actions as appropriate:

- **13.5.1** Temporarily withhold payments pending correction of the deficiency;
- 13.5.2 Disallow all or part of the cost of the activity or action not in compliance;
- 13.5.3 Wholly or partly suspend or terminate the current Project Award;
- 13.5.4 Withhold further funding for the Project Award; and
- **13.5.5** Take any other legally available remedies.

**13.6 Termination Costs.** The Parties will negotiate in good faith an equitable settlement for work performed under the Project Award, as appropriate. Costs incurred by the Project Awardee during a suspension or after termination of a Project Award are not allowable unless the OTAO, through the CMF, expressly authorizes them in either the notices of suspension, termination or subsequently. Other costs incurred during a suspension or after termination which are necessary and not reasonably avoidable may be allowable, as determined by the OTAO.

**13.7 Close-out Procedures.** If any Project Awards issued pursuant to this Agreement are completed or terminated, the following closeout procedures apply.

**13.7.1** "Close-out" is the process by which the Government determines that all applicable administrative actions and all required work have been completed by the Project Awardee, the CMF, and the Government for a given project.

**13.7.2** The Government shall obtain from the Project Awardee through the CMF within [\*\*\*] after the date of completion of the Project Award all financial, performance, and other reports required as the condition of the Project Award. The Government may grant extensions when requested by the RRPV CMF on behalf of the Project Awardee.

**13.7.3** Quick close-out procedures similar to those found at FAR 42.708 shall be followed when possible.

**13.7.4** When authorized at the Project Award level, the Government will make a settlement for any upward or adjustments to the Government's share of costs, not to exceed the Government's obligated amount, after these reports are received.

13.7.5 The Project Awardee, through the RRPV CMF, shall account for any property received from the Government.

# ARTICLE 14. REPRESENTATIONS AND WARRANTIES

#### 14.1 **Representations and Warranties of All Parties.** The Project Awardee represents that:

**14.1.1** It is a validly existing legal or Government entity;

14.1.2 It is free to enter into this Agreement;

14.1.3 In so doing, it will not violate any other agreement to which it is a Party; and

**14.1.4** It has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

**14.2 Limitations.** Except as expressly provided herein, neither the Project Awardee, the CMF nor the Government makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (a) any research conducted under this Agreement or (b) any invention conceived and/or reduced to practice under this Agreement or (c) any other intellectual property developed under this Agreement, and each one specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

# **ARTICLE 15. LIABILITY OF THE PARTIES**

**15.1 Waiver of Liability.** With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against another Party, another Party's employees, another Party's related entities (e.g., lower tier awardees, etc.) or employees of another Party's related entities, or the Government, for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage, or loss arises through negligence or otherwise, except in the case of willful misconduct.

**15.2 Damages.** To the extent that a risk of damage or loss is not dealt with expressly in this Agreement, the Government and/or the Parties' liability to the other Parties arising out of this Agreement whether or not arising as a result of an alleged breach of this Agreement, shall be limited to direct damages only, and shall not include any consequential, punitive, special and incidental damages, claims for lost profits, re-procurement costs, or other indirect or consequential damages.

**15.3** Extension of Waiver of Liability. The Project Awardee agrees to extend the waiver of liability as set forth above to its sub-tier awards at any tier under the Project Award, and requiring them, by contract or otherwise, to agree to waive all claims against the Government and the CMF.

15.4 Applicability. Notwithstanding the other provisions of this article, this waiver of liability shall not be applicable to:

15.4.1 Claims between the CMF, Project Awardee, and/or the Government regarding a material breach or non-payment of funds for a Project Award,

15.4.2 Claims for damage caused by willful misconduct, or

15.4.3 IP claims.

**15.5** Limitation of Liability. In no case will the financial liability of the Government, the CMF, or the Project Awardee exceed the amount obligated by the Government in connection to that Project Award. In no event shall the Parties be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, re-procurement costs, or other indirect damages. Each of the foregoing limitations on damages shall not apply to an action against the Government brought under 28 USC §1498. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

# **ARTICLE 16. DISPUTES**

**16.1 General.** The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable.

Any claim or dispute between the Parties concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, shall only be raised under this Article.

In no event shall a dispute, disagreement or misunderstanding that arose more than [\*\*\*] prior to the notification made under this article constitute the basis for relief under this article unless the BARDA OTAO, in the interests of justice, waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. Within [\*\*\*] after providing notice to the other Party, the aggrieved Party may, in writing and through the CMF, request a decision to be rendered from a position at least one level above the BARDA OTAO.

The other Party shall conduct a review of the matter(s) in dispute and submit a written response on the matter(s) within [\*\*\*] after being notified that a decision has been requested. Any such decision is final and binding, unless a Party, within [\*\*\*], requests further joint review by senior officials (e.g., the CMF Chief Operating Officer, an ASPR official at least two levels above the OTAO, and/or senior executive of the Project Awardee). In such case, the senior officials shall conduct a review of the matter(s) in dispute and the senior Government official shall render a decision in writing within [\*\*\*] of receipt of such written position.

In the absence of a joint decision, or after appropriate exhaustion of the administrative and other remedies identified in this Agreement, either party may pursue any right or remedy provided by law in a court of competent jurisdiction. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

# **ARTICLE 17. REGULATORY TERMS**

Specific regulations will be identified by the Government in Project Award documentation on a case-by-case basis, but may include:

#### 17.1 Protection of Human Subjects.

**17.1.1** The Project Awardee agrees that the rights and welfare of human subjects involved in research under this Agreement shall be protected in accordance with 45 CFR Part 46 and with the Project Awardee's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Project Awardee further agrees to provide certification 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.

**17.1.2** The Project Awardee shall bear full responsibility for the performance of its work and services involving the use of human subjects under this Agreement and shall ensure that work is conducted in a proper manner and as safely as is feasible. The Project Awardee shall retain the right to control and direct the performance of all its work under this Agreement. Nothing in this Agreement shall be deemed to constitute any Project Awardee or any lower tier awardee, agent or employee of Project Awardee, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Project Awardee agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent organization without imputing liability on the part of the Government for its acts or its employees.

**17.1.3** If at any time during the performance of this Agreement, the HHS OTAO determines, in consultation with the OHRP, OPHS, and ASH, that the Project Awardee is not in compliance with any of the requirements and/or standards stated in Subparagraphs (1) and (2) above, the HHS OTAO may immediately direct the CMF to suspend, in whole or in part, work and further payments under this Agreement until the Project Awardee fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the HHS OTAO may, in consultation with OHRP, OPHS, and ASH, terminate the Project Award under this Agreement in a whole or in part, and the Project Awardee's name may be removed from the list of those performers with approved Health and Human Services Human Subject Assurances.

#### 17.2 Human Materials (Assurance of OHRP Compliance).

**17.2.1** The acquisition and supply of all human specimen material (including fetal material) used under this Agreement shall be obtained by the Project Awardee in full compliance with applicable Federal, state and local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

**17.2.2** The Project Awardee shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this Agreement, by collaborating sites, or by sub-tier awardees, 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 Project Awardee.

**17.2.3** Provision by the Project Awardee to the HHS OTAO, through the CMF, 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).

**17.3 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. The Project Awardee 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 Project Awardee.

**17.4** Needle Exchange. The Project Awardee shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

# 17.5 Care of Live Vertebrate Animals.

**17.5.1** Before undertaking performance of any Project Award involving animal related activities, the Project Awardee shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Project Awardee, through the CMF, shall furnish evidence of the registration to the OTAO.

**17.5.2** The Project Awardee shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.

**17.5.3** The Project Awardee agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this Agreement will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1 - 4). In case of conflict between standards, the more stringent standard shall be used.

**17.5.4** If at any time during performance of this Agreement, the OTAO determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Project Awardee is not in compliance with any of the requirements and/or standards stated above, the OTAO may immediately direct the CMF to suspend, in whole or in part, work and further payments under the Project Award until the Project Awardee fails to complete corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Project Awardee fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the OTAO may, in consultation with OLAW, NIH, terminate the Project Award in whole or in part, and the Project Awardee's name may be removed from the list of those entities with approved PHS Animal Welfare Assurances.

**17.5.5** Note: The Project Awardee may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

**17.6** Animal Welfare. All Project Awardee research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: <u>https://olaw.nih.gov/policies-laws/phs-policy.htm</u>.

**17.7 Protection of Personnel Who Work with Nonhuman Primates**. All Project Awardee personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: <u>https://policymanual.nih.gov/3044-2</u>.

# 17.8 Information on Compliance with Animal Care Requirements.

**17.8.1** Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), located at <u>https://www.nal.usda.gov/animal-health- and-welfare/animal-welfare-act.</u>

**17.8.2** The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW), located at <u>https://olaw.nih.gov/</u>. An essential requirement of the PHS Policy, available at <u>https://olaw.nih.gov/policies-laws/phs-policy.htm</u>, is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

**17.8.3** The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals, available at <a href="https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf">https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf</a>, and that they comply with the regulations (9 CFR, Subchapter A), available at <a href="https://www.ecfr.gov/current/title-9/chapter-I/subchapter-A">https://www.ecfr.gov/current/title-9/chapter-I/subchapter-A</a>, issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

**17.8.4** The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) <u>http://www.aaalac.org</u> is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the Accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federation of Animal Science Societies, available at <u>https://www.fass.org/</u>.

**17.9 Approval of Required Assurance by Law.** Under governing regulations, federal funds which are administered by BARDA shall not be expended by the Project Awardee for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities under this award, unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within [\*\*\*] of the date of each Project Award under this award and approved by OLAW. Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities that do not directly involve live vertebrate animals (i.e., are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Project Awardee individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at <u>https://olaw.nih.gov/</u>.

#### 17.10 Registration with the Select Agent Program for Work Involving the Possession, Use, and/or Transfer of Select Biological Agents or Toxins

**17.10.1** Work involving select biological agents or toxins shall not be conducted under this Agreement until the Project Awardee and any affected subawards are granted a certificate of registration or are authorized to work with the applicable select agents.

**17.10.2** For Project Awards or sub-tier awards to domestic institutions who possess, use, and/or transfer Select Agents under this Agreement, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

**17.10.3** For Project Awards or sub-tier awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the Project Awardee must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (<u>https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73</u>) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Project Awardee must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the OTAO, through the CMF, the Project Awardee shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Project Awardee must provide the names of all individuals have access to Select Agents under the Project Agreement.

**17.10.4** Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program web site at <u>https://www.selectagents.gov/</u>.

# 17.11 Product Licensure.

**17.11.1** Any vaccines purchased, stored and distributed under this Agreement shall be manufactured under a current establishment and product licensure issued by the Food and Drug Administration.

**17.11.2** The Project Awardee agrees to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents.

**17.11.3** The Project Awardee agrees to advise the OTAO, through the CMF, and OTTR immediately of any relocation of their manufacturing facility or the relocation of any sub-tier awardee's facility. The Project Awardee also agrees to advise the OTAO, through the CMF, and OTTR immediately if at any time during the life of the Project Awards, the items under this Agreement fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

**17.12** Final Distribution. Prior to expiration or termination of any Project Award, the Government may affect final distribution of any vaccines remaining in storage by any one or combination of the following methods:

**17.12.1** The Government may elect to require shipment of the vaccine to US Government facilities or to state and local health agencies and/or other providers;

**17.12.2** The Government may direct the Project Awardee to destroy all quantities remaining in storage at a charge to be negotiated between the parties. Such charges shall not exceed the actual costs incurred by the Project Awardee (or milestone value, if fixed price), and agreed to by the Government in advance of the destruction and/or disposal.

17.12.3 The Project Awardee cannot reclaim title to product upon acceptance.

**17.13 Manufacturing Standards**. The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of any therapeutic product developed under this Agreement. If at any time during the life of this contract, the Project Awardee fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Project Awardee shall have [\*\*\*] from the time such material failure is identified to cure such material failure. If the Project Awardee fails to take such an action within the [\*\*\*] period, then the Project Award may be terminated.

17.14 Notwithstanding the paragraphs in this Article, updates to the regulatory requirements must be incorporated into Project Awards and may be discussed by the Parties to each individual Project Award on a case-by-case basis.

#### **ARTICLE 18. GENERAL PROVISIONS**

**18.1 Consortium Members and the CMF**. The relationship of the CMF and its Members established by the Consortium Member Agreement is of an independent nature and nothing contained in this Agreement shall be construed to (a) give the CMF or any Consortium Member hereto the power to direct or control the day to day activities of the Consortium or another Consortium Member hereto, (b) constitute the Consortium or Consortium Members as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking, or (c) allow the Consortium or any of the Consortium Members hereto to create or assume any obligation on behalf of another Consortium Member hereto for any purpose whatsoever.

**18.2 Parties Bound**. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, and legal representatives. Nothing herein shall be construed to give any Project Awardee subawards rights as a Party to or third-Party beneficiary of this Agreement.

**18.3** Assignment. The Project Awardee may not transfer or assign this Agreement to any party without the Government's written consent. Requests for consideration must be submitted to the Government, through the CMF, at least [\*\*\*] prior to any proposed transfer or assignment.

**18.4** Flow-Down Requirements. The Project Awardee shall include all relevant Articles in this Agreement, suitably modified in all subawards. These Articles shall, in turn, be included in all other forms of lower tier agreements, regardless of tier. The Government will be a third party in interest for purposes of these flow-down Articles of (5) Funding Obligation and Payments; (6) Administration; (7) Proprietary Information; (8) Rights in Data; (9) Inventions; (10) Foreign Access to Technology; (11) Publication and Publicity; (12) Term of the Agreement and Termination; (13) Consortium Membership Terms and Project Awards; (14) Representations and Warranties; (15) Liability of the Parties; (16) Disputes; and (18) General Provisions in any agreement where flow-down of rights and obligations is required.

**18.5** Affiliates. The Parties hereto acknowledge that the Project Awardee's Affiliates may carry out certain activities required or permitted pursuant to this Agreement. The Parties hereby represent and warrant that this Agreement shall be binding on their Affiliates in accordance with this Agreement as if such Affiliates were Parties to this Agreement. In the event that any Party to this Agreement is acquired by another company, the technology and programs of the acquiring company in existence at the time of such transactions shall not be subject to this Agreement, however the provisions of this Agreement shall continue with respect to all business conducted by the successor organization in connection to this Agreement.

**18.6** Civil Rights Act. This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to the nondiscrimination in federally assisted programs.

**18.7** Anti-Bribery and Anti-Corruption. Each Party agrees to perform its obligations under this Agreement in accordance with the applicable antibribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Agreement, to terminate this Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article. **18.8 Reporting Matters Involving Fraud, Waste, and Abuse.** Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to 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 <u>Htips@os.dhhs.gov</u> 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

**18.9 Prohibition on Involvement with Terrorist Activities.** The Project Awardee acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 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 Project Awardee to ensure compliance with these Executive Orders and Laws. The Project Awardee shall ensure that any agreements entered into after the execution of this Agreement with an affiliate or subaward (regardless of tier) for any experimental, developmental, or research work that will be submitted for reimbursement under this Agreement are consistent with this Paragraph.

**18.10** Foreign Owned Influence. The Project Awardee will ensure that no foreign entities from the Government's prohibited sources list of embargoed and sanctioned countries, as defined by U.S. Departments of Treasury and Commerce, are utilized by the Project Awardee, or any of its Affiliates or subawards.

**18.11** Entire Agreement. Unless otherwise specifically provided, this Agreement embodies the entire understanding between the Parties, and any prior or contemporaneous representations, either oral or written, are superseded. No amendments or changes to this Agreement's terms shall be effective unless made in writing and signed by authorized representatives of the Parties as prescribed in Section 6.8.

18.12 Further Assurances. At any time or from time to time, the Project Awardee shall, at the request of the Government through the CMF:

18.12.1 Deliver to the CMF or the Government, such records, data, or other documents consistent with the provisions of this Agreement;

18.12.2 Execute, and deliver, or cause to be delivered, all such assignments, consents, documents, or further instruments of transfer or license; and

**18.12.3** Take or cause to be taken all such other actions, as the Government may reasonably deem necessary or desirable in order for the Government to obtain the full benefits of the OTA and the transactions contemplated hereby.

**18.13 Principal Investigator.** The Project Award shall identify a Principal Investigator for each Project Award. This individual shall be continuously responsible for the conduct of the Project Award. The Project Awardee, through the CMF, shall obtain the OTAO's approval to change the Principal Investigator or to continue the research work during a continuous period in excess of [\*\*\*] without the participation of an approved Principal Investigator. Each Project Award is based upon the Principal Investigator devoting a defined percentage of effort to the project over the term of the Project Award. The Project Awardee shall advise the OTAO, through the CMF, if the Principal Investigator will, or plans to, revise the level of effort estimated in the Project Proposal. A curriculum vitae shall be provided for professional associates added to the Project Award or substituted during the course of work.

**18.14** Notices. Any notice or other communication required or permitted under this Agreement shall be in writing and (a) personally delivered or (b) sent by electronic mail to the appropriate Party or Parties at the addresses as set forth herein, or at such other addresses as may be given from time to time in accordance with the terms of this notice provision. Any notice or other communication given by personal delivery or electronic mail shall be deemed given on the date personally or electronically delivered. Appropriate points of contact to provide notice are listed in Article 6.

**18.15** Non-Federal USG Personnel. The Project Awardee acknowledges and consents to the participation in this Agreement and subsequent Project Awards by non-federal Government personnel supporting this program (e.g., SME's). All non-federal USG personnel who participate in RRPV are strictly bound by appropriate non-disclosure requirements and comply with applicable law and regulation. By executing this Agreement, the Project Awardee consents to this participation throughout the Term of the Agreement.

**18.16** Severability. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

**18.17 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The Project Awardee shall receive a copy of this executed Agreement and modifications thereto with the CMF retaining the originals.

**18.18** Order of Precedence. In the event of any inconsistency between the terms of this Agreement and the terms of any Project Award made pursuant to this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Project Award and the applicable Statements of Work, drawings, and specifications then (2) this Agreement.

**18.19** Organizational Conflict of Interest (OCI). The Project Awardee will be expected to implement and maintain a comprehensive set of policies to address potential conflicts of interest, ethics, and disclosures to accomplish the work required by this Agreement and subsequent Project Awards. The Project Awardee shall notify the CMF of any real or potential Organization Conflicts of Interest throughout the Term of this Agreement.

# 18.20 Salary Rate Limitation.

Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date Government funding was initially obligated to the Project Award is an unallowable cost under this Agreement and shall be addressed in accordance with this paragraph.

For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Managing Entity pays for an individual's direct effort (costs). Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Managing Entity. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Government contract, order, or Other Transaction; it merely limits the portion of that salary that may be paid with Federal funds.

The salary rate limitation also applies to individuals under subawards except to the extent that that a subaward is awarded on a fixed-price basis without analysis of labor costs. If a Project Award is a multiple-year agreement, it may be subject to unilateral modification by CMF, only as directed by the OTAO, to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Project Award funding.

See the salaries and wages pay tables on the U.S. Office of Personnel Management ("OPM") Web site for Federal Executive Schedule salary levels that apply to the current period.

43

# SPECIFIC TERMS IN THIS EXHIBIT HAVE BEEN REDACTED BECAUSE SUCH TERMS ARE BOTH NOT MATERIAL AND ARE THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. THESE REDACTED TERMS HAVE BEEN MARKED IN THIS EXHIBIT WITH THREE ASTERISKS AS [\*\*\*].

001
RRPV-24-04-NGVx-003; Oral Mucosal Vaccine for SARS-CoV2 Protection
WS6UMD1QTBC9

PARTIES: Advanced Technology International (RRPV Consortium Management Firm or CMF) and Vaxart Biosciences Inc (Project Awardee)

This RRPV Project Award is issued under the authority of the RRPV Base Agreement No. 2024-606, and incorporates all the terms and conditions thereof.

NOW, THEREFORE, the Parties hereto agree as follows:

#### 1. Payment Method

The Payment Method for this Project Award is Firm Fixed Price and Expenditure-Based with Fixed Fee Milestone with a not to exceed ceiling.

#### 2. Term of the Project Award

The period of performance for this Project Award is from the effective date, which is the date of last signature, through [\*\*\*].

#### 3. Obligation

The CMF's liability to make payments to the Project Awardee is limited to only those funds obligated under this Project Award or by modification to the Project Award. The CMF may incrementally fund this Project Award.

#### 4. PROJECT AGREEMENT CEILING

The total estimated ceiling for this Project Awardee is  $\underline{S[***]}$  broken out as follows:

#### **Firm Fixed Price**

The total fixed amount for the services to be provided by the Project Awardee are as follows:

Fixed Amount (Milestone 2 Only) \$[\*\*\*]

#### Estimated Expenditure and Fixed Fee

The total estimated expenditure and fixed fee for the services to be provided by the Project Awardee are as follows:

	ESTIMATED EXPENDITURE
Estimated Expenditure	\$[***]
Fixed Fee	\$[***]
<b>Total Cost</b>	<b>\$[</b> ***]

The United States Government (USG) and Vaxart agree that the current award amount will be [\*\*\*]. Billable costs for the duration of the agreement will not exceed the total amount of [\*\*\*] as any additional effort would require additional funds from the USG. Additional funds can be requested and may be approved provided Vaxart has an acceptable technical justification. However, Vaxart acknowledges that any costs above an agreed upon contract ceiling amount of [\*\*\*], to include potential indirect rate adjustments, will be the sole responsibility of Vaxart.

# 5. Incremental Funding

The total amount of funding currently allotted to this Project Award and available for payment is  $\underline{S}[***]$  for those milestones marked as authorized within the Statement of Work's Milestone Payment schedule. Any work performed in excess thereof shall be at the Project Awardee's risk. The Project Awardee shall notify the CMF if at any time the Project Awardee has reason to believe that the costs accrued in the next [\*\*\*] will exceed [\*\*\*] ([\*\*\*]%) of the current total authorized funding. Such notice should specify the estimate of additional funds required, along with the associated remaining tasking and timeframe. The Project Awardee is not obligated to continue performance under this Project Award (including actions under the Termination clause of the RRPV Base Agreement) or otherwise incur costs in excess of the amount identified in this clause.

The USG shall provide initial funding for the Project Award on a firm fixed price basis at the time of award that will fund trial preparation activities (Milestone 2). When the USG and Vaxart have mutually determined that the trial shall further proceed, the USG shall provide additional funding on an expenditure-based basis during the period of performance of the Project Award to support Vaxart's performance of the requirements set forth in the Project Award. The USG shall provide such additional funding in incremental amounts based upon Vaxart's continued fulfillment of requirements of the Project Award commensurate with the payment terms established in the Project Award.

# 6. Milestone Payment Schedule

The Project Awardee shall segregate and track all Project Award costs separately and shall document the accomplishments of each milestone under each Project Award. Acceptance of milestones shall be contingent upon approval from the Government's Project Award Representative (PAR) detailed in the Technical and Administrative Representatives clause below. Payment for Milestone #2 will be paid in the amount indicated in the Milestone Payment Schedule (Attachment A). For all other work, the Project Awardee shall invoice on a monthly (or twice monthly, as allowed by Paragraph 18, Special Invoicing) basis based on actual incurred costs.

# 7. Payment of Fixed Fee

The fixed fee specified herein, subject to any adjustments required by other provisions of this Project Award, will be paid in installments at the time of each provisional payment on account of the allowable costs. In the event the work cannot be completed within the estimated cost, the CMF may increase the estimated cost without increasing the fixed fee.

# 8. Statement of Work

The Statement of Work, Attachment A, provides a detailed description of the work and reports to be accomplished and delivered. All changes to Attachment A must be incorporated via written modification to this Project Award.

# 9. Technical and Administrative Representatives

The following technical and contractual representatives of the Parties are hereby designated for this Project Award. Either party may change their designated representatives by written notification to the other, except that changes to the Principal Investigator require Government approval as described in the RRPV Base Agreement.

# **RRPV** Consortium Management Firm Representative:

[\*\*\*] Advanced Technology International 315 Sigma Drive Summerville, SC 29486 Email: [\*\*\*] Phone: [\*\*\*]

# Project Award Representative (PAR):

[\*\*\*] [\*\*\*] [\*\*\*] Email: [\*\*\*] Phone: [\*\*\*]

#### **RRPV Project Awardee's Representatives:**

<b>Contractual Representative:</b>	Principal Investigator:
[***]	[***]
170 Harbor Way, Suite 300 South	170 Harbor Way, Suite 300 South
San Francisco, CA 94080	San Francisco, CA 94080
Email: [***]	Email: [***]
Phone: [***]	Phone: [***]

#### 10. Marking of Deliverables

Any Data delivered under this Project Award by the Awardee shall be marked with a suitable notice or legend.

## 11. Attachments

Attachments listed herein are hereby incorporated by reference into this RRPV Project Award.

- A. Statement of Work, "Oral Mucosal Vaccine for SARS-CoV2 Protection" and Milestone Payment Schedule
- B. Key Tenets

#### 12. Government Furnished Property

At this time, Government Furnished Property is not provided for use under this Project Award.

#### 13. Publication and Publicity

In accordance with Article 11 of the RRPV Base Agreement, any written announcements, press releases, or similar publicity with respect to the execution of this Project Award shall be agreed upon by the RRPV Consortium Manager, the Government, and the affected Consortium Member in advance of such Announcement. Refer to Article 11 of the RRPV Base Agreement for further information.

# 14. Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort will be delivered to the Government with Unlimited Rights in technical data.

See below for the data rights assertions that apply to Vaxart's proposal: [\*\*\*].

# 15. Special Research Considerations

Human Subjects – Offeror is to conduct all Human Subject Trials in accordance with Article 17.1 of the RRPV Base Agreement, entitled Protection of Human Subjects.

Human Specimen Material - Offeror is to conduct all trials pertaining to Human Specimen Material in accordance with Article 17.2 of the RRPV Base Agreement, entitled Human Materials (Assurance of OHRP Compliance).

Requested Use of Government Resources, Property, Labs, etc. – Vaxart notes that it will use BARDA/Government core services if available and applicable, to include serum testing of subjects in the Phase2B trial.

# 16. Key Tenants

The Project Awardee agrees that the Phase 2b clinical trial will be conducting in alignment with the Attachment B, "Key Tenants".

# 17. Fair Pricing

If, and for so long as, the product developed from Attachment A, SOW, is commercialized in the United States, in consideration of the Government's investment, the Government and the Project Awardee intend for the Project Awardee to commercialize the product in accordance with the following principles:

If the Project Awardee commercializes a product in the United States for prevention of SARS-CoV-2 comprised solely of a COVID-19 vaccine for which BARDA invests \$[\*\*\*] or more (in combination with this Agreement and in-kind support), then, subject to applicable law, the list price (at wholesale acquisition cost) for commercial sales of such product in the United States following full licensure of the product, shall be substantially equivalent to or less than the approved price for commercial sales in High Income Countries outside of the United States; provided that such sales are comparable sales taking place within the same time period. The Project Awardee is permitted to take into account all relevant factors in determining whether sales are comparable sales, including volume commitments, timing of purchase and supply, the terms and conditions of purchase and supply, market conditions and epidemiology of SARS-CoV-2. Notwithstanding the foregoing, in the event any other manufacturer enters into an agreement with the Government providing for a similar investment from the Government for its anti-SARS-CoV-2 product and such agreement does not contain a substantially similar (or more onerous) requirement for commercial sales of its product, then the Government shall notify the Project Awardee of such other agreement and this clause shall cease to apply and shall be of no further force and effect, effective upon the execution of such other agreement. For purposes of this provision, High Income Countries shall mean Canada, France, Germany, Italy, Japan, Poland, Spain, United Kingdom, Australia, Chile, Saudi Arabia, South Korea and Taiwan, which are as of this countries that. of the date award of Contract. are World Bank high income countries (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519) with populations greater than 20,000,000. The parties acknowledge that, over time, the foregoing criteria may result in a different list of High Income Countries. In any such case, the parties shall discuss and, upon mutual agreement, may change the countries included in the definition of High Income Countries.

#### 18. Special Invoicing

The Project Awardee may invoice ATI twice monthly up to six months after the provision of additional funding.

#### 19. Entire Agreement

This Project Award and the RRPV Base Agreement under which it is issued constitute the entire understanding and agreement between the parties with respect to the subject matter hereof.

Except as provided herein, all Terms and Conditions of the RRPV Base Agreement and its modifications remain unchanged and in full force and effect.

The Project Awardee is required to sign this document and return to Advanced Technology International to finalize this action.

Vaxart Biosciences Inc	Advanced Technology International
By: /s/[***]	By: /s/[***]
Name:[***]	Name:[***]
Title: [***]	Title: [***]
Date: 06/13/2024	Date: 06/13/2024

#### Attachment A Statement of Work

RPP#: 24-04-NGVx Project Identifier: RRPV24-04-NGVx-003 Project Title: Oral Mucosal Vaccine for SARS-CoV2 Protection RRPV Member Organization Name: Vaxart, Inc. Primary Place of Performance: 170 Harbor Way Suite 300 South San Francisco, CA 94080

#### 1.0 Introduction / Background

Vaxart Biosciences, Inc. ("Vaxart") is a development-stage biotechnology company with a pipeline of biologics across multiple therapeutic classes. Vaxart's platform technology makes it possible to administer vaccines in a thermo-stable tablet form, allowing for rapid deployment in mass vaccination programs, without the large logistical requirements and significant medical waste of conventional frozen vaccines. The vaccines are designed to trigger strong mucosal IgA and T-cell responses, as well as systemic antibodies. The technology is based on a non-replicating adenoviral vector with a molecular adjuvant that enhances antigen immune responses in the human intestine, the site of tablet release.

This project will compare Vaxart's updated COVID-19 vaccine candidate that incorporates the XBB variant sequence (VXA-CoV2-XBB) to an mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events.

# 2.0 Scope / Project Objective

The objective of this project is to complete a phase 2b clinical trial, comparing Vaxart's XBB-strain Covid-19 candidate vaccine (VXA-CoV2-3.1) to an approved mRNA XBB-strain COVID-19 vaccine. Vaxart has divided the program into two phases. Phase 1 includes the execution of a Phase 2b clinical trial comparing Vaxart's XBB vaccine candidate and an mRNA vaccine comparator for efficacy, immune induction, and safety. Phase 2 includes further analysis to characterize the durability of the immune responses initially characterized by tracking mucosal samples from vaccinated individuals for a year, and assessing cross-reactivity over time.

# Phase 1: Clinical Trial Execution for Phase 2b Clinical Trial

Vaxart shall execute a Phase 2b clinical trial in approximately 10,000 individuals comparing Vaxart's XBB vaccine candidate and an mRNA vaccine comparator for efficacy, immune induction, and safety. Specifically, Vaxart will:

- Determine the relative efficacy of the Vaxart's XBB COVID-19 vaccine candidate compared to the currently recommended booster dose for the prevention of symptomatic, PCR confirmed COVID-19
- Assess the safety and tolerability of Vaxart's XBB COVID-19 vaccine candidate
- Evaluate the humoral immunogenicity of Vaxart's XBB COVID-19 vaccine candidate

- Evaluate cellular immunogenicity of Vaxart's XBB COVID-19 vaccine candidate
- Evaluate the mucosal immune responses of Vaxart's XBB COVID-19 vaccine candidate
- Determine the durability of Vaxart's XBB COVID-19 vaccine candidate compared to the currently recommended booster dose for the prevention of symptomatic, PCR confirmed COVID-19
- Determine the relative efficacy of Vaxart's XBB COVID-19 vaccine candidate compared to the currently recommended booster dose for the prevention of asymptomatic, PCR confirmed COVID-19
- Determine the relative efficacy of Vaxart's XBB COVID-19 vaccine candidate compared to the currently recommended booster dose for the prevention of severe PCR confirmed COVID-19
- Efficacy subanalyses and Correlates of Protection analyses

#### **PHASE 2: Additional Characterization of Immune Responses**

Vaxart will expand on the durability of the immune responses initially characterized by tracking mucosal samples from vaccinated individuals for a year, and assessing cross-reactivity over time. Vaxart will characterize the B cell memory populations to understand how prior vaccination and infection exposure shapes the B cell repertoire. B cells elicited by vaccination will be cloned and characterized for the ability to produce cross-reactive antibodies to SARS-CoV-2 variants and other coronaviruses. Specifically, Vaxart will:

- To determine mucosal memory cell responses.
- Clone antibodies that bind to SARS-COV-2 and other coronaviruses induced by the two vaccines and evaluate cloned antibodies for cross-reactivity and affinity.

#### **3.0 Requirements**

#### Phase 1: Clinical Trial Execution for Phase 2b Clinical Trial (WBS 1)

Vaxart shall execute a Phase 2b clinical trial in approximately 10,000 individuals comparing Vaxart's XBB vaccine candidate and an mRNA vaccine comparator for efficacy, immune induction, and safety.

#### Task Area #1 – Program Management (WBS 1.1)

Vaxart's program management activities will follow procedures described in the Project Management Institute Project Management Book of Knowledge ("PMBOK©"). These activities align with requirements established by the BARDA. Consistent with those requirements, the primary objective to program management is to ensure that the activities and outputs that result are delivered on time, within scope and budget, and meet applicable quality standards.

Vaxart will undertake all of the required program management activities necessary to complete Phase 1 and Phase 2 of this project.

• The Principal Investigator (PI) for the project will work with Vaxart's program management team and will be responsible for the technical and contractual deliverables of the program. The Vaxart Program Team (VPT), which includes representatives from BARDA, will conduct weekly progress meetings through the period of performance. In addition, the VPT will conduct monthly performance reviews in accordance with the USG contract/communication plan requirements. (WBS 1.1.1)

- The Program Manager and Principal Investigator will have responsibility for deliverables from the Subcontractors. Each of the Subcontractors will be managed day-to-day by the program management team and the appropriate Vaxart Technical Lead. A Subcontract Management Plan will be submitted to BARDA within [\*\*\*] of award in accordance with the ASPR Business Toolkit. The Project Manager shall have the responsibility of reporting to BARDA any material subcontract issues that could impact the timing and quality of the program deliverables. (WBS 1.1.2)
- The PI and program management team are the leads and with the entire Project Teams input, have responsibility for Risk Identification and Mitigation. Included in this section is the generation of a Risk Management Plan (RMP) and Security Plan within [\*\*\*] of contract award to be approved by BARDA. While monitoring risk will be on-going through the program and a topic for discussion in the telecons/meeting with BARDA, the Risk Register and associated documentation from the RMP will be updated no less than monthly and included in the Monthly Technical Progress Report to BARDA. (WBS 1.1.3)
- Vaxart will perform and report on program performance as directed by BARDA. Included in this activity is program cost accounting and invoicing. (WBS 1.1.4)
- Vaxart will maintain a quality management system to ensure that all activities carried out in accordance with the standards applicable to medical devices and and pharmaceutical activities for clinical studies. Vaxart will use a Quality Assurance Surveillance Plan (QASP) with the key subcontractors in the program. The QASP, an element of Quality Management, will describe the methods used to monitor subcontractor performance, establish documentation/reporting requirements, and Vaxart's interactions with the subcontractor. The QASP is a means for evaluating whether the subcontractor is meeting the performance standards/quality levels identified in the project work plan and the contractor's quality control plan, and to ensure that the deliverables meet Vaxart's commitment to BARDA in the program. (WBS 1.1.5)
- As part of Vaxart's overall program management activities including subcontractor, risk and quality management activities will travel to sites as necessary to oversee the project. (WBS 1.1.6)
- Specific deliverables for WBS 1.1 subtasks are delineated in Section 4.0 Deliverables

# Task Area #2 – Analytical (WBS 1.2)

Vaxart's analytical activities encompasses those activities to be performed to collect, test, and report on samples taken from subjects in the Phase 2b trial.

Vaxart will provide serum and PBMC samples to BARDA for analysis at a central CRO (WBS 1.2.1).

• Serum samples will be taken from all subjects according to the schedule detailed in the synopsis. Samples will be shipped from the clinical sites to a central repository. Samples from the central repository will be shipped to the CRO contracted by BARDA to measure serum antibody responses. (WBS1.2.1.1)

PBMC samples will be taken from greater than 1,000 subjects, according to the timeline plan detailed in the protocol. These will be processed using the BARDA method of PBMC isolation. Samples will be shipped with a liquid N2 dry shipper to a central repository and provided to the CRO contracted by BARDA to measure to measure T cell responses to SARS-Cov-2 S protein. Additionally, 200 subjects (0 and 7 days post vaccination) enrolled in the study will be collected and processed using the Vaxart method for isolation. These samples will be used for assessing mucosal memory and mucosal homing markers in Phase 2.

BARDA and Vaxart will characterize immune responses at mucosal surfaces according to the schedule detailed in the synopsis. (WBS 1.2.2)

- [\*\*\*]
- [\*\*\*]

Vaxart will determine the efficacy of Vaxart's XBB vaccine candidate and the mRNA comparator vaccine against symptomatic and asymptomatic COVID-19 infection. (WBS 1.2.3)

- Subjects that report covid infection will be asked to provide nasal swab samples every day for 20 days to determine duration of shedding. Any subject testing positive for symptomatic infection will be sequenced from the first positive sample to determine the breakthrough strain. (WBS 1.2.3.1)
- All subjects enrolled will be provided kits to swab weekly for SARS-COv-2 infection. Samples will be returned to a central lab by mail. Samples will be tested for asymptomatic infection. The central lab will compile the data and at the end of the study, the two different vaccines will be compared for relative protection against infection. (WBS 1.2.3.2)

Vaxart will conduct an analysis to identify immune correlates of protection and assess the relative importance of the correlates. (WBS 1.2.4)

- Statistician with significant immune correlate analysis will develop an analysis plan to examine the relative importance of the correlates. (WBS 1.2.4.1)
- At the end of the study, the data will be compiled on the various immune parameters, and correlates of protection analyzed against both symptomatic and asymptomatic infection. If more analysis of secondary endpoints is needed, additional samples may be added in the analysis. (WBS 1.2.4.2)
- Vaxart will employ machine learning to refine the understanding risk factors and

immune correlates are steps. (WBS 1.2.4.3)

Vaxart will perform all of the required safety laboratory screening to provide a study subjects baseline of these parameters as well as monitoring during the study. (WBS 1.2.5)

- CBC, Coagulation and Chem 7 testing per study protocol will be conducted (WBS 1.2.5.1)
- Urine and pregnancy testing per study protocol will be conducted (WBS 1.2.5.2)
- Repeat testing as required per study protocol will be conducted (WBS 1.2.5.3)

# Task Area #3 – Clinical (WBS 1.3)

Vaxart's clinical efforts encompasses all activities and tasks to be performed in the execution of the phase 2b clinical trial from study initiation to delivery of the CSR.

Vaxart will complete all of the activities required for clinical trial site start-up. (WBS 1.3.1)

- A comprehensive set of documents that provide critical information about the study and ensure regulatory compliance will be prepared. These documents include the study protocol, informed consent forms, investigator's brochure, case report forms, institutional review board (IRB) approvals, clinical trial agreements, financial disclosure forms, source documents, adverse event reporting forms, and monitoring plans. (WBS 1.3.1.1)
- Site contract negotiation will be completed. This will include finalization of details including site payment, indemnification, intellectual property rights, publication rights, and data ownership. (WBS 1.3.1.2)
- Site budget negotiation will be completed. This will include finalization of the budget for activities such as participant recruitment, study visits, data collection, site personnel costs, and any additional expenses related to the trial. (WBS 1.3.1.3)
- Regulatory binders will be compiled and sent to clinical sites participating in the trial. These include study protocol, investigator's brochure, informed consent forms, IRB approvals, financial disclosure forms, and other regulatory submissions. (WBS 1.3.1.4)
- Site initiation visits (SIVs) will be conducted to ensure that the research site is ready to initiate the study. During SIVs, representatives from the sponsor or contract research organization (CRO) will meet with the site staff to review study procedures, data collection methods, and regulatory requirements. (WBS 1.3.1.5)
- Investigational product will be shipped to investigative sites. Based on the site's enrollment needs, the sponsor or contract research organization (CRO) will generate drug shipment orders. These orders specify the quantity of investigational product required. The orders are then processed through an Interactive Web Response System (IWRS), which helps manage and track drug supplies. The IWRS assigns unique randomization numbers and treatment codes to participants, ensuring blinded allocation. The drug is then packaged, labeled, and shipped to the investigative sites following regulatory and logistical requirements. The site receives the shipment, confirms its integrity, and maintains appropriate storage and accountability records for the investigational product throughout the trial. (WBS 1.3.1.6)

• All other required laboratory and essential supplies will be shipped to investigative sites. These supplies can include items such as laboratory kits, specimen collection materials, study-specific laboratory tests, shipping containers, and labeling materials. The CRO ensures the timely provision of these supplies, often in accordance with the study protocol and specific requirements outlined by the sponsor. (WBS 1.3.1.7)

Vaxart will enroll eligible volunteers and ensure that they are randomized and assigned to a treatment group. (WBS 1.3.2)

- Potential participants will undergo pre-screening including an initial evaluation to determine their eligibility (WBS 1.3.2.1)
- Various efforts to identify and enroll eligible participants will be undertaken. These may include developing targeted recruitment strategies and advertisements to reach the intended patient population. Patient recruitment vendors may be engaged to assist with recruitment campaigns, utilizing various channels such as online platforms, social media, print media, and community outreach. (WBS 1.3.2.2)
- If necessary, trial volunteer's past medical or surgical history to confirm eligibility into the study will be requested. (WBS 1.3.2.3)
- Patient informed consent will be obtained. (WBS 1.3.2.4)
- Screening visits will be performed. (WBS 1.3.2.5)
- Sites and investigators will verify patient eligibility for clinical trials by conducting a thorough evaluation. (WBS 1.3.2.6)
- Patients will be randomized using the Interactive Web Response System (IWRS) which will assign unique identification numbers and determines treatment allocation based on the randomization schedule. (WBS 1.3.2.7)

Vaxart will complete all the activities required to ensure clinical conduct of the trial. (WBS 1.3.3)

- Study visits will be performed as per the clinical trial protocol. Site visits will involve scheduling the visit, preparing study materials, administering assessments, and addressing study subjects' questions. Investigators oversee the visit, conducting physical examinations, reviewing data, making treatment decisions, and ensuring protocol adherence. (WBS 1.3.3.1)
- Safety monitoring will be conducted throughout as per the clinical trial protocol. The safety monitoring process during study visits will include AE reporting, safety assessments, protocol adherence, and proactive pharmacovigilance measures. Study coordinators will systematically collect information on adverse events (AEs) or any untoward medical occurrences experienced by participants during or after the study visit. AEs can range from mild side effects to serious adverse reactions. These events will be documented, assessed for severity and causality, and reported to the appropriate regulatory authorities and the trial sponsor as per the established reporting timelines and guidelines. (WBS 1.3.3.2)
- Biosamples will be collected as per the clinical trial protocol. Trained healthcare professionals will conduct phlebotomy to draw blood, and participants provide urine samples as required. After collection, the biosamples will be processed, labelled and

stored until shipping. Biosamples will be transported to designated laboratories using specialized containers that maintain required temperatures. The collection of PBMC (Peripheral Blood Mononuclear Cell) samples involves a specialized process to obtain these immune cells from the blood for research purposes. Trained healthcare professionals will perform venipuncture to draw blood from the participant. The sample will be processed, labeled and then cryopreserved or immediately used for various immune-based assays or research investigations. (WBS 1.3.3.3)

• An interim analysis will be conducted. To perform the analysis, data cut-offs will be established, specifying the point at which data is frozen and analyzed to minimize bias. Source data verification will be conducted. Biostatistical analysis will then be applied to evaluate treatment outcomes, safety profiles, and efficacy trends, providing insight into participant responses and potential risks. (WBS 1.3.3.4)

Vaxart will oversee routine monitoring visits during the conduct of the clinical trial to ensure compliance with the study protocol, regulatory requirements, and Good Clinical Practice (GCP) guidelines. (WBA 1.3.4)

- Clinical Research Associates (CRAs) will travel as necessary to conduct routine monitoring visits. During these visits, CRAs review study data, source documents, and participant records, ensuring compliance with protocols and regulations. Additionally, they will provide support and training to site personnel, address any issues or queries, and ensure adherence to Good Clinical Practice (GCP) standards. (WBS 1.3.4.1)
- Clinical Research Associates (CRAs) will conduct source data verification (SDV) to review and confirm the accuracy of data recorded in source documents against the study database. CRAs will cross-reference source documents like medical records and lab reports with case report forms (CRFs) to identify discrepancies or errors. Data queries are raised to resolve any issues, ensuring data accuracy and compliance with the study protocol and regulatory standards. CRAs also assess participant safety and provide guidance to site personnel, ultimately upholding data quality and the integrity of the clinical trial while safeguarding participant well-being. (WBS 1.3.4.2)
- Meetings with investigators will be conducted as necessary to ensure planning, coordination and to discuss essential trial-related topics. The sponsor
  or CRO schedules the meetings and prepares an agenda, covering aspects such as trial progress, protocol compliance, safety updates, data quality,
  participant retention, and investigational product management. During the meetings, investigators provide updates on recruitment, safety data, and
  protocol adherence while addressing challenges and proposing strategies for participant retention. (WBS 1.3.4.3)
- Monitoring or trip reports will be prepared by Clinical Research Associates (CRAs) after conducting routine monitoring visits to research sites. These reports will include a detailed account of the visit, including site activities, data verification, source document review, and any findings or discrepancies identified. They will document participant safety assessments, compliance with the study protocol and regulatory guidelines, and any issues or concerns raised during the visit. (WBS 1.3.4.4)
- Ongoing site supplies management will be performed during the clinical trial. These activities involve systematic inventory monitoring, timely replenishment, and distribution of essential materials and investigational products to research sites. (WBS 1.3.4.5)

Vaxart will undertake a comprehensive clinical data management program that will include the collection, validation, and analysis of participant data to ensure its accuracy, completeness, and confidentiality. (WBS 1.3.5)

- Query resolution activities will include identification and rectification of discrepancies or missing information in study data. Data managers or clinical research associates (CRAs) review the data for inconsistencies and raise queries to the site personnel or data entry personnel to seek clarification or corrections. These queries are documented and communicated to the site, and the site responds with the necessary information to resolve the query. (WBS 1.3.5.1)
- A statistical analysis plan (SAP) will be developed and finalized prior to database unblinding. The effort will begin with defining the trial's primary and secondary objectives, study endpoints, and the statistical methods to be employed. The SAP outlines the data handling procedures, data transformations, and imputation methods for missing data. Additionally, it specifies the statistical tests and models to be used, sample size calculations, and adjustments for multiple comparisons. The SAP also addresses subgroup analyses, sensitivity analyses, and any predefined interim analysis if applicable. (WBS 1.3.5.2)
- Programming specifications for biostatistical analysis will be developed. This effort involves collaboration between biostatisticians and programmers and will result in final programming specifications are established, ensuring robust and reliable data analysis for the clinical trial. (WBS 1.3.5.3)
- Method validation will be completed to ensure the statistical methods used for data analysis are appropriate, accurate, and reliable. (WBS 1.3.5.4)
- PI attestation will be completed. During this process, the PI reviews and confirms the appropriateness and accuracy of the statistical methods used for data analysis. The PI then provides a formal attestation, verifying that the statistical methods are aligned with the study objectives, are appropriate for the data collected, and comply with regulatory requirements. (WBS 1.3.5.5)
- Tables, figures and listings generation will be generated. Once approved, the TFLs are included in the clinical study report (CSR) and submitted to regulatory authorities as part of the trial documentation, providing a comprehensive representation of the trial's results and data. (WBS 1.3.5.6)
- A topline data report will be prepared. This report will summarize and presents key findings and results from a clinical trial in a concise and highlevel manner. This report focuses on the primary objectives and key secondary endpoints of the trial, providing a snapshot of the trial's outcomes without delving into detailed analyses or subgroup findings. (WBS 1.3.5.7)

Vaxart will complete database lock in which includes the process of finalizing and freezing the study database to prevent further modifications to the data. (WBS 1.3.6)

- Soft lock will be initiated with the temporary suspension of data entry or editing capabilities in the study database, allowing specific authorized personnel to address critical data-related issues or queries. (WBS 1.3.6.1)
- Hard lock will be completed including the final and permanent closure of the study database after all data entry, editing, and review processes are completed. (WBS 1.3.6.2)

### Task Area #4 - Regulatory (WBS 1.4)

Vaxart will prepare FDA submissions, keep track of relevant legislation, advise on legal and scientific requirements and limitations, and provide regulatory support for the evaluation of data for this study.

- In compliance with FDA regulations, Vaxart will prepare and submit for this study Annual Reports, Certificate of Analysis, Protocol(s), and pharmacovigilance documents. These submissions will be submitted under US FDA IND 27602 VXA-CoV2-1.1-S, an oral SARS-CoV-2 vaccine E1-/E3-deleted replication defective recombinant adenovirus 5 with dsRNA adjuvant. (WBS 1.4.1)
- In compliance with FDA regulations, Vaxart will submit all required annual regulatory submissions within [\*\*\*] of our approved IND 27602. This report will contain new information collected over the past year pertaining to the safety, effectiveness, and labeling of our vaccine in this study. (WBS 1.4.2)
- Vaxart will notify the appropriate regulatory authorities regarding the safety of the vaccine. The safety of the vaccine will be evaluated through the reporting of solicited symptoms of reactogenicity for one (1) week following each study drug administration. Because the vaccine contains a double stranded RNA (dsRNA) adjuvant, MAAEs will be collected through one (1) year post last dose to address the theoretical potential for induction of autoimmune or auto-inflammatory diseases, as is standard for this class of vaccines. Subjects will also be monitored for exposure to SARS-CoV2 and symptomatic SARS-CoV2 infection (COVID-19). (WBS 1.4.3)

### **PHASE 2: Additional Characterization of Immune Responses**

Vaxart will expand on the durability of the immune responses initially characterized by tracking mucosal samples from vaccinated individuals for a year, and assessing cross-reactivity over time.

### Task Area #1 – Analytical (WBS 1.1)

Vaxart will conduct extended immune analysis of the vaccines in human subjects.

- As part of phase 1, additional samples in a small subpopulation of subjects at 3, 6 and 12 months will have been collected. The mucosal (and serum) immune responses of these samples will be measured in order to examine durability, particularly against multiple different coronaviruses as well as new SARS-CoV-2 variants. (WBS 1.1.1)
- Vaxart will use flow cytometry to determine the changes to the memory pool in the subpopulation of patients using the samples collected in phase 1. B cell clones will be sequenced from the memory pools and used to characterize the diversity of the response based on vaccine and infection history. (WBS 1.1.2)
- Vaxart will analyze antibodies from the task in 1.1.2 and their diversity tested for binding and neutralizing various SARS-COV-2 variants and other coronaviruses. (WBS 1.1.3)

## Task Area #2 - Clinical (WBS 1.2)

Vaxart will complete all required close-out procedures for the clinical trial.

- Vaxart will complete all required reports including an amended CSR that the discusses the analysis in option 2 will be completed; a full final report describing all the Phase 2 analyses, any additional reports to BARDA and regulatory agencies on the conduct of the trial as required. (WBS 1.2.1)
- Vaxart will complete site closeout and unused vaccine will be returned or destroyed; and documents will be properly shipped and stored. (WBS 1.2.2)
- Vaxart will undertake essential document reconciliation in which records from the trial will be verified by medical monitors and database experts. Discrepancies will be resolved before finalizing the data. (WBS 1.2.3)
- Vaxart will employ an Electronic Trial Master File (eTMF) which leverages software and server technology to guide and assist the setup, collection, storage, tracking and archival of essential clinical study documents. (WBS 1.2.4)
- Vaxart will prepare an amended clinical study report which will include the additional analysis conducted under Phase 2. (WBS 1.2.5)

### 4.0 Deliverables

1. Meetings

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.1	Post Award Teleconference	[***]	[***]
1.2	Kickoff Meeting	[***]	[***]
1.3	Weekly Teleconference	[***]	[***]
1.4	Technical, Subgroup, Ad Hoc Teleconference(s)	[***]	[***]
1.5	Periodic Review Meetings	[***]	[***]
1.6	FDA Meetings and Interactions	[***]	[***]
1.7	Daily check-in with BARDA in the event of a PHE	[***]	[***]

## 2. Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.1	Project Management Plan (PMP)	[***]	[***]
2.4	Gantt Chart/Timeline of the project	[***]	[***]
2.5	Communication Plan	[***]	[***]
2.6	Performer Locations	[***]	[***]
2.7	Pandemic/Public Health Emergency Facility and Operational Management Plan	· [***]	[***]
2.8	Request for Information (RFI) Responses	[***]	[***]
2.9	Monthly & Annual Technical Progress Reports/Annual Meeting	[***]	[***]
2.10	Draft and Final Technical Progress Report	[***]	[***]

## 3. Physical Inventory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
3.1	Draft and Final Nonclinical Study Report(s)	[***]	[***]
3.2	Nonclinical Study Protocols	[***]	[***]
3.3	Nonclinical Study Final Data Submission Package	[***]	[***]

## 4. Technical Reporting: Clinical Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1	Clinical Trial Protocols	[***]	[***]
4.2	Clinical Trial Documentation <sup>1</sup>	[***]	[***]
4.3	ClinicalTrials.Gov Posting and Results Reporting	[***]	[***]
4.4	Draft and Final Clinical Study Report(s)	[***]	[***]
4.5	Project-Specific First Site Activated for First Subject First Visit	[***]	[***]
4.6	Clinical Report During Active Enrollment Periods <sup>2</sup>	[***]	[***]
4.7	Access to Electronic Systems Used in Trial Conduct	[***]	[***]
4.8	Blinded Safety Reports, Medical Data Listing, CIOMS Report, Pharmacovigilance Database Listing	[***]	[***]
4.9	Specimen Collection for Future Use	[***]	[***]
4.10	Clinical Trial Final Study Package	[***]	[***]
4.11	Data Exchange Package(s) Submitted to Regulatory Agency(s)	[***]	[***]
4.12 4.13	Clinical Trial Datasets Additional Data Package(s)	[***] [***]	[***] [***]

# 5. Technical Reporting: Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.1	Quality Management Plan (QMP)	[***]	[***]
5.2	BARDA Audit	[***]	[***]
5.3	FDA Inspections/Site visits	[***]	[***]
5.4	Quality Assurance Audits and SubPerformer Monitoring Visits	[***]	[***]
5.5	Risk Management Plan (RMP)	[***]	[***]
5.6	Integrated Master Schedule (IMS)	[***]	[***]
5.7	Deviation Notification and Mitigation Strategy	[***]	[***]
5.8	Incident Report	[***]	[***]

## 6. Advanced R&D Products

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
6.1	Technical Documents	[***]	[***]
6.2	Publications	[***]	[***]
6.3	Performer Clinical Publication Timeline and USG Right to Publish Data	[***]	[***]
6.4	Performer Nonclinical Publication Timeline and USG Right to Publish Data	[***]	[***]

# 7. Regulatory Deliverables

#	Deliverable	Deliverable Description	<b>Reporting Procedures and Due Dates</b>
7.1	Regulatory Strategy/Plan	[***]	[***]
7.2	FDA Correspondence	[***]	[***]
7.3	FDA Submissions	[***]	[***]

MS #	Task #	Description	Due Date	<b>Government Funds</b>	Authorized
		PHASE 1	Edudo 2		
	1.1	Project Management	[***]	<b>65</b> 4442	
1	1.1	Project Kick Off	[***]	\$[***]	
2		CRO Initiation. Subcontract Execution:	[***]	\$[***]	
2	1 1	[***]	L T T T T T	ው ር ጥ ጥ ጥ ጋ	
3	1.1	PM Plans	[***]	\$[***]	
4	1.1.1	Weekly Meetings - 118 total	[***]	\$[***]	
5	1.1.1	(\$[***] ea) Weekly Meetings - 2 total (\$[***] ea)	[***]	\$[***]	
6		PM Meetings at Vaxart	[***]	\$[***]	•
7		PM Meetings at Vaxart	[***]	\$[***]	
8		PM Meetings at Vaxart	[***]	\$[***]	
9		PM Meetings at Vaxart	[***]	\$[***]	
10		PM Meetings at Vaxart	[***]	\$[***]	
10		PM Meetings at Vaxart	[***]	\$[***]	
12	1.1.4	Monthly Cost Accounting/Invoicing 36-Months (\$[***] ea)	[***]	\$[***]	
13	1.1.1	Monthly Technical & Business Reports	[***]		
	1.1.1	Analytical			
	1.2.1	Serum & T Cells			
14	1.2.1	Start Up Meeting	[***]	\$[***]	
14		Log Samples	[***]	\$[***]	
16		Complete Sample Shipment	[***]	\$[***]	
17		Results Tabulated & Sent to Vaxart	[***]	\$[***]	
. /	1.2.2	Mucosal Analysis		Ψ[ ]	
18	1.2.2	Start Up	[***]	\$[***]	
18.1		Initial Start Up	[***]	\$[***]	Y
19		Order & Receive Materials	[***]	\$[***]	1
20		Controls & Qualification Complete	[***]	\$[***]	
20		Complete Nasal Analysis	[***]	\$[***]	
22		Complete Vasar Anarysis Complete Saliva analysis	[***]	\$[***]	
23		Complete additional analysis	[***]	\$[***]	
23	1.2.3	Infection & Efficacy		φ[ ]	
24	1.2.5	Start Up	[***]	\$[***]	
25		Lab Kit Replenishment	[***]	\$[***]	
26		Site to Central Lab Shipment	[***]	\$[***]	
27		Central Lab: 3 shipments / 6 months	[***]	\$[***]	
28		Statistical Analysis	[***]	\$[***]	
29		Analysis Complete	[***]	\$[***]	
		Phase 2b Relative Efficacy &	[***]	Ψ[ ]	
30	1.2.4	Infectious Report			
2.1	1.2.4	Correlates	[ ቍ ቍ ኯ ]	da Patricia da	
31		Machine Learning & Programming	[***]	\$[***]	
32		Statistical Analysis	[***]	\$[***]	
33		Verification / Analysis Complete	[***]	\$[***]	
34	12	Correlates of Protection Report	[***]		
	1.3	Clinical	54.4.43		
2.5	1.3.1	Site Start Up	[***]	As F at. 1. 1.	
35		Essential Documents Complete	[***]	\$[***]	17
36		Site Contracts Complete	[***]	\$[***]	Y
37		Regulatory Binders Complete	[***]	\$[***]	Y
38		Site Initiation Visits	[***]	\$[***] 0[***]	
39 40		IP Shipments to Sites	[***]	\$[***]	
40		Lab & Other Supplies to Sites	[***]	\$[***]	
41	1.2.2	Study Meetings/Training	[***]	\$[***]	
40	1.3.2	Enrollment	LAAAJ		
42		Pre-screening	[***]	\$[***]	
43		Screening	[***]	\$[***]	
44		Randomization	[***]	\$[***]	

	1.3.3	Clinical Conduct			
45		1st Person In	[***]	-	
46		Biosample Collection	[***]	\$[***]	
47		Interim Analysis	[***]	\$[***]	
48		Source Data Verification	[***]	\$[***]	
49		Sites Supplies Management	[***]	\$[***]	
50		Last Person Dosed	[***]	\$[***]	
51		Conclusion of Follow Up	[***]	\$[***]	
52		Unblinded Monitoring	[***]	\$[***]	
	1.3.4	Site Monitoring			
53		Routine Monitoring Visit - 2-3 Visits Per Site (360 visits)			
54		Routine Monitoring Visits, Quarter 1	[***]	\$[***]	
55		Routine Monitoring Visits, Quarter 2	[***]	\$[***]	
56		Routine Monitoring Visits, Quarter 3	[***]	\$[***] #[***]	
57 58		Routine Monitoring Visits, Quarter 4	[***]	\$[***] \$[***]	
58 59		Routine Monitoring Visits, Quarter 5           Routine Monitoring Visits, Quarter 6	[***]	\$[***] \$[***]	
59 60		Routine Monitoring Visits, Quarter 6 Routine Monitoring Visits, Quarter 7	[***]	\$[***]	
61		Routine Monitoring Visits, Quarter 7 Routine Monitoring Visits, Quarter 8	[***]	\$[***]	
62		Routine Monitoring Visits, Quarter 9	[***]	\$[***]	
63		Routine Monitoring Visits, Quarter 9 Routine Monitoring Visits, Quarter 10	[***]	\$[ \$[***]	
64		Routine Monitoring Visits, Quarter 10	[***]	\$[***]	
65		Routine Monitoring Visits, Quarter 11 Routine Monitoring Visits, Quarter 12	 [***]	\$[ \$[***]	
	1.3.5	Data Management / Statistics		Ψ[ ]	
66		Statistical Analysis Plan	[***]	\$[***]	Y
67		Programming Specification, Dvlpt, & Review	[***]	\$[***]	
68		Method Validation	[***]	\$[***]	
69		TFL Generation	[***]	\$[***]	
	1.3.6	Database Lock			
70		Soft Lock	[***]	\$[***]	
71		Hard Lock	[***]	\$[***]	
		Data Safety Monitoring Board			
72		DSMB Meetings (6/14/2024-11/23/2026)			
73		DSMB Meeting	[***]	\$[***]	
74		DSMB Meeting	[***]	\$[***]	
75		DSMB Meeting	[***]	\$[***]	
76		DSMB Meeting	[***]	\$[***]	
77		DSMB Meeting	[***]	\$[***]	
78		DSMB Meeting	[***] [***]	\$[***] #[***]	
79		DSMB Meeting	[***]	\$[***] \$[***]	
80 81		DSMB Meeting DSMB Meeting	[***]	\$[***]	
81		DSMB Meeting DSMB Meeting	[***]	\$[***]	
02		BARDA Update Meetings		¢۲]	
83		Year 1 Meeting - BARDA	[***]	\$[***]	
84		Year 2 Meeting - BARDA	[***]	\$[***]	
85		Year 3 Meeting - BARDA	[***]	\$[***]	
		Reporting		Ψ[ ]	
86		Annual Report 1	[***]	-	
87		Annual Report 2	[***]	-	
88		Annual Report 3	[***]	-	
	1.4.	Regulatory (6/2024-7/1/2027)			
89	1.4.2	FDA Annual Report 1	[***]	\$[***]	
90	1.4.2	FDA Annual Report 2	[***]	\$[***]	
91	1.4.2	FDA Annual Report 3	[***]	\$[***]	
92	1.4.1	Regulatory Interactions - Quarter 1	[***]	\$[***]	
93		Regulatory Interactions - Quarter 2	[***]	\$[***]	
94		Regulatory Interactions - Quarter 3	[***]	\$[***]	
95		Regulatory Interactions - Quarter 4	[***]	\$[***]	
96		Regulatory Interactions - Quarter 5	[***]	\$[***]	
97		Regulatory Interactions - Quarter 6	[***]	\$[***]	
98		Regulatory Interactions - Quarter 7	[***]	\$[***]	
99		Regulatory Interactions - Quarter 8	[***]	\$[***]	
100		Regulatory Interactions - Quarter 9	[***]	\$[***]	
101		Regulatory Interactions - Quarter 10	[***]	\$[***] #[***]	
102		Regulatory Interactions - Quarter 11	[***]	\$[***] #[***]	
103		Regulatory Interactions - Quarter 12	[***]	\$[***]	

	PHASE 2					
104		Kick Off / Program Initiation	[***]	\$[***]		
105		Materials & Supplies Acquisition	[***]	\$[***]		
106	1.1.1	Sample Processing	[***]	\$[***]		
107	1.1.1	Durability Sample Analysis	[***]	\$[***]		
108	1.1.1	Flow Analysis	[***]	\$[***]		
109	1.1.2	Sequence Memory Cells	[***]	\$[***]		
110	1.1.3	Produce Clones	[***]	\$[***]		
111	1.1.3	Complete Clone Analysis	[***]	\$[***]		
112	1.2	Phase 2 Final Report	[***]	-		
113		Final Technical and Business Status Report	[***]	-		
			Total	<b>\$</b> [***]		
			Contract Type	CPFF		

Note: Upon project initiation, only certain milestones have been authorized and are labeled as such.

## 6. Data Rights

Vaxart has filed broad domestic and international patents covering its proprietary technology and creations for oral vaccination using adenovirus and TLR3 (US patents 7,879,602 and 8,222,224). Vaxart has also filed for patent protection on their COVID-19 vaccine candidates. All intellectual property is fully owned by Vaxart, without any encumbrances.

Vaxart anticipates that it will utilize intellectual property (including patented inventions) in the performance of any contract that either has been developed at private expense (and in which Vaxart has ownership in the case of patented invention pursuant to FAR 52.227-11 or data pursuant to FAR 52.227-14), developed by a third-party (in which Vaxart has appropriate license rights) or pursuant to a prior government contract (in which case Vaxart has ownership rights as determined by that contract). Vaxart will provide a more detailed statement of rights in intellectual property for government review and approval (including any declarations of rights in intellectual property by Vaxart's subcontractors) and does not anticipate any impediments in Vaxart's ability to develop the vaccine technology based upon intellectual property that will be utilized in performance.

Technica	al Data to	Basis for	Asserted	Name of	Milestone
Be Furni	shed with	Assertion	Rights	Asserting	Affected
Restr	ictions		Category	Organization	
[***]		Vaxart development prior to contract at private expense	Limited rights	,	N/A; background

### Attachment B **Key Tenets**

### **Next Generation COVID-19 Vaccines Tenets**

The largest effort in the Next Generation COVID-19 Vaccines Area of Interest will focus on generation of proof-of-concept Phase IIb efficacy data from multiple development partners to de-risk further development of successful vaccine candidates that are delivered via mucosal administration, target other non-spike proteins, or target multiple SARS-CoV-2 receptor binding domains that may strengthen vaccine breadth, durability, and transmission-blocking. As part of this effort, BARDA plans to conduct correlate of protection (COP) and immunogenicity analyses, as well as meta-analyses using aggregate data to inform a better understanding of mechanistic correlates to further development of COVID-19 vaccines and improve responses to future pandemics or public health threats. Alignment of objectives/endpoints, implementation of a Diversity Plan, use of a Data Safety Monitoring Board (DSMB), standardized data collection, and a uniform approach to the collection and analysis of immunogenicity data across the Next Generation COVID-19 Vaccines initiative facilitates a harmonized strategy that ensures BARDA's strategic goals for the program are met. Adherence with the requirements set forth below to provide samples and data are critical for BARDA to strengthen its assays and analytical infrastructure to advance COPs and accelerate licensure of NextGen vaccines. The following conditions pertaining to operationalization of the Phase 2b clinical trials have been set as a requirement to entering into an agreement whereby the USG collaborates and helps finance the development of Next Generation COVID-19 Vaccines.

1) The vaccine developer to the collaboration will be the sole Sponsor and holder of the IND.

#### **Responsibilities: Clinical Studies Network Partnership (Not applicable** in this case)

Responsibility and accountability for the operational execution of the trial Final selection, approval, and activation of sites

Fulfilling monitoring responsibilities in all sites Sponsor Transfer of Regulatory Obligations (TORO); assume BARDA CRO SOPs will be followed

### BARDA Broad Agency Announcement/Rapid Response Partnership Vehicle

Responsibility and accountability for the operational execution of the trial Final selection, approval, and activation of sites

Fulfilling monitoring responsibilities in all sites Sponsor TORO as needed

The study protocols will be harmonized with respect to the defined primary efficacy endpoint, the minimal common set of secondary endpoints, and statistical analysis plans (SAPs). Specific secondary or exploratory endpoints can be included for each program. Execution of each Phase 2b clinical trial requires written authorization from BARDA.

3) Awardees must provide protocol development and writing support services, including the development of protocol-related documents such as sample informed consents. Protocol development and subsequent trial enrollment must take into consideration and align with diversity of the clinical trial population and as applicable take into account principles outlined in 'Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry' <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial</u>

4) Awardees must provide a Diversity Plan to improve enrollment of participants based on 'Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry' (Draft January 2024) <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials-and-clinical-studies-fda-regulated-medical?</u> <u>utm\_medium=email&utm\_source=govdelivery</u>. The Diversity Plan must include proposed targets to achieve deliverable. The Diversity Plan should include how PBMCs will be collected from a diverse population.

5) The Phase 2b clinical trials must be overseen by a Data and Safety Monitoring Board (DSMB) fulfilling all standard duties of DSMBs. The criteria for voting members and non-voting observer members of the DSMB as well as the final composition of the DSMB will be set by BARDA in consultation with the vaccine developer and finalization will require agreement from BARDA. 1-2 BARDA representatives will attend all safety committee meeting open sessions as non-voting observers.

6) Protocols will be harmonized with respect to using the FDA Guidance 'Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials' <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/toxicity-grading-scale-healthy-adult-and-adolescent-volunteers-enrolled-preventive-vaccine-clinical</u> for the purpose of grading adverse events.

7) Clinical Data Collection will be harmonized with respect to using the latest Clinical Data Interchange Standards Consortium (CDISC) Clinical Data Acquisition Standards Harmonization (CDASH) Model for eCRF design. The current version of CDASH can be downloaded at: <u>https://www.cdisc.org/standards/foundational/cdash</u>. This will allow a standard way to collect data consistency across the Phase 2b clinical trials. This also ensures an easy submission to regulatory agencies (e.g. FDA) and efficient data analyses.

8) The Sponsor is responsible to ensure medical case management during the trial, including the specific approach to care of participants with COVID-19.

<sup>9)</sup> Each Phase 2b clinical trial will obtain samples and data required for analysis of primary endpoint, secondary endpoints, and correlates of protection (COP) analysis<sup>1</sup>. The primary efficacy endpoint and certain secondary immunogenicity endpoints will be specified by BARDA. BARDA will provide an immune assay capability through a centralized network of laboratories that will perform the tests for the immunogenicity-related secondary endpoints on the specified number of samples for either COP or immunogenicity analyses. A sample analysis plan, including associated timelines for assay completion, will be developed through BARDA's Centralized Laboratory Network, and will be approved by BARDA in consultation with the developer. Samples and data from Phase 2b trials are intended to be used in COP and cross-trial metanalyses; data will be shared with parties and published. Data analyses for immunogenicity, COP, and metanalysis based on assays provided through BARDA's Centralized Laboratory Network (BCLN)<sup>2</sup> will be conducted according to an SAP that is developed jointly by the vaccine developer and BARDA and approved by BARDA.

<sup>1</sup> Additional details for sample collection and processing protocols related to testing performed through the BARDA Central Laboratory Network (BCLN) including immune assays and virus sequencing are provided in the BARDA LAB SAMPLE PROCESSING GUIDANCE: Project Next Generation COVID-19 Phase 2B Vaccine Trials (Ver. 2.0)

<sup>2</sup> BARDA has partnered with multiple organizations to establish the BARDA Central Laboratory Network (BCLN) to provide standardized immunological assay testing, sample storage and viral sequencing services to support the development of the next generation of COVID-19 vaccines (Project NextGen).

a) Primary efficacy endpoint. The vaccine developer will be responsible for clinical assessment and assays (RT-PCR for virologically confirmed SARS-CoV-2) per the defined primary efficacy endpoint. The vaccine developer must share all clinical data with the USG in accordance with any requirements to ensure timely and complete transfer to the BARDA database resource. The BCLN will provide a resource for viral genomic sequencing of samples where SARS-CoV-2 infection was virologically confirmed with a positive RT-PCR result; these samples must be provided by the vaccine developer to the BARDA resource according to BARDA requirements.

b) Immune assays. BARDA will be responsible for a minimum set of immunogenicity assays as defined herein. Immunogenicity assay data from the BCLN will constitute the secondary immunogenicity endpoint data. Immunogenicity assay data and analysis conducted by BARDA will be shared with the vaccine developer and released via publication. As our understanding of immunologic COPs and assay technology evolves in the near future, the approach described below may be modified to accommodate updated information. See item 10 for information on the number of subjects from which to collect samples.

i) The minimal set of immunogenicity assays required for any trial includes assessment of sera samples by pseudovirus neutralization assay (PsVNA) and IgG binding antibody (bAb) assay; and peripheral blood mononuclear cells (PBMCs) by flow cytometry for intracellular cytokine and cell surface marker staining (ICS).

ii) Any trial that includes a candidate administered via a mucosal route must include additional assays for assessment of: sera by IgA bAb assay; nasal samples by PsVNA, IgG bAb, and IgA bAb; and saliva samples by PsVNA, IgG bAb, and IgA bAb. Phase 2b trials that only include parenterally administered vaccines do not require these mucosal sample or IgA assays; however, these assays will be available at the request of the vaccine developer for testing at the partner's expense.

iii) Timepoints for immune assays will include samples collected at baseline (D1), day D31, D91, D181, and D366. Timepoints where BARDA-run assays will only be used for immunogenicity analysis will include D91 and D366 for all antibody assays and D91, D181 and 366 for testing of PBMCs by ICS; 200 randomly sampled subjects will be assessed for immunogenicity at each timepoint. Randomization requirements will be determined by BARDA. For requirements on timepoints for COP analysis see item 9c and for details for sample collection requirements, see item 10.

c) Correlates of Protection. Immune assays for COP analysis align with sample type and assay type requirements defined in item 9.b.i-ii. Timepoints and samples (for details on sample collection, see item 10) for COP analysis will include: baseline (D1) and D31 for sera, PBMCs\*, nasal, and saliva samples and for sera only at D181. For mucosal sample COP, whether COP assays and analysis are run for mucosal samples, and on which mucosal sample type (either nasal or saliva, but not both) will be determined by BARDA based on the outcome of immunogenicity analysis. BARDA will provide a centralized statistical and data coordinating center to conduct the COP analysis across all Phase 2b trials. Clinical data will be shared by BARDA's Centralized Laboratory Network. The mix of sampled subjects and COP analysis will be defined in and conducted according to the SAP. The SAP will be developed in collaboration with and agreed to by BARDA. COP data analysis will be shared with the vaccine developer and released via publication. See item 10 for information on the number of subjects from which to collect samples.

\*Please note: if insufficient COVID-19 symptomatic cases (as defined per protocol primary endpoint) are identified in the PBMC collected samples to enable CoP analysis, BARDA may test 200 samples at all time points for immunogenicity assessment only.

d) Assays will be run with a minimum of three strains/variants, including (for example):

i) Ancestral Wuhan strain

ii) The currently recommended variant for COVID-19 vaccines (e.g., XBB 1.5 <u>https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall2023#:~:text=Based%20on%20the%20totality%20of,a%20monovalent%20XBB%201.5%20composition)</u>

iii) A variant, to be determined by BARDA in consultation with the vaccine developer, based on the most prevalent circulating SARS-COV-2 strain/virus at the time and place of Phase 2b trial conduct.

Assessment of any additional SARS-CoV-2 strains/variants will be decided by BARDA based on scientific justification, program priorities, and available funding. The vaccine developer may conduct their own independent additional assays with other SARS-CoV-2 variants; however, associated costs will be incurred by the vaccine developer.

10) Sample Draws for Immune Assays. Each Phase 2b trial will obtain samples required for testing in assays as defined under item 9. Samples from the trials will be used in assays for primary endpoint analysis, immunogenicity analysis, COP analyses, and metanalyses. Samples must be collected according to requirements defined by BARDA and, where required, must be delivered to the BARDA sample acquisition and storage resource. BARDA will share documentation that describes harmonized sample collection, processing, and storage procedures and requirements. Subject randomization and sample size for immunogenicity samples will occur according to the COP SAP, which will be determined by BARDA in coordination with the vaccine developer and finalized by BARDA.

a) Blood samples. The vaccine developer must collect blood samples for the preparation of sera and PBMCs for immune assays. i) Sera. Sera samples must be collected from the total enrolled subjects at the baseline (D1), D31, and D181 timepoints; these timepoints will be used for COP analysis and must be collected from all subjects to ensure any future COVID-19 cases are captured. Sera samples must be collected from 200 randomly selected subjects at the D91 and D366 timepoints. A total sera volume of 4mL (8 mL of whole blood), in 8 x 0.5mL aliquots, must be collected from required subjects at the defined timepoints for the BARDA assays. Standard red-top tubes (i.e., contains no anticoagulant or preservative) should be used to collect sera samples. Additional sample volume for assays run by the industrial party should be accounted for in addition to the required volume for BARDA assays. Samples that will be shipped to the BARDA sample storage resource must be collected, aliquoted, stored, and shipped according to BARDA requirements.

ii) PBMCs. PBMC samples should be collected from a minimum of 1000 subjects at baseline (D1) and D31; however, companies are encouraged to collect PBMC from at least 1667 and up to 2,000 subjects at these timepoints to maximize possibility of capturing enough COVID-19 cases (as defined per protocol primary endpoint) for BARDA to conduct COP analysis. PBMCs must be collected from at least 200 randomly selected subjects at the D91, D181, and D366 timepoints. A total of 15x106 PBMCs, in three aliquots each of 5x106 PBMCs, must be collected from required subjects at the defined timepoints for the BARDA assays. Additional sample volume for assays run by the industrial party should be accounted for in addition to the required volume for BARDA assays. Samples that will be shipped to the BARDA sample storage resource must be collected, stored, and shipped according to BARDA requirements. PBMCs must be collected according to the *Standard Operating Procedure: Peripheral Blood Mononuclear Cells (PBMC) and Associated Plasma Collection* (No.: DMID-OCRR-SOP-002; Effective Date: 30-SEP-2021), BARDA preference is the option that defines the protocol specific to collection using Cellular Preparation Tubes (CPTs).

b) Mucosal samples. The vaccine developer must collect nasal and saliva samples if required by BARDA or requested by the vaccine developer per item 9.b.ii. Both nasal and saliva samples must be collected from the total enrolled subjects at the baseline (D1), D31, and D181 timepoints; these timepoints will be used for COP analysis and must be collected from all subjects to ensure any future COVID-19 cases are captured. Nasal and saliva samples must be collected from 200 randomly selected subjects at the D91 and D366 timepoints. Nasal samples must be collected using the Nasosorption device and saliva samples much be collected using the Oracol device. Samples must be collected per the device instructions for use and specific collection procedure requirements as defined by BARDA; Nasal samples must be diluted up to a final volume of 1mL with 1X Mucosal Buffer and divided into four aliquots of 0.25mL. Saliva samples will be diluted at a 1:1 ratio with 2x Mucosal Buffer for a final volume of 1 ml and aliquoted into four x 0.25 mL aliquots. Additional sample volume for assays run by the industrial party should be accounted for in addition to the required volume for BARDA sample storage resource must be collected, stored, and shipped according to BARDA requirements. c) Informed Consent. The clinical trial informed consent developed by the vaccine developer or CSN partner must capture how clinical immune samples collected during the study will be used – both for per protocol use and future non-per protocol use. Long term storage of these samples will occur at the BARDA Biological Specimen and Investigational Product storage facility (BSIP).

### CERTIFICATION

### I, Steven Lo, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Vaxart, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(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 our supervision, to
    ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those
    entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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: August 8, 2024

By: /s/ STEVEN LO

Steven Lo President and Chief Executive Officer (Principal Executive Officer)

## CERTIFICATION

I, Phillip Lee, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Vaxart, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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: August 8, 2024

By: /s/ PHILLIP LEE

Phillip Lee Chief Financial Officer (Principal Financial and Accounting Officer)

### CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Steven Lo, President and Chief Executive Officer of Vaxart, Inc. (the "Company"), and Phillip Lee, Chief Financial Officer of the Company, each hereby certifies that, to his knowledge:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Date: August 8, 2024

By: /s/ STEVEN LO

Steven Lo President and Chief Executive Officer (Principal Executive Officer)

Date: August 8, 2024

By: /s/ PHILLIP LEE

Phillip Lee Chief Financial Officer (Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to Vaxart, Inc. and will be retained by Vaxart, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.