UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 7, 2025

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35285**	**59-1212264**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

170 Harbor Way, Suite 300, South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 550-3500

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

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

Item 1.01 Entry into a Material Definitive Agreement.

On February 7, 2025, Vaxart, Inc. (the "Company") entered into Modification No. 5 (the "Modification") to the ATI-RRPV Project Award Agreement No. 001, dated June 13, 2024 (the "Project Agreement"), with Advanced Technology International, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by the Biomedical Advanced Research and Development Authority ("BARDA") of the U.S. Department of Health and Human Services. As previously disclosed, pursuant to the Project Agreement, the Company received funding to conduct a Phase 2b comparative study (the "Trial") evaluating the Company's oral pill COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the U.S. Food and Drug Administration. The Company previously announced that it had completed enrollment of the sentinel cohort portion of the study comprising approximately 400 patients comparing its oral pill XBB candidate against an mRNA XBB comparator and an independent data safety monitoring board recommended the study to proceed without modifications based on initial safety assessment of 30-day data from the sentinel cohort.

The Modification increased the total amount of funding currently allotted to the Trial and available for payment to approximately $240.1 million, representing an increase of approximately $105.9 million. The Modification also clarifies the design of the Trial by specifying that the next portion of the Trial will compare the efficacy and safety of the Company's KP.2 oral vaccine candidate against an mRNA comparator directed against KP.2, and will be comprised of 10,000 participants. The Company is awaiting approval from BARDA to commence dosing in the Trial.

The foregoing description of the Modification does not purport to be complete and is qualified in its entirety by reference to the full text of the Modification, which is filed as Exhibit 10.1 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
10.1*	Modification No. 5, dated February 7, 2025, to the ATI-RRPV Project Award Agreement No. 001, dated June 13, 2024, between the Company and Advanced Technology International.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

* 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.

Forward-Looking Statements

Statements contained or incorporated by reference in this Current Report on Form 8-K which relate to other than strictly historical facts, such as statements about the Company's expectations with respect to clinical and regulatory development plans for its product candidates, the data to be derived in the Company's ongoing and planned clinical trials, the timing of funding pursuant to the Project Agreement and/or the Modification, additional funding of the Trial under the Project Agreement and/or the Modification, and the structure, design, and objectives of the Trial. The words "believe," "expect," "intend," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date of this Current Report on Form 8-K. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, risks and uncertainties associated with the Company's ability to achieve milestones and deliverables under the Project Agreement and achieve successful results in the Trial, the Company's continuing operating losses, and other risks detailed in the Company's most recent Annual Report on Form 10-K and other filings with the U.S. Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements, other than as may be required under applicable law.

SIGNATURES

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

VAXART, INC.

Dated: February 10, 2025

By: */s/ Phillip Lee*
Phillip Lee
Chief Financial Officer

Exhibit 10.1

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 [***].

February 7, 2025

Vaxart Biosciences Inc
170 Harbor Way Ste 300
South San Francisco, California 94080

Attention: [***]

Subject: Modification No. 05 to RRPV Project Award No. 01; RRPV-24-04-NGVx-003

Reference: RRPV Base Agreement No. 2024-606

Dear [***]:

In accordance with the terms and conditions of the referenced RRPV Base Agreement, Modification No. 05 hereby amends the Project Award No. 01 as follows:

DESCRIPTION OF MODIFICATION

1) The Incremental Funding clause of the Project Award is hereby amended to read as indicated in bold below:

5. Incremental Funding

The total amount of funding currently allotted to this Project Award and available for payment is **$240,082,397** *(this is an increase of $105,908,453)* 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 [***] days 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.

2) Attachment A, Statement of Work, of the Project Award is hereby amended to read as attached herein.

Except as provided herein, all Terms and Conditions of the referenced RRPV Base Agreement, Project Award and preceding 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	
By:	/s/[***]
Name:	[***]
Title:	[***]
Date:	02/07/2025

Advanced Technology International	
By:	/s/[***]
Name:	[***]
Title:	[***]
Date:	02/07/2025

Attachment A
Statement of Work
(Incorporated via Modification No. 05. Changes to Sections 2, 3 and 5 are indicated in bold italics.)

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 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 Covid-19 candidate vaccine to an approved mRNA 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 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 vaccine candidate and an mRNA vaccine comparator for efficacy, immune induction, and safety. The clinical trial will begin with a sentinel cohort of 400 individuals using Vaxart's XBB vaccine and an mRNA XBB comparator.

Specifically, Vaxart will:

- Determine the relative efficacy of the Vaxart's 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 COVID-19 vaccine candidate
- Evaluate the humoral immunogenicity of Vaxart's COVID-19 vaccine candidate
- Evaluate cellular immunogenicity of Vaxart's COVID-19 vaccine candidate
- Evaluate the mucosal immune responses of Vaxart's COVID-19 vaccine candidate
- Determine the durability of Vaxart's 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 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 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

~~***Concurrently,***~~ Vaxart will manufacture new KP.2 lots ~~***to support a 10,000 subject follow-on trial***~~ as described under Task Area 5 (1.5), CMC, ***to support the 10,000-participant arm of the study.***

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 assess 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 vaccine candidate and an mRNA vaccine comparator for efficacy, immune induction, and safety. The clinical trial will begin with a sentinel/safety cohort of 400 individuals using Vaxart's XBB vaccine and an mRNA XBB comparator.

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 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 stage 1 and stage 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 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 encompass those activities to be performed to collect, test, and report on samples taken from subjects in the Phase 2b trial. The lead-in cohort samples will be stored for analysis, pending an agreed upon plan from BARDA/ATI.
Vaxart will provide serum and PBMC samples to BARDA for analysis at a central CRO (WBS 1.2.1).

- Serum samples will be collected 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)
- ***KP2 specific positive controls will be made and KP2 mouse immunogenicity data will be acquired. KP2 specific human antibodies (IgG and dIgA) will be identified/isolated/cloned from infected convalescent subjects (internal volunteers), or acquired via commercial sources, if available. These reagents will be used in assays at Vaxart for qualification of their assays. Animal studies demonstrating immunogenicity of the new KP2 vaccines will be performed and immunogenicity will be characterized. The data will be used in any FDA correspondence to allow for clinical evaluation of the KP2 oral vaccine candidate (WBS1.2.1.2)***
- 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 protocol 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 protocol for isolation. These samples will be used for assessing mucosal memory and mucosal homing markers in Phase 2. (WBS 1.2.1.3)

BARDA and Vaxart will characterize immune responses at mucosal surfaces according to the schedule detailed in the synopsis. (WBS 1.2.2). ***Activation of milestones for additional XBB mucosal analysis (MS 21.2, 22.2, and 23.3) will not proceed without written authorization from BARDA (PAR or Alt PAR).***

- To test the effects of mucosal vaccination, saliva samples will be collected using [***] at timepoints post vaccination according to the schedule detailed in the synopsis. Samples will be shipped to the mucosal processing lab contracted by BARDA. Spike specific antibody levels will be assessed using MSD technology and functional antibodies (nAb) will be measured by [***]. Vaxart will evaluate a small subset for pan-coronavirus immune responses and nAb using surrogate neutralization assays (sVNTs). (WBS 1.2.2.1)
- To test the effects of mucosal vaccination, nasal samples will be collected using Nasosorption devices (Mucosal Diagnostics) at timepoints post vaccination according to the schedule detailed in the synopsis. Samples will be shipped to the mucosal processing lab contracted by BARDA. Spike specific antibody levels will be assessed using MSD technology and functional antibodies (nAb) will be measured by [***]. Vaxart will evaluate a small subset for pan-coronavirus immune responses and nAb using surrogate neutralization assays (sVNTs). (WBS 1.2.2.2)

Vaxart will determine the efficacy of Vaxart's 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 [***] 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 ~~**asymptomatic and symptomatic**~~ infection. (WBS 1.2.3.2)

In addition to BARDA analysis of correlates, 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 ***encompass*** all activities and tasks to be performed in the execution of the ***Phase*** 2b clinical trial ***from*** study ***initiation of XBB*** safety ***lead-in*** group of 400 participants, ***to delivery of the CSR with 10,000 participants completing the trial with KP.2. Study enrollment will be paused between strain change to allow*** safety ***data*** review of ***the lead-in*** cohort ***by the DSMB committee, as well as FDA*** and ***BARDA, before re-starting.***

Vaxart will complete all of the activities required for clinical trial site start-up. BARDA representatives will be included in all key discussions with the CRO for clinical trial site start-up to include but not limited to diversity, recruitment, enrollment, and retention.(WBS 1.3.1)

- A comprehensive set of documents that provide critical information about the study and ensure regulatory compliance will be ***prepared for the XB and KP.2 cohorts*** . 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, any adverse events, and additional safety-related reporting forms, and monitoring plans. (WBS 1.3.1.1)
- Site contract negotiation ***and start-up*** will be completed ***for the XBB and KP.2 cohorts, continuing until all anticipated sites are activated.*** 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 ***for the XBB and KP.2 cohorts*** 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 ***for the XBB and KP.2 cohorts*** 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)
- ***Prior to both the XBB and KP.2 cohorts, s***ite 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). BARDA representative(s) will be invited at SIVs and IMVs with appropriate notice to allow for coordination with all parties.

- ***CTM***, as well as the mRNA comparator, 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 supported by automated re-supply triggers. 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***).***
    - The shipment of ***CTM*** for the initial 400 sentinel participants ***and the 10,000 participant KP.2 cohorts*** will be closely managed by Vaxart. The remaining unused XBB material can be disposed per written agreement with BARDA.
- 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 participants first in the sentinel safety cohort (400) followed by the 10,000 cohort. Vaxart will ensure participants are randomized and assigned to a treatment group. (WBS 1.3.2)

Vaxart will enroll eligible volunteers first in the safety lead-in cohort (400) and, upon successful DSMB 30-day safety review along with FDA and BARDA approval, then in the follow-on 10,000 subject full enrollment cohorts, and ensure that they are randomized and assigned to a treatment group. (WBS 1.3.2). The Project Awardee agrees that the Phase 2b clinical trial will be conducted in alignment with Attachment B, “Key Tenets”. Awardees must provide a Diversity Plan that includes enrollment of participants in both the lead-in cohort of 400 participants and the full enrollment of 10,000 participants based on the agreed upon plan. Diversity targets will align with the 2020 US Census Data provided here:

OMB/FDA/US Census Categories	2020/2023 US Census Data*	Planned Enrollment	Actual Enrollment
Subgroup Population			
Sex			
Female	50.5%		
Male	49.5%		
Total	***100%***	***100%***	***100%***
Ethnicity			
Hispanic or Latino	19.5%		
Not Hispanic or Latino**	N/A		
Total	***N/A***	***100%***	***100%***
Race			
American Indian or Alaska Native	1.3%		
Asian	6.4%		
Black or African American	13.7%		
Native Hawaiian or Other Pacific Islander	0.3%		

White	75.3%		
Two or More Races* **	3.1%	N/A	N/A
Total	***100%***	***100%***	***100%***
Age			
18-64 years	60.6%	75%	
≥ 65 years	17.7%	25%	
Total	***N/A***	***100%***	***100%***
High Risk for Severe COVID** **	75.4%		
# Proposed Sites			

*Current US Census data refers to 2020 US Census data = 2023 US Census Data; U.S. Census Bureau QuickFacts: United States; accessed 12/12/2024

**2020/2023 US Census data does not include reporting for Not Hispanic or Latino; however, OMB and FDA include reporting for this category; comparison to 2020/2023 US Census data is N/A

***2020/2023 US Census data includes reporting for Two or More Races; however, OMB and FDA do not include reporting for this category; individual race categories should be reported instead according to participant selections

****US adults with at least one increased-risk condition; U.S. population at increased risk of severe illness from COVID-19 - ScienceDirect; accessed 12/12/2024

Diversity Plan includes proposed targets to achieve the deliverable and also includes how PBMCs will be collected from a diverse population. Post enrollment of 2500, 5000 and 7500 participants, the parties will meet to ensure alignment with the goals of the diversity plan. ***Activation of each enrollment milestone (MS 50 – 50.3) will not initiate without written authorization from BARDA (PAR or Alt PAR).*** Plans to continue or adjust strategy for diverse enrollment will be discussed and agreed to at that time, if necessary. BARDA reserves the right to issue a stop work order if alignment is not reached.

- 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 an eligible and diverse participant population will be undertaken. These may include developing targeted recruitment strategies and advertisements to reach the intended participant population. Participant recruitment vendors may be engaged to assist with recruitment campaigns, utilizing various channels such as online platforms, social media, print media, and community outreach. BARDA, ASPR, and HHS logos are not allowable in any source of materials for recruitment (WBS 1.3.2.2)
- Enrollment data will be provided daily, in a format and to a location agreed to by BARDA. to ensure that study enrollment is tracking study goals, including diversity goals. Strategies will be implemented to correct any enrollment lag or diversity imbalances identified.
- If necessary, trial participants' past medical or surgical history to confirm eligibility into the study will be requested. (WBS 1.3.2.3)
- Participant 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 participant eligibility for clinical trials by conducting a thorough evaluation. (WBS 1.3.2.6)
- Participants 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)
- Dosing data will be updated into EDC within 24 hours to support the daily data dashboard reporting. All other data will be updated into EDC within 48 hours.

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 participants' 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 ***and the testing outlined in 1.2.5***. 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)
    - As recommended by the FDA, a Drug Safety Monitoring Board (DSMB) will convene and review safety data of the initial 400 participants in the sentinel cohort after they complete Day 31 (Visit 3). The raw data and the DSMB recommendation will then be submitted to BARDA and the FDA.
- 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)

Vaxart will oversee routine and for-cause 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 may 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 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 high-level 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)

Pending BARDA and FDA approval of the safety data and DSMB recommendation for the initial 400 participant sentinel cohort, the remaining participants will be enrolled.

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-***3***.1-S, an oral SARS-CoV-2 vaccine E1-/E3-deleted replication defective recombinant adenovirus 5 with dsRNA adjuvant ***and VXA- CoV2-3.3, 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 the anniversary date 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. Participants will also be monitored for exposure to SARS-CoV2 and symptomatic SARS-CoV2 infection (COVID-19). (WBS 1.4.3)
- ***Regulatory submissions***
  400 participant XBB sentinel submissions (1.4.4.1) are as follows
  - ***30-day safety follow up***
  - ***DSMB recommendation for 400 participants XBB sentinel group 30-day safety follow up***
  - ***Any additional information requests that FDA may want in support of the submissions.***
- ***10,000 participant KP.2 submissions (1.4.4.2) are as follows:***
  - ***KP.2 Protocol Amendment and supporting clinical documents (ICF, CMC update, etc.)***
  - ***Any additional information requests that FDA may want in support of the submissions.***

Task Area #5 – CMC (WBS 1.5) - Trial Material Manufacturing, Acquisition, Packaging & Distribution
Vaxart will complete all activities and GMP documentation, ensuring that clinical trial material will be ready to support the 400-participant sentinel study (XBB) and the 10,000 participant Ph2b head-to-head clinical trial with an mRNA comparator targeting the KP.2 COVID variant. **Activation of milestones for comparator vaccine purchase (MS 113.1 & 113.2) and kitting (MS 116.1 & 116.2) will not proceed without written authorization from BARDA (PAR or Alt PAR).**

Vaxart Trial Material Manufacturing & Packaging (1.5.1)

- A KP.2 RVB (research virus bank) will be completed prior to use in GMP manufacturing of KP.2 clinical trial material.
- KP.2 GMP Bulk Drug Substance Material will be manufactured, tested, and released with appropriate methods at sufficient quantities to ensure the supply of the entire Ph2b trial is from a single lot.
- KP.2 GMP Drug Product will be manufactured, tested, and released with appropriate methods at sufficient quantities to ensure the supply of the entire Ph2b trial is from a single lot.
- All GMP material will be placed on appropriate stability studies.
- Vaxart will utilize industry standard risk mitigation practices and manufacture additional clinical trial material above the amount required to supply the 10,000 participant Ph2b clinical trial.
- Vaxart KP.2 COVID vaccine clinical trial materials will be shipped to the depot (WBS 1.5.1.6) to allow for distribution to clinical sites (WBS 1.5.2.1).
- Vaxart XBB COVID vaccine clinical trial materials will be distributed to the clinical sites supporting the 400-participant safety lead in study per protocol

Comparator & Placebo Acquisition & Kitting (1.5.2)

- Vaxart will perform technical management (WBS 1.5.2.1) of non-Vaxart clinical trial material acquisition, packaging, and distribution, including acquisition of the mRNA comparator, saline, and ancillary kits. (WBS 1.5.2.2).
- Vaxart COVID vaccine clinical trial materials will be distributed with the mRNA comparator and saline according to the milestones in Section 5 (WBS 1.5.2.3).

Storage and Distribution of Clinical Trial Materials (1.5.3)

- Vaxart will ensure storage (1.5.3.1) of the kitted trial materials and distribution of the clinical trial materials to clinical depots and/or sites (1.5.3.2).

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 assess cross-reactivity over time.

Task Area #1 – Analytical (*WBS 2.1*)

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 **2.**1.1)
- Vaxart will use flow cytometry to determine the changes to the memory pool in the subpopulation of participants 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 2.1.2)
- Vaxart will analyze antibodies from the task in 2.1.2 and their diversity tested for binding and neutralizing various SARS-COV-2 variants and other coronaviruses. (WBS 2.1.3)

Task Area #2 – Clinical (WBS *2.2)*

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 *2*.2.1)
- Vaxart will complete site close-out and unused vaccine will be returned or destroyed; and documents will be properly shipped and stored. (WBS 2.2.2)
- 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 *2*.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 ***2***.2.4)
- Vaxart will prepare an amended clinical study report which will include the additional analysis conducted under Phase 2. (WBS ***2***.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[1]	[***]	[***]
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[2]	[***]	[***]
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	Clinical Trial Datasets	[***]	[***]
4.13	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 Sub-performer 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	Reporting Procedures and Due Dates
7.1	Regulatory Strategy/Plan	[***]	[***]
7.2	FDA Correspondence	[***]	[***]
7.3	FDA Submissions	[***]	[***]

5. Milestones

MS #	Task #	Description	Due Date	Government Funds	Authorized
PHASE 1					
	1.1	**Project Management**	[***]		
1	1.1	Project Kick Off	[***]	$[***]	Y
2		CRO Initiation. Subcontract Execution: [***]	[***]	$[***]	Y
3	1.1	PM Plans	[***]	$[***]	Y
4	1.1.1	Weekly Meetings - 110 total ($[***] ea)	[***]	$[***]	Y
5	1.1.1	Weekly Meetings - 10 total ($[***] ea)	[***]	$[***]	Y
5.1	1.1.1	Weekly Meetings – 12 additional ($[***] ea)	[***]	$[***]	Y
6		PM Meetings at Vaxart	[***]	$[***]	Y
7		PM Meetings at Vaxart	[***]	$[***]	Y
8		PM Meetings at Vaxart	[***]	$[***]	***Y***

9		PM Meetings at Vaxart	[***]	$[***]	
10		PM Meetings at Vaxart	[***]	$[***]	
11		PM Meetings at Vaxart	[***]	$[***]	
11.1		PM Subcontract – Latham	[***]	$[***]	Y
11.2		PM Subcontract – Latham	[***]	$[***]	Y
11.3	1.1.3	Risk Management	[***]	$[***]	Y
12	1.1.4	Monthly Cost Accounting/Invoicing	[***]	$[***]	
12.1		2 Invoices	[***]	$[***]	Y
12.2		3 Additional Invoices	[***]	$[***]	Y
12.3		Financial Management & Reporting	[***]	$[***]	Y
12.4		Accounting Subcontract – Latham	[***]	$[***]	Y
12.5		Accounting Subcontract – Latham	[***]	$[***]	Y
13	1.1.1	Monthly Technical & Business Reports	[***]	-	
	1.2	**Analytical**			
	1.2.1	**Serum & T Cells**			
14		Start Up Meeting	[***]	$[***]	Y
15		Log Samples	[***]	$[***]	Y
16		Complete Sample Shipment	[***]	$[***]	
17		Results Tabulated & Sent to Vaxart	[***]	$[***]	
	1.2.2	**Mucosal Analysis**			
18		Start Up	[***]	$[***]	Y
18.1		Initial Start Up	[***]	$[***]	Y
19		Order & Receive Materials	[***]	$[***]	Y
20		Controls & Qualification Complete	[***]	$[***]	Y
21***.1***		Complete Nasal Analysis ***- KP.2***	[***]	$[***]	
21.2		***Complete Nasal Analysis - XBB***	[***]	$[***]	***Y***
22***.1***		Complete Saliva Analysis ***- KP.2***	[***]	$[***]	
22.2		***Complete Saliva Analysis - XBB***	[***]	$[***]	***Y***
23***.1***		Complete Additional Analysis ***- KP.2***	[***]	$[***]	
23.2		***Complete Additional Analysis - XBB***	[***]	$[***]	***Y***
	1.2.3	**Infection & Efficacy**			
24		Start Up	[***]	$[***]	Y
24.1		Task Kick-Off	[***]	$[***]	Y
25		Lab Kit Replenishment	[***]	$[***]	***Y***
25.1		Lab Kit Replenishment– first shipment	[***]	$[***]	Y
26		Site to Central Lab Shipment	[***]	$[***]	
26.1		Site to Central Lab Shipment – first shipments	[***]	$[***]	Y
27		Central Lab: 3 shipments / 6 months	[***]	$[***]	
28		Statistical Analysis	[***]	$[***]	
29		Analysis Complete	[***]	$[***]	
30		Phase 2b Relative Efficacy & Infectious Report	[***]	-	
	1.2.4	**Correlates**			
31		Machine Learning & Programming	[***]	$[***]	

32		Statistical Analysis	[***]	$[***]	
33		Verification / Analysis Complete	[***]	$[***]	
34		Correlates of Protection Report	[***]	$[***]	
	1.3	**Clinical**			
	1.3.1	**Site Start Up**	[***]		
35		Essential Documents Complete	[***]	$[***]	Y
35.1		Essential Documents 50% Complete	[***]	$[***]	Y
36		Site Contracts Complete	[***]	$[***]	Y
37		Regulatory Binders Complete	[***]	$[***]	Y
37.1		Regulatory Binders Draft	[***]	$[***]	Y
38		Site Initiation Visits	[***]		
38.1		SIV – Initial Sites	[***]	$[***]	Y
38.2		SIV – Additional Sites 1	[***]	$[***]	Y
38.3		SIV – Additional Sites 2	[***]	$[***]	***Y***
39		IP Shipments to Sites	[***]	$[***]	***Y***
39.1		IP Shipment to Sites – Initial Sites	[***]	$[***]	Y
40		Lab & Other Supplies to Sites	[***]	$[***]	Y
40.1		Lab & Other Supplies to Sites – Initial Sites	[***]	$[***]	Y
41		Study Meetings/Training	[***]	$[***]	Y
41.1		Study Meetings/Training – Initial Sites	[***]	$[***]	Y
	1.3.2	**Enrollment**			
42		Pre-screening	[***]	$[***]	Y
43		Screening	[***]	$[***]	Y
44		Randomization	[***]	$[***]	***Y***
44.1		Randomization – 400 subjects	[***]	$[***]	Y
	1.3.3	**Clinical Conduct**			
45		1st Person In	[***]	-	
46		Biosample Collection	[***]	$[***]	
46.1		Biosample Collection – 400 subjects	[***]	$[***]	Y
47		Interim Analysis	[***]	$[***]	
48		Source Data Verification	[***]	$[***]	
48.1		SDV – 400 subjects	[***]	$[***]	Y
49		Site Supplies Management	[***]		
49.1		Site Supplies Management through 1/31/2025	[***]	$[***]	Y
49.2		Site Supplies Management from 2/1/2025	[***]	$[***]	***Y***
50		First 2500 Participants Dosed	[***]	***$***[***]	***Y***
50.1		Second 2500 Participants Dosed	[***]	$[***]	***Y***
50.2		Third 2500 Participants Dosed	[***]	$[***]	***Y***
50.3		Final 2500 Participants Dosed	[***]	$[***]	***Y***
51		Conclusion of Follow Up	[***]	$[***]	
52		Unblinded Monitoring	[***]		
52.1		Unblinded Monitoring through 1/31/2025	[***]	$[***]	Y
52.2		Unblinded Monitoring from 2/1/2025	[***]	$[***]	

	1.3.4	**Site Monitoring**			
53		Routine Monitoring Visit - 2-3 Visits Per Site (360 visits)			
54		Routine Monitoring Visits, Quarter 1	[***]	$[***]	Y
55		Routine Monitoring Visits, Quarter 2	[***]	$[***]	Y
56		Routine Monitoring Visits, Quarter 3	[***]	$[***]	***Y***
57		Routine Monitoring Visits, Quarter 4	[***]	$[***]	***Y***
58		Routine Monitoring Visits, Quarter 5	[***]	$[***]	
59		Routine Monitoring Visits, Quarter 6	[***]	$[***]	
60		Routine Monitoring Visits, Quarter 7	[***]	$[***]	
61		Routine Monitoring Visits, Quarter 8	[***]	$[***]	
62		Routine Monitoring Visits, Quarter 9	[***]	$[***]	
63		Routine Monitoring Visits, Quarter 10	[***]	$[***]	
64		Routine Monitoring Visits, Quarter 11	[***]	$[***]	
65		Routine Monitoring Visits, Quarter 12	[***]	$[***]	
	1.3.5	**Data Management / Statistics**			
66		Statistical Analysis Plan	[***]	$[***]	Y
66.1		SAP – Initial Work	[***]	$[***]	Y
67		Programming Specification, Dvlpt, & Review	[***]	$[***]	Y
67.1		Set up of TFL shells for 1st DSMB review	[***]	$[***]	Y
67.2		Stats reprogramming for kit size change, 5 blocks vs 10 blocks	[***]	**$[***]**	
68		Method Validation	[***]	$[***]	Y
69		TFL Generation	[***]		
69.1		TFL Generation for DSMB Review	[***]	$[***]	Y
69.2		TFL Generation for remaining trial	[***]	$[***]	
	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	[***]	$[***]	Y
74		DSMB Meeting	[***]	$[***]	Y
75		DSMB Meeting	[***]	$[***]	Y
76		DSMB Meeting	[***]	$[***]	***Y***
77		DSMB Meeting	[***]	$[***]	***Y***
78		DSMB Meeting	[***]	$[***]	
79		DSMB Meeting	[***]	$[***]	
80		DSMB Meeting	[***]	$[***]	
81		DSMB Meeting	[***]	$[***]	
82		DSMB Meeting	[***]	$[***]	
		BARDA Update Meetings			
83		Year 1 Meeting - BARDA	[***]	$[***]	***Y***
84		Year 2 Meeting - BARDA	[***]	$[***]	

85		Year 3 Meeting - BARDA	[***]	$[***]	
		Reporting			
86		Annual Report 1	***[***]***	-	***Y***
87		Annual Report 2	***[***]***	-	
88		Annual Report 3	***[***]***	-	
	1.4.	**Regulatory (6/2024-7/1/2027)**			
89	1.4.2	FDA Annual Report 1	[***]	$[***]	Y
90	1.4.2	FDA Annual Report 2	[***]	$[***]	
91	1.4.2	FDA Annual Report 3	[***]	$[***]	
92	1.4.1	Regulatory Interactions - Quarter 1	[***]	$[***]	Y
93		Regulatory Interactions - Quarter 2	[***]	$[***]	Y
94		Regulatory Interactions - Quarter 3	[***]	$[***]	Y
95		Regulatory Interactions - Quarter 4	[***]	$[***]	Y
96		Regulatory Interactions - Quarter 5	[***]	$[***]	***Y***
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	[***]	$[***]	
	1.5	CMC / KP.2 Manufacturing			
104	1.5.1.1	Manufacturing Start - **FFP**	[***]	$[***]	Y
105	1.5.1.2	Research Virus Bank manufacturing	[***]		
		KP.2 Bulk Drug Substance manufacture, test, and release			
106	1.5.1.3.1	Lot A - **FFP**	[***]	$[***]	Y
107	1.5.1.3.2	Lot B	[***]		
		KP.2 GMP Drug Product manufacture, test, and release			
108	1.5.1.4.1	Lot A - **FFP**	[***]	$[***]	Y
109	1.5.1.4.2	Lot B - **FFP**	[***]	$[***]	Y
110	1.5.1.5	Stability Studies	[***]		
111	1.5.1.6	Labeling, Packaging and Shipment to Depot (Vaxart KP.2 Product) - **FFP**	[***]	$[***]	Y
112	1.5.2.1	Technical Management of Non-Vaxart Trial Material Acquisition, Packaging & Distribution	[***]	$[***]	Y
113.1	1.5.2.2.1	Acquisition of mRNA Comparator (First 3,750 PFS)	[***]	$[***]	Y
113.2	1.5.2.2.1	Acquisition of mRNA Comparator (Additional 3,750 PFS)	[***]	$[***]	***Y***
114	1.5.2.2.2	Acquisition of Saline	[***]	$[***]	Y
115	1.5.2.2.3	Acquisition of Ancillary Kits	[***]	$[***]	Y
116.1	1.5.2.3.1	Kitting of mRNA Comparator (First 3,750 PFS)	[***]	$[***]	Y
116.2	1.5.2.3.1	Kitting of mRNA Comparator (Additional 3,750 PFS)	[***]	***$[***]***	***Y***

117	1.5.2.3.2	Kitting of Saline	[***]	$[***]	Y
118	1.5.3.1	Storage	[***]	$[***]	Y
119	1.5.3.2	Distribution to Clinical Sites	[***]	$[***]	Y
		PHASE 2			
120		Kick Off / Program Initiation	[***]	$[***]	
121		Materials & Supplies Acquisition	[***]	$[***]	
122	1.1.1	Sample Processing	[***]	$[***]	
123	1.1.1	Durability Sample Analysis	[***]	$[***]	
124	1.1.1	Flow Analysis	[***]	$[***]	
125	1.1.2	Sequence Memory Cells	[***]	$[***]	
126	1.1.3	Produce Clones	[***]	$[***]	
127	1.1.3	Complete Clone Analysis	[***]	$[***]	
128	1.2	Phase 2 Final Report	[***]	-	
129		Final Technical and Business Status Report	[***]	-	
			Total	$[***]	
			Contract Type	**CPFF/FFP**	

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.

Technical Data to Be Furnished with Restrictions	**Basis for Assertion**	**Asserted Rights Category**	**Name of Asserting Organization**	**Milestone Affected**
[***]	**Vaxart development prior to contract at private expense**	**Limited rights**	**Vaxart, Inc.**	**N/A; background**