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

FORM 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023
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	**59-1212264**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
170 Harbor Way, Suite 300, South San Francisco, CA 94080	**(650) 550-3500**
(Address of principal executive offices, including zip code)	(Registrant's telephone number, including area code)

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**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2023, based on the last reported sales price of the Registrant's common stock of $0.73 per share, was $110,318,242. As of March 7, 2024, the registrant had a total of 173,861,684 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2023. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") for the year ended December 31, 2023, 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 Annual 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." 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 Annual 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 factors and risks 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 Annual Report.

This Annual 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. See our Summary of Risk Factors on page 17.

PART I

Item 1. Business

Overview

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. Unless otherwise indicated, all references to "Vaxart," "we," "us," "our" or the "Company" in this Annual Report mean Vaxart, Inc., the combined company.

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").

We believe our oral tablet vaccine candidates offer important advantages:

First, they are designed to generate broad and durable immune responses, including systemic, mucosal and T cell responses, which may enhance protection against certain infectious diseases, such as norovirus, COVID-19 and influenza, and may have potential clinical benefit for certain cancers and chronic viral infections, such as those caused by HPV.

Second, our tablet vaccine candidates are designed to provide a more efficient and convenient method of administration, enhance patient acceptance and reduce distribution bottlenecks, which we believe will improve the effectiveness of vaccination campaigns.

Our Tablet Vaccine Platform

Platform Components

Our platform technology employs a vector-based approach and consists of the following components:

- A vector, which is a virus used as a carrier to deliver DNA coding for vaccine antigens and an adjuvant selected to activate the immune system. Specifically, we use non-replicating adenovirus type 5 ("Ad5"), which delivers the DNA encoding both the antigen and adjuvant to the cells of the small intestine, where the antigen and adjuvant are co-expressed. Over 200 clinical trials conducted by others have used Ad5 for a wide range of applications, and we believe that using the same adenovirus in our tablet vaccine candidates may reduce regulatory risk because it is known to regulatory authorities.

- An antigen, which is a viral or bacterial protein that stimulates an immune response to the targeted pathogen. Our antigens are encoded in the Ad5 DNA rather than being directly included in the vaccine. We use a different antigen for each of our clinical vaccine candidates.

- An adjuvant, which is a substance that enhances the immune-stimulating properties of the vaccine. We use a short section of double-stranded RNA ("dsRNA") encoded in the Ad5 DNA as an adjuvant. dsRNA is a Toll-like receptor 3 ("TLR3") agonist and is recognized by the innate immune system as a signal of a viral infection and thereby triggering it to mount an immune response in defense.

- Our proprietary enteric-coated tablet which is designed to deliver the Ad5 vector to the small intestine.

How Our Tablet Vaccine Candidates Work

Our tablets are designed to deliver vaccines to the small intestine. The tablets are covered with a protective coating that remains intact in the low-pH environment of the stomach and protects the active ingredient contained in the tablet core from degradation in the stomach. The coating is designed to dissolve in the neutral-pH environment of the small intestine. The tablets disintegrate, and the vaccine is released into the small intestine where it can reach and enter the mucosal cells lining the intestine. Once inside the mucosal cells, the Ad5 vector instructs the cells to manufacture antigen protein and adjuvant. The adjuvant is always produced within the exact same intestinal cells that also produce the antigen, so that no excess adjuvant is produced, resulting in enhanced safety. Importantly, the production of antigens in our approach closely mimics the process of actual infection by a pathogenic virus. In addition, we believe that delivering the replication-incompetent Ad5-vectored vaccine via tablet directly to the gut avoids neutralization by systemic immunity.

The Significance of Mucosal Immunity and T Cell Responses

The immune system has developed defenses against pathogens by creating special classes of immune effectors, such as mucosal antibodies directed to wet surfaces and killer T cells that can kill pathogen-infected cells. Most vaccines available today have been developed primarily to elicit blood circulating, or systemic B cell responses, such as serum antibodies. However, there remain many infections, such as norovirus, for which no approved or marketed vaccines exist. These infections and other pathogens may need greater immune responses outside of serum antibodies. These infections largely evade the serum antibody immune response because the pathogen can infect cells that line the mucosal membranes without coming into direct contact with blood.

One of the key benefits of our technology is delivery to the gastrointestinal tract, enabling the vaccine to directly enter the mucosal surface of the intestine and activate the immune system of the gut. Mucosal vaccine delivery is believed to enhance protection against mucosal pathogens by generating immunity at the surface where such pathogens invade. Our tablet vaccine candidates target the mucosal immune cells with a vector-based approach and are designed to create a more potent cytotoxic T cell response and mucosal antibody response, which may provide more effective immunity for certain diseases. Further, we have demonstrated that our vaccine delivered to the intestine can produce mucosal responses at sites distal to the intestine such as the nose and the mouth.

Oral Non-Replicating Ad5 Vector is Designed to Circumvent Anti-Vector Issues

Injected Ad5 vectored vaccines generate strong anti-Ad5 responses, with up to a 100-fold increase in the anti-Ad5 neutralizing antibody titers. In contrast, our oral Ad5 vectored vaccine is designed to circumvent the complications related to anti-Ad5 immunity, allowing the platform to be used for multiple vaccines and repeat annual and booster vaccinations.

Our Product Pipeline

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

Our Norovirus Program

Market Overview

Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis among people of all ages in the United States. Each year, on average, 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. In the U.S., we believe a norovirus vaccine would be beneficial for high-risk groups such as infants and children up to five years old, older adults and the elderly, as well as for workers in the food and travel industries, for healthcare, childcare and elder care workers, first responders, the military, and travelers. In a study published by Johns Hopkins University and the CDC in 2016, the total global annual economic burden of norovirus was estimated at $60 billion. In a more recent health economic study published in the Journal of Infectious Diseases in July 2020, the economic impact to the U.S. was estimated to be $10.6 billion annually. There are currently no approved vaccines or therapies to prevent or treat norovirus infection.

Our Norovirus Vaccine Candidate

We are developing a VP1-based bivalent oral tablet vaccine candidate that would protect against norovirus GI and norovirus GII, the two major norovirus genogroups affecting humans, by targeting the norovirus GI.1 Norwalk strain and the norovirus GII.4 Sydney strain. Because norovirus is an enteric pathogen that infects epithelial cells of the small intestine, we believe that a vaccine that produces antibodies against norovirus locally in the intestine, such as our tablet vaccine candidate which is delivered directly to the gut, may induce optimal protection against infection.

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

- 29% relative reduction in the rate of infection in the vaccinated cohort compared with placebo (82% vs. 58%) ($p=0.003$)
- Significant increase in the induction of norovirus-specific immunoglobulin A (“IgA") antibody-secreting cells (ASC) in the vaccinated cohort, with a 79% response rate in the vaccinated cohort, compared with 2.5% in the placebo cohort ($p<0.001$) on Day 8 post-vaccination; mean response was 375 ASC per million cells for the vaccinated cohort, compared with 26 ASC per million cells for placebo
- Significant increase in the induction of histo-blood group antigen (“HBGA”) blocking anti-bodies in the vaccinated cohort (GMFR 3.23) compared with the placebo cohort (GMFR 1.0) on Day 29 post-vaccination ($p<0.001$)
- Significant increases in norovirus-specific serum IgA (GMFR 7.14) and IgG (GMFR 4.64) in the vaccinated cohort compared with placebo from baseline to Day 29 post-vaccination ($p<0.001$)
- No vaccine-related serious adverse events (“SAEs”) or dose-limiting toxicities were reported

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.

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 (Table 1). 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.

Table 1. Mean Fold Rise Summary (Day 1 to Day 29) Preliminary Data

		GI.1			**GII.4**	
Serum Antibodies	IgA	IgG	BT50	IgA	IgG	BT50
Medium Dose (n=50)	5.9	4.8	3.0	9.3	6.1	4.3
High Dose (n=59)	6.4	4.2	2.3	8.6	5.1	7.8
Placebo (n=25)	1.0	1.0	1.1	1.1*	1.0	1.0*

*excluding subject with confirmed gastroenteritis.

We expect to meet with the Food and Drug Administration ("FDA") in the second quarter of 2024 to discuss data on correlates of protection, which will inform potential next steps, such as conducting a Phase 2b study and potentially a GII.4 challenge study. We believe the Phase 2b study will generate sufficient safety data to enable us to have an end of Phase 2 meeting with the FDA. The end of Phase 2 meeting is expected to allow us to gain concurrence on the scope and design of the Phase 3 pivotal efficacy study in adults over 18 years of age.

Additional Age Groups and Subpopulations

Pediatric Population. Our current tablet vaccine formulation is designed for delivery to the gut in solid dosage form using an enteric-coated tablet which we believe is the optimal vaccine delivery system for the adult population and children eight years and older. For children six months to seven years in age, we plan to develop minitablet formulations that can deliver the vectored vaccine intact to the gut. Development of our norovirus vaccine in the pediatric population will proceed with a stepdown approach through progressively younger age segments (i.e. 8 to 5 years, 4 to 2 years, 2 years to 6 months).

Breastfeeding Mothers. We are currently partnering with the Bill & Melinda Gates Foundation to execute a Phase 1 norovirus bivalent vaccine candidate study in 76 healthy, lactating post-partum, women volunteers, to determine the impact of our norovirus vaccine on breast milk norovirus-specific IgA and its potential presence, post-breastfeeding, within infant fecal samples. The study is randomized, double-blinded, and placebo controlled and will evaluate the safety, tolerability, and immunogenicity of the placebo cohorts and two vaccine cohorts: medium dose (1×10^{11} IU) and high dose (2×10^{11} IU). 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 expect top line results in the middle of 2024. As a grant recipient from the Bill & 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.

Our COVID-19 Program

Market Overview

Coronaviruses comprise a group of respiratory viruses, encompassing SARS-CoV-1, SARS-CoV-2, and Middle East respiratory syndrome coronavirus (MERS-CoV), among various others. SARS-CoV-2, the virus responsible for COVID-19, induces a severe respiratory tract infection and stands as a significant cause of hospitalization and mortality globally. Currently approved COVID-19 vaccines seem to have varying levels of efficacy to emerging strains of SARS-CoV-2.

Our COVID-19 Vaccine Candidates

We have spent significant effort developing COVID-19 vaccine candidates over the past few years. The data generated show our COVID-19 vaccine candidates have induced cross-reactivity in clinical trials, which is relevant for developing a vaccine responsive to future coronavirus pandemics.

Our first COVID-19 vaccine candidate (rAd-S-N, known as Vaxart clinical candidate VXA-CoV2-1) expresses two different genes from the SARS-CoV-2 virus, the spike ("S") protein and the nucleoprotein ("N"). The N protein is more conserved among the coronavirus family of viruses, and inclusion in our vaccine candidate was done in order to create a T cell target even if new and emerging strains of SARS-CoV-2 have substantial mutations in the S protein, thereby reducing the ability of the vaccine to create protective immune responses that recognize the S from these strains. In February 2021, we announced our Phase 1 open-label, dose-ranging trial evaluating the safety and immunogenicity of VXA-CoV2-1 met primary and secondary endpoints of safety and immunogenicity based on preliminary data. In this Phase 1 trial, VXA-CoV2-1 was generally well-tolerated and triggered immune responses against SARS-CoV-2 antigens in a majority of subjects, including: CD8+ cytotoxic T-cell response to the S and N proteins (may contribute to long-lasting cross-reactive immunity), activation of B cells that will home to the mucosa, an increase in proinflammatory Th1 cytokines (responsible for creating a productive immune response against viral infection) and IgA responses. 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.

Our second COVID-19 vaccine candidate (rAd-S, known as Vaxart clinical candidate VXA-CoV2-1.1-S) expresses only the S protein from the SARS-CoV-2 Wuhan strain. This candidate made improved antibody immune responses in a non-human primate ("NHP") study compared to other vaccine candidates and was able to inhibit transmission in a hamster transmission experiment. 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 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 responses (antibodies in the nose and mouth) were observed in approximately 50% of subjects. Subjects that had an increase in the mucosal IgA 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 do not currently intend to proceed with the second part of the study.

We have also made a COVID-19 vaccine candidate that expresses only the S protein from the SARS-CoV-2 XBB strain. In January 2024, we were awarded a contract by the United States Biomedical Advanced Research and Development Authority (BARDA) for $9.27 million to fund preparation for a 10,000 subject Phase 2b clinical study. 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.

We are currently preparing for this Phase 2b clinical trial and believe the trial may initiate as soon as in the second quarter of 2024.

Our Influenza Program

Market Overview

Influenza is one of the most common global infectious diseases, causing mild to life-threatening illness with symptoms such as sore throat, nasal discharge, fever, and even death. It is estimated that there are around one billion cases of seasonal influenza annually worldwide, of which 3 million to 5 million cases are considered severe, causing 290,000 to 650,000 deaths per year globally. Very young children and the elderly are at greatest risk from death. In the United States, between 9,000,000 and 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.

The CDC generally recommends that individuals six months and older be vaccinated annually against influenza. In the U.S., this means an influenza vaccination is recommended for more than 300 million people.

Our Seasonal Influenza Vaccine Candidate

We are developing a tablet vaccine candidate for the immunization of healthy adults against seasonal influenza. Commercial seasonal influenza vaccines today are composed of either three (trivalent) or four (quadrivalent) strains, either one influenza B and two influenza A strains, or two of each. Our seasonal influenza vaccine candidate is a trivalent seasonal influenza vaccine consisting of two circulating influenza A lineage viruses (H1N1 and H3N2) as well as one circulating influenza B lineage virus (B/Victoria lineage), matching the seasonally updated recommendations by the World Health Organization. We envision formulating our tablet vaccine candidate as one tablet per strain, or three tablets in total for the trivalent vaccine. We believe this modularity will allow for enhanced flexibility. For instance, in the event of a late season strain change, the tablet containing the obsolete strain could be easily replaced without having to discard the two correctly matched vaccine tablets. We will also consider formulating all three strains into a single tablet. This format would be the simplest to administer but would take away some of the flexibility advantages that separate tablets would afford. We will assess the final formulation of our tablet vaccine candidates after conducting market studies to evaluate market acceptance closer to commercialization.

Seasonal Influenza Clinical Trials

To date, we have completed two Phase 1 trials and have conducted the active portion of a Phase 2 challenge trial of our H1N1 influenza vaccine candidate. We have also completed a Phase 1 trial of an influenza B vaccine candidate (B Yamagata lineage).

H1N1 Influenza Phase 2 Challenge Study Funded by HHS BARDA

In 2015, we were awarded a $13.9 million contract by BARDA, part of the HHS. This two-year contract was awarded under a Broad Agency Announcement issued to support the advanced development of more effective influenza vaccines to improve seasonal and pandemic influenza preparedness. The contract primarily funded a Phase 2 challenge study in human volunteers, designed to evaluate whether our H1N1 tablet vaccine candidate offers broader and more durable protection than currently marketed injectable vaccines. The contract with HHS BARDA was subsequently increased to $15.7 million and the term was extended until September 2018.

In this Phase 2 study, volunteers were randomized into three groups. One group received our oral H1N1 influenza tablet vaccine candidate, a second group received a commercially licensed inactivated influenza vaccine by intramuscular injection, and a third group received placebo. Three months following immunization, volunteers were challenged (deliberate experimental administration) with live H1N1 (A/H1N1 pdm09) influenza virus by intranasal administration. The placebo group served as the control group to determine how many unvaccinated volunteers became infected and how severe their influenza symptoms became. Data from our vaccine candidate group and the commercially licensed inactivated vaccine group were compared to placebo to determine each vaccine's efficacy in this challenge study. Importantly, the two vaccines were also compared head-to-head. The goal of the study was to compare the efficacy of our vaccine to protect volunteers from illness caused by H1N1 influenza challenge, compared to both the injectable vaccine and placebo three months after immunization.

Clinical Trial Results VXA-CHAL-201

The Phase 2 challenge study was enrolled during 2016 and 2017. During this time, 179 subjects that cleared the screening requirements were randomized to receive a single dose of our tablet vaccine, the commercial injectable vaccine, or placebo. Of these 179 subjects, 143 subjects were subsequently challenged with live H1N1 influenza virus 90 to 120 days after dosing.

- ***Safety.*** The side effects of the vaccines and placebo in the first seven days following administration were generally mild. In the first seven days following administration, the solicited adverse events reported in the vaccine and placebo groups were mostly grade 1 in severity, and none were above grade 2. The most frequent solicited adverse event was headache in our tablet vaccine group (7%), injection site tenderness in the commercially licensed inactivated vaccine group (26%) and headache in the placebo group (19%). There were no serious adverse events and no new onsets of chronic illnesses related to our vaccine adjuvant recorded during the follow up period of the study.

Efficacy – Reduction of PCR Confirmed Influenza Illness.

The primary efficacy objective was to determine vaccine efficacy of our tablet vaccine following the challenge with the wild-type influenza A H1 virus strain (A/H1N1 pdm09). The primary efficacy endpoint was illness. The illness rate was 29% for our tablet vaccine, 35% for the commercial inactivated influenza vaccine, and 48% for subjects in the placebo group. Our tablet vaccine had a lower rate of illness than the commercial vaccine (-6% difference in illness rate in favor of our vaccine), although given the small size of the study, these differences were not statistically significant. Similarly, the difference in illness rates between our tablet vaccine and placebo (-19.1%) and the commercial injected vaccine and placebo (-13.2%) trended toward protection but were not statistically significant. These results suggest that our vaccine is no worse, and trended better than the commercial vaccine for protection. These results are summarized in Table 2 below.

Table 2. H1 Influenza Phase 2 Challenge Study: Illness Rates*.

VAXART		Commercial		VAXART-Commercial	Placebo	
n	% (95% CI)	n	% (95% CI)	Rate Difference (95% CI)	n	% (95% CI)
58	29.3 (18.1, 42.7)	54	35.2 (22.7, 49.4)	-5.9 (-24.3, 12.5)	31	48.4 (30.2, 66.9)

**Illness was defined as a combination of symptoms reported on a patient reported outcome tool (Flu-PROTM) and quantitative reverse transcriptase polymerase chain reaction (qRT-PCR) detectable shed influenza virus.*

Efficacy – Shedding

Shedding represents influenza virus that is detected in nasal swabs post infection and is representative of viral infection and replication. In the study, 44.8% of subjects in VXA-A1.1 had at least one day positive for shedding, versus the commercial injected vaccine where 53.7% were positive for shedding and where 71.0% of placebo subjects were positive for shedding. There were no statistically significant differences observed between our tablet vaccine and the commercial inactivated influenza vaccine for viral shedding area under the curve ("AUC"). However, AUC was calculated using a standard logarithmic trapezoidal method and included only detectable shedding during the first five days of the duration of shedding, with subjects removed from the analysis that didn't shed influenza for five days (a zero value cannot be used in log calculations and integrated). This may have led to an underestimate of the effect on viral shedding for the two vaccines relative to placebo. Therefore, in order to better determine the effect of the vaccines on shedding, an alternative method was used in which volunteers were defined as infected if they had detectable viral shedding at any time 36 hours after challenge. This approach eliminated possible issues related to calculations (log calculations of zero values) and of large doses of challenge virus (first 36 hours might be pass through rather than replicating influenza). In a Bayesian analysis, both vaccines significantly reduced the probability of shedding relative to placebo (Bayesian posterior p=0.001 for our tablet vaccine and p=0.009 for the commercial inactivated influenza vaccine). There is also trend toward greater efficacy for our vaccine with a posterior probability of approximately 80% (**Table 3**).

Table 3. H1 Influenza Phase 2 Challenge Study: Infection Rates*.

Treatment Arm	N	Number Infected	Percent (95% CI)	Posterior P
Placebo	31	22	71% (55-85%)	-
Commercial	54	24	44% (32-58%)	0.009
Vaxart Vaccine	58	21	36% (24-49%)	0.001

**Infection was defined as any positive quantitative reverse transcriptase polymerase chain reaction (qRT-PCR) detectable shed influenza virus on any day after 36 hours from viral challenge. In a Bayesian analysis, both vaccines provide a statistically significant protection against infection. There is also trend toward greater efficacy for our vaccine with a posterior probability of approximately 80%.*

Phase 1 Trial. Influenza B (Yamagata lineage)

In 2015 and 2016, we conducted a randomized, double-blind, placebo-controlled Phase 1 trial to test the safety and immunogenicity of an influenza B tablet vaccine. A total of 54 healthy adults aged 18 to 49 were enrolled, with 38 receiving the vaccine and 16 receiving placebo. To participate in this trial, subjects were required to have an initial HAI measure of no greater than 1:20. The active phase of the trial was through day 28, with the follow-up phase for monitoring safety to continue for one year. All subjects who received the vaccine received a single dose of either 1 x 10^{10} IU or 1 x 10^{11} IU on Day 0.

Safety. The side effects of the vaccine or placebo in the first seven days following administration were generally mild with no serious adverse events. There were no notable differences between the active dose groups and placebo in safety and tolerability.

HAI. In the placebo group, HAI GMT remained essentially unchanged (1:33) at day 28 post dosing. The GMFR of HAI titers both active treated groups at day 28 post dosing was about 2-fold, and independent of dose. For the vaccinated groups receiving either 1×10^{10} IU or 1×10^{11} IU, seroconversion was observed in 5/19 subjects (26.3%) and 3/19 subjects (15.8%), respectively. There were no seroconversions in the placebo group.

Antibody Secreting Cells (ASCs). In order to measure total antibody responses to HA, the numbers of circulating B cells that recognize influenza HA in peripheral blood were measured by ASC assay on days 0 and 7 after immunization. Results show that ASCs could be reliably measured on day 7 in the vaccine-treated groups. Background ASCs were generally negligible on day 0. By IgG ASC, 68% of 1×10^{10} IU dose subjects responded, and 84% of subjects in the 1×10^{11} IU dose group responded. For the 1×10^{11} IU dose vaccine treated group, an average of 21 IgA ASCs (95% CI: 7 – 35) and 73 IgG ASCs (95% CI: 35 – 111) each per 1×10^{6} peripheral blood mononuclear cell (PBMC) were found at day 7. For the 1×10^{10} IU dose vaccine treated group, an average of 16 IgA ASCs (95% CI: 2 – 29) and 44 IgG ASCs (95% CI: 21 – 66) were found at day 7. The placebo group had no responders, and negligible average number of spots (1 or less) on Day 7 (95% CI: -0.6 – -2).

Next Steps

We have also initiated early-stage development 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.

Our HPV Therapeutic Vaccine Program

HPV is a family of more than 120 viruses which are extremely common globally. At least 13 HPV types are cancer-causing. HPV is primarily transmitted through sexual contact and infection is very prevalent following the onset of sexual activity. Nearly all cases of cervical cancer are attributable to HPV infection, with two HPV types – HPV-16 and HPV-18 – responsible for 70% of cervical cancers and precancerous cervical lesions. Cervical cancer is the fourth most common cancer in women worldwide, and about 13,000 new cases are diagnosed annually in the United States according to the National Cervical Cancer Coalition. Studies have indicated a high lifetime probability of any HPV infection by both men and women in the United States, with some estimates indicating at least 80% of women and men acquire HPV by age 45. The CDC estimates 80 million U.S. citizens are currently infected with HPV, representing 25% of the population, with about 14 million new infections per year.

In women, many HPV infections of the cervix will spontaneously resolve and clear within two to three years, but women who have a persistent infection are at high risk of developing cellular abnormalities known as cervical intraepithelial neoplasia (“CIN”), which can progress to invasive cancer over time. More than 400,000 women are diagnosed with CIN annually in the United States, with an annual incidence estimate for CIN1 and CIN2/3 at 1.6 and 1.2 per 1,000 women, respectively.

There are currently no approved therapeutic vaccines to treat HPV infection or cancer. Current treatment options for women infected with HPV include monitoring CIN status, surgical procedures to remove affected tissue, and chemotherapeutic or radiation therapies to treat localized or metastatic cervical cancer. Therefore, a medical need remains for a therapeutic vaccine to treat women with HPV-associated CIN and/or cervical cancer.

Our HPV Therapeutic Vaccine Candidate

We are in the early stages of developing a bivalent HPV vaccine against HPV-16 and HPV-18, the strains responsible for approximately 70% of cases of cervical cancer. We plan to target the E6 and E7 gene products of each strain, which are the primary oncogenic proteins responsible for progression through the stages of CIN to invasive cervical cancer. In pre-clinical studies, we have demonstrated immunogenicity for both our HPV-16 and our HPV-18 vaccine candidates. Specifically, mice given our HPV-16 or HPV-18 vaccines induced T cell responses to HPV as measured by IFN gamma ELISPOT. In addition, our HPV-16 vaccine has demonstrated tumor growth suppression as well as increased survival in a robust HPV tumor model in mice.

Next Steps

We will need to make a regulatory filing to proceed with clinical trials for an HPV vaccine candidate. Our clinical plan is to test the vaccine candidate in subjects with cervical dysplasia related to HPV-16 or HPV-18, and to evaluate the ability of the vaccine candidate to clear HPV infection, reduce the cervical dysplasia score, and induce T cells known to be important in the clearance of HPV. The primary endpoint will be safety and the secondary endpoint will be immunogenicity by examining T cell responses. Although clinical responses will be tracked, it is expected that the first study may not be powered to obtain statistically significant efficacy readouts.

Anti-Virals

- Through the Merger, we acquired two royalty earning products, Relenza and Inavir. We also acquired three Phase 2 clinical stage antiviral compounds, which we have discontinued independent clinical development of. However, for one of these, Vapendavir, we have 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. In May 2022, Altesa announced its intention to initiate clinical trials.

- 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 December 2029. 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.

Manufacturing

Manufacturing our oral tablet vaccines consists of two main stages, the production of bulk vaccine (drug substance), and the formulation and tableting thereof (drug product). Drug substance manufacturing consists primarily of the production and purification of the active ingredient. Bulk drug substance is then lyophilized, formulated and subsequently tableted and coated using a proprietary formulation and tableting process that we developed.

Bulk Vaccine Manufacturing (Drug Substance)

From inception, we relied on a combination of third-party contract manufacturers and in-house facilities to manufacture clinical cGMP bulk drug substance for our tablet vaccine candidates. Starting in 2017, we invested in developing our own bulk vaccine manufacturing process with the aim to establish a small cGMP bulk manufacturing facility at our corporate headquarters in California for manufacturing cGMP product for our Phase 1 and small Phase 2 trials. We expanded in November 2021 by subleasing another GMP manufacturing facility which we use to perform the same bulk manufacturing processes in-house. In April 2022, we executed agreements with Lyophilization Technology, Inc. for lyophilization of drug substance at a larger scale.

Vaccine Tablet Manufacturing (Drug Product)

From inception we contracted with third-party contract manufacturers for the manufacture, labeling, packaging, storage, and distribution of our drug product. In 2016, we established drug product manufacturing capabilities at our corporate headquarters. Our facility is licensed by the State of California Department of Public Health Food and Drug Branch to manufacture drug product for clinical trials. In July 2022, we executed an agreement with Attwill for further drug product manufacturing (tableting and coating) at a larger scale and we have invested in building a new GMP facility in California for tableting, coating and packaging of our vaccine candidates.

We have limited experience with process development, and the manufacture, testing, quality release, storage and distribution of drug substance and drug product according to cGMP and regulatory filings. The cGMP regulations include requirements relating to the organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Our facilities, and our third-party manufacturers, are subject to periodic inspections by FDA and local authorities, which include, but are not limited to procedures and operations used in the testing and manufacture of our vaccine candidates to assess our compliance with applicable regulations. If we or our third-part manufacturers fail to comply with statutory and regulatory requirements we and they could be subject to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material adverse impact on the availability of our tablet vaccine candidates. Similar to contract manufacturers, we have in the past encountered difficulties involving production yields, quality control and quality assurance, and if we are not able to produce drug product or drug substance in sufficient quantities our ability to conduct our clinical trials and commercialize our tablet vaccine candidates, if approved, will be impaired.

Research and Development

In the ordinary course of business, we enter into agreements with third parties, such as clinical research organizations, medical institutions, clinical investigators and contract laboratories, to conduct our clinical trials and aspects of our research and preclinical testing. These third parties provide project management and monitoring services and regulatory consulting and investigative services.

Competition

The pharmaceutical and vaccine industries are characterized by intense competition to develop new technologies and proprietary products. In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position.

While we believe that our proprietary tablet vaccine candidates provide competitive advantages, we face competition from many different sources, including biotechnology and pharmaceutical companies, and we may also face competition from academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies as well as new products and therapies that may become available in the future.

There are other organizations working to improve existing therapies, vaccines or delivery methods, or to develop new vaccines, therapies or delivery methods for their selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of our vaccine candidates, if approved.

We anticipate that we will face intense and increasing competition as new vaccines enter the market and advanced technologies become available. We expect any tablet or other oral delivery vaccine candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can obtain approval for our vaccine candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

We face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies. We may also face significant competition in pursuing partnership opportunities and strategic acquisitions from other companies, financial investors and enterprises whose cost of capital may be lower than ours. Competition for future partnerships or asset acquisition opportunities in our markets is intense and we may be forced to increase the price we pay for such assets.

We also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the development and commercialization of our products.

Norovirus Vaccine Candidate

Currently there are no approved norovirus vaccines. We are aware that HilleVax, Inc. and Moderna, Inc. are developing norovirus vaccines that would be delivered by injection. Another company developing a norovirus vaccine candidate is Anhui Zhifei Longcom Biopharmaceutical Co. Ltd. There may be other development programs that we are not aware of.

COVID-19 Vaccine Candidate

There is significant competition in the COVID-19 vaccine market. Pfizer-BioNTech's COVID-19 vaccine, Moderna's COVID-19 vaccine, and Novavax's COVID-19 vaccine have been approved in the United States and many countries around the world. Johnson & Johnson's COVID-19 vaccine and AstraZeneca's COVID-19 vaccine have been approved in many other countries around the globe and have supplied the majority of the "western doses" to the world.

Seasonal Influenza Vaccine Candidate

We believe our seasonal influenza vaccine candidate would compete directly with approved vaccines in the market, which include non-recombinant and recombinant products that are administered via injection or intranasally. Major players include Astrazeneca Plc, Csl Limited, Emergent BioSolutions, F. Hoffmann-La Roche Ltd., GSK, Merck & Co., Inc., Novartis Ag, Pfizer, Inc., Sanofi, and Sinovac Biotech Ltd.

HPV Therapeutic Vaccine Candidate

There is currently no approved HPV therapeutic vaccine for sale globally; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. We believe that several companies are in various stages of developing an HPV therapeutic vaccine including Inovio Pharmaceuticals, Inc. ("Inovio"), Genexine, and several others.

Inavir

Other anti influenza antivirals are marketed in Japan, including Tamiflu and Relenza. On February 23, 2018, Osaka-based drug maker Shionogi gained marketing approval for Xofluza, a new drug to treat influenza in Japan. The drug was approved for use against type A and B influenza viruses and requires only a single dose regardless of age. Since its launch, Xofluza has gained significant market share from Inavir in Japan, substantially reducing the sales of Inavir in Japan by Daiichi Sankyo. This has had a significant negative impact on the royalty payments we have received from Daiichi Sankyo and may continue to have a significant negative impact on our future royalty revenues.

Intellectual Property

We strive to protect and enhance our proprietary technology, inventions and improvements that are commercially important to our business by seeking, maintaining, and defending patent rights. We also rely on trade secrets relating to our platform and on know-how, continuing technological innovation to develop, strengthen and maintain our proprietary position in the vaccine field. In addition, we rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. We also utilize trademark protection for our company name and expect to do so for products and/or services as they are marketed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our tablet vaccine candidates may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

We have developed numerous patents and patent applications and own substantial know-how and trade secrets related to our platform and tablet vaccine candidates.

- ***Vaccine Platform Technology***. As of December 31, 2023, we held three U.S. patents with claims relating to our platform technology. Two of these U.S. patents include claims related to our seasonal influenza vaccine candidate. These patents will expire in 2027, or later if patent term extension applies. As of December 31, 2023, we held more than 45 issued foreign patents and one pending foreign patent application related to our platform technology and/or our vaccine candidates. These patents will expire in 2027, or later if patent term extension applies.

- ***Tablet Vaccine Formulation***. We own considerable know-how and hold patents in the U.S., E.U., Canada, Japan, China, Singapore, Australia, Russia, Israel, Indonesia, Vietnam, South Korea, and South Africa. We also have pending applications in the United States and around the world related to our tablet vaccine formulation technology. Patents issuing from these applications will expire in 2035/2036, or later if patent term extension applies.

- ***COVID-19 Vaccine Candidate***. As of December 31, 2023, we have filed provisional applications in the United States and have pending applications in the United States, EPO, Australia, Canada, China, Japan, South Korea, India and South Africa relating to our COVID-19 vaccine candidate. Any patents issuing from these applications will expire in 2041, or later if patent term extension applies.

- ***Norovirus Vaccine Tablet Candidates***. As of December 31, 2023, we hold a patent in South Africa, the European Union, and a number of countries therein, and have pending applications in the United States and around the world relating to our norovirus vaccine candidate. Any patents issuing from these applications will expire in 2036, or later if patent term extension applies.

- ***Influenza Vaccine Candidates***. We have been issued 13 foreign patents related to our current H1N1 influenza vaccine candidate. These patents will expire in 2030, or later if patent term extension applies.

- ***Relenza***. As of December 31, 2023, we no longer own any Relenza patents, the last Japanese patent related to Relenza, which was exclusively licensed to GSK, having expired in July 2019.

- ***Inavir***. As of December 31, 2023, we own Japanese patents related to Inavir, which is exclusively licensed to Daiichi Sankyo. The last patent related to Inavir in Japan is set to expire in December 2029, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expires in 2024, at which time generic competition may enter the market, potentially decreasing or eliminating the royalties received.

In addition to the above, we have established expertise and development capabilities focused in the areas of preclinical research and development, manufacturing and manufacturing process scale-up, quality control, quality assurance, regulatory affairs and clinical trial design and implementation. We believe that our focus and expertise will help us develop products based on our proprietary intellectual property.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a U.S. patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a new drug application, or NDA, we expect to apply for patent term extensions for patents covering our vaccine candidates and their methods of use.

Trade Secrets

We rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these procedures, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Government Regulation and Product Approval

Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our vaccine candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, even though it may differ in certain respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. The rules and regulations that apply to our business are subject to change and it is difficult to foresee whether, how, or when such changes may affect our business.

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act, or PHSA, and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice ("GCP"), and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a Biologics License Application ("BLA") for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

Before testing any biological vaccine candidate, including our tablet vaccine candidates, in humans, the vaccine candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as toxicological and pharmacological studies in animal species, to assess the potential safety and activity of the vaccine candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs for certain animal studies and the Animal Welfare Act, which is enforced by the Department of Agriculture. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. Any person or entity sponsoring clinical trials in the United States to evaluate a product candidate's safety and effectiveness must submit to the FDA, prior to commencing such trials, an IND application, which provides a basis for the FDA to conclude that there is an adequate basis for testing the product in humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials are subject to extensive regulation. Clinical trials must be conducted and monitored in accordance with the FDA's bioresearch monitoring regulations and regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Foreign studies conducted under an IND must meet the same requirements applicable to studies conducted in the United States. However, if a foreign study is not conducted under an IND, the data may still be submitted to the FDA in support of a product application, if the study was conducted in accordance with GCP and the FDA is able to validate the data.

The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as clinicaltrials.gov.
Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The biological product is initially introduced into a small number of healthy human subjects and tested for safety and to develop detailed profiles of its pharmacological and pharmacokinetic actions, determine side effects associated with increasing doses, and if possible, gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in subjects.

- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit profile of the product and provide an adequate basis for product labeling. Phase 3 data often form the core basis on which the FDA evaluates a product candidate's safety and effectiveness when considering the product application.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. FDA performance goals generally provide for action on a BLA within 12 months of submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The complete response letter may also request additional information, including additional preclinical or clinical data, for the FDA to reconsider the application. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Obtaining approval can take years, requires substantial resources and depends on a number of factors, including the severity of the targeted disease or condition, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses. If ongoing regulatory requirements are not met, or if safety problems occur after a product reaches market, the FDA may take actions to change the conditions under which the product is marketed, including limiting, suspending or even withdrawing approval.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our tablet vaccine candidates under development.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act ("FCA"), as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the HITECH Act, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Additionally, the Federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures". Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any tablet vaccine candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our tablet vaccine candidates, in addition to the costs required to obtain the FDA approvals. Our tablet vaccine candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any tablet vaccine candidates for which it receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect the pressure on healthcare pricing will continue to increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

US Healthcare Reform

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our tablet vaccine candidates. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Information Privacy and Security

We are subject to federal and state laws and regulations that regulate the use, security, and disclosure of certain types of personal data. These include the federal regulations promulgated under the authority of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) that require us to provide certain protections to individuals regarding their health information. The HIPAA privacy and security regulations extensively regulate the use and disclosure of protected health information (“PHI”) and require covered entities, which include healthcare providers and health plans, and their business associates to implement and maintain administrative, physical, and technical safeguards to protect the security of such information. Additional security requirements apply to electronic PHI. These regulations also provide individuals with substantive rights with respect to their health information.

The HIPAA privacy and security regulations also require us to enter into written agreements with our covered entity customers and our subcontractors, also known as business associates, to whom we disclose PHI. Covered entities may be subject to penalties as a result of a business associate violating HIPAA, if the business associate is found to be an agent of the covered entity. Business associates are also directly subject to liability under certain HIPAA privacy and security regulations and may be found liable for the violations of their agents.

HIPAA requires covered entities to notify affected individuals of breaches of unsecured PHI without unreasonable delay but no later than 60 days after discovery of the breach. If a business associate is acting as an agent of a covered entity, then the covered entity must provide the required notifications to individuals based on the time when the business associate discovered the breach. Reporting must also be made to the HHS Office for Civil Rights (“OCR”) and, for breaches of unsecured PHI involving more than 500 residents of a state or jurisdiction, to the media. Impermissible uses or disclosures of unsecured PHI are presumed to be breaches unless the covered entity or business associate establishes that there is a low probability the PHI has been compromised. Various state laws and regulations may also require us to notify affected individuals and the state regulators in the event of a data breach involving personal information without regard to the probability of the information being compromised. State laws and standard practice often provide for shorter data breach reporting timelines than required by HIPAA.

Violations of the HIPAA privacy and security regulations may result in criminal penalties and in substantial civil penalties per violation. The civil penalties are adjusted annually based on updates to the consumer price index. OCR is required to perform compliance audits and investigates HIPAA compliance in response to complaints and reports of breaches. In addition to enforcement by OCR, state attorneys general are authorized to bring civil actions seeking either injunction or damages in response to violations of HIPAA privacy and security regulations that threaten the privacy of state residents. OCR may resolve HIPAA violations through informal means, such as allowing a covered entity to implement a corrective action plan, but OCR has the discretion to move directly to impose monetary penalties and is required to impose penalties for violations resulting from willful neglect. There can be no assurance that we will not be the subject of an investigation (arising out of a reportable breach incident, audit or otherwise) alleging noncompliance with HIPAA regulations in our maintenance of PHI.

The Federal Trade Commission Act (“FTCA”) also empowers the Federal Trade Commission to implement rules and regulations protecting personal information, and to take enforcement action when data practices constitute unfair or deceptive acts or practices. The FTC regularly takes enforcement action and has emphasized the protection of medical and other health care information as an enforcement priority. Following the United Stated Supreme Court’s Dobbs decision and state laws that may criminalize certain health care procedures, types of personal information not traditionally thought of as health-related now may reveal personal information about health care decisions, heightening governmental scrutiny of data privacy practices.

In addition to HIPAA and the FTCA, numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, creation, receipt, transmission, storage, and other processing of medical. health care, employment, consumer, and other personal information. Privacy and data security statutes and regulations vary from state to state, and these laws and regulations in many cases are more restrictive than, and generally are not preempted by, the FTCA and HIPAA and their implementing rules. These laws and regulations regulate how personal information is used, sold, and shared; grant individuals substantive rights regarding their data that data processers are obligated to honor; impose rigorous information security and data breach obligations; and in some instances provide private rights of action to individuals affected by alleged violations of the laws in addition to the costs and liabilities arising from government enforcement.

We also may be subject to international data protection regulations related to the collection, transmission, storage and use of employee data. For example, the General Data Protection Regulation (“GDPR”), which became effective on May 25, 2018, imposes strict compliance obligations on the collection, use, retention, security, processing, transfer and deletion of personal information and creates enhanced rights for individuals, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the information relates in certain circumstances, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors that will have access to personal data. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Economic Area, including the United States and the United Kingdom. Entities that fail to comply with the requirements of the GDPR may be subject to very significant penalties, including potential fines of up to the greater of €20 million or 4% of annual global revenue.

Government regulators, privacy advocates and class action attorneys are also increasingly scrutinizing how companies collect, process, use, store, share and transmit other types of personal data. For example, the California Consumer Privacy Act of 2018 ("CCPA"), which went into effect on January 1, 2020, and was significantly modified by the California Privacy Rights Act ("CPRA"), which became fully effective on January 1, 2023, applies broadly to information that identifies or is associated with any California household or individual, and requires that we implement several operational changes, including processes to respond to individuals' requests regarding their personal information. The CPRA also creates a new enforcement agency to enforce the CCPA and CPRA and imposes additional requirements, including privacy risk assessments, audits and vendor contractual requirements for data sharing, license and access arrangements. The CCPA and CPRA provide for civil penalties for violations and allow private rights of action for data breaches. Virginia, Colorado, Connecticut and Utah have also passed comprehensive privacy legislation that take effect during 2023, and several other states, as well as federal lawmakers, have proposed additional consumer privacy legislation. The complex, dynamic legal landscape regarding privacy, data protection and information security creates significant compliance challenges for us, potentially restricts our ability to collect, use and disclose data, and exposes us to additional expense, and, if we cannot comply with applicable laws in a timely manner or at all, adverse publicity, harm to our reputation, and liability.

Greenhouse Gas Emission Related Policies, Regulation, and Legislation

Governments across the globe have announced and implemented various policies, regulation, and legislation to support the transition from fossil fuels to low-carbon forms of energy and the infrastructure around that transition. The operation of our business and our customers' use of our products and solutions and services as well as our digital applications are and may in the future be, impacted by these various government actions. For example, the United States rejoined the Paris Agreement effective February 19, 2021, an international climate change agreement among almost 200 nations and the European Union, that established a long-term goal of keeping the increase in global average temperature well below 2°C above pre-industrial levels and which calls for countries to set their own GHG emissions targets and be transparent about the measures each country will use to achieve these targets. In August 2022, the United States passed the Inflation Reduction Act ("IRA"), which consists of a number of provisions aimed directly at confronting the climate change crisis. The climate-related provisions of the IRA are projected to cut emissions by up to 40% from 2005 GHG levels in the United States by 2030. Among other things, the IRA introduces an ITC for standalone energy storage, which is anticipated to lower capital cost of equipment. The IRA also contains provisions with incentives for grid modernization equipment, including domestic battery cell manufacturing, battery module manufacturing and its components as well as various upstream applications.

Employees and Human Capital Resources

Our management and scientific teams possess considerable experience in vaccine and anti-infective research, clinical development and regulatory matters. Our research and development team includes Ph.D.-level scientists with expertise in mucosal immunology, T cells, viral vectors and virology. General and administrative includes finance, human resources, administration, business and general management. For the year ended December 31, 2023, our full-time employee rollforward, excluding interns, was as follows:

	Research and Development	General and Administrative	TOTAL
December 31, 2022	137	27	164
Joined	2	5	7
Terminated	51	11	62
December 31, 2023	88	21	109

We also had 16 full-time equivalent contractors as of December 31, 2023. In the first quarter of 2023, the Company implemented a restructuring plan to reduce operating costs and better align its workforce with the needs of its business. The plan resulted in a reduction of approximately 27% of the Company's workforce.

We do not have collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Our human capital resources objectives include identifying, recruiting, training, retaining, and incentivizing our existing and new employees. We maintain an equity incentive plan, the principal purpose of which is to attract, retain and reward personnel through the granting of stock-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. In the fourth quarter of 2022, we began to offer an employee stock purchase plan, the principal purpose of which is to assist employees in acquiring a share ownership interest in Vaxart, and to help such employees provide for their future security and to encourage them to remain in the employment of Vaxart. To facilitate talent attraction and retention, we strive to make Vaxart a safe and rewarding workplace, with opportunities for our employees to grow and develop in their careers, supported by competitive compensation, benefits and health and wellness programs, and by programs that build connections between our employees.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Annual Report, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", as well as our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, discussed in more detail in the following section. These risks include, among others, the following key risks:

Risks Related to Our Business, Financial Position and Capital Requirements

- Throughout our operating history, we have generated limited product revenue.
- We have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We are largely dependent on the success of our tablet vaccine candidates for the prevention of norovirus and coronavirus infection.
- We have not yet produced a commercially viable vaccine and we may be never able to.
- We will require additional capital to fund our operations.
- We will need to expand our organization and may experience difficulties in managing growth.
- Our business may be adversely affected by a pandemic, epidemic, or outbreak of an infectious disease, such as the ongoing coronavirus pandemic and the emergence of additional variants.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

- The regulatory pathway for coronavirus vaccines is evolving, as is the random appearance of novel variants, which may result in unexpected or unforeseen challenges.
- Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome.
- We face significant competition from other biotechnology and pharmaceutical companies.
- Our tablet vaccine candidates may cause adverse effects resulting in failure to obtain approval from the U.S. Food and Drug Administration (the "FDA") and/or product liability lawsuits against us.
- We may be unable to manufacture sufficient bulk vaccine for our ongoing needs.
- We are dependent on third parties for manufacturing and clinical trials.
- We face numerous risks associated with our intellectual property.

Risks Related to Dependence on Third Parties

- Our dependence on third parties could delay or prevent the development, approval, manufacturing, or any eventual commercialization of our product candidates.
- We rely on third-party contract manufacturers for certain portions of our manufacturing process. If third-party contract manufacturers do not perform, fail to manufacture according to our specifications, or fail to comply with strict government regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated, or we could incur significant additional expenses.

Risks Related to Intellectual Property

- If we are unable to obtain and maintain patent protection for our oral vaccine platform technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.
- If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates, which could materially harm our business.
- Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- We may not be able to protect our intellectual property rights throughout the world, which could impair our business.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Risks Related to Our Business, Financial Position and Capital Requirements

Throughout our operating history, we have generated limited product revenue.

Even though we generate royalty revenue from Inavir, our commercialized influenza product, we are at an early stage in our clinical development process and have not yet successfully completed a large-scale, pivotal clinical trial, obtained marketing approval, manufactured our tablet vaccine candidates at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing product candidates.

Our ability to generate significant revenue and achieve and maintain profitability will depend upon our ability to successfully complete the development of our tablet vaccine candidates for the prevention of norovirus, coronavirus and influenza infection and the treatment of cervical cancer and dysplasia caused by human papillomavirus ("HPV") and other infectious diseases, and to obtain the necessary regulatory approvals. As disclosed elsewhere in this document, the Company is evaluating the best way to progress certain programs.

Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate significant revenue, if at all. Our ability to generate significant revenue depends on a number of factors, including our ability to:

- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- receive royalties on our products and product candidates including in connection with sales of Inavir;
- establish sales, marketing, manufacturing and distribution systems;
- add or continue to scale our operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts;
- develop, in collaboration with others, manufacturing capabilities for bulk materials and manufacture commercial quantities of our product candidates at acceptable cost levels;
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of our product candidates, whether alone or in collaboration with others;
- develop, in-license or acquire product candidates or commercial-stage products that we believe can be successfully developed and commercialized; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with vaccine development and manufacturing, we are unable to predict the timing or amount of increased development expenses, or when we will be able to achieve or maintain profitability, if at all. Our expenses could increase beyond expectations if we are required by the FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for our product candidates. If we cannot successfully execute on any of the factors listed above, our business may not succeed.

We have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have generated only limited product revenues and we expect to continue to incur substantial and increasing losses as we continue to pursue our business strategy. Our product candidates have not been approved for marketing in the United States and may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate significant revenue and achieve profitability is dependent on our ability to complete development, obtain necessary regulatory approvals, and have our product candidates manufactured and successfully marketed. We cannot be sure that we will be profitable even if we successfully commercialize one of our product candidates. If we do successfully obtain regulatory approval to market our tablet vaccine candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is received, the number of competitors in such markets, the price at which we can offer our product candidates and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become and remain profitable, the market price of our common stock and our ability to raise capital and continue operations will be adversely affected.

We expect overall research and development expenses to increase significantly for any of our tablet vaccines, including those for the prevention of norovirus, coronavirus and influenza, as well as those for the treatment of HPV-related dysplasia and cancer, although we intend to fund a significant portion of these costs through partnering and collaboration agreements. In addition, even if we obtain regulatory approval, significant sales and marketing expenses will be required to commercialize the tablet vaccine candidates. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital. As of December 31, 2023, we had an accumulated deficit of $409.6 million.

Our recurring losses from operations and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern. We will require substantial additional funding to finance our operations, and if we are unable to raise capital, we could be forced to delay, reduce the scope of or eliminate certain of our development programs, or explore other strategic options.

Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. As of December 31, 2023, we had $39.7 million of cash, cash equivalents and investments. Since December 31, 2023, we raised $10.0 million before estimated offering expenses through a registered direct offering in January 2024 and, through March 12, 2024, we raised $5.7 million in gross proceeds net of commissions from the issuance of shares under the Controlled Equity Offering Sales Agreement. We believe these funds are sufficient to fund our operations into the fourth quarter of 2024. Our ability to continue as a going concern is dependent upon our ability to raise additional capital through outside sources. We plan to raise additional capital through the sale of convertible stock, additional equity, debt financings, government programs, or strategic alliances with third parties. Such financing and funding may not be available at all, or on terms that are favorable to us. Failure to raise additional capital could have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all. If we are unable to continue as a going concern, we may be forced to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

We are largely dependent on the success of our tablet vaccines for the prevention of norovirus and coronavirus infection, which are still in early-stage clinical development, and if one or both of these tablet vaccines do not receive regulatory approval or are not successfully commercialized, our business may be harmed.

None of our product candidates are in late-stage clinical development or approved for commercial sale and we may never be able to develop marketable tablet vaccine candidates. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our tablet vaccine candidates for norovirus and coronavirus. We are committing financial resources to the development of a norovirus vaccine and a coronavirus vaccine, which may cause delays in or otherwise negatively impact our other development programs. In addition, our management and scientific teams have dedicated substantial efforts to our norovirus vaccine and coronavirus vaccine development. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of our norovirus and coronavirus tablet vaccine. These tablet vaccines may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of tablet vaccine candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market our tablet vaccines in the United States until we receive approval of a Biologics License Application ("BLA") from the FDA, or in any foreign countries until we receive the requisite approval from such countries. To date, we have only completed early-stage clinical trials for our norovirus vaccine candidate and our COVID-19 vaccine candidate. As a result, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of our tablet vaccines for many reasons, including:

- We may not be able to demonstrate that our tablet vaccine is safe and effective to the satisfaction of the FDA;
- the FDA may not agree that the completed Phase 1 and Phase 2 clinical trials of the norovirus vaccine and the Phase 1 and Phase 2 clinical trials of the COVID-19 vaccine satisfy the FDA's requirements and may require us to conduct additional testing;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of one or more of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials;
- the FDA may not find the data from our preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of our tablet vaccines outweigh the safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our NDA or BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy as a condition of approval;
- the FDA may identify deficiencies in our manufacturing processes or facilities; and
- the FDA may change its approval policies or adopt new regulations.

Our development of a norovirus vaccine candidate and a coronavirus vaccine candidate is at an early stage. We may be unable to produce an effective vaccine that successfully immunizes humans against norovirus or an effective vaccine that successfully immunizes humans against coronavirus in a timely manner, if at all.

We are in the business of developing oral vaccines that are administered by tablet rather than by injection. Our development of the norovirus vaccine and a coronavirus vaccine is at an early stage, and we may be unable to produce an effective vaccine that successfully immunizes humans against norovirus or an effective vaccine that successfully immunizes humans against coronavirus in a timely manner, if at all.

If we are unsuccessful in maintaining our relationships with critical third parties such as CROs and CMOs, our ability to develop our oral norovirus vaccine candidate or our oral coronavirus vaccine candidate and consequently compete in the marketplace could be impaired, and our results of operations may suffer. Even if we are successful, we cannot assure you that these relationships will result in successful development and commercialization of our oral norovirus vaccine candidate. Our failure, or the failure of such partners or potential partners, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, delays, suspension or withdrawal of approval to conduct clinical investigations, license revocation, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our potential norovirus vaccine.

Manufacturing any drug product with recombinant technology such as our adenovirus type 5 based vaccines presents technical challenges. Our manufacturing partners may not be able to successfully manufacture any vaccine with our VAAST platform, or to comply with cGMP, regulations or similar regulatory requirements. The number of doses of our potential vaccine that we are able to produce is dependent on our ability to successfully and rapidly scale-up manufacturing capacity. The number of doses that we will be able to produce is also dependent in large part on the dose of the vaccine required to be administered to patients which will be determined in our clinical trials. To properly scale-up and develop a commercial process, we may need to expend significant resources, expertise, and capital.

Scale up can present problems such as difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our contract manufacturers may not perform as agreed. If any manufacturer encounters these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our tablet vaccine candidates.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our tablet vaccine candidates. We will require substantial additional capital to complete the development and potential commercialization of our tablet vaccine candidates for norovirus, coronavirus, influenza and HPV and the development of other product candidates. If we are unable to raise capital or find appropriate partnering or licensing collaborations, when needed or on acceptable terms, we could be forced to delay, reduce or eliminate one or more of our development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

As of December 31, 2023, we had $39.7 million of cash, cash equivalents and investments. Since December 31, 2023, we raised $10.0 million before estimated offering expenses through a registered direct offering in January 2024 and, through March 12, 2024, we raised $5.7 million in gross proceeds net of commissions from the issuance of shares under the Controlled Equity Offering Sales Agreement. We maintain our cash, cash equivalents and investments with high quality, accredited financial institutions. However, some of these accounts exceed federally insured limits, and, while we believe the Company is not exposed to significant credit risk due to the financial strength of these depository institutions or investments, the failure or collapse of one or more of these depository institutions or default on these investments could materially adversely affect our ability to recover these assets and/or materially harm our financial condition.

Although we believe such cash, cash equivalents and investments are not sufficient to fund our operations under our current operating plan for at least one year from the date of issuance of this Annual Report, our estimate as to what we will be able to accomplish is based on assumptions that may prove to be inaccurate, and we could exhaust our available capital resources sooner than is currently expected. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- our ability to enter into partnering and collaboration agreements;
- the initiation, progress, timing, costs and results of our planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including any patent infringement actions brought by third parties against us now or in the future;
- the effect of competing technological and market developments;
- the cost of establishing sales, marketing and distribution capabilities in regions where we choose to commercialize our product candidates on our own; and
- the initiation, progress, timing and results of the commercialization of our product candidates, if approved, for commercial sale.

Additional funding may not be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or potentially discontinue operations.

Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, royalties, debt financings, government programs, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

The price of our common stock has been volatile and fluctuates substantially, which could result in substantial losses for stockholders.

Our stock price has been, and in the future may be, subject to substantial volatility. As a result of this volatility, our stockholders could incur substantial losses. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your initial purchase price.

The market price for our common stock may be influenced by many factors, including the results of clinical trials of our products or those of our competitors, regulatory or legal developments, developments, disputes, or other matters concerning patent applications, issued patents, or other proprietary rights, our ability to recruit and retain key personnel, public announcements by us or our strategic collaborators regarding the progress of our development candidates similar public announcements by our competitors, and other factors set forth in this quarterly report and our other reports filed with the SEC.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In addition, public statements by us, government agencies, the media or others relating to the SARS-CoV-2 outbreak (including regarding efforts to develop a COVID-19 vaccine) have in the past resulted, and may in the future result, in significant fluctuations in our stock price. Given the global focus on the coronavirus outbreak, any information in the public arena on this topic, whether or not accurate, could have an outsized impact (either positive or negative) on our stock price. Information related to our development, manufacturing and distribution efforts with respect to our vaccine candidates, or information regarding such efforts by competitors with respect to their potential vaccines, may also impact our stock price.

Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including the other factors discussed in our filings incorporated by reference herein or in future periodic reports; variations in our quarterly operating results from our expectations or those of securities analysts or investors; downward revisions in securities analysts' estimates; and announcement by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments.

Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that cause the market price of our common stock to fluctuate include:

- our ability to develop product candidates and conduct clinical trials that demonstrate our product candidates are safe and effective;
- our ability to negotiate and receive royalty payments on the sales of our product candidates including Inavir;
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure to maintain our existing third-party license, manufacturing and supply agreements;
- our failure, or that of our licensors, to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by our competitors;
- failure to meet or exceed financial and development projections that we may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including intellectual property or stockholder litigation;
- if securities or industry analysts do not publish research or reports about us, or if they issue adverse or misleading opinions regarding our business and stock;

- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by our existing stockholders in the future;
- trading volume of our common stock;
- adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

If we cannot continue to satisfy the listing requirements of The Nasdaq Capital Market, our securities may be delisted, which could negatively impact the price of our securities and stockholders' ability to sell them.

Although our common stock is listed on The Nasdaq Capital Market, we may be unable to continue to satisfy the continued listing requirements and rules, including the minimum bid price per share requirement and certain financial metrics relating to our stockholders' equity, market value of listed securities, or net income from continuing operations. If we are unable to satisfy The Nasdaq Capital Market criteria for maintaining our listing, our securities could be subject to delisting. If The Nasdaq Capital Market delists our securities, we could face significant consequences, including:

- a limited availability for market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading;
- activity in the secondary trading market for our common stock;
- limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

In addition, we would no longer be subject to The Nasdaq Capital Market rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards.

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.

Our business may be adversely affected by a pandemic, epidemic, or outbreak of an infectious disease, such as the ongoing coronavirus pandemic and the emergence of additional variants.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third-party contract manufacturers and contract research organizations upon whom we rely, as well as our ability to recruit patients for our clinical trials. For example, the ongoing coronavirus (COVID-19) pandemic continues to have unpredictable impacts on global societies, economies, financial markets, and business practices around the world. The extent to which the ongoing coronavirus pandemic may impact our business, results of operations, and future growth prospects will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope, and severity of the pandemic, particularly as virus variants continue to spread.

The outbreak and any preventative or protective actions that governments or we may take in respect of any epidemic may result in a period of business disruption and reduced operations. Any resulting financial impact cannot be reasonably estimated at this time but may materially affect our business, financial condition and results of operations. The extent to which an epidemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of an epidemic and the actions to contain the epidemic or treat its impact, among others. There may be interruptions to our supply chain due to the inability of manufacturers to continue normal business operations and to ship products. In addition, a significant outbreak of an infectious disease could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations. We are currently working to enhance our business continuity plans to include measures to protect our employees in the event of infection in our corporate offices, or in response to potential mandatory quarantines.

Ongoing military conflicts could cause geopolitical instability, economic uncertainty, financial markets volatility and capital markets disruption may adversely affect our revenue, financial condition, or results of operations.

Current military conflicts may disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions that have already been initiated or may in the future be initiated by nations including the U.S., the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.) can adversely affect our business, our contract research organizations, contract manufacturing organizations and other third parties with which we conduct business. Resulting volatility, disruption, or deterioration in the credit and financial markets may further make any necessary debt or equity financing more difficult and more costly. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may be adversely impacted by deteriorating economic conditions, which could directly affect our ability to attain our operating goals and to accurately forecast and plan our future business activities.

If we fail to obtain or maintain adequate reimbursement and insurance coverage for our product candidates, our ability to generate significant revenue could be limited.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow us to realize a sufficient return on our investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our product candidates on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the level of reimbursement for our products is likely to be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

Our future success depends on our ability to retain executive officers and attract, retain and motivate qualified personnel.

We rely on our executive officers and the other principal members of the executive and scientific teams. The employment of our executive officers is at-will and our executive officers may terminate their employment at any time. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain “key person” insurance for any executive officer or employee.

Recruiting and retaining qualified scientific, clinical and sales and marketing personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to us, our business may be harmed.

We will need to expand our organization, and may experience difficulties in managing this growth, which could disrupt operations.

Our future financial performance and our ability to commercialize our product candidates, continue to earn royalties and compete effectively will depend, in part, on our ability to effectively manage any future growth. As of December 31, 2023, we had 109 employees, which we believe would be insufficient to commercialize our vaccine product candidates. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our product candidates. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than us. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we are able to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can select and develop our product candidates and our business will be limited.

We are subject to certain legal proceedings, and may be subject to additional legal proceedings, which may result in substantial costs, divert management's attention and have a material adverse effect on our business, financial condition and results of operations.

We are currently subject to certain pending legal proceedings, as described in this report. We may become involved in additional legal proceedings relating to the aforementioned matters or, from time to time, we may become involved in legal proceedings involving unrelated matters. Due to the inherent uncertainties in legal proceedings, we cannot accurately predict their ultimate outcome. Our stock price has been extremely volatile, and we may become involved in additional securities class action lawsuits in the future. Any such legal proceedings, regardless of their merit, could result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business, could impair the Company's ability to recruit and retain directors, officers, and other key personnel, could impact its ability to secure financing, insurance, and other transactions (or the terms of any such financings, insurance, or other transactions), and for these and other reasons could have a material adverse impact on our business, financial condition, results of operations, and prospects.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable reports about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced by independent research and reports that securities or industry analysts publish about us or our business from time to time. If one or more of the analysts who cover us should downgrade our shares or change their opinion of our business prospects, our share price would likely decline.

In light of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. If we were to develop a COVID-19 vaccine, the economic value of such a vaccine to us could be limited.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our COVID-19 vaccine, if any.

We are a smaller reporting company and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are currently a "smaller reporting company" as defined in the Exchange Act. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings and have certain other decreased disclosure obligations in their SEC filings. We cannot predict whether investors will find our common stock less attractive because of our reliance on the smaller reporting company exemption. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

There are currently no approved vaccines for the prevention of norovirus-related illness. Therefore, the regulatory pathway for any approval of a norovirus vaccine is not entirely clear and may result in unexpected or unforeseen challenges.

As there are currently no vaccines for the prevention of norovirus that are approved by the FDA or another regulatory agency, the regulatory pathway for any approval of a norovirus vaccine is not entirely clear and may result in unexpected or unforeseen challenges. Successful discovery and development of a norovirus vaccine is highly uncertain and dependent on numerous factors, many of which are beyond our control. Our development of the vaccine is in early stages, and we may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all. Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. In addition, the FDA's analysis of clinical data may differ from our interpretation and the FDA may require that we conduct additional analyses.

The regulatory pathway for COVID-19 vaccines is evolving and may result in unexpected or unforeseen challenges.

The speed at which all parties are acting to create and test therapeutics and vaccines for COVID-19 is unusual, and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for COVID vaccine candidates. Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. Results from our vaccine (and other COVID-19) trials may require us to perform additional preclinical studies in order to advance our vaccine candidates. Discussions with FDA regarding the design of the anticipated Phase 2 and 3 studies for COVID-19 vaccine candidates are ongoing and important aspects of the trial design have yet to be determined, including the number of patients to be enrolled, the specific endpoints of the trial and the methods for obtaining and testing samples in the trial. The incidence of COVID-19 in the communities where our studies might be conducted will vary across different locations. If the overall incidence of COVID-19 in those locations is low, it may be difficult for us to recruit subjects or for any study we might perform to demonstrate differences in infection rates between participants in the study who receive placebo and participants in the study who receive COVID-19 vaccine candidates. The availability of other authorized vaccines may decrease the population of clinical trial subjects willing to participate in our future trials.

The FDA has the authority to grant an Emergency Use Authorization to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an Emergency Use Authorization for COVID-19 vaccine candidates, we would be able to commercialize the vaccine candidate prior to FDA approval. Furthermore, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an Emergency Use Authorization would remain in place. Such revocation could adversely impact our business in a variety of ways, including if the vaccine candidate is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide the vaccine candidate under an Emergency Use Authorization.

In addition, any success in preclinical testing we might observe for our COVID-19 vaccine candidates may not be predictive of the results of later-stage human clinical trials. Factors such as efficacy, immunogenicity, and adverse events can emerge at any time in clinical testing and have the potential to have adverse consequences for our ability to proceed with clinical trials. Other factors such as manufacturing challenges, availability of raw materials, and slowdowns in the global supply chain may delay or prevent us from receiving regulatory approval of our vaccine candidate or, if we do receive regulatory approval, prevent a successful product launch. We may not be successful in developing a vaccine, or another party may be successful in producing a more efficacious vaccine or other treatment for COVID-19.

Evolving dynamics in the market for COVID-19 vaccines are likely to impact our financial results.

With the global transition of COVID-19 from pandemic to endemic, the commercial market for COVID-19 vaccines is facing several challenges, including a more fragmented customer base, less predictability in orders, greater seasonality of demand, increased distribution costs, and higher costs of goods sold due to single-dose or lower-dose presentations. Such factors could impact the potential market for our COVID-19 vaccine, if approved. Further, our continued development efforts for our COVID-19 vaccine could face increased research and development costs, including for clinical trials, when updating COVID-19 vaccines for new variants of concern.

If we fail to continue to develop and refine the formulations of our tablet vaccine candidates, we may not obtain regulatory approvals, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited.

In our H1N1 influenza Phase 2 trial we used vaccine tablets that contained approximately 1.5×10^{10} IU of vaccine. Accordingly, subjects in this trial were required to take seven tablets in a single setting to reach the aggregate dose of 1×10^{11} IU, the target dose for this trial. We believe that in order to fully capture the commercial success of our seasonal influenza vaccine candidate, we will need to continue to refine our formulation and develop influenza vaccine tablets that contain the desired dose for each vaccine strain in a single tablet, resulting in a vaccination regime of no more than three tablets. Increasing the potency of the vaccine tablets may affect the stability profile of the vaccine and we may not be able to reduce the vaccination regime for an influenza strain to a single tablet or combine the three influenza strains into one vaccine tablet. In addition, increasing the potency of the vaccine tablets or combining the influenza strains necessary to create a trivalent vaccine may adversely affect manufacturing yields and render such tablets too costly to manufacture at commercial scale. Our efforts to develop tablet vaccine candidates for norovirus face similar formulation challenges. If we are unable to further develop and refine the formulations of our tablet vaccine candidates, we may be unable to obtain regulatory approval from the FDA or other regulatory authorities, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited.

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize our tablet vaccine candidates.

Our tablet vaccine candidates for norovirus, coronavirus and influenza are still in early-stage clinical development. Our vaccine candidates will require extensive additional clinical testing before we are prepared to submit a BLA for regulatory approval for either indication or for any other treatment regime. Such testing is expensive and time-consuming and requires specialized knowledge and expertise. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our tablet vaccine candidates, which are currently in clinical development, or whether any such BLAs will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that the clinical trials we need to conduct to be in a position to submit BLAs for our tablet vaccine candidates for norovirus, coronavirus and influenza will take several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Our vaccine candidates in the later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Also, the results of early clinical trials of the tablet vaccine candidates for norovirus, coronavirus and influenza may not be predictive of the results of subsequent clinical trials. Furthermore, the FDA may impose additional requirements to conduct preclinical studies to advance the HPV therapeutic vaccine candidates which could delay initiation of Phase 1 studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their vaccine candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, success in preclinical testing and early clinical trials does not ensure success in later clinical trials, which involve many more subjects and, for influenza, all four strains rather than the one strain we have studied in Phase 1 clinical trials to date. Accordingly, the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing or may be interpreted in a way that may not be sufficient for marketing approval.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our tablet vaccine candidates, including that:

- regulators or institutional review boards ("IRBs") may delay or not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or CROs;
- clinical trials of our tablet vaccine candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our tablet vaccine candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our tablet vaccine candidates may be greater than we anticipate; and
- the supply or quality of our tablet vaccine candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our tablet vaccine candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our tablet vaccine candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our tablet vaccine candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our tablet vaccine candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our tablet vaccine candidates, any of which may harm our business and results of operations.

A resurgence of the COVID-19 pandemic or the emergence of another public health emergency/pandemic could adversely impact our preclinical studies and clinical trials.

We have active and planned preclinical studies and clinical trial sites in the United States.

While both COVID-19 and countermeasures have abated to some degree, there can be no assurance that the COVID-19 pandemic will not cause disruptions to our business development activities, including our clinical trials. In the event of a resurgence of the COVID-19 pandemic or emergence of another public health emergency, we may experience disruptions that could severely impact our planned and ongoing preclinical studies and clinical trials, including preclinical and clinical studies and manufacturing of our vaccine candidates. Effects on our preclinical studies and clinical trial programs include, but are not limited to:

- delays in procuring subjects in our preclinical studies;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in preclinical and clinical site initiation, including difficulties in establishing appropriate and safe social distancing and other safeguards at preclinical and clinical sites;
- diversion of healthcare resources away from the conduct of preclinical and clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key preclinical study and clinical trial activities, such as preclinical and clinical trial site monitoring, subject recruitment and subject testing due to the course of the pandemic, limitations on freight and/or travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, delays or difficulties in conducting site visits and other required travel, and the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate or continue our planned preclinical studies and clinical trials;
- regulatory or legal developments in the United States or other countries; and
- the success of competitive vaccine products or COVID-19 treatments and related technologies.

If a patient participating in one of our clinical trials contracts COVID-19, this could negatively impact the data readouts from these trials; for example, the patient may be unable to participate further (or may have to limit participation) in our clinical trial, the patient may show a different efficacy assessment than if the patient had not been infected, or such patient could experience an adverse event that could be attributed to our drug product.

The extent to which COVID-19 may impact our preclinical studies and clinical trials will depend on future developments, which remains highly uncertain and cannot be predicted with confidence.

Our platform includes a novel vaccine adjuvant and all of our current tablet vaccine candidates include this novel adjuvant, which may make it difficult for us to predict the time and cost of tablet vaccine development as well as the requirements the FDA or other regulatory agencies may impose to demonstrate the safety of the tablet vaccine candidates.

Novel vaccine adjuvants, included in some of our tablet vaccine candidates, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Our current tablet vaccine candidates, including for norovirus, include a novel adjuvant, and future vaccine candidates may also include one or more novel vaccine adjuvants. Any vaccine, because of the presence of an adjuvant, may have side effects considered to pose too great a risk to patients to warrant approval of the vaccine. Traditionally, regulatory authorities have required extensive study of novel adjuvants because vaccines typically get administered to healthy populations, in particular infants, children and the elderly, rather than to people with disease. Such extensive study has often included long-term monitoring of safety in large general populations that has at times exceeded 10,000 subjects. This contrasts with the few thousand subjects typically necessary for approval of novel therapeutics. To date, the FDA and other major regulatory agencies have only approved vaccines containing five adjuvants, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our tablet vaccine candidates in the United States or elsewhere.

Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late-stage clinical trials of our tablet vaccine candidate for norovirus and coronavirus, in particular, will require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the study. Further, since there are no reliable animal models to norovirus infection, human challenge studies have been used to understand viral activity and possible immune correlates that prevent infection making trials costlier than animal-based studies.

Furthermore, any negative results we may report in clinical trials of our tablet vaccine candidates may make it difficult or impossible to recruit and retain participants in other clinical trials of that same tablet vaccine candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our tablet vaccine candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Vaccine development is highly competitive and subject to rapid and significant technological advancements. We face competition from various sources, including larger and better funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and public and private research institutions. In particular, our influenza vaccine candidate would compete with products that are available and have gained market acceptance as the standard treatment protocol. Further, it is likely that additional drugs or other treatments will become available in the future for the treatment of the diseases we are targeting.

For tablet vaccines, we face competition from approved vaccines, against which new tablet vaccines must demonstrate compelling advantages in efficacy, convenience, tolerability and safety, and from competitors working to patent, discover, develop or commercialize medicines before we can do the same with tablet vaccines.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of products for the treatment of diseases, as well as in obtaining regulatory approvals of those products in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any tablet vaccine candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize tablet vaccine candidates that are superior to other vaccines in the market;
- demonstrate through our clinical trials that our tablet vaccine candidates are differentiated from existing and future therapies;
- attract qualified scientific, vaccine development and commercial personnel;
- obtain patent or other proprietary protection for our tablet vaccine candidates;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new tablet vaccine candidates.

The availability of our competitors' vaccines could limit the demand, and the price we are able to charge, for any tablet vaccine candidate we develop. The inability to compete with existing or subsequently introduced vaccines would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make any of our tablet vaccine candidates less competitive. In addition, any new vaccine that competes with an approved vaccine must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA's approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. While we believe that our proprietary tablet vaccine candidates provide competitive advantages, we face competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies as well as new products and therapies that may become available in the future.

There are other organizations working to improve existing therapies, vaccines or delivery methods, or to develop new vaccines, therapies or delivery methods for their selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of our vaccine candidates, if approved.

We anticipate that we will face intense and increasing competition as new vaccines enter the market and advanced technologies become available. We expect any tablet or other oral delivery vaccine candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our vaccine candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

There is currently no approved norovirus vaccine for sale globally. We are aware that HilleVax, Inc. and Moderna, Inc. are developing norovirus vaccines that would be delivered by injection. Another company developing a norovirus vaccine candidate is Anhui Zhifei Longcom Biopharmaceutical Co. Ltd. There may be other development programs that we are not aware of.

There is significant competition in the COVID-19 vaccine market. Pfizer-BioNTech's COVID-19 vaccine, Moderna's COVID-19 vaccine and Novavax's COVID-19 vaccine have been approved in the United States and many countries around the world. Johnson & Johnson's COVID-19 vaccine and AstraZeneca's COVID-19 vaccine have been approved in many countries around the globe and have supplied the majority of the "western doses" to the world.

Our tablet vaccine candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by our tablet vaccine candidates could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in clinical trials for our tablet vaccine candidates, our ability to obtain regulatory approval for such tablet vaccine candidates may be negatively impacted.

Furthermore, if any of our tablet vaccines are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the tablet vaccine candidates or impose restrictions on their distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way our tablet vaccine candidates are administered or to conduct additional clinical trials;
- we could be sued and held liable for injuries sustained by patients;
- we could be subject to the Vaccine Injury Compensation Program;
- we could elect to discontinue the sale of our tablet vaccine candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected tablet vaccine candidate and could substantially increase the costs of commercialization.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our tablet vaccine candidates, and our ability to generate significant revenue will be impaired.

Our tablet vaccine candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a tablet vaccine candidate will prevent us from commercializing the tablet vaccine candidate. We have not received approval to market any of our tablet vaccine candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the tablet vaccine candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our tablet vaccine candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the tablet vaccine candidates involved. We cannot be sure that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a tablet vaccine candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize our tablet vaccine candidates in any other jurisdiction, which would limit our ability to realize each product's full market potential.

In order to market any of our tablet vaccine candidates in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional tablet vaccine candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our tablet vaccine candidates in those countries. We do not have any tablet vaccine candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any tablet vaccine candidate we develop will be unrealized.

Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and our tablet vaccine candidates may face future development and regulatory difficulties.

Any tablet vaccine candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such tablet vaccine candidate, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current good clinical practice, or GCP, requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a tablet vaccine candidate is granted, the approval may be subject to limitations on the indicated uses for which the tablet vaccine candidates may be marketed or to the conditions of approval. If a tablet vaccine candidate receives marketing approval, the accompanying label may limit the approved use of that tablet vaccine, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of our tablet vaccine candidates. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our tablet vaccine candidates for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our tablet vaccine candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such tablet vaccine candidate;
- restrictions on the labeling or marketing of a tablet vaccine candidate;
- restrictions on tablet vaccine distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the tablet vaccine candidate from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of such tablet vaccine candidate;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such tablet vaccine candidate;
- tablet vaccine candidate seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted, that could prevent, limit or delay regulatory approval of any of our tablet vaccine candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Even if our tablet vaccine candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If our tablet vaccine candidates, including our vaccine for coronavirus and norovirus, receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer our tablet vaccine candidates for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers our tablet vaccine candidate option in addition to, or in the place of, injectable vaccines;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our tablet vaccine together with other medications.

Because we expect sales of our tablet vaccine candidate for coronavirus and/or norovirus, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of these tablet vaccines to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we would otherwise plan.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could harm our business.

Although we do not provide healthcare services or submit claims for third-party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- the civil False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the Affordable Care Act, among other things, amended the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, while we do not, and will not, submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance to our customers from time to time. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any tablet vaccine candidates we may develop.

We face an inherent risk of product liability exposure related to the testing of our tablet vaccine candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. For instance, since our norovirus tablet challenge study is being conducted in healthy human volunteers, any adverse reactions could result in claims from these injuries and we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any tablet vaccine candidates that it may develop;

- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;

- significant costs to defend any related litigation;

- substantial monetary awards to trial subjects or patients;

- loss of revenue; and

- the inability to commercialize any products we may develop.

Although we maintain product liability insurance coverage in the amount of up to $10 million per claim and in the aggregate, it may not be adequate to cover all liabilities that we may incur. Additionally, seasonal influenza is a covered vaccine of the National Vaccine Injury Compensation Program, and our participation in that program may require time and resources that impede product uptake, if approved. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our ongoing clinical trials in the amount of up to $5 million. Further, we also require clinical research and manufacturing organizations that assist us in the conduct of our trials or manufacture materials used in these trials to carry product liability insurance against such claims. This insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect ourselves against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event any of our product candidates are approved for sale by the FDA or similar regulatory authorities in other countries and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our tablet vaccine candidates, if approved.

We do not have any infrastructure for the sales, marketing or distribution of our tablet vaccine candidates, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any tablet vaccine candidates that may be approved, it must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any tablet vaccine candidates for which we have obtained marketing approval, we will need a sales and marketing organization. While we expect to partner our tablet vaccine for seasonal influenza, we expect to build a focused sales, distribution and marketing infrastructure to market our other tablet vaccine candidates in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any tablet vaccine candidate launch, which would adversely impact commercialization.

Factors that may inhibit our efforts to commercialize our tablet vaccine candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to administer our tablet vaccines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We intend to pursue collaborative arrangements regarding the sale and marketing of our tablet vaccine candidates, if approved, for certain international markets; however, we may not be able to establish or maintain such collaborative arrangements and, if able to do so, our collaborators may not have effective sales. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and we cannot assure you that such efforts will be successful.

If we are unable to build our own sales force in the United States or negotiate a collaborative relationship for the commercialization of our tablet vaccine candidates outside the United States, we may be forced to delay the potential commercialization or reduce the scope of our sales and marketing activities. We could have to enter into arrangements with third parties at an earlier stage than we would otherwise choose and we may be required to relinquish rights to our intellectual property or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any tablet vaccine candidates outside of the United States, a variety of risks associated with international operations could harm our business.

If our tablet vaccine candidates are approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;

- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- tablet vaccination shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

Government involvement may limit the commercial success of our tablet vaccine candidates.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus and influenza, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our coronavirus or influenza vaccines.

In addition, current influenza vaccines are generally trivalent (containing three strains) or quadrivalent (containing four strains). If the FDA requires or recommends changes in influenza vaccines, for example, for a monovalent vaccine or for use of a strain that is not currently circulating in the human population, it is uncertain whether we will be able to produce or manufacture such a vaccine at commercially reasonable rates.

The seasonal nature of our target indications, in particular influenza, and competition from new products may cause unpredictable royalty revenues from Inavir and significant fluctuations in our operating results.

Influenza is seasonal in nature with sales of current vaccines occurring primarily in the first and fourth quarters of the calendar year. In addition, outbreaks of norovirus typically occur in the winter season. This seasonal concentration of product sales could cause quarter-to-quarter operating results to vary widely and can exaggerate the consequences of revenues of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, the inability to estimate the effect of returns and rebates, normal or unusual fluctuations in customer buying patterns, or of any unsuccessful sales or marketing strategies during the sales seasons.

We earn royalty revenue from the net sales of Inavir, which is marketed by our licensee. Although the royalty rates paid to us by our licensees are fixed at a proportion of the licensee's net sales of these products, our periodic and annual revenues from these royalties have historically been variable and subject to fluctuation based on the seasonal incidence and severity of influenza. It is the seasonality of influenza, which occurs mainly in the winter months, that causes our revenue to be low in the second and third fiscal quarters, since our agreement with HealthCare Royalty Partners III, L.P. (see Note 7 to our Consolidated Financial Statements on Part II, Item 8) has no impact on total revenue recognized, it only impacts our net cash flow in the quarter following revenue recognition. We cannot predict with any certainty what our royalty revenues are likely to be in any given year.

In addition, our licensee may encounter competition from new products entering the market, including generic copies of Inavir, which could adversely affect our royalty income. The last patent related to Inavir is set to expire in December 2029 in Japan, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expires in 2024, at which time generic competition may enter the market, potentially decreasing or eliminating the royalties received. On February 23, 2018, Osaka-based drug maker Shionogi & Co., Ltd. gained marketing approval for Xofluza, a new drug to treat influenza in Japan. The drug was approved for use against type A and B influenza viruses and requires only a single dose regardless of age. Xofluza has gained significant market share from Inavir in Japan, substantially reducing the sales of Inavir. This will significantly decrease the royalty payments we receive from Daiichi Sankyo Company, Limited.

Our success depends largely upon our ability to advance our product candidates through the various stages of drug development. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

Even though we generate royalty revenue from a commercialized influenza product, all of our remaining product candidates are in early stages of development and their commercial viability remains subject to the successful outcome of future preclinical studies, clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of one or more of our product candidates may have a material adverse effect on our business. For example, the Phase 2 trial of teslexivir, a product acquired through the merger with Aviragen, was costly and diverted resources from our other product candidates and did not achieve the primary efficacy endpoint, resulting in abandonment of development activities. The long-term success of our business ultimately depends upon our ability to advance the development of our product candidates through preclinical studies and clinical trials, appropriately formulate and consistently manufacture them in accordance with strict specifications and regulations, obtain approval of our product candidates for sale by the FDA or similar regulatory authorities in other countries, and ultimately have our product candidates successfully commercialized, either by us or by a strategic partner or licensee. We cannot be sure that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

Our product candidates must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete their development and before they can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost-effective manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not:

- demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population;
- be shown to be safe and effective in future preclinical studies or clinical trials;
- have the desired therapeutic or medical effects;
- be tolerable or free from undesirable or unexpected side effects;
- meet applicable regulatory standards;
- be capable of being appropriately formulated and manufactured in commercially suitable quantities or scale and at an acceptable cost; or
- be successfully commercialized, either by us or by our licensees or collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot be sure that the results of late-stage clinical trials will be sufficient to support the continued development of our product candidates. Many, if not most, companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in future late-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our product candidates demonstrate a satisfactory safety, tolerability and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the United States, or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

If the actual or perceived therapeutic benefits, or the safety or tolerability profile of any of our product candidates are not equal to or superior to other competing treatments approved for sale or in clinical development, we may terminate the development of any of our product candidates at any time, and our business prospects and potential profitability could be harmed.

We are aware of a number of companies marketing or developing various classes of anti-infective product candidates or products for the treatment of patients infected with HPV that are either approved for sale or further advanced in clinical development than ours, such that their time to approval and commercialization may be shorter than that for our product candidates.

If at any time we believe that any of our product candidates may not provide meaningful or differentiated therapeutic benefits, perceived or real, equal to or better than our competitors' products or product candidates, or we believe that our product candidates may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate the future development of any of our product candidates. We cannot provide any assurance that the future development of any of our product candidates will demonstrate any meaningful therapeutic benefits over potentially competitive compounds currently approved for sale or in development, or an acceptable safety or tolerability profile sufficient to justify their continued development.

Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude their development or regulatory approval or limit their use if ever approved.

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our product candidates in order to obtain regulatory approval to further advance their clinical development, or to eventually market them. Even if our product candidates demonstrate adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug-drug interactions in preclinical studies or clinical trials of our product candidates, which could result in the delay or termination of their development, prevent regulatory approval, or limit their market acceptance if they are ultimately approved.

If the results from preclinical studies or clinical trials of our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

In order to further advance the development of, and ultimately receive marketing approval to sell our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can and do occur at any time, and in any phase of preclinical or clinical testing, and can result from concerns about safety, tolerability, toxicity, a lack of demonstrated biologic activity or improved efficacy over similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or early-stage clinical trials are not predictive of the results we may observe in late-stage clinical trials. In many cases, product candidates in clinical development may fail to show the desired tolerability, safety and efficacy characteristics, despite having favorably demonstrated such characteristics in preclinical studies or early-stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive marketing approval for, or commercialize our product candidates, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials, or placing the development of a product candidate on clinical hold or delaying the next phase of development until questions or issues are satisfactorily resolved, including performing additional studies to answer their queries;
- regulatory authorities or IRBs not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting participants or participants drop out of our clinical trials at a higher rate than we anticipated;
- our third-party contractors, upon whom we rely to conduct preclinical studies, clinical trials and the manufacturing of our clinical trial materials, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- having to suspend or ultimately terminate a clinical trial if participants are being exposed to unacceptable health or safety risks;
- regulatory authorities or IRBs requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and
- the supply or quality of material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory tolerability, safety and efficacy profile, such results may not be sufficient to support the submission of a BLA or NDA to obtain regulatory approval from the FDA in the United States, or other similar regulatory authorities in other foreign jurisdictions, which is required for us to market and sell our product candidates.

We have a limited capacity for managing clinical trials, which could delay or impair our ability to initiate or complete clinical trials of our product candidates on a timely basis and materially harm our business.

We have a limited capacity to recruit and manage all of the clinical trials necessary to obtain approval for our product candidates by the FDA or similar regulatory authorities in other countries. By contrast, larger pharmaceutical and biopharmaceutical companies often have substantial staff or departments with extensive experience in conducting clinical trials with multiple product candidates across multiple indications and obtaining regulatory approval in various countries. In addition, these companies may have greater financial resources to compete for the same clinical investigators, sites and patients that we are attempting to recruit for our clinical trials. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing and completion of our clinical trials and obtaining of marketing approvals, if achieved at all, for our product candidates.

Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative or differentiated products, which could harm our business.

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicology, tolerability, safety, resistance or cross-resistance, interaction or dosing profile of a product or product candidate; the timing and scope of marketing approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity to produce our product candidates; relative manufacturing costs; establishing, maintaining and protecting our intellectual property and patent rights; and sales and marketing capabilities.

Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that may compete with our product candidates, have substantially more resources than us, as well as much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, formulating and manufacturing drug substances, products and devices, and marketing and sales. Our competitors may be more successful than us in obtaining regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' products or product candidates may be more effective, have fewer adverse effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any product that we, or our potential future licensees or collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidates obsolete or non-competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we, or our potential future licensees or collaborators, will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidates do not demonstrate any meaningful competitive advantages over existing products, or new products or product candidates, we may terminate the development or commercialization of our product candidates at any time.

Our competitors, either alone or with their collaborators, may succeed in developing product candidates or products that are more effective, safer, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining regulatory approval for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required marketing approvals and commercialize their products before their competitors do so may achieve a significant competitive advantage, including certain patent and marketing exclusivity rights that could delay the ability of competitors to market certain products.

We also face, and expect that we will continue to face, intense competition from other companies in a number of other areas, including (i) attracting larger pharmaceutical and biopharmaceutical companies to enter into collaborative arrangements with us to acquire, license or co-develop our product candidates, (ii) identifying and obtaining additional clinical-stage development programs to bolster our pipeline, (iii) attracting investigators and clinical sites capable of conducting our clinical trials, and (iv) recruiting patients to participate in our clinical trials. There can be no assurance that product candidates resulting from our research and development efforts, or from joint efforts with our potential future licensees or collaborators, will be able to compete successfully with our competitors' existing products or product candidates in development.

We may be unable to successfully develop a product candidate that is the subject of an existing or future license agreement or collaboration if our licensee or collaborator does not perform or fulfill its contractual obligations, delays the development of our product candidate, or terminates the agreement.

We expect to continue to enter into and rely on license and collaboration agreements in the future, or other similar business arrangements with third parties, to further develop and/or commercialize some or all of our existing and future product candidates. Such licensees or collaborators may not perform as agreed upon or anticipated, may fail to comply with strict regulations, or may elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement.

A majority of the potential revenue from existing and any future licenses and collaborations we may enter into will likely consist of contingent milestone payments, such as payments received for achieving development or regulatory milestones, and royalties payable on the sales of approved products. Milestone and royalty revenues that we may receive under these licenses and collaborations will depend primarily upon our licensees' or collaborators' ability to successfully develop and commercialize our product candidates. In addition, our licensees or collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly or closely involved in the development or commercialization of our product candidates that are subject to licenses or collaborations and, accordingly, we will depend largely on our licensees or collaborators to develop or commercialize our product candidates. Our licensees may encounter competition from new products entering the market, which could adversely affect our royalty income. Our licensees or collaborators may fail to develop or effectively commercialize our product candidates because they:

- do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or internal programs may have a higher likelihood of obtaining regulatory approval, or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to fully support the product candidate through clinical development, regulatory approval and commercialization;
- are unable to obtain the necessary regulatory approvals; or
- prioritize other programs or otherwise diminish their support for developing and/or marketing our product candidate or product due to a change in management, business operations or strategy.

Should any of these events occur, we may not realize the full potential or intended benefit of our license or collaboration arrangements, and our results of operations may be adversely affected. In addition, a licensee or collaborator may decide to pursue the development of a competitive product candidate developed outside of our agreement with them. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the arrangement, or other license agreement terms. If a licensee or collaborator fails to develop or effectively commercialize our product candidates for any of these reasons, we may not be able to replace them with another third party willing to develop and commercialize our product candidates under similar terms, if at all. Similarly, we may disagree with a licensee or collaborator as to which party owns newly or jointly-developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the arrangement, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate. There can be no assurance that any product candidates will emerge from any existing or future license or collaboration agreements we may enter into for any of our product candidates.

If government and third-party payers fail to provide adequate reimbursement or coverage for our products or those that are developed through licenses or collaborations, our revenues and potential for profitability may be harmed.

In the United States and most foreign markets, product revenues or related royalty revenue, and therefore the inherent value of our products, will depend largely upon the reimbursement rates established by third-party payers for such products. Third-party payers include government health administration authorities, managed-care organizations, private health insurers and other similar organizations. Third-party payers are increasingly examining the cost effectiveness of medical products, services and pharmaceutical drugs and challenging the price of these products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved pharmaceutical products. Further, the comparative effectiveness of new products over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by payers to establish reimbursement rates. We, or our licensees or collaborators if applicable, may also be required to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. There can be no assurance that any products that we or our licensees or collaborators may successfully develop will be reimbursed in part, or at all, by any third-party payers in any country.

Many governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical products. In many foreign markets, governmental agencies control the pricing of prescription drugs. In the United States, significant changes in federal health care policy were approved over the past several years and continue to evolve and will likely result in reduced reimbursement rates for many pharmaceutical products in the future. We expect that there will continue to be federal and state proposals to implement increased government control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products there. Recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisitions of the rights to certain drug products. In particular, U.S. federal prosecutors recently issued subpoenas to a pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies relating to post-acquisition drug-price increases. Our revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products that may be approved for sale in the future. Legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidates are approved for sale, which could further limit or eliminate their reimbursement rates. Further, social and patient activist groups, whose goal it is to reduce the cost of healthcare, and in particular the price of pharmaceutical products, may also place downward pressure on the price of these products, which could result in decreases in the price of our products.

If any product candidates that we develop independently, or through licensees or collaborators if applicable, are approved but do not gain meaningful acceptance in their intended markets, we are not likely to generate significant revenues.

Even if our product candidates are successfully developed and we or a licensee or collaborator obtains the requisite regulatory approvals to market them in the future, they may not gain market acceptance or broad utilization among physicians, patients or third-party payers. The degree of market acceptance that any of our products may achieve will depend on a number of factors, including:

- the efficacy or perceived clinical benefit of the product, if any, relative to existing therapies;
- the timing of market approval and the existing market for competitive drugs, including the presence of generic drugs;
- the level of reimbursement provided by third-party payers to cover the cost of the product to patients;
- the net cost of the product to the user or third-party payer;
- the convenience and ease of administration of the product;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, incidence and severity of adverse effects;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA or similar regulatory agencies in other jurisdictions.

There can be no assurance that physicians will choose to prescribe or administer our products, if approved, to the intended patient population. If our products do not achieve meaningful market acceptance, or if the market for our products proves to be smaller than anticipated, we may never generate significant revenues.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the past decade, the U.S. government has shut down, at least partially, several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Dependence on Third Parties

Our dependence on third parties could delay or prevent the development, approval, manufacturing, or any eventual commercialization of our product candidates.

We depend on third-party collaborators, service providers, and others in the research, development, manufacturing, and any eventual commercialization of our product candidates. We rely heavily on these parties for multiple aspects of our drug development and manufacturing activities and anticipate that we will rely on third parties for commercialization activities including testing of our product candidates. We have very limited control over many aspects of those activities. Failure by one or more of the third-party collaborators, service providers, or others to complete activities on schedule or in accordance with our expectations or to meet their contractual or other obligations to us; failure of one or more of these parties to comply with applicable laws or regulations; or any disruption in the relationships between us and these parties, could delay or prevent the development, approval, manufacturing, or any eventual commercialization of our product candidates, expose us to suboptimal quality of service delivery or deliverables, result in repercussions such as missed deadlines or other timeliness issues, erroneous data and supply disruptions, and could also result in non-compliance with legal or regulatory requirements or industry standards or subject us to reputational harm, all with potential negative implications for our product pipeline and business.

We rely on third-party contract manufacturers for certain portions of our manufacturing process. If third-party contract manufacturers fail to manufacture according to our specifications, or fail to comply with strict government regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated, or we could incur significant additional expenses.

To the extent that we rely on third-party contract manufacturers, which in some cases may be sole sourced, we are exposed to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues in the future. Some of these risks include, but are not limited to:

- our potential contract manufacturers failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our product candidates;
- our potential contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, cGMP, or regulatory guidelines, or otherwise manufacturing material that we or regulatory authorities deem to be unsuitable for our clinical trials or commercial use;
- our potential contract manufacturers being unable to increase the scale of or the capacity for, or reformulate the form of, our product candidates, which may cause us to experience a shortage in supply or cause the cost to manufacture our product candidates to increase. There can be no assurance that our potential contract manufacturers will be able to manufacture our product candidates at a suitable commercial scale, or that we will be able to find alternative manufacturers acceptable to us that can do so;
- our potential contract manufacturers placing a priority on the manufacture of other customers' or their own products, rather than our products;
- our potential contract manufacturers failing to perform as agreed or exiting from the contract manufacturing business; and
- our potential contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical drug products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration, or DEA, and corresponding state and other foreign agencies to ensure strict compliance with FDA-mandated cGMP, other government regulations and corresponding foreign standards. We do not have control over our third-party contract manufacturers' compliance with these regulations and standards and accordingly, failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or our manufacturers, which could significantly and adversely affect our business.

In the event that we need to change a third-party contract manufacturer, our preclinical studies or our clinical trials, and the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business.

Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various steps in the manufacture of our product candidates are sole-sourced to certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing a contract manufacturer may be difficult and could be extremely costly and time-consuming, which could result in our inability to manufacture our product candidates for an extended period of time and a delay, as well as an increase in costs, in the development of our product candidates.

We may not be able to manufacture our product candidates in sufficient quantities to commercialize them.

In order to receive FDA approval of our product candidates, we will need to manufacture such product candidates in larger quantities. We may not be able to successfully increase the manufacturing capacity for our product candidates in a timely or economic manner, or at all. In the event FDA approval is received, we will need to increase production of our product candidates. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for our product candidates, the clinical trials, the regulatory approval and the commercial launch of our product candidates may be delayed, or there may be a shortage in supply. Our product candidates require precise, high-quality manufacturing. Failure to achieve and maintain high-quality manufacturing, including the incidence of manufacturing errors, could result in patient injury or death, delays or failures in testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

The manufacture of pharmaceutical products in compliance with cGMP regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidates and quality assurance testing, or shortages of qualified personnel. If we were to encounter any of these difficulties or otherwise fail to comply with our obligations under applicable regulations, our ability to provide study materials in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate the studies and trials completely.

We must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards, for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our failure, or that our third-party manufacturers, to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of any product candidates we may develop or acquire in the future, or entail higher costs, or impair our reputation.

We currently rely on single source vendors for key tablet vaccine components and certain strains needed in our tablet vaccine candidates, which could impair our ability to manufacture and supply our tablet vaccine candidates.

We currently depend on single source vendors for certain raw materials used in the manufacture of our tablet vaccine candidates. Any production shortfall that impairs the supply of the relevant raw materials could have a material adverse effect on our business, financial condition and results of operations. An inability to continue to source product from these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could materially adversely affect our operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We also rely on CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of these regulatory responsibilities.

We and our CROs are required to comply with the Good Laboratory Practice and GCP, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit enough subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we cannot control whether they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate significant revenues could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. While we endeavor to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

We may seek to selectively establish collaborations and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, including our seasonable influenza tablet, we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal FCA imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring vaccine manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

We may not be successful in establishing and maintaining additional strategic partnerships, which could adversely affect our ability to develop and commercialize products, negatively impacting our operating results.

We continue to strategically evaluate our partnerships and, as appropriate, we expect to enter into additional strategic partnerships in the future, including potentially with major biotechnology or biopharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of such candidates and reduce their competitiveness even if they reach the market. If we are not able to generate revenue under our strategic partnerships when and in accordance with our expectations or the expectations of industry analysts, this failure could harm our business and have an immediate adverse effect on the trading price of our common stock.

If we fail to establish and maintain additional strategic partnerships related to our unpartnered product candidates, we will bear all the risks and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise, such as regulatory expertise, for which we have not budgeted. If we were not successful in seeking additional financing, hiring additional employees or developing additional expertise, our cash burn rate would increase or we would need to take steps to reduce our rate of product candidate development. This could negatively affect the development of any unpartnered product candidate.

Strategic partnerships or acquisitions we have made or may make could turn out to be unsuccessful.

As part of our strategy, we monitor and analyze strategic partnership or acquisition opportunities that we believe will create value for our stockholders. We may acquire companies, businesses, products and technologies that complement or augment our existing business; however, such acquisitions could involve numerous risks that may prevent us from fully realizing the benefits that we anticipated as a result of such transactions.

We may not be able to integrate any acquired business successfully or operate any acquired business profitably. In addition, integrating any newly acquired business could be expensive and time-consuming, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships.

We may fail to derive any commercial value from the acquired technology, products and intellectual property, including as a result of the failure to obtain regulatory approval or to monetize products once approved, as well as risks from lengthy product development and high upfront development costs without guarantee of successful results. Patents and other intellectual property rights covering acquired technology and/or intellectual property may not be obtained, and if obtained, may not be sufficient to fully protect the technology or intellectual property. We may also be subject to liabilities, including unanticipated litigation costs, that are not covered by indemnification protection we may obtain. As we pursue strategic transactions, we may value the acquired company or partner incorrectly, fail to successfully manage our operations as our asset diversity increases, expend unforeseen costs during the acquisition or integration process, or encounter other unanticipated risks or challenges. We may fail to value a partnership or acquisition accurately, properly account for it in our consolidated financial statements, or successfully divest it or otherwise realize the value which we originally anticipated or have subsequently reflected in our consolidated financial statements.

Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

Any failure by us to effectively limit such risks as we implement our strategic partnership or acquisitions could have a material adverse effect on our business, financial condition or results of operations and may negatively impact our net income and cause the price of our securities to fall.

In the event that a third-party contract manufacturer cannot timely supply sufficient bulk vaccine to allow us to manufacture our vaccine tablets, our preclinical studies or our clinical trials and the commercialization of our product candidates could be delayed, adversely affected or terminated, or may result in the need for us to incur significantly higher costs, which could materially harm our business.

Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various steps in the manufacture of our product candidates are sole-sourced to certain contract manufacturers. In accordance with cGMP, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing a contract manufacturer may be difficult and could be extremely costly and time consuming, which could result in our inability to manufacture our product candidates for an extended period and a delay in the development of our product candidates. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates.

If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We have historically relied on, and intend to continue to rely on, third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidates may be delayed or prove unsuccessful.

Further, the FDA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to GCP or similar regulations. If we, or a regulatory authority, determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our oral vaccine platform technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover any of our product candidates in the United States or in other countries. There is no assurance that the entire potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold with respect to our platform technology and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize future drugs. Any such outcome could harm our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and vaccines. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes several significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, notably, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and tablet vaccines, or limit the duration of the patent protection of our technology and product candidates. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future tablet vaccine candidates, we may be open to competition from generic versions of such product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates, which could materially harm our business.

Our success will largely depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the "freedom to operate." However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may be subject to claims of infringement of the patent rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the United States and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the United States are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to product candidates similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding, in the USPTO, or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, should we be unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights to our product candidates or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidates, or be prevented from developing, manufacturing and commercializing our product candidates at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successfully developed product candidate or approved drug. If we or our licensees or collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts and attention of our technical and management personnel could be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidates in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with several procedures, documentary fee payments and other provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we and our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own vaccines and, further, may export otherwise infringing vaccines to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These vaccines may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at universities or other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future, litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive vaccines and medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

We are currently engaged in an ongoing opposition proceeding, now at the appeal stage, of a Vaxart European patent in the European Patent Office. If we are not successful in these proceedings, we may not be able to prevent others in Europe from copying some of our product candidates for as long as we otherwise would if the European patent is upheld.

We are currently engaged in an ongoing opposition proceeding of one of our European patents in the European Patent Office (EPO). European Patent No. 3307239, which has claims directed to vaccine compositions for norovirus, was opposed in the EPO. The opposition challenged the validity of European Patent No. 3307239 and the EPO maintained the patent with the original independent claim and with cancelation of some subject matter from dependent claims. The opponent has appealed this decision and thus the ultimate outcome of the opposition remains uncertain. If Vaxart is not ultimately successful in the appeal, it may not be able to prevent others from copying its norovirus product in some or all European countries where the patent is pending for as long as it otherwise might be able to if the patent's validity is upheld in the opposition appeal. If the opposed European patent is partially or fully revoked by the EPO, competitors may be able to sell competing vaccines for norovirus earlier without Vaxart being able to assert patents against them. Vaxart has another patent in Europe that covers its norovirus products, but lack of success in the opposition appeal would prevent us from extending that patent protection out to 2036.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

General Risk Factors

Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, royalties, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Sales of a substantial number of shares of our common stock in the public market, or the perception that the sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Changes in tax laws and regulations or in our operations may impact our effective tax rate and may adversely affect our business, financial condition and operating results.

Changes in tax laws in any jurisdiction in which we operate, or adverse outcomes from any tax audits that we may be subject to in any such jurisdictions, could result in an unfavorable change in our effective tax rate in the future, which could adversely affect our business, financial condition, and operating results.

Anti-takeover provisions under Delaware law could make an acquisition more difficult and may prevent attempts by our stockholders to replace or remove our management.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding company voting stock from merging or combining with the company. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer was considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of management.

Our business and operations would suffer in the event of system failures.

Our business and operations, including our CROs, as well as the operations and systems of entities whose services are necessary to our operations, rely greatly on information technology systems and are vulnerable to damage in the event of failure, natural disasters, security breaches and attacks, interruptions or other cybersecurity incidents. These events may compromise the stability, integrity, or confidentiality of these systems, and the accuracy and integrity of information stored or processed through these systems, and may significantly interrupt our ability to run the business successfully. Ransomware attacks, which are becoming increasingly common across all industry sectors and have focused in part on businesses operating in health care markets, can disrupt and even halt ongoing business operations completely. Increasing global tensions, including the ongoing military conflict between Russia and Ukraine, among others, are likely to increase the frequency of cybersecurity incidents.

Our systems, including onsite datacenters and cloud services, continue to increase in size and complexity making them potentially vulnerable to breakdown and other disruptions. Disruptions include issues with routine maintenance, upgrades, and patching. These systems continue to become more critical and integrated within our business, especially as we continue to work remotely, and our dependence on them will continue to increase. We rely on the high-availability and redundancies built into our cloud services, but these systems are managed and maintained by the providers and are out of our direct control. Any potential problems and interruptions associated with the implementation, support, security, availability, or maintenance of new or existing systems could disrupt or reduce the efficiency of our operations, and materially impact the delivery of development programs.

Cybersecurity incidents, including phishing and spear phishing attacks, distributed denial of service attacks, man-in-the-middle attacks, as well as ransomware and other malware insertions, are becoming more sophisticated and frequent. If these attempts to misappropriate or compromise confidential or proprietary information or infiltrate or sabotage enterprise IT systems were successful, they could result in a loss of or damage to data or applications and even the interruption of basic business operations and financial loss, as well as the risk of legal and regulatory liability. As a result, further development of our product candidates could be substantially delayed. A data breach could risk the exposure of mission critical data or other intellectual property, or expose PII (Personally Identifiable Information) and PHI (Protected Health Information) of company employees or people participating in clinical trials. A successful phishing attempt could lead to further hacking attempts, unauthorized email access or messaging, or other vertical/horizontal cyberattacks. Any of these events could cause substantial reputational injury impacting our business.

Artificial intelligence ("AI") presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information and personal data.

We incorporate AI solutions into our platform, and these applications may become important in our operations over time. AI presents risks such as inaccuracy, bias, toxicity, intellectual property infringement or misappropriation, data privacy and cybersecurity and data provenance. In addition, AI may have errors or inadequacies that are not easily detectable and may also be subject to data herding and interconnectedness (i.e., multiple market participants utilizing the same data), which may adversely impact our business. These issues, combined with an uncertain regulatory environment, may further result in reputational harm, liability, or other adverse consequences to our business operations. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may negatively impact the trading price of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a quarterly report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We are required to disclose changes made in our internal control over financial reporting on a quarterly basis. In addition, because our public float was less than $700 million on June 30, 2022, we re-qualified as a smaller reporting company as of December 31, 2022 and, therefore, we are no longer subject to the requirements for auditor attestation for internal control over financial reporting.

We must maintain effective disclosure and internal controls to provide reliable financial reports. We have been assessing our controls to identify areas that need improvement. Based on our evaluation as of December 31, 2023, we concluded that our internal controls and procedures were effective as of December 31, 2023, however we have identified material weaknesses in the past and may do so again in the future. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Failure to maintain the improvements in our controls as necessary to maintain an effective system of such controls could harm our ability to accurately report our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our common stock.

Most of our facilities are located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business and financial condition.

We are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. The majority of our operations are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires.

We do not have a disaster recovery and business continuity plan in place. Earthquakes, floods, hurricanes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our financial systems or manufacturing facility, or that otherwise disrupted our operations, it may be difficult or, in certain cases, impossible for us to continue business operations for a substantial period of time.

Our business and operations are subject to risks related to climate change.

The long-term effects of global climate change could present both physical risks and transition risks (such as regulatory or technology changes), which are expected to be widespread and unpredictable. Transitional risks include, for example, a disorderly global transition away from fossil fuels that may result in increased energy prices; customer preference for low or no-carbon products; stakeholder pressure to decarbonize assets; or new legal or regulatory requirements that result in new or expanded carbon pricing, taxes, restrictions on greenhouse gas emissions, and increased greenhouse gas disclosure and transparency. These risks could increase operating costs, including the cost of our electricity and energy use, or other compliance costs. Physical risks to our operations include water stress and drought; flooding and storm surge; wildfires; extreme temperatures and storms, which could impact trials, increase costs, or disrupt supply chains. Our supply chain is likely subject to these same transitional and physical risks and would likely pass along any increased costs to us. We do not anticipate that these risks will have a material financial impact to the Company in the near term.

Increased scrutiny of our environmental, social or governance responsibilities have and will likely continue to result in additional costs and risks and may adversely impact our reputation, employee retention and willingness of customers and suppliers to do business with us.

There is an increasing focus from certain customers, consumers, employees and other stakeholders concerning environmental, social and governance ("ESG") matters, including corporate citizenship and sustainability. Additionally, public interest and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet regulatory requirements or stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted, and customers and suppliers may be unwilling to do business with us.

In addition, as we work to align our ESG practices with industry standards, we have expanded and, in the future, will likely continue to expand our disclosures in these areas. From time-to-time, we communicate certain initiatives, including goals, regarding environmental matters, responsible sourcing and social investments. We also expect to incur additional costs and require additional resources to monitor, report and comply with our various ESG practices. The standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. The disclosure frameworks we choose to align with, if any, may change from time-to-time and may result in a lack of consistent or meaningful comparative data from period to period. Ensuring there are systems and processes in place to comply with various ESG tracking and reporting obligations will require management time and expense. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals.

If we fail to adopt ESG standards or practices as quickly as stakeholders desire, fail, or be perceived to fail, in our achievement of such initiatives or goals, or fail in fully and accurately reporting our progress on such initiatives and goals, our reputation, business, financial performance and growth may be adversely impacted. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

Item 1B. Unresolved Staff Comments

None**.**

Item 1C. Cybersecurity

The Company maintains general cybersecurity policies and procedures to assess, identify, and manage cyber threats, and has designated personnel to implement and maintain these policies and procedures, subject to oversight by our management and board of directors.

The Company has implemented various technical, physical and administrative security controls to account for these and other cybersecurity threats. For example, we have implemented technical security controls focused on ensuring the security and protection of computer systems and networks; all pertinent domestic operating entities of the Company are required to adhere to a standardized "Company Confidentiality System," which is centrally overseen and enforced, subject to oversight by our management and board of directors. This Company Confidentiality System includes specific provisions for information pertaining to network security, data security, and information that, if compromised, could have detrimental effects on the public interest and the Company. The Company and its employees are also required to sign confidentiality agreements for purposes including helping to ensure cybersecurity. The Company has taken measures to better ensure that key employees are aware of data security threats (including cybersecurity threats), and Company security policies and procedures, as appropriate. Improper or illegitimate use of the Company's information system resources or violation of the Company's information security policies and procedures may result in disciplinary action.

As of the date of this report, we are not aware of any material risks from cybersecurity threats that have in the reporting calendar year materially affected or are reasonably likely to materially affect the Company, including our business strategy, results of operations, or financial condition.

The Company relies on third-party service providers for critical or key infrastructure and solutions across various Company operations. Cybersecurity incidents that impact third-party service providers have significantly increased in recent years and represent a continuing risk to the Company. The Company has sought to mitigate this risk through specific cybersecurity controls, designed to assess the business and security controls implemented by key information services to the Company, which are annually audited and subject to oversight by management and the board of directors.

Item 2. Properties

We do not own any real property. Our leased facilities as of December 31, 2023, are as follows:

Location	Square Feet	Primary Use	Lease Terms
South San Francisco and Burlingame, CA	71,997 sq ft	Laboratory, manufacturing and office	Six leases expiring between May 2025 and March 2029

We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings

The information included in "Note 9. Commitments and Contingencies, section—(c) Litigation" to the Consolidated Financial Statements in Part II, Item 8. is incorporated by reference into this Item.

The Company 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 it in excess of established reserves, in the aggregate, is not material 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 our business successfully, and could have a material adverse impact on our business, financial condition and results of operations.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Trading Information

Our common stock is listed on The Nasdaq Capital Market under the symbol "VXRT".

As of March 7, 2024, there were approximately 2,264 holders of record of our common stock (including Cede & Co.). The actual number of stockholders is greater than this number of holders of record and includes stockholders who are beneficial owners but whose shares are held in "street name" by brokerage firms, banks and other financial institutions or nominees.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information as of December 31, 2023, under equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, restricted stock units and rights (1)	Weighted average exercise price of outstanding options (2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (3)
Equity compensation plans approved by security holders	20,065,099	$ 2.90	6,751,131
Equity compensation plans not approved by security holders	—	$ —	—
Total	20,065,099	$ 2.90	6,751,131

(1) Includes 17,938,726 shares issuable upon the exercise of stock options outstanding under the 2016 Equity Incentive Plan and the 2019 Equity Incentive Plan and 2,126,373 shares issuable upon the vesting and payment of outstanding time-based restricted stock units outstanding under the 2019 Equity Incentive Plan.

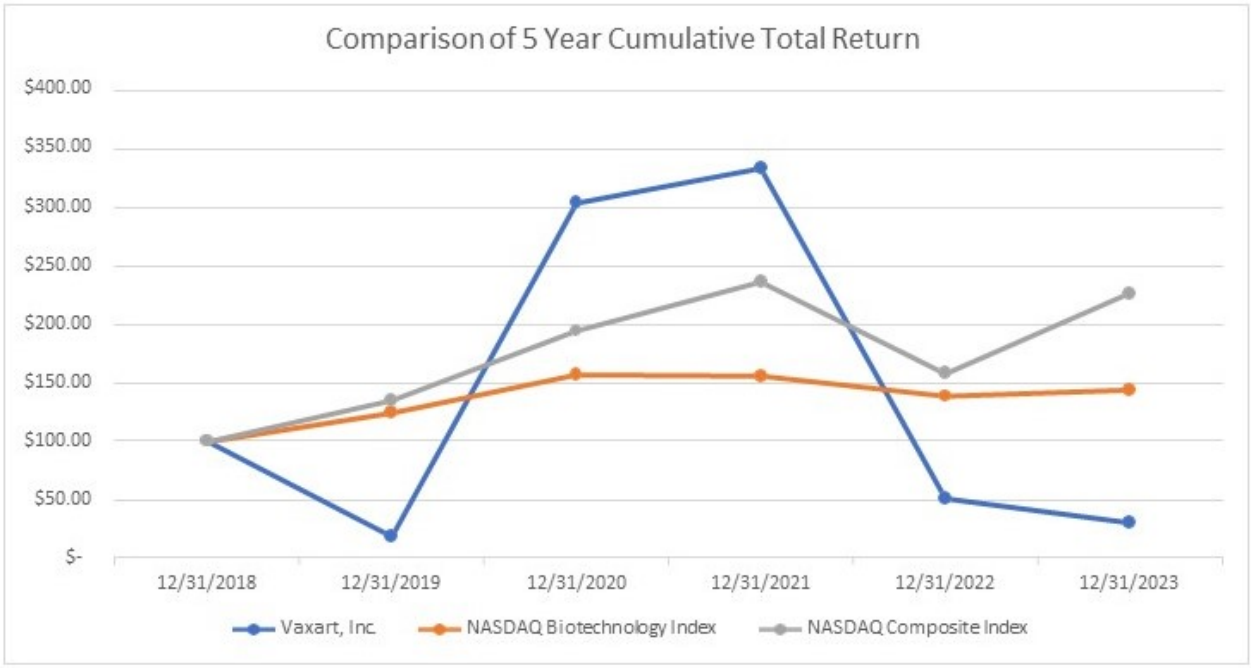
(2) Excludes the time-based restricted stock units set forth in footnote 1 above, because those awards do not have an exercise price.

(3) Includes 5,685,806 shares of common stock available for future issuance under the 2019 Equity Incentive Plan, and 1,065,325 shares of common stock available for purchase under the 2022 Employee Stock Purchase Plan. No new awards may be granted under the 2016 Equity Incentive Plan.

Stock Performance Graph

The following performance graph shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Vaxart, Inc. under the Securities Act or the Exchange Act.

The following graph shows a comparison from December 31, 2018, through December 31, 2023, of the cumulative total return for our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index, each of which assumes an initial investment of $100 and reinvestment of any dividends. Such returns are based on historical prices which, prior to the Merger on February 13, 2018, are those of Aviragen Therapeutics, Inc. and may not be indicative of future performance.



Dividend Policy

We have never declared or paid dividends on shares of our common stock. We intend to retain future earnings, if any, to support the development of our business and therefore do not anticipate paying cash dividends for the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after considering various factors, including current financial condition, operating results and current and anticipated cash needs.

Item 6. [Reserved]

Item 7. 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 the other sections of this Annual Report, including our consolidated financial statements and notes thereto included elsewhere. This discussion contains a number of forward-looking statements that reflect our plans, estimates and beliefs. 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 elsewhere in the Annual Report, particularly in Item 1A – "Risk Factors." The forward-looking statements made in this Annual Report are made only as of the date hereof.

See "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K filed on March 15, 2023, for discussion and analysis of results of operations for the year ended December 31, 2022.

Company Overview

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.

The Company re-qualified as a smaller reporting company as of December 31, 2022 and, therefore, is no longer subject to the requirements for auditor attestation for internal control over financial reporting.

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 31st, for the first royalty interest period of April 1, 2016 through March 31, 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, 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, we are not obligated to pay HCRP any royalty payment beyond what the Company is paid from Daiichi Sankyo Company Limited ("Daiichi Sankyo"). The cumulative remaining shortfall amount is the aggregate amount of the shortfall for each annual period, which was $7.0 million and $4.3 million as of December 31, 2023 and 2022, respectively. At the time of the Merger, the estimated future benefit to HCRP was remeasured at fair value and was estimated to be $15.9 million, which we account for as a liability and amortize using the effective interest method over the remaining estimated life of the arrangement. The estimated future benefit was remeasured as of December 31, 2022 and 2021 when the fair value was estimated to be $5.0 million and $10.6 million, respectively, resulting in a revaluation gain of $7.0 million in the year ended December 31, 2022 and $3.8 million in the year ended December 31, 2021. Even though we do not currently retain the related royalties under the transaction, as the amounts are remitted to HCRP, we will continue to record revenue related to these royalties until the amount of the associated liability and related interest is fully amortized.

Grant *Revenue*

In 2022, the Company accepted a grant of $3.5 million to perform research and development work for the Bill & Melinda Gates Foundation (the "BMGF Grant"). The Company recognizes revenue under research contracts only when a contract has been executed and the contract price is fixed or determinable. Revenue from the BMGF Grant is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable conditions under the contract have been met. Costs of contract revenue are recorded as a component of operating expenses in the consolidated statements of operations and comprehensive loss.

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 in 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.

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 (in thousands):

	Year Ended December 31,	
	2023	**2022**
External program costs:		
Norovirus program	$ 10,570	$ 11,066
COVID-19 program	3,110	6,758
All other programs	—	129
Preclinical research	764	1,414
Process development	953	2,262
Total external costs	15,397	21,629
Internal costs	52,745	59,425
Total research & development costs	$ 68,142	$ 81,054

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 consolidated statements of operations and comprehensive loss (in thousands, except percentages):

	Year Ended December 31,		
	2023	% Change	2022
Revenue	$ 7,379	*	$ 107
Operating expenses	90,726	(21)%	114,694
Operating loss	(83,347)	(27)%	(114,587)
Net non-operating income	1,143	(83)%	6,896
Loss before income taxes	(82,204)	(24)%	(107,691)
Provision for income taxes	261	*	67
Net loss	$ (82,465)	(23)%	$ (107,758)

* Percentages greater than 100% or not meaningful

Total Revenues

The following table summarizes the period-over-period changes in our revenues for years ended December 31 (in thousands, except percentages):

	2023	% Change	2022
Non-cash royalty revenue related to sale of future royalties	$ 3,920	*	$ 107
Grant revenue	3,459	*	—
Total revenue	$ 7,379	*	$ 107

* Percentages greater than 100% or not meaningful

Non-cash Royalty Revenue Related to Sale of Future Royalties

For the year ended December 31, 2023, non-cash royalty revenue related to sale of future royalties from Daiichi Sankyo was $3.9 million, compared to $0.1 million for the year ended December 31, 2022. A flu epidemic in Japan caused the increase in non-cash revenue in 2023. The Company continues to have non-cash royalty revenue as all royalties received in the year ended December 31, 2023 and 2022, were required to be paid to HCRP.

Grant Revenue

The Company recognized revenue from the BMGF Grant of $3.5 million and zero for the years ended December 31, 2023 and 2022, respectively.

Total Operating Expenses

The following table summarizes the period-over-period changes in our operating expenses for years ended December 31 (in thousands, except percentages):

	2023	% Change	2022
Research and development	$ 68,142	(16)%	$ 81,054
General and administrative	22,584	(23)%	29,386
Impairment of intangible assets	—	(100)%	4,254
Total operating expenses	$ 90,726	(21)%	$ 114,694

Research and Development

For the year ended December 31, 2023, research and development expenses were $68.1 million, a decrease of $12.9 million, or 16%, compared to $81.1 million for the year ended December 31, 2022. The decrease was primarily due to decreases in manufacturing costs, personnel related costs and clinical trial expenses related to our COVID-19 vaccine candidates, partially offset by increased facilities and depreciation expense.

We expect to incur significant research and development expenses for manufacturing and clinical trials related to our COVID-19 vaccine candidate in 2024.

General and Administrative

For the year ended December 31, 2023, general and administrative expenses were $22.6 million, a decrease of $6.8 million, or 23%, compared to $29.4 million for the year ended December 31, 2022. The decrease was primarily due to decreases in legal and professional fees, litigation settlement costs and directors' and officers' insurance, partially offset by an increase in personnel stock-based costs.

Impairment of Intangible Assets

Impairment of intangible assets were zero and $4.3 million for the years ended December 31, 2023 and 2022, respectively. The partial impairment of developed technology in the year ended December 31, 2022, related to royalty revenue receivable for the Inavir flu vaccine in Japan which we have lowered our projections, principally due to increased quarantining, social distancing and mask wearing due to the COVID-19 pandemic.

Other Income (Expense)

The following table summarizes the period-over-period changes in our non-operating income for years ended December 31 (in thousands, except percentages):

	2023	% Change	2022
Interest income	$ 2,652	*	$ 1,247
Non-cash interest expense related to sale of future royalties	(1,447)	11%	(1,305)
Gain on remeasurement of future royalty liability	—	(100)%	6,960
Other expense, net	(62)	*	(6)
Net non-operating income	$ 1,143	(83)%	$ 6,896

* Percentages greater than 100% or not meaningful

For the year ended December 31, 2023, we recorded net non-operating income of $1.1 million, compared to net non-operating income of $6.9 million in 2022.

The gain on remeasurement of future royalty liability in 2022 arose due to the lowered projections of amounts payable to HCRP, as royalties from Inavir flu vaccine in Japan have declined since the start of the COVID-19 pandemic and we lowered our projections, principally due to increased quarantining, social distancing and mask wearing due to the COVID-19.

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 $1.4 million in 2023, from the $1.3 million in 2022, 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 years ended December 31 (in thousands, except percentages):

	2023	% Change	2022
Foreign withholding tax on royalty revenue	$ 196	*	$ 5
Foreign taxes payable on intercompany interest	62	5%	59
State income taxes	3	—	3
Provision for income taxes	$ 261	*	$ 67

* Percentages greater than 100% or not meaningful

A significant portion of the provision for income taxes in the years ended December 31, 2023 and 2022, respectively, is foreign taxes payable on intercompany interest and foreign withholding tax on royalty revenue earned on sales of Inavir in Japan. Our foreign 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, and has declined in line with reductions in royalty revenue. In addition, we incurred charges for state income taxes in the United States.

Liquidity and Capital Resources

We are a clinical-stage biotechnology company with no product sales. Our primary source of financing is from the sale and issuance of common stock and common stock warrants in public offerings, along with proceeds from the exercise of warrants. In the past, we have also obtained funds from the issuance of secured debt and preferred stock and from collaboration agreements.

As of December 31, 2023, we had $39.7 million of cash, cash equivalents and investments. In January 2024, Vaxart completed an offering (the “January 2024 Offering”) in which 15,384,615 shares of its common stock were sold at an offering price of $0.65 per share pursuant to the Company’s effective shelf registration statement on Form S-3 (the “2023 Shelf Registration”). The gross proceeds from the January 2024 Offering were $10.0 million and, after deducting underwriting discounts, commission and estimated offering expenses, net proceeds were $9.9 million. See Note 15 of the Consolidated Financial Statements in Part II, Item 8 for further details.

On September 15, 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, and will pay sales commissions of up to 3.0% of gross proceeds from the sale of shares. As of December 31, 2023, there was approximately $77.4 million in net proceeds still available to us under the September 2021 ATM. Since December 31, 2023, the Company sold an additional 5,071,472 shares under the September 2021 ATM for gross proceeds net of commissions of $5.7 million through March 12, 2024.

In the first quarter of 2023, the Company implemented a restructuring plan to reduce operating costs and better align its workforce with the needs of its business. The plan resulted in a reduction of approximately 27% of the Company’s workforce and severance costs of $0.5 million for the year ended December 31, 2023.

Our expectation is that we will continue to generate operating losses and negative operating cash flows in the future and the need for additional funding to support our planned operations raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the consolidated financial statements are issued.

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. The sale of additional equity would result in additional dilution to our stockholders. 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. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we would otherwise prefer to develop and market ourselves. Any of these actions could harm our business, results of operations and prospects.

Based on management's current plan, the Company expects to have enough cash runway into the fourth quarter of 2024. If the Company is unable to raise additional capital in sufficient amounts or on acceptable terms, management’s plans include further reducing or delaying operating expenses. These conditions raise substantial doubt about the Company’s ability to continue as a going concern for a period of one year from the date of the issuance of these consolidated financial statements. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

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):

	Year Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (70,453)	$ (94,779)
Net cash provided by (used in) investing activities	43,952	(20,415)
Net cash provided by financing activities	15,243	17,462
Net decrease in cash, cash equivalents and restricted cash	$ (11,258)	$ (97,732)

Net Cash Used in Operating Activities

We experienced negative cash flow from operating activities for the years ended December 31, 2023, and 2022, in the amounts of $70.5 million, and $94.8 million, respectively. The cash used in operating activities for the year ended December 31, 2023, was due to cash used to fund a net loss of $82.5 million and an increase in working capital of $10.9 million, partially offset by adjustments for net non-cash income related to depreciation and amortization, stock-based compensation and non-cash interest expense related to sale of future royalties, net of non-cash revenue related to sale of future royalties and amortization of discount on investments, net totaling $22.9 million. The cash used in operating activities for the year ended December 31, 2022, was due to cash used to fund a net loss of $107.8 million and an increase in working capital of $4.7 million, partially offset by adjustments for net non-cash income related to depreciation and amortization, stock-based compensation, impairment of intangible assets and non-cash interest expense related to sale of future royalties, net of gain on remeasurement of future royalty liability, amortization of discount on investments, net and non-cash revenue related to sale of future royalties totaling $17.7 million.

Net Cash Provided by (Used in) Investing Activities

In 2023, we received $45.7 million from maturities of investments, net of purchases and used $1.8 million to purchase property and equipment, net of disposals. In 2022, we used $10.8 million to purchase investments, net of maturities and used $9.6 million to purchase property and equipment.

Net Cash Provided by Financing Activities

In 2023, we received $13.6 million from the issuance of common stock in a registered direct offering, $1.4 million from the sale of common stock under the September 2021 ATM and $0.6 million from the issuance of common stock under the employee stock purchase plan, partially offset by $0.4 million from common stock acquired to settle employee tax withholding liabilities. In 2022, we received $17.2 million from the sale of common stock under the September 2021 ATM and $0.2 million from the exercise of stock options.

Contractual Obligations and Commercial Commitments

We have the following contractual obligations and commercial commitments as of December 31, 2023 (in thousands):

Contractual Obligation	Total	< 1 Year	1 - 3 Years	3 - 5 Years	> 5 Years
Long Term Debt, HCRP	$ 19,287	$ 3,802	$ 5,494	$ 5,520	$ 4,471
Operating Leases	25,867	4,381	9,542	10,596	1,348
Purchase Obligations	3,811	3,811	—	—	—
Total	$ 48,965	$ 11,994	$ 15,036	$ 16,116	$ 5,819

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 Note 7 to the Consolidated Financial Statements in Part II, Item 8 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 Note 8 to the Consolidated Financial Statements in Part II, Item 8 for further details.

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.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated 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 consolidated balance sheets and within research and development expense in the 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 by an independent third party based on discounted cash flows of estimated future revenue streams, which are highly subjective. The fair value as of December 31, 2023, is being amortized on a straight-line basis over the remaining period of future royalties of 5.9 years.

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 2023, a notional 10% decrease in expected term would have reduced the fair value and the related compensation expense by approximately 2.2%.

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 2023, a notional 10% decrease in expected volatility (from 128% to 115%) would have reduced the fair value and the related compensation expense by approximately 4.2%.

Risk-free interest rate – 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.

Forfeiture rate – 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 to 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.

Recently Issued Accounting Pronouncements

See the "Recent Accounting Pronouncements" in Note 2 to the Consolidated Financial Statements in Part II, Item 8 for information related to the issuance of new accounting standards in 2023, none of which have had, or are expected to have, a material impact on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Sensitivity

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. All of our cash is held in bank accounts or money market funds that presently earn very little interest and our investments are in marketable debt securities with high credit ratings. We believe a 1% increase in the borrowing base rate would result in a negligible impact on our consolidated financial statements.

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 recently and do not anticipate that foreign exchange gains or losses will be significant in the near future.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Vaxart, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Vaxart, Inc. (the “Company”) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has an accumulated deficit at December 31, 2023 and, since inception, has suffered significant operating losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Clinical and Manufacturing Expenses - Refer to Note 2 to the consolidated financial statements

Critical Audit Matter Description

The Company recognizes costs it incurs for preclinical studies, clinical trials, and manufacturing activities as research and development expenses based on its evaluation of its third-party service providers' progress toward completion of specific tasks. Payment timing may differ significantly from the period in which the costs are recognized as expense. Costs for services incurred that have not yet been paid are recognized as accrued expenses.

In estimating the vendors' progress toward completion of specific tasks, the Company uses data such as patient enrollment, clinical site activations or vendor information of actual costs incurred. This data is obtained through reports from and discussions with Company personnel and third-party service providers as to the progress or state of completion of trials, or the completion of services.

Given the number of ongoing preclinical study and clinical trial activities and the subjectivity involved in estimating clinical trial and manufacturing expenses, auditing the accrued clinical and manufacturing expenses involved especially subjective judgment, thereby causing us to determine that the matter is a critical audit matter.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to accrued preclinical studies, clinical trials and manufacturing expenses included the following, among others:

- We obtained an understanding of the design and implementation of internal controls over the estimation of accrued preclinical studies, clinical trials and manufacturing expenses.
- We obtained and read a sample of research, collaboration, and manufacturing agreements and contracts, as well as amendments thereto.
- We evaluated publicly available information (such as press releases and investor presentations) and board of directors' materials regarding the status of preclinical studies, clinical trial and manufacturing activities.
- For a selection of agreements and contracts, we compared the amount of accrual at the end of the prior period to current year activity and evaluated the accuracy of the Company's estimation methodology.
- We obtained a written confirmation of the status of clinical trials and manufacturing from the Company's third-party service providers.
- We made selections of specific amounts recognized as research and development expense as well as those recognized as accrued expenses to evaluate management's estimate of the vendor's progress and performed the following procedures:
    - Performed corroborating inquiries with Company clinical operations and manufacturing operations personnel.
    - Read the related statement of work, purchase order, or other supporting documentation (such as communications between the Company and third-party service providers).
    - Evaluated management's judgments by comparing such judgments to the evidence obtained.
    - Obtained the listing of all contracts related to research and development expenses to evaluate the completeness of accruals.
    - Tested the mathematical accuracy of management's calculation of clinical trial and manufacturing activities accruals in the consolidated financial statements.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2019.

San Francisco, California
March 14, 2024

PCAOB ID Number 100

VAXART, INC. AND SUBSIDIARIES

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 34,755	$ 46,013
Short-term investments	4,958	49,704
Accounts receivable	3,008	20
Prepaid expenses and other current assets	2,815	3,714
Total current assets	45,536	99,451
Property and equipment, net	11,731	15,585
Right-of-use assets, net	24,840	25,715
Intangible assets, net	4,289	5,020
Goodwill	4,508	4,508
Other long-term assets	926	3,568
Total assets	$ 91,830	$ 153,847
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,584	$ 5,514
Deferred grant revenue	—	2,000
Other accrued current liabilities	5,634	8,084
Current portion of operating lease liability	2,703	2,228
Current portion of liability related to sale of future royalties	3,803	95
Total current liabilities	13,724	17,921
Operating lease liability, net of current portion	17,385	19,477
Liability related to sale of future royalties, net of current portion	2,623	5,621
Other long-term liabilities	293	231
Total liabilities	34,025	43,250
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred Stock: $0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of December 31, 2023 or 2022	—	—
Common Stock: $0.0001 par value; 250,000,000 shares authorized as of December 31, 2023 and 2022; 153,959,853 shares issued and 153,452,833 shares outstanding as of December 31, 2023 and 134,199,429 shares issued and outstanding as of December 31, 2022	15	13
Additional paid-in capital	467,731	437,992
Treasury Stock at cost, 507,020 shares and none as of December 31, 2023 and 2022, respectively	(366)	—
Accumulated deficit	(409,574)	(327,109)
Accumulated other comprehensive loss	(1)	(299)
Total stockholders' equity	57,805	110,597
Total liabilities and stockholders' equity	$ 91,830	$ 153,847

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

VAXART, INC. AND SUBSIDIARIES

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

	Year Ended December 31,	
	2023	**2022**
Revenue:		
Non-cash royalty revenue related to sale of future royalties	$ 3,920	$ 107
Grant revenue	3,459	—
Total revenue	7,379	107
Operating expenses:		
Research and development	68,142	81,054
General and administrative	22,584	29,386
Impairment of intangible assets	—	4,254
Total operating expenses	90,726	114,694
Operating loss	(83,347)	(114,587)
Other income (expense):		
Interest income	2,652	1,247
Non-cash interest expense related to sale of future royalties	(1,447)	(1,305)
Gain on remeasurement of future royalty liability	—	6,960
Other expense, net	(62)	(6)
Loss before income taxes	(82,204)	(107,691)
Provision for income taxes	261	67
Net loss	$ (82,465)	$ (107,758)
Net loss per share – basic and diluted	$ (0.57)	$ (0.84)
Shares used to compute net loss per share – basic and diluted	144,819,781	127,683,813
Comprehensive loss:		
Net loss	$ (82,465)	$ (107,758)
Unrealized gain (loss) on available-for-sale investments, net of tax	298	(225)
Comprehensive loss	$ (82,167)	$ (107,983)

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

VAXART, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Gain	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances as of January 1, 2022	125,594,393	$ 13	—	—	$ 406,943	$ (219,351)	$ (74)	$ 187,531
Issuance of common stock under September 2021 ATM, net of offering costs of $786	8,419,700	—	—	—	17,237	—	—	17,237
Issuance of common stock upon exercise of common stock warrants	5,000	—	—	—	2	—	—	2
Issuance of common stock upon exercise of options	180,336	—	—	—	223	—	—	223
Stock-based compensation	—	—	—	—	13,587	—	—	13,587
Unrealized loss on available-for-sale investments	—	—	—	—	—	—	(225)	(225)
Net loss	—	—	—	—	—	(107,758)	—	(107,758)
Balances as of December 31, 2022	134,199,429	$ 13	$ —	$ —	$ 437,992	$ (327,109)	$ (299)	$ 110,597
Issuance of common stock under September 2021 ATM, net of offering costs of $103	1,362,220	1	—	—	1,429	—	—	1,430
Issuance of common stock under 2023 Shelf Registration, net of offering costs of $284	16,000,000	1	—	—	13,599	—	—	13,600
Issuance of common stock upon exercise of stock options	54,720	—	—	—	17	—	—	17
Issuance of common stock under ESPP	734,675	—	—	—	562	—	—	562
Release of common stock for vested restricted stock units	1,608,809	—	—	—	—	—	—	—
Repurchase of common stock to satisfy tax withholding	—	—	(507,020)	(366)	—	—	—	(366)
Stock-based compensation	—	—	—	—	14,132	—	—	14,132
Unrealized gain on available-for-sale investments	—	—	—	—	—	—	298	298
Net loss	—	—	—	—	—	(82,465)	—	(82,465)
Balances as of December 31, 2023	153,959,853	$ 15	(507,020)	$ (366)	$ 467,731	$ (409,574)	$ (1)	$ 57,805

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

VAXART, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (82,465)	$ (107,758)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,624	5,805
Loss on disposal of property and equipment	55	—
Amortization of discount on investments, net	(659)	(163)
Impairment of intangible assets	—	4,254
Stock-based compensation	14,132	13,587
Gain on remeasurement of future royalty liability	—	(6,960)
Non-cash interest expense related to sale of future royalties	1,447	1,305
Non-cash revenue related to sale of future royalties	(737)	(151)
Change in operating assets and liabilities:		
Accounts receivable	(2,988)	51
Prepaid expenses and other assets	3,561	(3,783)
Accounts payable	(2,444)	357
Deferred grant revenue	(2,000)	2,000
Accrued liabilities	(6,979)	(3,323)
Net cash used in operating activities	(70,453)	(94,779)
Cash flows from investing activities:		
Purchase of property and equipment	(1,871)	(9,601)
Proceeds from sale of property and equipment	120	—
Purchases of investments	(27,497)	(55,014)
Proceeds from maturities of investments	73,200	44,200
Net cash provided by (used in) investing activities	43,952	(20,415)
Cash flows from financing activities:		
Net proceeds from issuance of common stock in registered direct offering	13,600	—
Net proceeds from issuance of common stock through at-the-market facilities	1,430	17,237
Proceeds from issuance of common stock upon exercise of warrants	—	2
Proceeds from issuance of common stock upon exercise of stock options	17	223
Shares acquired to settle employee tax withholding liabilities	(366)	—
Proceeds from issuance of common stock under the employee stock purchase plan	562	—
Net cash provided by financing activities	15,243	17,462
Net decrease in cash, cash equivalents and restricted cash	(11,258)	(97,732)
Cash, cash equivalents and restricted cash at beginning of the period	46,013	143,745
Cash, cash equivalents and restricted cash at end of the period	$ 34,755	$ 46,013

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

VAXART, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows (continued)
(In thousands)

	Year Ended December 31,	
	2023	**2022**
Supplemental disclosure of non-cash investing and financing activity:		
Operating lease liabilities arising from obtaining right-of-use assets	$ 495	$ 9,997
Acquisition of property and equipment included in accounts payable and accrued expenses	$ 4	$ 1,803

The following table presents a reconciliation of the Company's cash, cash equivalents and restricted cash in the Company's consolidated balance sheets:

	December 31,	
	2023	**2022**
Cash and cash equivalents	$ 34,755	$ 44,013
Restricted cash	—	2,000
Cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 34,755	$ 46,013

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

VAXART, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements

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.

On September 15, 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, and will pay sales commissions of up to 3.0% of gross proceeds from the sale of shares. In the year ended December 31, 2023, 1,362,220 shares were issued and sold under the September 2021 ATM for gross proceeds of $1.5 million, which, after deducting sales commissions and expenses incurred to date, resulted in net proceeds of $1.4 million. As of December 31, 2023, a total of 9,781,920 shares had been issued and sold under the September 2021 ATM since its inception for gross proceeds of $19.6 million which, after deducting sales commissions and expenses, resulted in net proceeds of $18.6 million.

In June 2023, Vaxart completed an underwritten public offering (the "June 2023 Offering") in which 16,000,000 shares of its common stock were sold at an offering price of $0.8680 per share pursuant to the Company's effective shelf registration statement on Form S-3 (the "2023 Shelf Registration"). The net proceeds from the June 2023 Offering were $13.6 million after deducting underwriting discounts and commission and estimated offering expenses payable by Vaxart.

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 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 Securities and Exchange Commission (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 of December 31, 2023, the Company had cash, cash equivalents and investments of $39.7 million. The Company's cash, cash equivalents and investments are not sufficient to fund the Company's planned operations for a period of 12 months from the date the consolidated financial statements are issued. In the first quarter of 2023, the Company implemented a restructuring plan to reduce operating costs and better align its workforce with the needs of its business. The plan resulted in a reduction of approximately 27% of the Company's workforce and severance costs of $0.5 million for the year ended December 31, 2023.

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.

Based on management's current plan, the Company expects to have enough cash runway into the fourth quarter of 2024. If the Company is unable to raise additional capital in sufficient amounts or on acceptable terms, management's plans include further reducing or delaying operating expenses. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date of the issuance of these consolidated financial statements. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

These consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Basis of Consolidation – The 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 (including accrued clinical and manufacturing accruals described within this Note 2), revenues and expenses and disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Actual results and outcomes could differ from these estimates and assumptions.

Foreign Currencies – Foreign exchange gains and losses for assets and liabilities of the Company's non-U.S. subsidiaries for which the functional currency is the U.S. dollar are recorded in foreign exchange gain or loss, net within other income and (expenses) in the Company's consolidated statements of operations and comprehensive loss. The Company has no subsidiaries for which the local currency is the functional currency.

VAXART, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements

Cash, Cash Equivalents and Restricted Cash – The Company considers all highly liquid debt investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents, which may consist of amounts invested in money market funds, corporate bonds and commercial paper, are stated at fair value. The Company's restricted cash includes refundable advance payments received as of December 31, 2023 and 2022, of zero and $2.0 million, respectively.

Investments – Excess cash balances may be invested in marketable debt securities. All marketable debt securities that are readily convertible to known amounts of cash with stated maturities greater than three months when purchased are classified as investments.

The Company determines the appropriate classification of its investments in marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. Marketable debt securities are classified and accounted for as available-for-sale. After consideration of the Company's objectives to preserve capital, as well as its liquidity requirements, it may sell any debt securities prior to their stated maturities.

Marketable debt securities are carried at fair value and unrealized gains and losses, net of taxes, are reported as a component of stockholders' equity. Any realized gains or losses on the sale of marketable debt securities are determined on a specific identification method, and such gains and losses are recorded as a component of other income (expense). Available-for-sale investments are classified as either current or non-current assets based on each instrument's underlying effective maturity date and whether the Company has the intent and ability to hold the investment for a period of greater than 12 months. Marketable debt securities with remaining maturities of 12 months or less are classified as current and are reported as short-term investments in the consolidated balance sheets. Marketable debt securities with remaining maturities of more than 12 months for which the Company has the intent and ability to hold the investment for more than 12 months are classified as non-current and are included in long-term investments in the consolidated balance sheets.

At each reporting date, the Company evaluates marketable debt securities with unrealized losses to determine whether such losses, if any, are due to credit-related factors. The Company records an allowance for credit losses when unrealized losses are due to credit-related factors. The Company evaluates, among other factors, whether the Company has the intention to sell any of its investments and whether it is more likely than not that the Company will be required to sell any of them before recovery of the amortized cost basis. Neither of these criteria were met in any period presented. In addition, the Company invests in marketable debt securities with high credit ratings that are classified in Level 1 and 2 of the fair value hierarchy and it has received and expects to continue to receive interest and principal payments as the investments become due. Based on this evaluation, as of December 31, 2023, and 2022, the Company determined that unrealized losses of its marketable debt securities were primarily attributable to changes in interest rates and other non-credit related factors. As such, no allowance for credit losses were recorded for the years ended December 31, 2023 and 2022.

Concentration of Credit Risk – Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, restricted cash, available-for-sale investments and accounts receivable. The Company places its cash, cash equivalents, restricted cash 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, cash equivalents and restricted cash 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.

Accounts Receivable – Accounts receivable arise from the Company's royalty revenue receivable for sales, net of estimated returns, of Inavir and are reported at amounts expected to be collected in future periods. 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 December 31, 2023 and 2022.

Accounts receivable are subject to concentration risk whenever a customer has a balance that meets or exceeds 10% of the Company's total accounts receivable balance. As of December 31, 2023 and 2022, Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), represented 100% of the Company's total accounts receivable balance.

Property and Equipment – Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation begins at the time the asset is placed in service. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is reflected in other income and (expenses) in the period realized.

The useful lives of the property and equipment are as follows:

Laboratory equipment (in years)	5
Office and computer equipment (in years)	3
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Goodwill and Other Intangible Assets – Goodwill, which represents the excess of the purchase price over the fair value of assets acquired, is not amortized. Intangible assets comprise developed technology and intellectual property. Intangible assets are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over useful life of 11.75 years for developed technology and 20 years for intellectual property.

Impairment of Long-Lived Assets – The Company reviews its long-lived assets, including property and equipment, goodwill and intangible assets with finite lives, for impairment in the fourth quarter of each year, and more frequently whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. When indications of impairment are present and the estimated undiscounted future cash flows from the use of these assets is less than the assets' carrying value, the related assets will be written down to fair value. The Company assessed its developed technology as not impaired in the year ended December 31, 2023 and impaired in the year ended December 31, 2022 (see Note 5).

Accrued Clinical and Manufacturing Expenses – The Company accrues 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. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided and includes the costs incurred but not yet invoiced within other accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statements of operations and comprehensive loss. These costs can be a significant component of the Company's research and development expenses.

The Company estimates the amount of services provided 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. The Company makes significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, it adjusts its accrued estimates. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed, the number of subjects enrolled, and the rate of enrollment may vary from its estimates and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from contract research organizations and other third-party service providers. To date, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Leases – The Company records operating leases as right-of-use assets and operating lease liabilities in its consolidated balance sheets for all operating leases with terms exceeding *one* year. Right-of-use assets represent the right to use an underlying asset for the lease term, including extension options considered reasonably certain to be exercised, and operating lease liabilities to make lease payments. Right-of-use assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. To the extent that lease agreements do *not* provide an implicit rate, the Company uses its incremental borrowing rate based on information available at the lease commencement date to determine the present value of lease payments. The expense for operating lease payments is recognized on a straight-line basis over the lease term and is included in operating expenses in the Company's consolidated statement of operations and comprehensive loss. The Company has elected to *not* separate lease and non-lease components of facilities leases, whereas non-lease components of equipment leases are accounted for separately from lease components.

Revenue Recognition – The Company recognizes revenue when it transfers control of promised goods or services to its customers, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition, the Company performs the following five steps:

(i) identification of the promised goods or services in the contract;

(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account.

Revenue from royalties earned as a percentage of end-user sales, including milestone payments based on achieving a specified level of sales, where a license is deemed to be the predominant item to which the royalties relate, is recognized as revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied), as required under the sales- and usage-based royalty exception.

Revenue from contracts with customers is recognized ratably, based on costs incurred, as the Company provides promised services to its customers in amounts that reflect the consideration that the Company expects to receive for those services.

In 2022, the Company accepted a $3.5 million grant to perform research and development work for the Bill & Melinda Gates Foundation (the "BMGF Grant"). The BMGF Grant funds received represent a contribution with a donor imposed condition under Accounting Standards Codification 958-605. The BMGF Grant involved the transfer of an advance deposit to the Company before specified conditions were substantially met. Therefore, the transfer of cash was recorded as restricted cash and deferred revenue. When conditions were substantially met, the refundable advance was recognized as revenue. The Company recognizes revenue under research contracts only when a contract has been executed and the contract price is fixed or determinable. Revenue from the BMGF Grant is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable conditions under the contract have been met. Costs of contract revenue are recorded as a component of operating expenses in the consolidated statements of operations and comprehensive loss. The Company recognized $3.5 million and zero revenue from the BMGF Grant for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, restricted cash and deferred revenue were zero and $2.0 million, respectively (see Note 6).

Research and Development Costs – Research and development costs are expensed as incurred. Research and development costs consist primarily of salaries and benefits, stock-based compensation, consultant fees, third-party costs for conducting clinical trials and the manufacture of clinical trial materials, certain facility costs and other costs associated with clinical trials. Payments made to other entities are under agreements that are generally cancelable by the Company. Advance payments for research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related services are performed.

Stock-Based Compensation – Stock-based compensation arrangements include stock option grants and restricted stock units ("RSU"s) awards under our equity incentive plans, as well as shares issued under our Employee Stock Purchase Plan ("ESPP"), through which employees may purchase our common stock at a discount to the market price. Stock-based compensation is measured at the grant date for all stock-based awards made to employees and non-employees based on the fair value of the awards, net of estimated forfeitures. Compensation expense for purchases under the ESPP is recognized based on the fair value of the award on the date of offering. The fair value of these awards is estimated using the Black-Scholes valuation model. The expected term of each option is estimated by taking the arithmetic average of its original contractual term and its average vesting term.

Net Income (Loss) Per Share – Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period, without consideration of potential common shares.

Diluted net income (loss) per common share is computed giving effect to all potential dilutive common shares, comprising common stock issuable upon exercise of stock options, warrants, RSUs and ESPP. The Company uses the treasury-stock method to compute diluted income (loss) per share with respect to its stock options, warrants, RSUs and ESPP. For purposes of this calculation, options, warrants, RSUs and ESPP plan grants to purchase common stock are considered to be potential common shares and are only included in the calculation of diluted net income per share when their effect is dilutive. In the event of a net loss, the effects of all potentially dilutive shares are excluded from the diluted net loss per share calculation as their inclusion would be antidilutive.

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 will not have a material impact on its financial position or results of operations.

NOTE 3. Business Combination

On November 30, 2021, the Company closed its acquisition of Kindred BioSciences, Inc.'s GMP manufacturing line in Burlingame, California in exchange for $4.8 million in cash. The transaction was accounted for as a business combination and the Company incurred transaction related expenses totaling $82,000, which were recorded within general and administrative expenses in the consolidated statement of operations in the year ended December 31, 2021.

The fair value of the assets acquired in connection with the acquisition are as follows (in thousands):

Property and equipment	$	321
Goodwill		4,508
Total purchase price	$	4,829

Goodwill, which represents the excess of the purchase price over the fair value of assets acquired, is attributable primarily to the expected cost savings of manufacturing internally, as opposed to outsourcing, and the assembled workforce. All of the goodwill is expected to be deductible for income tax purposes.

NOTE 4. 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 consolidated financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, investments, 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 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 December 31, 2023 and 2022 (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2023				
Financial assets:				
Money market funds	$ 31,403	$ —	$ —	$ 31,403
U.S. Treasury securities	—	4,958	—	4,958
Total assets	$ 31,403	$ 4,958	$ —	$ 36,361

	Level 1	Level 2	Level 3	Total
December 31, 2022				
Financial assets:				
Money market funds	$ 30,834	$ —	$ —	$ 30,834
U.S. Treasury securities	—	41,542	—	41,542
Corporate securities	—	8,162	—	8,162
Total assets	$ 30,834	$ 49,704	$ —	$ 80,538

The Company held no financial liabilities measured on a recurring basis as of December 31, 2023 or 2022.

NOTE 5. Balance Sheet Components

(a) Cash, Cash Equivalents, Restricted Cash and Investments

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Short-Term Investments
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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash, Cash Equivalents and Restricted Cash	Short-Term Investments
December 31, 2022						
Cash at banks	$ 15,179	$ —	$ —	$ 15,179	$ 15,179	$ —
Money market funds	30,834	—	—	30,834	30,834	—
U.S. Treasury securities	41,812	—	(270)	41,542	—	41,542
Corporate securities	8,191	—	(29)	8,162	—	8,162
Total	$ 96,016	$ —	$ (299)	$ 95,717	$ 46,013	$ 49,704

As of December 31, 2023 and 2022, all investments were available-for-sale debt securities with remaining maturities of 12 months or less. As of December 31, 2023 and 2022, the Company held 1 and 18 securities, respectively, in an unrealized loss position for 12 months or less. Interest receivable as of December 31, 2023 and 2022, was $0.1 million and $0.2 million, respectively and is recorded as a component of prepaid expenses and other current assets on the consolidated balance sheets.

(b) Accounts Receivable

Accounts receivable comprises royalties receivable of $3.0 million and $20,000 as of December 31, 2023 and 2022, respectively. The Company has provided no allowance for credit losses as of December 31, 2023 and 2022, based on past events and subsequent receipts.

(c) Property and Equipment, Net

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

	December 31, 2023	December 31, 2022
Laboratory equipment	$ 13,448	$ 12,035
Office and computer equipment	1,105	1,078
Leasehold improvements	3,985	1,760
Construction in progress	24	3,984
Total property and equipment	18,562	18,857
Less: accumulated depreciation	(6,831)	(3,272)
Property and equipment, net	$ 11,731	$ 15,585

Depreciation expense was $3.8 million, and $2.0 million for the years ended December 31, 2023 and 2022, respectively. There were no impairments of the Company's property and equipment recorded for the years ended December 31, 2023 or 2022.

(d) Right-of-Use Assets, Net

Right-of-use assets, net comprises facilities of $24.8 million and $25.7 million as of December 31, 2023 and 2022, respectively. The right of use of additional leased premises in California commenced in 2023 and 2022, resulting in an additional $3.1 million and $15.0 million right-of-use assets recorded in the year ended December 31, 2023 and 2022 respectively.

(e) Intangible Assets, Net

Intangible assets comprise developed technology, intellectual property and, until it was considered fully impaired, in-process research and development. Intangible assets are carried at cost less accumulated amortization. As of December 31, 2023, developed technology and intellectual property had remaining lives of 5.9 and 4.0 years, respectively. Intangible assets consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Developed technology	$ 5,000	$ 5,000
Intellectual property	80	80
Total cost	5,080	5,080
Less: accumulated amortization	(791)	(60)
Intangible assets, net	$ 4,289	$ 5,020

Intangible asset amortization expense was $0.7 million and $1.3 million for the years ended December 31, 2023 and 2022, respectively. The Company assessed its developed technology as not impaired in the year ended December 31, 2023. Due to a decline in royalties earned since the outbreak of COVID-19 (see Note 7), developed technology was assessed as partially impaired as of December 31, 2022, and accordingly an impairment charge of $4.3 million were recorded within operating expenses.

As of December 31, 2023, the estimated future amortization expense by year is as follows (in thousands):

Year Ending December 31,	Amount
2024	$ 731
2025	732
2026	731
2027	731
2028	727
Thereafter	637
Total	$ 4,289

(f) Goodwill

Goodwill, which represents the excess of the purchase price over the fair value of assets acquired, comprises $4.5 million for both years ended December 31, 2023 and 2022. For the years ended December 31, 2023 and 2022, there was no change in goodwill. As of December 31, 2023 and 2022, there have been no indicators of impairment.

(g) Other Accrued Liabilities

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

	December 31, 2023	December 31, 2022
Accrued compensation	$ 4,576	$ 3,112
Accrued clinical and manufacturing expenses	312	2,413
Accrued professional and consulting services	211	691
Accrued other expenses	535	1,868
Total	$ 5,634	$ 8,084

NOTE 6. Revenue

Royalty agreement

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, 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. The last patent related to Inavir is set to expire in December 2029 in Japan, at which time royalty revenue will cease. The royalty revenue related to Inavir recognized for the years ended December 31, 2023 and 2022, was zero. The Company recognized non-cash royalty revenue related to sale of future royalties of $3.9 million and $0.1 million for the years ended December 31, 2023 and 2022, respectively (see Note 7). Both the royalty revenue and the non-cash royalty revenue related to sale of future royalties have been subjected to a 5% withholding tax in Japan, for which $0.2 million and $5,000 was included in income tax expense in the years ended December 31, 2023 and 2022, respectively.

Grant Revenue

In *November 2022,* the Company accepted the $3.5 million BMGF Grant to perform research and development work for the Bill & Melinda Gates Foundation 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 has been executed and the contract price is fixed or determinable. Revenue from the BMGF Grant is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable conditions under the contract have been met. Costs of contract revenue are recorded as a component of operating expenses in the consolidated statements of operations and comprehensive loss. The Company recognized revenue from the BMGF Grant of $3.5 million and zero for the years ended December 31, 2023 and 2022, respectively. As December 31, 2023 and 2022, restricted cash and deferred revenue were zero and $2.0 million, respectively.

NOTE 7. 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 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, 2029, excluding the period of April 1, 2028 through December 24, 2029.

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 $7.0 million and $4.3 million as of December 31, 2023 and 2022, 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 year ended December 31, 2023 (in thousands):

Total liability related to sale of future royalties, start of year	$	5,716
Non-cash royalty revenue paid to HCRP		(737)
Non-cash interest expense recognized		1,447
Total liability related to sale of future royalties, end of year		6,426
Current portion		(3,803)
Long-term portion	$	2,623

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NOTE 8. 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 Company obtained the right of use of real estate located in South San Francisco, California, in November 2020 under a lease that was scheduled to terminate on September 30, 2025, which has been extended until March 31, 2029, with no additional extension option. The Company obtained the right of use of another property also located in South San Francisco, California, in June 2015 that was scheduled to terminate on April 30, 2020, with a five-year extension option that the Company exercised in July 2019, extending the lease until April 30, 2025, which has been further extended until March 31, 2029, with an option to extend for an additional eight years. 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, with an option to extend for an additional eight years. This lease includes a component for tenant improvements that were substantially completed in the three months ended September 30, 2022, when the lease for this component was deemed to have commenced for accounting purposes. It also includes a component for which tenant improvements of $3.1 million were completed and were recorded within right-of-use assets in the consolidated balance sheets when they were substantially completed in the three months ended March 31, 2023. Further, the Company has the right of use of a facility located in South San Francisco, California, under a lease that terminates on March 30, 2029, with a five-year renewal option. The Company also has the right of use of two facilities in Burlingame, California, under leases that terminate on May 31, 2025, both of which have two 30-month extension options.

As of December 31, 2023, the weighted average discount rate for operating leases with initial terms of more than one year was 9.80% and the weighted average remaining term of these leases was 5.12 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 twelve months as of December 31, 2023 (in thousands):

Year Ending December 31,	Amount
2024	$ 4,381
2025	4,511
2026	5,031
2027	5,207
2028	5,389
Thereafter	1,348
Undiscounted total	25,867
Less: imputed interest	(5,779)
Present value of future minimum payments	20,088
Current portion of operating lease liability	(2,703)
Operating lease liability, net of current portion	$ 17,385

Certain operating lease agreements for facilities include non-lease costs, such as common area maintenance, which are recorded as variable lease costs. Operating lease expenses for the years ended December 31, 2023 and 2022, including variable lease costs for one lease that has not yet commenced for accounting purposes, are summarized as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Operating lease cost	$ 6,170	$ 4,159
Short-term lease cost	52	436
Variable lease cost	1,864	1,312
Total operating lease cost	$ 8,086	$ 5,907

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NOTE 9. Commitments and Contingencies

(a) Purchase Commitments

As of December 31, 2023, the Company had approximately $3.8 million of non-cancelable purchase commitments, principally for contract manufacturing and clinical services and leasehold improvements which are expected to be paid within the next year. In addition, the Company has operating lease commitments as detailed in Note 8.

(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, damages, 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' and officers' 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 *Himmelberg v. Vaxart, Inc. et al.* was filed on August 24, 2020. The second action, titled *Hovhannisyan v. Vaxart, Inc. et al.* 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 and 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 *Roth v. Armistice Capital LLC, et al.* 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.

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 *Chan v. Vaxart, Inc. et al.* (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.

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NOTE 10. 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 December 31, 2023, the Company was authorized to issue 250,000,000 shares of common stock, $0.0001 par value per share, which includes an increase of 100,000,000 on August 4, 2022, 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 150,000,000. 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 in 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 December 31, 2023, no dividends had been declared by the board of directors.

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:

	December 31, 2023	December 31, 2022
Options issued and outstanding	17,938,726	14,725,261
RSUs issued and outstanding	2,126,373	808,310
Available for future grants of equity awards	5,685,806	12,074,692
Common stock warrants	227,434	227,434
2022 Employee Stock Purchase Plan	1,065,325	1,800,000
Total	27,043,664	29,635,697

(c) Warrants

The Company has the following warrants outstanding as of December 31, 2023, 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	44,148	$ 1.10	April 2024
Common Stock	26,515	$ 1.375	April 2024
Common Stock	29,150	$ 2.50	March 2025
Common Stock	100,532	$ 3.125	February 2025
Common Stock	16,175	$ 3.125	March 2024
Common Stock	10,914	$ 22.99	December 2026
Total	227,434		

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 $1.10 and $2.50 and those exercisable for $3.125 expiring in February 2025 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.

NOTE 11. 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, 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, and by a Plan Amendment on August 4, 2022, to 28,900,000. 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.

A summary of stock option and RSU transactions for the years ended December 31, 2023 and 2022 follows:

	Shares Available For Grant	Number of Options Outstanding	Weighted Option Average Exercise Price	Number of RSUs Outstanding	Weighted RSU Average Grant Date Fair Value
Balance at January 1, 2022	5,582,742	10,216,106	$ 4.96	—	$ —
Authorized under 2019 Plan Amendment	12,000,000	—	$ —	—	$ —
Granted	(7,291,935)	6,376,657	$ 4.10	915,278	$ 3.58
Exercised	—	(180,336)	$ 1.24	—	$ —
Forfeited	1,625,133	(1,518,230)	$ 6.19	(106,968)	$ 3.62
Canceled	158,752	(168,936)	$ 7.17	—	$ —
Balance at December 31, 2022	12,074,692	14,725,261	$ 4.48	808,310	$ 3.57
Granted	(10,631,320)	7,399,849	$ 0.78	3,231,471	$ 0.78
Exercised	—	(54,720)	$ 0.31	(1,608,809)	$ 1.09
Forfeited	2,444,486	(2,139,887)	$ 5.00	(304,599)	$ 2.42
Canceled	1,797,948	(1,991,777)	$ 4.51	—	$ —
Balance at December 31, 2023	5,685,806	17,938,726	$ 2.90	2,126,373	$ 1.37

As of December 31, 2023, there were 17,938,726 options outstanding with a weighted average exercise price of $2.90, a weighted average remaining contractual term of 8.18 years and an aggregate intrinsic value of $26,000. Of these options, 9,667,285 were vested, with a weighted average exercise price of $3.17, a weighted average remaining contractual term of 7.70 years and an aggregate intrinsic value of $26,000.

The Company received $17,000 for the 54,720 options exercised in the year ended December 31, 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 December 31, 2023, based on the Company's common stock closing price of $0.57 on December 29, 2023, 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 Company received $223,000 for the 180,336 options exercised during the year ended December 31, 2022, which had an intrinsic value of $481,000.

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The weighted average grant date fair value of options awarded in the years ended December 31, 2023 and 2022, was $0.78 and $4.10, respectively. Fair values were estimated using the following assumptions:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.45% - 4.15%	1.62% - 4.02%
Expected term (in years)	5.50 - 6.00	5.42 - 6.08
Expected volatility	128% - 134%	125% - 131%
Dividend yield	—%	—%

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 was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 8,362	$ 9,183
General and administrative	5,770	4,404
Total stock-based compensation	$ 14,132	$ 13,587

As of December 31, 2023, the unrecognized stock-based compensation cost related to outstanding stock options and RSUs expected to vest was $20.5 million, which the Company expects to recognize over an estimated weighted average period of 2.13 years.

On August 4, 2022, the 2022 Employee Stock Purchase Plan (the "2022 ESPP") was approved by the Company's stockholders and the Company reserved 1,800,000 shares of the Company's common stock for purchase under the 2022 ESPP. The 2022 ESPP has a 6-month offering period comprised of one purchase 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 6-month offering period or the end of such offering period. During the year ended December 31, 2023, the Company received $0.6 million and issued 734,675 shares under the 2022 ESPP. As of December 31, 2023, 1,065,325 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. Stock-based compensation expense related to the ESPP for the years ended December 31, 2023 and 2022, was $0.4 million and zero, respectively. As of December 31, 2023, the unrecognized stock-based compensation cost related to outstanding ESPP expected to be recognized is $0.1 million by May 2024. The fair value of the 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 Ended November 30, 2023	Six-Month Offering Period Ended May 31, 2023
Risk-free interest rate	5.26%	5.37%	4.60%
Expected term (in years)	0.50	0.50	0.50
Expected volatility	75.20%	98.55%	84.66%
Dividend yield	—%	—%	—%

NOTE 12. Benefit Plan

The Company provides a tax-qualified employee savings and retirement plan commonly known as a 401(k) plan (the "Plan"), which covers the Company's eligible employees. Pursuant to the Plan, employees may elect to defer their current compensation up to the IRS annual contribution limit of $22,500 for calendar year 2023 and $20,500 for calendar year 2022. Employees age 50 or over may elect to contribute an additional $7,500 annually for 2023 and $6,500 for 2022.

Employees direct their contributions, which vest immediately, across a series of mutual funds. In the years ended December 31, 2023 and 2022, the Company matched employee contributions up to 3% of each employee's eligible earnings, vesting immediately. The Company's matching contributions totaled $0.6 million and $0.7 million in the years ended December 31, 2023 and 2022, respectively. The costs of administering the Plan totaled $28,000 and $19,000 in the years ended December 31, 2023 and 2022, respectively.

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NOTE 13. Income Taxes

The provision for income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Current:		
Federal	$ —	$ —
State	3	3
Foreign	258	64
Total Current	261	67
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total Deferred	—	—
Provision for income taxes	$ 261	$ 67

The components of the deferred tax assets are as follows (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating loss carryforwards	$ 47,720	$ 39,822
Research and development tax credits	10,187	7,943
Capitalized research and development	21,676	14,260
Sale of future royalties	1,623	2,886
Lease liability	4,206	4,581
Accruals, reserves and other	4,827	5,004
Total deferred tax assets	90,239	74,496
Valuation allowance	(82,500)	(66,323)
Deferred tax assets net of valuation allowance	7,739	8,173
Deferred tax liabilities:		
Intangible assets	(2,308)	(2,614)
Right-of-use assets	(5,216)	(5,427)
Depreciation on property and equipment	(215)	(132)
Total deferred tax liabilities	(7,739)	(8,173)
Net deferred tax assets	$ —	$ —

A reconciliation of the provision for income taxes with the expected provision for income taxes computed by applying the federal statutory income tax rate of 21% to the net loss before provision for income taxes:

	Year Ended December 31,	
	2023	2022
U.S. federal taxes at statutory rate	21.0%	21.0%
State taxes (net of federal benefit)	0.1	0.1
Foreign rate differential	(1.1)	(0.3)
Permanently non-deductible items	(1.1)	(1.5)
Tax credits	2.7	3.0
Change in valuation allowance	(19.7)	(22.0)
Prior year true-up	(0.1)	(0.2)
Other	(2.1)	(0.2)
Provision for income taxes	(0.3)%	(0.1)%

The Company's actual tax expense differed from the statutory federal income tax expense using a tax rate of 21% for the years ended December 31, 2023 and 2022, respectively, primarily due to foreign income taxes being taxed at different rates, nondeductible expenses, research and development tax credits, and the change in valuation allowance.

As of December 31, 2023 and 2022, the Company had net operating loss ("NOL") carryforwards of $201.1 million and $162.1 million for federal purposes, and $87.5 million and $85.0 million for state purposes, respectively. If not utilized, federal net operating losses of $1.8 million will begin to expire in 2024 and $199.3 million will be carried forward indefinitely; state net operating losses of $2.9 million will begin to expire in 2028 and $84.6 million will be carried forward indefinitely.

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As of December 31, 2023, the Company also has accumulated tax losses of $4.9 million for Australia available for carryforward against future earnings, which under relevant tax laws do not expire but may not be available under certain circumstances.

As of December 31, 2023 and 2022, the Company had research and development tax credit carryforwards for federal purposes of $9.4 million and $6.9 million, respectively, and state research and development tax credit carryforwards of $8.5 million and $7.0 million, respectively. The federal research and development tax credit carryforwards will expire at various dates between 2039 and 2043. The state research and development tax credit carryforwards do not expire.

Beginning on January 1, 2022, the Tax Cuts and Jobs Act ("the Act"), enacted in December 2017, eliminated the option to deduct research and development expenditures in the current period and requires taxpayers to capitalize and amortize U.S.-based and non-U.S. based research and development expenditures over five and fifteen years, respectively. This legislation does not impact the Company's current tax obligations.

Sections 382 and 383 of the Internal Revenue Code provide for a limitation on the annual use of NOL and tax credit carryforwards following certain ownership changes that could limit the Company's ability to utilize these carryforwards. The Company has completed an analysis to determine if such ownership changes have occurred and concluded it was more likely than not that there were changes in ownership. Due to the existence of a full valuation allowance, limitations under Section 382 and 383 will not impact the Company's effective tax rate. Further analyses will be performed prior to recognizing the benefits of any losses or credits in the consolidated financial statements.

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover recorded net deferred taxes in future periods. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets as of December 31, 2023 and 2022. The net change in total valuation allowance was an increase of approximately $16.2 million and $23.7 million for the years ended December 31, 2023 and 2022, respectively.

The Company records unrecognized tax benefits, where appropriate, for all uncertain income tax positions. The Company recorded unrecognized tax benefits for uncertain tax positions of approximately $6.6 million and $4.9 million as of December 31, 2023 and 2022, respectively, of which none would impact the effective tax rate, if recognized, because the benefit would be offset by an increase in the valuation allowance.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Beginning Balance	$ 4,945	$ 2,422
Additions based on tax positions related to the current year	1,621	2,589
Increase (decreases) related to prior years' tax positions	—	(66)
Ending Balance	$ 6,566	$ 4,945

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the year ended December 31, 2023 and 2022, the Company recognized no interest and penalties associated with unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

The Company files income tax returns in the U.S, Australia, as well as with various U.S. states. The Company is subject to tax audits in all jurisdictions in which it files income tax returns. Tax audits by their very nature are often complex and can require several years to complete. There are currently no tax audits that have commenced with respect to income tax returns in any jurisdiction.

Under the tax statute of limitations applicable to the Internal Revenue Code, the Company and its U.S. subsidiary, either standalone or as part of the consolidated group, is no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for tax years before tax year 2017. Under the statute of limitations applicable to most state income tax laws, the Company is no longer subject to state income tax examinations by tax authorities for tax years before 2016 in states in which it has filed income tax returns. However, because the Company is carrying forward income tax attributes, such as net operating losses and tax credits from 2004 and earlier tax years, these attributes can still be audited when utilized on returns filed in the future. The Company is subject to foreign tax examinations by tax authorities for fiscal year 2015 and forward.

VAXART, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements

NOTE 14. 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):

	Year Ended December 31,	
	2023	2022
Net loss	$ (82,465)	$ (107,758)
Shares used to compute net loss per share, basic and diluted	144,819,781	127,683,813
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.84)

No adjustment has been made to the net loss attributable to common stockholders 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:

	Year Ended December 31,	
	2023	2022
Options to purchase common stock	17,270,980	13,567,390
Restricted stock unit to purchase common stock	2,931,662	460,975
Warrants to purchase common stock	227,434	228,725
Employee Stock Purchase Plan	402,699	392,095
Total potentially dilutive securities excluded from denominator of the diluted earnings per share computation	20,832,775	14,649,185

NOTE 15. Subsequent Events

Securities Purchase Agreement

In January 2024, the Company entered into a securities purchase agreement (the "2024 Securities Purchase Agreement") with RA Capital Healthcare Fund, L.P. in which 15,384,615 shares of its common stock were sold 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 underwriting discounts, commission and estimated offering expenses, the net proceeds were $9.9 million.

Update on September 2021 ATM

Since December 31, 2023, the Company has issued 5,071,472 shares of common stock under the September 2021 ATM (see Note 1) for gross proceeds net of commissions totaling $5.7 million through March 12, 2024.

ASPR Contract

On January 12, 2024, the Company was awarded a contract ("ASPR Contract") by the U.S. Government through the Department of Health and Human Services, Office of the Administration for Strategic Preparedness and Response ("ASPR") with a base and all options value of $9.3 million. Under the ASPR Contract, the Company will receive 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.

Changes in Management and Board of Directors

On January 15, 2024, Andrei Floroiu resigned (i) as President and Chief Executive Officer of the Company, and (ii) as a member of the Company's Board of Directors.

On January 16, 2024, the Company's Board of Directors announced that, effective as of January 16, 2024, the current Chair of the Board of Directors, Michael J. Finney, Ph.D., has been appointed as Interim Chief Executive Officer of the Company. Dr. Finney also serves as the Company's principal executive officer and will continue to serve on the Company's Board of Directors while serving as Interim Chief Executive Officer.

Subsequently, on March 4, 2024, the Board of Directors appointed Steven Lo as the Company's Chief Executive Officer, President, and principal executive officer, as well as a member of the Board of Directors, in each case effective as of March 18, 2024. In connection with Mr. Lo's appointment, it is anticipated that Michael J. Finney, Ph.D. will step down as the Company's Interim Chief Executive Officer and principal executive officer on March 17, 2024; however, Dr. Finney will continue to serve as Chair of the Board of Directors. In addition, David Wheadon, M.D., will resign as Lead Director of the Board of Directors effective as of March 31, 2024. Dr. Wheadon will continue to serve as a director on the Board of Directors.

2024 Inducement Award Plan

On February 27, 2024, the 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 will be 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 Company's 2019 Equity Incentive 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.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Inherent Limitations Over Internal Controls

Our management, including our Interim Chief Executive Officer and Chief Financial Officer, do 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.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment under the framework in the Internal Control—Integrated Framework (2013), our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial statements.

Item 9B. Other Information

During our last fiscal quarter, 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 Regulation S-K Item 408.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

The Company expects to file with the U.S. Securities and Exchange Commission (the "SEC") in April 2024 (and, in any event, not later than 120 days after the close of the Company's last fiscal year), a definitive proxy statement (the "Proxy Statement"), pursuant to SEC Regulation 14A in connection with the Company's Annual Meeting of Stockholders to be held in 2024 (the "Annual Meeting"), which involves the election of directors.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item will be set forth in the Company's Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item will be set forth in the Company's Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item will be set forth in the Company's Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item will be set forth in the Company's Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item will be set forth in the Company's Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) (1) Financial Statements (see "Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).

(a) (2) Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto).

(a) (3) Exhibits (see "Exhibit Index" below).

(b) Refer to (a)(3).

(c) Not applicable.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization dated October 27, 2017, by and among Aviragen Therapeutics, Inc., Vaxart, Inc. and Agora Merger Sub, Inc.	8-K	001-35285	2.1	October 30, 2017
2.2	Amendment No. 1, dated as of February 7, 2018, to the Agreement and Plan of Merger and Reorganization dated October 27, 2017, by and among Aviragen Therapeutics, Inc., Vaxart, Inc. and Agora Merger Sub, Inc.	8-K	001-35285	2.1	February 7, 2018
3.1	Restated Certificate of Incorporation of Aviragen Therapeutics, Inc.	10-K	001-35285	3.1	September 13, 2016
3.2	Certificate of Amendment to Restated Certificate of Incorporation of Aviragen Therapeutics, Inc.	8-K	001-35285	3.1	February 20, 2018
3.3	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	8-K	001-35285	3.2	February 20, 2018
3.4	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	8-K	001-35285	3.1	April 24, 2019
3.5	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	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 By-laws of Vaxart, Inc., effective as of October 18, 2023	8-K	001-35285	3.1	October 23, 2023
4.1	Reference is made to Exhibits 3.1 to 3.7				
4.2	Specimen Common Stock Certificate	S-3	333-228910	4.2	December 20, 2018
4.3	Form of Pre-Funded Warrant (April 2019)	S-1	333-229536	10.25	February 6, 2019
4.4	Form of Common Stock Warrant (April 2019)	S-1/A	333-229536	4.4	April 8, 2019
4.5	Form of Representative Warrant (April 2019)	S-1/A	333-229536	4.5	April 8, 2019
4.6	Form of Pre-Funded Warrant (September 2019)	S-1	333-233717	4.3	September 11, 2019
4.7	Form of Common Stock Warrant (September 2019)	S-1	333-233717	4.4	September 11, 2019
4.8	Form of Representative Warrant (September 2019)	S-1/A	333-233717	4.5	September 24, 2019
4.9	Form of Common Stock Warrant (March 2020)	8-K	001-35285	4.1	March 2, 2020
4.10	Form of Placement Agent Warrant (March 2020)	8-K	001-35285	4.2	March 2, 2020
4.11 *	Description of Securities of the Registrant				
10.1 +	Collaboration and License Agreement dated September 29, 2003, between Biota Holdings Limited and Sankyo Co., Ltd.	10-Q	001-35285	10.5	May 10, 2013
10.2 +	Amendment #1 to Collaboration and License Agreement dated June 30, 2005, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Sankyo Company, Ltd.	10-Q	001-35285	10.6	May 10, 2013
10.3	Amendment #2 to Collaboration and License Agreement, dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Daiichi Sankyo Company, Limited	10-Q	001-35285	10.7	May 10, 2013
10.4 +	Commercialization Agreement dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd and Daiichi Sankyo Company, Ltd.	10-Q	001-35285	10.8	May 10, 2013
10.5 +	Contract dated March 31, 2011, between Biota Scientific Management Pty. Ltd. and Office of Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for preparedness and Response at the U.S. Department of Health and Human Services	10-Q	001-35285	10.9	May 10, 2013
10.6 +	Research and License Agreement dated February 21, 1990, by and among Biota Scientific Management Pty. Ltd., Biota Holdings Limited, Glaxo Australia Pty. Ltd. and Glaxo Group Limited	10-K	001-35285	10.6	September 27, 2013
10.7 #	2007 Omnibus Equity and Incentive Plan (included as Appendix A to the proxy statement)	DEF 14A	000-04829	-	April 12, 2007
10.8 #	Form of Employee Stock Option Agreement under the 2007 Omnibus Equity and Incentive Plan	8-K	001-35285	10.1	December 10, 2013

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
10.9 +	Royalty Interest Acquisition Agreement by and between Aviragen Therapeutics, Inc., Biota Holdings Pty Ltd, Biota Scientific Management Pty. Ltd. and HealthCare Royalty Partners III, L.P. dated April 22, 2016	8-K	001-35285	10.1	April 26, 2016
10.10	Protective Rights Agreement between Aviragen Therapeutics, Inc. and HealthCare Royalty Partners III, L.P. dated April 22, 2016	8-K	001-35285	10.2	April 26, 2016
10.11 #	Form of Employee Stock Option Agreement under the 2016 Equity Incentive Plan	10-Q	001-35285	10.1	May 8, 2017
10.12 #	2016 Equity Incentive Plan (included as Appendix A to the proxy statement)	DEF 14A	001-35285	-	September 27, 2016
10.13 #	Director Stock Option Agreement	S-4	333-222009	10.22	December 12, 2017
10.14	Form of Indemnification Agreement by and between Vaxart, Inc. and its Directors and Executive Officers	8-K	001-35285	10.3	February 20, 2018
10.15 #	Vaxart, Inc. Amended and Restated 2007 Equity Incentive Plan, Stock Option Agreement, form of Notice of Stock Option Grant, form of Additional Terms and Conditions to Option and Stock Option Exercise Agreement	S-4/A	333-222009	10.24	December 29, 2017
10.16 #	Offer Letter, dated May 25, 2011, and Amendment to Offer Letter and Option Grant Agreement, dated October 1, 2011, by and between Vaxart, Inc. and Wouter W. Latour, M.D.	S-4/A	333-222009	10.25	December 29, 2017
10.17	Industrial Lease dated October 28, 2013, by and between Vaxart, Inc. and Oyster Point LLC	S-4/A	333-222009	10.26	December 29, 2017
10.18	Lease Agreement dated April 17, 2015, by and between Vaxart, Inc. and CRP Edgewater, LLC	S-4/A	333-222009	10.27	December 29, 2017
10.19 #	Severance Benefit Plan and Form of Severance Benefit Plan Participation Notice	8-K	001-35285	10.1	June 6, 2018
10.20	Form of Sales Agreement dated December 19, 2018, by and between Vaxart, Inc. and B. Riley FBR, Inc.	S-3	333-228910	1.2	December 02, 2018
10.21	Amended and Restated Warrant issued to Oxford Finance LLC, dated February 13, 2018	8-K	001-35285	10.2	February 20, 2018
10.22	Engagement Letter, dated as of January 25, 2019, by and between Vaxart, Inc. and H.C. Wainwright & Co., LLC, as amended	8-K	001-35285	10.2	March 20, 2019
10.23	Form of Placement Agent Warrant (March 2019)	8-K	001-35285	10.3	March 20, 2019
10.24 #	2019 Equity Incentive Plan, as amended	8-K	001-35285	10.1	June 21, 2021
10.25 #	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the 2019 Equity Incentive Plan	S-8	333-239727	10.2	July 7, 2020
10.26 #	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2019 Equity Incentive Plan	8-K	001-35285	10.3	April 24, 2019
10.27 +	Manufacturing Services Agreement dated July 17, 2019, by and between Vaxart, Inc. and Lonza Houston, Inc.	S-1/A	333-233717	10.30	September 24, 2019
10.28	First Amendment to Lease Agreement dated September 17, 2019, by and between Vaxart, Inc. and HCP Inc.	8-K	001-35285	10.1	September 19, 2019
10.29	Form of Securities Purchase Agreement, dated February 27, 2020, by and among Vaxart, Inc. and the Purchasers named therein	8-K	001-35285	10.1	March 2, 2020
10.30 #	Offer Letter, dated May 1, 2006, by and between the Company and Dr. Sean Tucker	10-Q	001-35285	10.2	May 12, 2020
10.31 #	Offer Letter, dated March 26, 2018, by and between the Company and Margaret Echerd	10-Q	001-35285	10.3	May 12, 2020
10.32 #	Letter dated December 27, 2018, from the Company to Margaret Echerd	10-Q	001-35285	10.4	May 12, 2020
10.33 #	Separation Agreement, dated June 14, 2020, between Vaxart, Inc. and Wouter W. Latour, M.D.	8-K	001-35285	10.1	June 15, 2020
10.34 #	Letter Agreement, dated June 14, 2020, between Vaxart, Inc. and Andrei Floroiu	8-K	001-35285	10.2	June 15, 2020
10.35	Sales Agreement, dated July 8, 2020, by and between SVB Leerink LLC, B. Riley FBR, Inc. and Vaxart, Inc.	S-3ASR	333-239751	1.2	July 8, 2020
10.36 +	Master Services Agreement, dated April 17, 2020, by and between Vaxart, Inc. and Kindred Biosciences, Inc.	10-Q	001-35285	10.4	November 12, 2020
10.37 +	Statement of Work 003, dated September 11, 2020, under the Master Services Agreement, dated April 17, 2020, by and between Vaxart, Inc. and Kindred Biosciences, Inc.	10-Q	001-35285	10.5	November 12, 2020
10.38 +	Statement of Work 004, dated September 11, 2020, under the Master Services Agreement, dated April 17, 2020, by and between Vaxart, Inc. and Kindred Biosciences, Inc.	10-Q	001-35285	10.6	November 12, 2020
10.39	Open Market Sale Agreement, dated October 13, 2020, by and between Vaxart, Inc., Jefferies LLC, and Piper Sandler & Co.	8-K	001-35285	1.1	October 14, 2020
10.40	Sublease Agreement dated November 16, 2020, by and between Vaxart, Inc. and Vera Therapeutics, Inc.	10-K	001-35285	10.40	February 25, 2021

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
10.41	Controlled Equity Offering Sales Agreement dated September 15, 2021, by and among the Company, Cantor Fitzgerald & Co. and B. Riley Securities, Inc.	8-K	001-35285	1.1	September 16, 2021
10.42	Lease Agreement, dated September 17, 2021, by and between Vaxart, Inc. and Britannia Pointe Grand Limited Partnership	8-K	001-35285	10.1	September 21, 2021
10.43	Second Amendment to Lease Agreement, dated September 17, 2021, by and between Vaxart, Inc. and Healthpeak Properties, Inc.	8-K	001-35285	10.2	September 21, 2021
10.44 #	Offer Letter, dated August 16, 2021, by and between the Company and James Cummings MD	10-Q	001-35285	10.4	November 4, 2021
10.45 +	Asset Purchase Agreement, dated November 24, 2021, by and between Vaxart, Inc. and Kindred Biosciences, Inc.	10-K	001-35285	10.45	February 24, 2022
10.46 #	Offer letter, dated January 18, 2022, by and between the Company and Edward Berg	10-K	001-35285	10.46	February 24, 2022
10.47 #	Non-Employee Director Compensation Program, effective as of April 1, 2022	10-Q	001-35285	10.2	May 9, 2022
10.48 #	Confidential Consulting Agreement between the Company and FLG Partners, LLC, effective as of April 20, 2022	8-K	001-35285	10.1	May 11, 2022
10.49 #	Consulting Services Agreement between the Company and Ms. Echerd, effective as of May 11, 2022	8-K	001-35285	10.2	May 11, 2022
10.50 +	Pre-Challenge Study Services Agreement dated June 29, 2022, between the Company and hVIVO Services Limited	10-Q	001-35285	10.4	August 8, 2022
10.51 #	2019 Equity Incentive Plan	8-K/A	001-35285	10.1	August 5, 2022
10.52 #	2022 Employee Stock Purchase Plan	8-K/A	001-35285	10.2	August 5, 2022
10.53 #	Offer Letter, dated December 5, 2022, by and between the Company and Phillip Lee	10-K	001-35285	10.53	March 15, 2023
10.55 #	Amendment to Letter Agreement dated May 2, 2023, between Andrei Floroiu and Vaxart, Inc.	10-Q	001-35285	10.1	May 4, 2023
10.56 #	Amendment to the Vaxart, Inc. Severance Benefit Plan dated May 2, 2023	10-Q	001-35285	10.2	May 4, 2023
10.57	Underwriting Agreement, dated June 6, 2023, by and between Vaxart, Inc. and Cantor Fitzgerald & Co.	8-K	001-35285	1.1	June 8, 2023
10.58 #	Letter Agreement, dated January 16, 2024, between Vaxart, Inc. and Michael J. Finney	8-K	001-35285	10.1	January 16, 2024
10.59 *	ASPR-BARDA Award/Contract, dated January 12, 2024, between Vaxart, Inc. and the U.S. Government through the Department of Health and Human Services				
10.60	Securities Purchase Agreement, dated January 16, 2024, by and between Vaxart, Inc. and RA Capital Healthcare Fund, L.P.	8-K	001-35285	10.1	January 16, 2024
10.61 #	Separation Agreement, dated January 31, 2024, by and between the Company and Andrei Floroiu	8-K	001-35285	10.1	February 2, 2024
14.1	Code of Conduct	10-Q	001-35285	14.1	May 4, 2023
19.1 *	Insider Trading and Securities Law Compliance Policy of Vaxart, Inc., last amended as of March 12, 2024				
21.1 *	Subsidiaries of the Registrant				
23.1 *	Consent of WithumSmith+Brown, PC, Independent Registered Public Accounting Firm				
24.1 *	Power of Attorney. Reference is made to the signature page hereto				
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 and 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				

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
97.1 *	Vaxart, Inc. Compensation Recovery Policy as adopted as of October 2, 2023				
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

\+ Confidential portions of this exhibit have been omitted and filed separately with the Commission pursuant to confidential treatment granted under Rule 24b-2 promulgated under the Exchange Act

§ 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 Annual Report on Form 10-K 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

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

VAXART, INC.

By: /s/ MICHAEL J. FINNEY
Michael J. Finney, Ph.D.
Interim Chief Executive Officer and Chair of the Board of Directors

Date: March 14, 2024

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael J. Finney and Phillip Lee, and each of them, as his or her attorneys-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, and each of them, or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ MICHAEL J. FINNEY Michael J. Finney, Ph.D.	Interim Chief Executive Officer and Chair of the Board of Directors *(Principal Executive Officer)*	March 14, 2024
/s/ PHILLIP LEE Phillip Lee	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 14, 2024
/s/ ELAINE J. HERON Elaine J. Heron, Ph.D.	Director	March 14, 2024
/s/ DAVID WHEADON David Wheadon M.D.	Lead Director of the Board of Directors	March 14, 2024
/s/ W. MARK WATSON W. Mark Watson	Director	March 14, 2024
/s/ ROBERT A. YEDID Robert A. Yedid	Director	March 14, 2024

DESCRIPTION OF COMMON STOCK

The following summary description of our common stock is based on the provisions of our amended and restated certificate of incorporation, as amended from time to time, and amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and the Delaware General Corporation Law.

General

Our authorized capital stock consists of (i) 250,000,000 shares of common stock, par value $0.0001 per share and (ii) 5,000,000 shares of preferred stock, par value $0.0001 per share.

The following is a summary of the material provisions of the common stock provided for in our amended and restated certificate of incorporation, as amended from time to time, and amended and restated bylaws.

Common Stock

Voting

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, except that directors will be elected by a plurality of votes cast. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors are able to elect all of the directors standing for election, if they so choose.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. We have never paid cash dividends and have no present intention to pay cash dividends.

Liquidation

In the event of a liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Anti-Takeover Effects of Provisions of Our Charter Documents and Delaware Law

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Certificate of Incorporation and Bylaws

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change-in-control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our certificate of incorporation and bylaws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in control);
- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders or by action taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice; and
- provide that special meetings of our stockholders may be called only by the chairman of the board, the president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exist any vacancies).

Choice of Forum

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for enumerated types of internal corporate claims, including derivative suits, claims for breach of fiduciary duty, actions under the General Corporation Law of Delaware, amended and restated certificate of incorporation or the amended and restated bylaws, and actions under the internal affairs doctrine.

Nasdaq Capital Market Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "VXRT."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

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 [***].

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 | 50

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50124C00002	See Block 20C	ASP323575

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
ASPR-BARDA	ASPR-BARDA	ASPR-BARDA	ASPR-BARDA
200 Independence Ave., S.W.		US DEPT OF HEALTH & HUMAN SERVICES	
Room 640-G		BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT	
Washington DC 20201		200 INDEPENDENCE AVE, S.W.	
		Washington DC 20201	
		SCD-C	

7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code)	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT
VAXART, INC. [***]	☐ FOB ORIGIN ☒ OTHER (See below)	
SEAN TUCKER ;170 HARBOR WAY STE 300		
170 HARBOR WAY STE 300		
SUITE 9A		
SOUTH SAN FRANCISCO CA 94080		
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM G.5.2
CODE [***]	FACILITY CODE	

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
Office of the Secretary	OS	ASPR-BARDA	ASPR-BARDA
Office of the Secretary		US DEPT OF HEALTH & HUMAN SERVICES	
200 Independence Ave. S.W.		BIOMEDICAL ADVANCED RESEACH & DEVEL	
Washington DC 20201		200 INDEPENDENCE AVE, S.W; ROOM 640	
		Washington DC 20201	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 3304 (a) ( )	2024.Q99C102.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT				$9,271,193.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	47
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	4			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	9	X	J	LIST OF ATTACHMENTS	50
X	D	PACKAGING AND MARKING	12			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	13		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	14				
X	G	CONTRACT ADMINISTRATION DATA	21		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	31		M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (*Attachments are listed herein.*)

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

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
ANDREI FLOROIU	RICHARD A. HALL

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
VAXART, INC. [***]	01/12/2024	BY Richard A. Hall -S Digitally signed by Richard A. Hall -S Date: 2024.01.12 21:12:42 -05'00'	
BY (Signature of person authorized to sign)		(Signature of the Contracting Officer)	

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Previous edition is NOT usable

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

NAME OF OFFEROR OR CONTRACTOR

VAXART, INC. [***]

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 80-0101064 UEI: [***] OTA: N Delivery: [***] Appr. Yr.: 2024 CAN: Q99C102 Object Class: 25106 Period of Performance: [***] to [***]				
1	ASPR-24-00456 Base Period funds to Vaxart Inc for development of an oral mucosal vaccine for SARS-CoV2 Obligated Amount: $9,271,193.00				9,271,193.0

CONTRACT TABLE OF CONTENTS

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SERVICES

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

This firm fixed priced contract with Vaxart, Inc is for clinical trial planning activities for a phase 2b clinical trial that compares Vaxart'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 Government has determined a Bona Fide Need for each non-severable discrete work segment which will conclude upon the completion of a defined tasks that provide(s) independent merit and value to the Government. The Contractor's success in completing the required tasks under the work segments must be demonstrated through the Deliverables and Milestones specified under Article F of this contract.

The period of performance is time driven. The contract is fully funded for the period of performance and shall only be used for the scope of work. The period of performance is listed under Article B.2.1.

B.2. COST AND PERIOD OF PERFORMANCE

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

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

B.2.1 BASE PERIOD

1. The Base Period is a Firm Fixed Priced (FFP) Contract.

2. The total cost of the base period of this contract is $9,271,193.00.

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

Base Period 1: CLIN 0001

Table 1. Base Period Firm Fixed Price CLIN			
CLIN	**Period of Performance**	**Supplies/Services**	**Total Cost**
0001	[***] – [***]	Planning activities to support a Phase 2b clinical trial comparing Vaxart vaccine to a currently approved product	$9,271,193.00

***Section G.7 outlines the payments under the fixed price to be made based on specific milestones**

B.2.2. OPTIONS - Reserved

B.3. ESTIMATED COST - COST SHARING - Reserved

B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS

1. Items Unallowable Unless Otherwise Provided

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

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

b. Special rearrangement or alteration of facilities;

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

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

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

e. Travel to attend general scientific meetings/conferences;

f. Promotional Items

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

h. Overtime (premium) compensation;

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

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

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

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

2. Travel Costs

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

2) Subject to the dollar limitation specified under B.4.2.1. above, the Contactor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulation (FAR) 31.2 – Contracts with Commercial Organizations, Sub-Section 31.205- 46, Travel Costs and Federal Travel Regulations.

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

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

• Meeting(s) and place(s) to be visited, with costs and dates; name(s) and title(s) of Contractor personnel to travel and their functions in the contract project;

• Contract purposes to be served by the travel;

• How travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of BARDA contract funds;

• How such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and

• What additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

B.5. ADVANCE UNDERSTANDINGS

1. Person-in-Plant

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

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

2. Security

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

3. Subcontracts

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

- Is of the cost-reimbursement, time-and-materials or labor-hour type or
- Is of the fixed price type and exceeds $[***] or [***]% of the contract

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

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Section.

4. Overtime Compensation

[***]

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

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

6. Approval of Human and Animal Protocols

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

7. Rights in Data

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

Limited Rights Data is defined as data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

(i) Use (except for manufacture) by support service contractors.
(ii) Evaluation by nongovernment evaluators.
(iii) Use (except for manufacture) by other contractors participating in the Government's program of which the specific contract is a part

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

B.6 ORGANIZATIONAL CONFLICT OF INTEREST

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

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

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

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

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

C.2. REPORTING REQUIREMENTS

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

C.3. PROJECT MEETING CONFERENCE CALLS

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

C.4. PROJECT MEETINGS

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

1. Kickoff Meeting

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

2. Quarterly and Ad-Hoc Meetings

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

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

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

3. Project Review Meetings

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

C.5 RISK MANAGEMENT

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

1. Preliminary hazard analyses as necessary for each product component

2. Design, user, and process FMEA plans

3. Risk control plans to verify the proposed mitigations

C.6 REGULATORY ACTIVITIES

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

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

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

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

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

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

C.7 QUALITY

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

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

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

SECTION D – PACKAGING, MARKING, AND SHIPPING

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

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

SECTION E – INSPECTION AND ACCEPTANCE

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

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: https://www.acquisition.gov/FAR/

FAR Clause **Title and Date**

FAR 52.246-2, Inspection of Supplies – Fixed-Price (Aug 1996)
FAR 52.246-4, Inspection of Services – Fixed-Price (Aug 1996)
FAR 52.246-8, Inspection of Research and Development – Fixed-Price (Aug 1996)
FAR 52.246-16, Responsibility for Supplies (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

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

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Delivery, technical inspection and acceptance will take place at a location designated by the Contracting Officer or the Contracting Officer Representative.

1. Site Visits and Inspections

At the discretion of the Government and independent of activities conducted by the Contractor, with 48-hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48-hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

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

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

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the Base Period in Section B.2.1.

F.2. DELIVERABLES

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

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

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

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

Contract Data Requirements List (CDRLs)

Meetings

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Post Award Teleconference	[***] [***] [***]	● [***] ● [***] ● [***] ● [***] ● [***]
	Kickoff Meeting	[***]	● [***] ● [***] ● [***] ● [***] ● [***]
	Weekly Teleconference	[***] [***]	● [***] ● [***] ● [***] ● [***] ● [***]
	Technical, Subgroup, Ad Hoc Teleconference(s)	[***]	● [***] ● [***]

	Periodic Review Meetings	[***]	• [***] • [***] • [***] • [***]
	FDA Meetings and Interactions	[***] [***]	• [***] • [***] • [***] • [***] • [***]

Technical Reporting General

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Project Management Plan (PMP)	[***] [***]	• [***] o [***] o [***]
	Gantt Chart/Timeline	[***]	• [***]
	Communication Plan	[***] [***]	• [***] o [***] o [***]
	Contractor Locations	[***] [***]	• [***] o [***] o [***] • [***]

	Pandemic/Public Health Emergency Facility and Operational Management Plan	[***]	● [***] o [***] o [***]
	Request for Information (RFI) Responses	[***] [***]	● [***]
	Monthly & Annual Technical Progress Reports/Annual Meeting	[***] 1. [***] 2. [***] ● [***] ● [***] ● [***] ● [***] ● [***] ● [***] ● [***] ● [***]	● [***] ● [***] ● [***]

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

Detailed Description of Select Contract Deliverables

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

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

a. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. Reports shall be submitted on the 15th day of the month after the preceding month being covered.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this Section. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

The format should include:

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

- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses.
  This Section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

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

b. Annual Progress Report

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

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE -
  A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Schedule. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.

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

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

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

c. Draft Final Report and Final Report

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

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

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

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

d. Summary of Salient Results

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

e. Audit Reports

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

f. Periodic Document Review

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

g. Risk Management Plan

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

- Due within 45 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- The COR shall provide Contractor with a written list of concerns in response plan submitted

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

2. Deliverables Arising from FDA Correspondence

a. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people including the COR and up to 3 subject matter experts.

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 2 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

b. FDA Submissions

The Contractor shall provide the COR all documents submitted to the FDA at least 15 days prior to submission.

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

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

c. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of any potential FDA Form 483 and the Establishment Inspection Report (EIR) received within one (1) business day after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA Audit Findings report received from subcontractors that occur as a result of this contract or for this product within 1 business day of receiving correspondence from the FDA, Subcontractor, or third party.
- Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

d. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All documents shall be duly marked as either “Draft” or “Final.” Contractor shall provide written summary of any FDA correspondence within 2 business days of correspondence.

F.3. ELECTRONIC SUBMISSION

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

F.4. SUBJECT INVENTION REPORTING REQUIREMENT

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

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

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

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

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

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

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

Contracting Officer
Contract Management and Acquisition (CMA)
Biomedical Advanced Research & Development Authority (BARDA)
Administration for Strategic Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (DHHS)
Email: Richard.hall@hhs.gov

Name: Kevin Dean Contract Specialist
Contract Management and Acquisition (CMA)
Biomedical Advanced Research & Development Authority (BARDA)
Administration for Strategic Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (DHHS)
Email: kevin.dean1@hhs.gov

1. The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
2. The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
3. No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.
4. The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

NOTE: An unauthorized commitment is an agreement that **is not binding** solely because the Government representative who made it lacked the authority to enter into that agreement on behalf of the Government. An unauthorized commitment (UC) usually results in the receipt of goods or services on behalf of the Government by someone with apparent authority, but that lacks the authority to obligate the Government; it can be intentional or unintentional. Only a warranted contracting officer has authority to obligate government funds and contractually bind the government for supplies and services within their warrant authority.

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

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

Name: Christina Latagan
U.S. Department of Health & Human Services
Administration for Strategic Preparedness and Response
Biomedical Advanced Research & Development Authority (BARDA)
Phone: (202) 741-8484
Email: christina.latagan@hhs.gov

The COR is responsible for:

1. Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
2. Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
3. Performing technical evaluation as required;
4. Performing technical inspections and acceptances required by this contract; and
5. Assisting in the resolution of technical problems encountered during performance.

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

G.3. KEY PERSONNEL

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

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

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

G.4. CONTRACT FINANCIAL REPORT

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

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

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

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

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

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

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

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

Limitation of Cost (Apr 1984)

- The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.
- The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—
- The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or
- The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.
- As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.
- Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—
- The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and
- The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost- sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

- No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.
- If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.
- Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.
- If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

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

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

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

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when total amount is over $10,000
5. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car etc), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
8. Equipment - Cite authorization and amount. Cite appropriate COA
9. Other Direct Costs - Include detailed breakdown when total amount is over $10,000.
10. G&A - Cite rate and amount.
11. Total Cost (and applicable cost-shared ratio)
12. Fixed Fee (if applicable)
13. Total Cost-Plus Fixed Fee

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

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

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

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

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

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

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

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

(End of Clause)

G.5.1 INVOICE ELEMENTS

a. The Contractor agrees to include (as a minimum) the following information on each invoice:
    i. Contractor's Name & Address
    ii. Contractor's Tax Identification Number (TIN)
    iii. Contract Number
    iv. Invoice Number
    v. Invoice Date
    vi. Contract Line Item Number (CLIN)
    vii. Requisition number associated with each CLIN
    viii. Quantity
    ix. Unit Price & Extended Amount for each line item
    x. Total Amount of Invoice
    xi. Name, title and telephone number of person to be notified in the event of a defective invoice
    xii. Payment Address

b. The invoice shall be signed by a person authorized to bind the Contractor.
c. The Contractor shall not submit an invoice prior to delivery of goods or services.
d. The Contractor shall include the following certification at the bottom of the payment request: "I hereby certify that the salaries billed in this payment request are in compliance with the current HHS Salary Rate Limitation Provisions in Section I of the contract."

G.5.2 ELECTRONIC INVOICING AND PAYMENT REQUIREMENTS – INVOICE PROCESSING PLATFORM (IPP)

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

- Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
    - Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
    - The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
- If your company is already registered to use IPP, you will not be required to re-register.
- If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

Additional Administration for Strategic Preparedness and Response (ASPR) requirements:

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

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

(iii) Invoices must include the Unique Entity ID of the Contractor.

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

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

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

G.6. REIMBURSEMENT OF COST

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

a. All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b. All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c. All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d. Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

1. Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).
2. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.
3. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).
4. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

G.7. MILESTONE PAYMENTS

Invoicing during the Base Period will occur with the achievement of milestones as agreed to with BARDA. Vaxart will provide substantiation to BARDA and require approval by the Contract Officer and COR ahead of submitting the request for payment to the invoicing system.

The table below outlines the payments under the fixed price to be made based on specific milestones.

Activity / Milestone	Verification	Amount
WBS 1.1 Program Management		
Project Management Plans	Plans submitted to BARDA	[***]
Project Management	[***]	[***]
WBS 1.2 Analytics **Additional staff and resources applied for the period of performance**		
Sample Management Plan	Sample Management Plan to BARDA	[***]
Laboratory Manual	Laboratory Manual	[***]
Analytical Equipment	Purchase Order issued to vendors	[***]
	Equipment delivered. Invoice from vendors	[***]
	Qualification confirmation to BARDA	[***]
Materials & Supplies Mucosal Testing	• Purchase orders issued • Supplies received. Invoice from Vendors	[***] [***]

Assay Development & Qualification	• Assay Development Report • Assay Qualification Report	[***] [***]
Lab Kits	• Purchase orders issued • Supplies received. Invoice from Vendors	[***] [***]
Analytical Lab - Outsourced Selection	• Selected analytical lab provided to BARDA	[***]
Statistician	• Agreement with SOW	[***]
WBS 1.3 Clinical **Additional staff and resources applied for the period of performance**		
Clinical Team	• Kick-Off Meeting Minutes	[***]
Clinical Protocol Development	• Protocol Synopsis • Clinical Trial Protocol	[***] [***]
eCRF Development	• eCRF Form	[***]
Site Selection • Feasibility, qualification, start-up • Site Visits	 [***] [***]	[***] [***]
Comparator Vaccine • Order issued - deposit • Order received	 PO issued to supplier Invoice for delivered vaccine	 [***] [***]
Subcontractor Selection • Subcontractor Visits • Vendor Budget Analysis • Proposal Evaluation Approved Subcontractors	 Invoiced Monthly / Completed Visits Vendor Budget Analysis Subcontractor Evaluation Report List of Approved Subcontractors	 [***] [***] [***]
Data Safety Monitoring Board • DSMB Established • Conduct Meetings • Recommendations reviewed, accepted, & implemented. • Travel, 1 Meeting	 • List of members & qualifications to BARDA for review • Meeting Minutes •BARDA approval • Meeting Minutes	 [***] [***] [***] [***]

Clinical Plans	• Statistical Analysis Plan • Data Management Plan • Risk Management Plan • Recruitment, Enrollment, and Retention Plan • Monitoring Plan accepted by BARDA • Publications Agreement	[***] [***] [***] [***] [***] [***]
Document Generation	• List of Program Documents to BARDA • Draft documents to BARDA • Final documents to BARDA	[***] [***] [***]
WBS 1.4 Regulatory		
Regulatory Affairs Activities	[***]	[***]
Total Base Period Firm Fixed Price		**$ 9,271,192**

G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

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

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

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

Electronic Access to Contractor Performance Evaluations

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

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

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

CPARS Point of Contact

Name: Sean Tucker
Title: Deputy Principal Investigator
Phone Number: 650-550-3500
Email Address: stucker@vaxart.com

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

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

G.10. GOVERNMENT PROPERTY

Any material/property generated in the course of this contract's performance or purchased with government funds is considered government material/property.

Section H – Special Contract Requirements

H.1 CLINICAL AND NON-CLINICAL TERMS OF AWARD

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

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

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

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

The Government shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form to ensure the Government has the ability to review and distribute the deliverables as the Government deems necessary. Important information regarding performing human subject research is available at https://www.niaid.nih.gov/research/clinical-research.

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

1. Non-Clinical Terms of Award

This contract does not involve the use of animals.

2. Clinical Terms of Award

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

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

a. Safety and Monitoring Issues

i. Institutional Review Board or Independent Ethics Committee Approval

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

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

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

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

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

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

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

ii. Data and Safety Monitoring Requirements

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

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

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

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

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

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

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

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

iii. BARDA Protocol Review Process Before Patient Enrollment Begins

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

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

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

iv. Investigational New drug or Investigational Device Exemption Requirements

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

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

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

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

v. Required Time-Sensitive Notification

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

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

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

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

iii. IDE reports of unanticipated adverse device effect:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE

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

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

H.5. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

H.6. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

H.7. IDENTIFICATION AND DISPOSITION OF DATA

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

H.8. EXPORT CONTROL NOTIFICATION

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

H.9. CONFLICT OF INTEREST

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

H.10. NEEDLE DISTRIBUTION

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

H.11. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.12. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

H.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.14. ACCESS TO DOCUMENTATION/DATA

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

H.15. EPA ENERGY STAR REQUIREMENTS

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

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

H.16. ACKNOWLEDGMENT OF FEDERAL FUNDING

Contractors funded with Federal dollars, in whole or in part, shall acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity (Not Including Press Releases)

No information related to data obtained under this contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

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

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

(2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Contract No. (to be inserted upon award)."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

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

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

H.17. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 2015)

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

(a) Publicity or propaganda purposes;

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

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

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

H.18. LABORATORY LICENSE REQUIREMENTS

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

H.19. QUALITY ASSURANCE (QA) AUDIT REPORTS

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

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

H.20. BARDA AUDITS

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

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

H.21. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

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

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

H.22. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIALRISKS

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

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

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

H.23. DISSEMINATION OF INFORMATION (May 2004)

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

H.24. MANUFACTURING STANDARDS

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

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

H.25. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs

are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under Section F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment.

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

H.26. HUMAN SUBJECTS

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

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

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

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

H.27. SHARING RESEARCH DATA

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

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

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

H.28. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

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

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

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

d. The Contractor shall not use any Federal funds for the cloning of human beings.

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

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

H.30. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

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

https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

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

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

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

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

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

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

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

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

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

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

H.31. FOREIGN TRANSFER OF ASSETS OR TECHNOLOGY

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

a. Definitions

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

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

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

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

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

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

b. General

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

c. Export Controls

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

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

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

Prior to transferring any Asset funded by the USG under this Contract, the Contractor should carefully review the USG rights under FAR Subpart 42.12 pertaining to Novation, specifically FAR section 42.1204. That provision provides that the USG may recognize a third party assignment only if the transfer of Assets and Technology is determined to be in the USG's interests. The Contractor should be aware that the USG is under **no** obligation to recognize a successor in interest. If the Contracting Officer determines that a transfer of Assets and Technology may have adverse consequences to the economic well-being or national health security interests of the U.S., the Contractor, and the Contracting Officer shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which may provide substantially equivalent benefits to the Contractor.

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

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

e. Transfer to a Prohibited Source

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

f. Lower Tier Agreements

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

H.32. CERTIFICATE OF CONFIDENTIALITY

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

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

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

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

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

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

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

The Contractor shall not:

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

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

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

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

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

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

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

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

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

PART II

SECTION I CONTRACT CLAUSES

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

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

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352.html

General Clauses for Firm Fixed Price Research and Development Contract

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

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jun 2020	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Jun 2020	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Jun 2020	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Nov 2021	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Nov 2021	Display of Hotline Poster(s)
FAR	52.203-17	Jun 2020	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-10	Jun 2020	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.204-18	Aug 2020	Commercial and Government Entity Code Maintenance
FAR	52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
FAR	52.204-21	Nov 2021	Basic Safeguarding of Covered Contractor Information Systems
FAR	52.204-23	Nov 2021	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.204-24	Nov 2021	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment
FAR	52.204-25	Nov 2021	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
FAR	52.204-27	Jun 2023	Prohibition on a ByteDance Covered Application
FAR	52.209-6	Nov 2021	Protecting the Government's Interests When Subcontracting With Offerors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.209-11	FEB 2016	Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law
FAR	52.210-1	Nov 2021	Market Research
FAR	52.215-2	Jun 2020	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format

FAR	52.215-14	Nov 2021	Integrity of Unit Prices
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.217-9	Mar 2000	Option to Extend the Term of the Contract
FAR	52.219-8	Oct 2018	Utilization of Small Business Concerns
FAR	52.219-28	Sep 2021	Post-Award Small Business Program Representation
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-2	July 1990	Payment for Overtime Premiums
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Jun 2020	Equal Opportunity for Veterans
FAR	52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Jun 2020	Employment Reports on Veterans
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Nov 2021	Combating Trafficking in Persons
FAR	52.222-54	May 2022	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Jun 2020	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.224-1	Apr 1984	Privacy Act Notification
FAR	52.224-2	Apr 1984	Privacy Act
FAR	52.225-13	Feb 2021	Restrictions on Certain Foreign Purchases
FAR	52.225-25	JUN 2020	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	June 2020	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data - General
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Nov 2021	Providing Accelerated Payments to Small Business SubOfferors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-2	Apr 1991	Production Progress Reports
FAR	52.242-3	Sep 2021	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes—Fixed-Price
FAR	52.243-6	Apr 1984	Change Order Accounting
FAR	52.243-7	Jan 2017	Notification of Changes
FAR	52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Jan 2022	Subcontracts for Commercial Products and Commercial Services
FAR	52.245-1	Sep 2021	Government Property

FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.247-67	Feb 2006	Submission of Transportation Documents for Audit
FAR	52.249-2	Apr2012	Termination for Convenience of the Government (Fixed-Price)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

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

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

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

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

52.217-8 Option to Extend Services (Nov 1999)

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. **Statement of Work**
2. **Invoice Instructions for Fixed Price Contracts**
3. **Financial Report of Individual Project/Contract**
4. **Instructions for Completing Financial Report of Individual Project/Contract**
5. **Inclusion Enrollment Report**
6. **Research Patient Care Costs**
7. **BARDA Security Requirements**

Biomedical Advanced Research and Development Authority
(BARDA)
Broad Agency Announcement (BAA)
BARDA BAA BAA-18-100-SOL-00003

Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures

Oral Mucosal Vaccine for SARS-CoV2 Protection
Area of Interest Number 15

Contractual Statement of Work
Dated December 22, 2023

PREAMBLE

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

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

Overall Objectives and Scope

The overall objective of this contract is to advance the development of Vaxart's oral Covid-19 XBB vaccine candidate as a/an tableted prophylactic vaccine for the treatment of SARS-CoV2. The scope of work for this contract encompasses the completion of the planning of and preparation for a phase 2b clinical trial, comparing Vaxart's oral Covid-19 vaccine Vaxart's XBB vaccine candidate to an approved mRNA vaccine. It includes program management, analytical development, preparation for a 10,000 patient phase 2b clinical trial, and required regulatory support to achieve these objectives. The major activities will include:

1) Vaxart, with the support of its external vendors, will develop a full clinical protocol;
2) Collect, review and complete all relevant regulatory documents;
3) Complete contract negotiations;
4) Conduct site qualification visits
- Resolve any issues to enable an adequate number of clinical sites to conduct the proposed trial
5) Procure Investigational vaccine and marketed comparator;
6) Order critical reagents to prepare for starting a clinical trial early in 2024.

7) Database programming and a draft statistical analysis plan (SAP) will be developed.
8) The protocol, the SAP, and other key documents will be reviewed with BARDA in real time to ensure concurrence and that start-up can occur on schedule.
9) Focus will be given to completing and finalizing a Monitoring Plan that is acceptable to BARDA so that full approval is received during the Base Period.

For this contract, Program Management is comprised of the following elements:
- Project Management
- Subcontract Management
- Risk Management
- Schedule & Budget Management
- Quality Management
- Travel

The clinical trial preparation activities for Vaxart's oral Covid-19 XBB vaccine candidate will progress in specific stages that cover the base performance segment (I) to be labeled Contract Line Item Number (CLIN) 0001. The Scope of Work is broken down into the following four (4) discreet tasks:

1.1 Program Management

Vaxart shall provide the following as outlined below and in the contract deliverables list (Insert Article No.)

1.1.1 The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

1.1.2 [***] is the principal investigator (PI) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract;

1.1.3 [***] is the project manager (PM) with responsibility for monitoring and tracking day-to- day progress and timelines; coordinating communication and project activities; costs incurred; and program management. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract;

1.1.4 A BARDA liaison with responsibility for effective communication with the Contracting Officer (CO) and Contracting Officer's Representative (COR). The liaison may be the PI or PM;

1.1.5 Administrative and legal staff with responsibility for developing compliant subcontracts, consulting, and other legal agreements; ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights; and reporting all inventions made in the performance of the contract;

1.1.6 Administrative staff with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors;

1.1.7 Contract Review Meetings;

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

1.1.7.2 Vaxart shall participate in teleconferences every two weeks with the CO and COR to discuss the performance of the contract. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

1.1.8 Integrated Master Schedule (IMS)

1.1.8.1 Within 30 calendar days of the effective date of the contract, the contractor shall submit a first draft of an updated IMS to the CO and COR for review and comment. The IMS shall be incorporated into the contract and will be used to monitor performance of the contract. The contractor shall include the key milestones and Go/No-Go Decision Gates (see 1.1.9.2).

1.1.9 Integrated Master Plan (IMP)

1.1.9.1 Work Breakdown Structure (WBS): Vaxart shall utilize a WBS template agreed upon by the government for reporting on the contract. The contractor shall expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by the government as part of their IMP for contract reporting. The CWBS shall be discernable and consistent. The CO may require the contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.

1.1.9.2 Go/No-Go Decision Gates: The IMP outlines key milestones with “Go/No-Go” decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, non-clinical and clinical studies, and regulatory submissions.

1.1.9.3 Project Management Plan: In the management of this contract, Vaxart shall utilize Project Progress Management tools/techniques to track and monitor the cost and schedule of the project. Vaxart and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverables list (Insert Article No.)for project management purposes. Vaxart shall submit the project progress management report to the CO and COR on a monthly basis.

1.1.10 Risk Management Plan: Vaxart shall develop a risk management plan within 30 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract; their impact on cost, schedule, and performance; and appropriate remediation plans. This plan shall reference relevant WBS elements where appropriate. Updates to this plan shall be included, at a minimum, on a monthly basis (every month) in the monthly Project Status Report (see 1.1.14).

1.1.11 Deviation Request: During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the contractor shall submit a Deviation Report. This report shall request a change in the agreed upon IMS and timelines. This report shall include: (i) discussion of the rationale/justification for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

1.1.12 Monthly and Annual Reports: Vaxart shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW, WBS, IMS, and EVM or other Project Management Plan tool(s):

i. Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities;
ii. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
iii. Updated IMS;
iv. Updated EVM/other Project Monitoring Tool(s);
v. Updated Risk Management Plan (every three months);
vi. Three-month rolling forecast of planned activities;
vii. Progress of regulatory submissions; and
viii. Estimated and actual expenses.

1.1.13 Data Management: Vaxart shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;

1.1.14 Provide for the statistical design and analysis of data resulting from the research; and

1.1.15 Provide raw data or specific analyses of data generated with contract funding to the CO and COR, upon request.

1.1.16 Perform those activities in the Base Period described in the following WBS dictionary:

1.1	**Program Management** Program Management follows procedures described in the Project Management Institute Project Management Book of Knowledge ("PMBOK©") and aligns it with requirements established by the program Sponsor, 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. For the Base Period, Program Management is comprised of the following elements which are also the Control Accounts for the specified WBS package. ● Project Management ● Subcontract Management ● Risk Management ● Schedule & Budget Management ● Quality Management ● Travel
1.1.1	**Technical and Project Management** [***] is the Program Manager (PM). [***] is the Principle Investigator (PI). Together they will take the lead responsibilities for the Technical and Contractual deliverables of the program. The Vaxart Program Team which includes representatives from BARDA, will hold weekly progress meetings through the period of performance. In addition, the Vaxart Program Team will conduct monthly performance reviews in accordance with the USG contract/communication plan requirements. In the Base Period, T&PM are focused on having the program configured to assure a reliable start on Day-1 of the initiation of the Phase 2b clinical trial; all of the resources in place, materials and supplies on order or inventoried, all of the team members actively engaged, and all of the support systems (E.g. cost accounting) on- line.
1.1.2	**Subcontract Management** The Program Manager and Principle Investigator will have overall responsibility for deliverables from the Subcontractors. Each of the Subcontractors will be managed day- to-day by the PM and the Vaxart Technical Lead who is also the Control Account Manager. A Subcontract Management Plan will be submitted to BARDA within 30 days 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.

	In the Base Period, subcontract management is primarily directed at working with the Control Account Managers in Analytical and Clinical and their teams to make final selection of the major subcontractors in the program. The contracts will be fully scoped, budgeted, and ready for signature on exercise by BARDA of the initiation of the Phase 2b clinical trial.
1.1.3	**Risk Management** These are activities specifically associated with the identification, monitoring, preventative and corrective action of program risks. The PM and PI 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 30 days 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. The primary responsibility of Risk Management in the Base Period is to identify, categorize, and mitigate risks that could affect the start of the Phase 2b clinical trial. In this responsibility, risks associated with performance of the clinical trial will also be characterized and addressed.
1.1.4	**Schedule & Budget Management** In the Base Period, PM will have responsibility for tracking the progress to deliverables and updating the program schedule weekly. This update will be provided to BARDA as part of the weekly dashboard. The Gantt Chart in this proposal is best estimate at the time of submission. Within 15 days of contract initiation, Vaxart will provide a Performance Measurement Baseline that establishes the schedule and associated expense through the Base Period. Attached to this will be a schedule network diagram that defines the critical path for the project. The weekly updates will then be compared against this baseline and status of critical path activities. Schedule management requires continual communication with the program stakeholders. Any occurrence or issue that could affect scheduled deliverables and in particular, the critical path will be addressed and, depending on impact, reported to BARDA. With respect to budget management, as an FFP acquisition, PM will report on changes to the proposed costs, as detailed later in this section. Vaxart is responsible for cost overruns in the Base Period.
1.1.4	**Quality Management** The scope of the Quality Management covers all activities carried out in accordance with the standards applicable to pharmaceutical activities for clinical studies. As applied to PM, this is an overarching view of quality that includes Quality Management Systems and the associated documentation. In the Option periods, quality oversight of the subcontractors is added to this work package.
1.1.5	**Travel** This work package captures travel in the Base period.

1.2 Analytical (WBS 1.2)

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1.3 Clinical (WBS 1.3)

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1.4 Regulatory (WBS 1.4)
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[***]	**[***]** [***] [***]
[***]	**[***]** [***]
[***]	**[***]** [***]

Objective: [***]

Deliverable: [***]

Go/No-Go:

Go / No Go	Expected Date MM/YY	Event	Condition / Requirement
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

2. OTHER ITEMS

2.1 Facilities, Equipment, and Other Resources (Insert Section No.)

Vaxart shall provide equipment; facilities and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

2.1.1 The humane care and use of vertebrate animals;
2.1.2 The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study;
2.1.3 The production, characterization, and release testing of active pharmaceutical ingredient and final drug product under cGMP;
2.1.3.1 The design and conduct of NDA-enabling non-clinical studies under GLP; and
2.1.4 Design and conduct clinical trials in humans under GCP.

ATTACHMENT 2

Invoice Instructions and Template

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS
General: The Contractor shall submit vouchers or invoices as prescribed herein.

Format: Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.
Number of Copies: As indicated in the contract.

Frequency: Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice: The invoice shall be prepared as follows:
(a) Designated Billing Office and address:
The Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

ELECTRONIC INVOICING AND PAYMENT REQUIREMENTS – INVOICE PROCESSING PLATFORM (IPP)

- All Invoice submissions for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).
- Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov.

- The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business
- Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
    - Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
    - The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
- If your company is already registered to use IPP, you will not be required to re-register.
- If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

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

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

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

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

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

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

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

SAMPLE INVOICE/PAYMENT REQUEST - TABLE 1

(a) Designated Billing Office Name and Address: DHHS/OS/ASPR/BARDA/CMA Attn: Richard Anthony Hall, Contracting Officer US DEPT OF HEALTH & HUMAN SERVICES ADMINISTRATION FOR STRATEGIC PREPAREDNESS & RESPONSE Division of Contract Management & Acquisitions Constitution Center | 400 7th SW Washington, DC 20024 (b) Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number: ABC CORPORATION 100 Main Street Anywhere, USA Zip Code Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. **VIN:** **DUNS or DUNS+4:**	(c) Invoice/Financing Request No.: (d) Date Invoice Prepared: (e) Contract No. and Order No. (if applicable): _____ (f) Effective Date: (g) Total Estimated Cost of Contract/Order: (h) Total Fixed-Fee (if applicable): (i) ☐Two-Way Match: ☐Three-Way Match: (j) Office of Acquisitions: (k) Central Point of Distribution:

(l) This invoice/financing request represents reimbursable costs for the period from ____ to

	Cumulative Percentage of Effort/Hrs.		Amount Billed				
Expenditure Category* A	Negotiated B	Actual C	(m) Current D	(n) Cumulative E	Cost at Completion F	Contract Amount G	Variance H
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____

(Name of Official) (Title)

* Attach details as specified in the contract

SAMPLE INVOICE/PAYMENT REQUEST - TABLE 2

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

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

ATTACHMENT 3

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT Note: Complete this Form in Accordance withAccompanying Instructions.	**Project Task:**	**Contract No.:**	**Date of Report:**	**0990-0134** **0990-0131**
	Reporting Period:	**Contractor Name and Address:**		

Expenditure Category	**Percentage of Effort/Hours**		**Cumulative Incurred Cost at Endof Prior Period**	**Incurred Cost-- Current Period**	**Cumulative Cost to Date (D + E)**	**Estimated Cost to Complete**	**Estimated Cost at Completion (F + G)**	**Negotiated Contract Amount**	**Variance (Over or Under) (I - H)**
	Negotiat	**Actual**							
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**

ATTACHMENT 4
INSTRUCTIONS FOR COMPLETING
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by the Government in monitoring the application of financial and personnel resources to the BARDA funded contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significantvariations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award.The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contractingofficer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer's Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only afunding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing the Quarterly Report. For the purpose of establishing expenditure categoriesin Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whoseeffort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in additionto regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or moreand with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report ofAccountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes thecost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normallyincludes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costsonly.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel forstaff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure,destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, andamount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line itemreporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item willusually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Quarterly Report.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to duringcontract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked byeach employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the priorreporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditurecategory will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for allexpenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J byColumn I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate costcategory.
Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretionof the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

ATTACHMENT 5

INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:				
Total Enrollment:		**Protocol Number:**		
Contract Number:				
PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date(Cumulative)				
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				
*These totals must agree **These totals must agree				

ATTACHMENT 6

RESEARCH PATIENT CARE COSTS

a. Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.
b. Research patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine research patient care costs. Research patient care rates or amounts shall be established by the Secretary of HHS or his/her duly authorized representative.
c. Prior to submitting an invoice for research patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for research patient care.
d. The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.
e. (Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

ATTACHMENT #7

BARDA SECURITY REQUIREMENTS

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

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

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

	Should have procedures to prevent employee piggybacking. Access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. Should have a manual key accountability and inventory process. Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	Should issue company photo identification to all employees. Photo identification should be displayed above the waist anytime the employee is on company property. Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program and the potential threat environment.
Protective Security Forces	Requirements for a security force will be determined by the criticality of the program and the potential threat environment.
6. Security Operations	
Information Sharing	Establish formal liaison with law enforcement and implement procedures for receiving and disseminating threat information.
Training	Conduct new employee security awareness training. Conduct and maintain records of annual security awareness training.
Security Management	Designate a knowledgeable security professional to manage security of the facility. Ensure subcontractor compliance with BARDA security requirements.
7. Personnel Security	
Records Checks	Verification of date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, and local / national criminal history search.

Hiring and Retention Standards	Policies and procedures concerning hiring, and retention of employees to include employee conduct expectations.
8. Information Security	
Physical Document Control	Applicable documents shall be identified and marked as procurement sensitive, proprietary or with appropriate government markings. Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet / desk or other storage device and not be left unattended. Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents shall be destroyed using approved destruction measures (i.e. shredders / approved third party vendors / pulverizing / incinerating).
9. Information Technology & Cybersecurity	
Access Control	Limit information systems access to authorized users. Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. Limit physical access to information systems, equipment, and server rooms with electronic access controls.
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	Create, protect, and retain information system audit records to the extent to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Ensure the actions of individual information system users can be uniquely traced to those users.
Configuration Management	Establish and enforce security configuration settings.
Contingency Planning	Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.

Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents.
Media and Information Protection	Protect information system media, both paper and digital. Limit access to information on information systems media to authorized users Sanitize and destroy media no longer in use. Control the use of removable media through technology or policy.
Physical and Environmental Protection	Limit access to information systems, equipment, and the respective operating environments to authorized individuals. Protect the physical and support infrastructure for all information systems. Protect information systems against environmental hazards.
Network Protection	Employ intrusion prevention and detection technology.
10. Transportation Security	
Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	Drivers should be vetted in accordance with BARDA Personnel Security Requirements. Drivers should be trained on specific security and emergency procedures. Drivers should be equipped with backup communications. Driver identity should be 100 percent confirmed before pick-up of any BARDA product. Drivers should never leave BARDA product unattended and two drivers may be required for longer transport routes or critical products during times of emergency.
Transport Routes	Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. Transport routes should be continuously evaluated based upon new threats, large planned events, weather, and other situations that may delay or disrupt transport.

Product Security	BARDA products should be secured with tamper resistant seals during transport and the transport trailer should be locked and sealed. Tamper resistant seals should be verified as “secure” after the product is placed in the transport vehicle. BARDA product should be continually monitored by GPS technology while in transport and any deviations from planned routes should be investigated and documented. Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
11. Security Reporting Requirements	
The partner facility shall immediately report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
12. Security Audits	
The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub locations.	

INSIDER TRADING AND SECURITIES LAW COMPLIANCE POLICY

OF

VAXART, INC.

Revised March 12, 2024

I. BACKGROUND

The Board of Directors of Vaxart, Inc. ("**Vaxart**" or the "**Company**") has adopted this Insider Trading and Securities Law Compliance Policy relating to transactions in Vaxart securities as well as the securities of publicly-traded companies with whom Vaxart engages in transactions or has a business relationship. The terms "Vaxart," "we," "us," and "our" mean Vaxart, Inc. and all of its subsidiaries.

Federal and state securities laws prohibit the purchase or sale of a company's securities by persons who are aware of material information about that company that is not generally known or available to the public. These laws also prohibit persons who are aware of such material nonpublic information from disclosing this information to others who may trade. Companies and their controlling persons are also subject to liability if they fail to take reasonable steps to prevent insider trading by company personnel.

It is important that you understand the breadth of activities that constitute illegal insider trading and the resulting consequences, which can be severe. This policy is applicable to all transactions in our securities. Both the Securities and Exchange Commission (the "**SEC**") and the Nasdaq investigate and are very effective at detecting insider trading. The SEC and U.S. Attorneys pursue insider trading violations vigorously. Cases have been successfully prosecuted against trading by employees through foreign accounts, trading by family members and friends and trading involving only a small number of shares.

This policy is designed to prevent insider trading or allegations of insider trading and protect our reputation for integrity and ethical conduct. It is your obligation to understand and comply with this policy. Should you have any questions regarding this policy, please contact our General Counsel or, if the General Counsel is not then available or the person seeking advice or approval from the Compliance Officer is the General Counsel, then the Chief Executive Officer or such other individual(s) designated by the Chair of the Company's board of directors (each, a "**Compliance Officer**").

II. BASIC POLICY / ADDITIONAL RESTRICTIONS ON RESTRICTED PERSONS

No director, officer, employee, consultant or agent (or their family members and members of their household) of Vaxart and its subsidiaries and affiliates may engage in transactions in securities on the basis of material nonpublic information or engage in any other action to take advantage of, or pass on to others, that information. To avoid even the appearance of impropriety, additional restrictions on engaging in transactions in our securities apply to our directors, executive officers and certain other persons identified by us from time to time and who have been notified that they have been so identified (collectively with our directors and executive officers, "**Restricted Persons**"). For the purposes of this policy, the term "Restricted Persons" shall also include any person who works in any of the following departments or is a member on any of the following committees:

- Accounting Department;
- Disclosure Committee;

- Investor Relations Department; and
- Business Development Department.

Transactions in our securities by Restricted Persons are subject to pre-clearance. See "***Regular Blackout Periods,***" "***Special Blackout Periods***" ***and*** "***Pre-Clearance Provisions.***"

III. SCOPE OF POLICY

Persons. This policy applies to directors, officers, employees, consultants, contractors, advisors, and agents of Vaxart and its subsidiaries and affiliates. The same restrictions that apply to you apply to your family members who reside with you, anyone else who lives in your household and any family members who do not live in your household but whose transactions in our securities are directed by you or are subject to your influence or control (such as parents or children who consult with you before they engage in transactions in securities), including any entities over which you have control (such as a business entity or a trust). You are responsible for making sure that the purchase or sale of, or other transaction in, any security covered by this policy by any such person complies with this policy.

Companies. The prohibition on insider trading in this policy is not limited to transactions in our securities. It includes transactions in the securities of other firms, such as our customers or suppliers and those with which we may be negotiating major transactions, such as an acquisition, investment or sale. Information that is not material to Vaxart may nevertheless be material to one of those other firms.

Transactions. The transactions covered by this policy includes purchases and sales of our common stock (including initial elections, changes in elections or reallocation of funds relating to 401(k) plan accounts), derivative securities relating to our common stock (such as options for our common stock, put and call options and convertible debentures), preferred stock, warrants and debt securities (debentures, bonds and notes). Loans, pledges, gifts, charitable donations and other contributions of our securities are also subject to this policy.

IV. DEFINITION OF MATERIAL NONPUBLIC INFORMATION

Material Information. Information is material if there is a substantial likelihood that a reasonable investor would consider it important in deciding whether to buy, hold or sell a security. Any information that could reasonably be expected to affect the price of the security is material. Common examples of material information are:

- Financial results, projections of future earnings or losses, or other earnings guidance;
- Earnings that are inconsistent with the consensus expectations of the investment community or any earnings guidance released by Vaxart;
- Communications with government agencies about pending regulatory actions;
- Determinations to continue or to end the discovery or development of product candidates;
- Significant write-downs in assets or increases in reserves;
- Significant changes in the Company's prospects;
- Proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, potential tender offers or proxy fights, contract awards or cancellations, or purchases or sales of substantial assets;
- Partner or collaborator relationships;

- Change in management or the board of directors;
- Extraordinary borrowings;
- Major changes in accounting methods or policies;
- Major events regarding our securities, including the declaration of a stock split, the offering of additional securities;
- Material clinical trial or regulatory updates;
- Developments regarding significant litigation or government agency investigations;
- Financial liquidity problems;
- Cybersecurity or data privacy incidents, including vulnerabilities and breaches, or any other significant disruptions in the Company's operations, or unauthorized access of the Company's property or assets;
- The effects of any natural disaster, terrorist event or other catastrophic event on the Company's business, including any epidemic or pandemic;
- Actual or threatened major litigation, or a significant development with respect to such litigation;
- New major contracts, material agreements, licenses, orders, suppliers, customers or finance sources, or the loss or termination thereof; and
- The imposition of a special blackout on transactions in the Company's securities or the securities of another company or the extension or termination of such restriction.

This list is not exhaustive; other types of information may also be material. Both positive and negative information can be material. Because a transaction in securities that receives scrutiny will be evaluated after the fact with the benefit of hindsight, questions concerning the materiality of particular information should be resolved in favor of materiality.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, clinical trial, or regulatory update, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular nonpublic information is material, you should presume it is material.

If you are unsure whether information is material, you should either consult a Compliance Officer before making any decision to disclose such information (other than to persons who need to know it) or to engage in transactions in or recommend securities to which that information relates or assume that the information is material.

Nonpublic Information. Insider trading prohibitions come into play only when you possess information that is material and "nonpublic." Nonpublic information is information that is not generally known or available to the public.

The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. In addition, a common misconception is that material information loses its "nonpublic" status as soon as a press release is issued disclosing the information. In fact, information is considered to be available to the public only when it has been released broadly to the marketplace (such as by a press release or an SEC filing) and the investing public has had time to absorb the information fully. As a general rule, after nonpublic information is publicly disseminated, one full trading day must elapse before such information loses its status as nonpublic information.

Nonpublic information may include:

- information available to a select group of analysts or brokers or institutional investors;
- undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and
- information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally one trading day).

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with a Compliance Officer or assume that the information is nonpublic and treat it as confidential.

V. RESTRICTIONS ON PURCHASES, SALES AND TIPPING

Trading on Inside Information. You may not engage in transactions in our securities, directly or indirectly (through family members or other persons or entities), if you are aware of material nonpublic information relating to Vaxart. Similarly, you may not engage in transactions in the securities of any other company, directly or indirectly, if you are aware of material nonpublic information about that company which you obtained in the course of your relationship with Vaxart.

Tipping. You may not pass material nonpublic information on to others or recommend that anyone engage in transactions in any securities when you are aware of such information. This practice, known as "tipping," also violates the securities laws and can result in the same civil and criminal penalties that apply to insider trading, even though you did not trade and did not gain any benefit from another's trading.

Short Sales. You may not engage in any short sales of our securities (sales of securities that are not then owned), including a "sale against the box" (a sale with delayed delivery).

Hedging Transactions. Certain forms of hedging or monetization transactions relating to our securities (such as zero-cost collars and forward sale contracts) could involve the establishment of a short position in our securities and limit or eliminate your ability to profit from an increase in the value of our securities. Therefore, you are prohibited from engaging in any hedging or monetization transactions involving our securities.

Publicly-Traded Options. You may not engage in transactions in publicly-traded or other third-party options relating to our securities, such as puts, calls and other derivative securities, on an exchange, in any other organized market or otherwise.

Limit Orders. You are prohibited from placing limit orders for our securities that remain effective after the day on which they are placed (such as "good until cancelled" orders).

Margin Accounts. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to engage in transactions in our securities, directors, officers and other employees of the Company and its subsidiaries are prohibited from holding our securities in a margin account or otherwise pledging our securities as collateral for a loan. (Pledges of our securities arising from certain types of hedging transactions are governed by the paragraph above captioned "Hedging Transactions.")

Blackout Periods.

- *Regular Blackout Periods Applicable to Restricted Persons*. In addition to the general policy prohibiting engaging in transactions in securities while in possession of material nonpublic information, all Restricted Persons, and all family members of such persons and members of their household, are also prohibited from engaging in transactions in our securities during the period beginning at the close of the market on the third trading day prior to the date the Company's financial results are publicly disclosed and ending after the passage of one full trading day after earnings have been publicly released with respect to such quarter or fiscal year (each, a "**regular blackout period**").

- *Special Blackout Periods*. From time to time, Vaxart may also prohibit our Restricted Persons and potentially a larger group of employees, consultants and agents from engaging in transactions our securities because of material developments known to Vaxart and not yet disclosed to the public (each, a "**special blackout period**"). The existence of a special blackout period will not be announced, other than to those who are aware of the event giving rise to the special blackout. If, however, a person subject to a special blackout period requests permission to engage in transactions in our securities during such period, a Compliance Officer will inform the requesting person of the existence of a special blackout period, without disclosing the reason for the special blackout. Any person made aware of the existence of a special blackout period shall not disclose the existence of the blackout to any other person.

- *Open Orders*. If you have any open orders during any regular or special blackout period, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after the commencement of any regular or special blackout period, it is a violation of our insider trading policy and may also be a violation of the insider trading laws.

- *No Safe Harbor*. **For those persons who are subject to blackout periods, the existence of such blackouts shall not be considered a safe harbor for engaging in transactions in securities during other periods, and all of our officers, directors, other employees and agents should use good judgment at all times.** For example, occasions may arise when individuals covered by this policy become aware prior to the blackout period that earnings for that quarter are likely to exceed, or fall below, market expectations to an extent that is material. In such a case, the general policy against trading on inside information would still prohibit engaging in transactions in securities even though the time period is not within the blackout period or even if you are not a Restricted Person subject to the blackout periods. If you have any questions about whether you are permitted to engage in transactions in our securities at any particular time, you should contact a Compliance Officer.

VII. PRE-CLEARANCE PROVISIONS APPLICABLE TO RESTRICTED PERSONS

To help prevent inadvertent violations of the federal securities laws and avoid even the appearance of trading on the basis of inside information, the following pre-clearance provisions are applicable to our Restricted Persons.

All Restricted Persons, together with their family members and other members of their household (including any entities over which such person has control), shall not engage in any transaction involving our securities (including a stock plan transaction such as an option exercise, or a gift, loan, pledge, contribution to a trust, 401(k) transfer or any other transfer) without first obtaining pre-clearance of the transaction from a Compliance Officer in accordance with the following procedures:

- No Restricted Person may, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge or loan of) any Company security at any time without first obtaining prior approval from a Compliance Officer.
- Requests for pre-clearance should be submitted to a Compliance Officer at least two business days in advance of the proposed transaction.
- The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved.
- No Compliance Officer is under any obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction.
- Unless revoked, a grant of permission will normally remain valid until the close of trading five business days following the date on which it was granted, but regardless may not be exercised if material nonpublic information is obtained during that time. If the transaction does not occur during such period, pre-clearance of the transaction must be re-requested.
- No Compliance Officer may engage in transactions in our securities unless another Compliance Officer has approved the transaction in accordance with the procedures set forth herein.

When requesting pre-clearance, please provide the following information to the Compliance Officer:

- Whether you believe may be aware of any material non-public information about Vaxart;
- Whether you have effected any non-exempt “opposite-way” transactions within the past six months;
- Whether you intend to purchase, sell, or otherwise gift or transfer, and whether such transaction will be conducted through in the open market or otherwise;
- Approximate timing and number of shares that you intend to purchase, sell or otherwise gift or transfer; and
- That you will notify the Compliance Officer promptly upon the completion of the pre-cleared transaction.

These procedures also apply to transactions by such person’s spouse, other persons living in such person’s household and minor children and to transactions by entities over which such person exercises control.

Pre-clearance is not required for purchases and sales of securities under an Approved 10b5-1 Plan (as defined below) once the applicable cooling-off period has expired. No trades may be made under an Approved 10b5-1 Plan until expiration of the applicable cooling-off period. With respect to any purchase or sale under an Approved 10b5-1 Plan, the third-party effecting transactions on behalf of the Restricted Person should be instructed to send duplicate confirmations of all such transactions to a Compliance Officer.

VIII. EXCEPTIONS

Approved Rule 10b5-1 Plans. Trades in our securities that are executed pursuant to an Approved 10b5-1 Plan (as defined below) are not subject to the prohibition on trading on the basis of material nonpublic information contained in this policy or the restrictions relating to pre-clearance procedures and blackout periods. Rule 10b5-1 provides an affirmative defense from insider trading liability under the federal securities laws for trading plans that meet certain requirements. In general, a 10b5-1 plan must be entered into before you are aware of material nonpublic information. You may not adopt a 10b5-1 plan during any regular or special blackout period. Note that once the Approved 10b5-1 Plan is adopted, you must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded, or the date of the trade. The plan must either specify (including by formula) the amount, pricing, and timing of transactions in advance or delegate discretion on those matters to an independent third party. All persons entering into a 10b5-1 plan must act in good faith with respect to that plan.

For purposes of this Policy, an "**Approved 10b5-1 Plan**" means a pre-existing written plan, contract, instruction, or arrangement under Rule 10b5-1 under the Securities Exchange Act of 1934 that:

(i) has been reviewed and approved in writing at least one month in advance of being entered into by a Compliance Officer (or, if revised or amended, such revisions or amendments have been reviewed and approved by a Compliance Officer at least one month in advance of being entered into);

(ii) is entered into in good faith by the Restricted Person, and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1, at a time when the Restricted Person is not in possession of material nonpublic information about the Company; and, if the Restricted Person is a director or officer, the 10b5-1 plan must include representations by the Restricted Person certifying to that effect;

(iii) gives a third party the discretionary authority to execute such purchases and sales, outside the control of the Restricted Person, so long as such third party does not possess any material nonpublic information about the Company; or explicitly specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions;

(iv) provides that no trades may occur thereunder until expiration of the applicable cooling-off period specified in Rule 10b5-1(c)(ii)(B), and no trades occur until after that time. The appropriate cooling-off period will vary based on the status of the Restricted Person. For directors and officers, the cooling-off period ends on the later of (A) 90 days after adoption or certain modifications of the 10b5-1 plan; or (B) 2 business days following disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the quarter in which the 10b5-1 plan was adopted (in any case, subject to a 120-day maximum). For all other Restricted Persons, the cooling-off period ends 30 days after adoption or modification of the 10b5-1 plan. This required cooling-off period will apply to the entry into a new 10b5-1 plan and any revision or modification of a 10b5-1 plan; and

(v) is the only outstanding Approved 10b5-1 Plan entered into by the Restricted Person (subject to the exceptions set out in Rule 10b5-1(c)(ii)(D)).

You may only enter into one single-trade Rule 10b5-1 plans during any 12-month period, subject to limited exceptions.

Option Exercises. You may exercise stock options where cash is paid for the exercise price and tax withholding obligation, and in turn receive shares. However, ***you may not sell any securities so acquired*** (either outright or in connection with a "cashless" exercise transaction through a broker) or otherwise settle the option during a regular or special blackout period or any time that you are aware of material nonpublic information. If you choose to exercise and hold the shares, you will be responsible at that time for any taxes due.

Other Employee Plans. This policy does not apply to:

- acquisitions or dispositions of the Company's common stock under the Company's 401(k) or other individual account plan that are made pursuant to standing instructions not entered into or modified while you were aware of material nonpublic information or were subject to a regular or special blackout period (*provided*, *however*, that (A) this policy does apply to sales of the Company's securities purchased received pursuant to such plan, and (B) any changes in your investment election regarding the Company's stock are subject to trading restrictions under this policy); or

- other purchases of securities from the Company (including purchases under any employee stock purchase plan) or sales of securities to the Company.

Special Circumstances. Notwithstanding anything to the contrary contained herein, you may request that any regular blackout period or special blackout period be waived by the Company's Compliance Officers, provided that you affirm in writing that you do not have any material non-public information. Any such waivers shall be in the sole discretion of the Compliance Officers, shall be limited in scope and duration, and may be revoked at any time.

Underwritten Public Offerings. Nothing in this policy is intended to limit the ability of any person to sell the Company's securities as a selling stockholder in an underwritten public offering pursuant to an effective registration statement in accordance with applicable securities law.

For clarity, please be reminded that the following are subject to this policy, including any regular and special blackout periods: (a) any "cashless" exercise of stock options or other equity awards; (b) any market sale of the Company's securities for the purpose of generating the cash needed to pay the exercise price of any stock option or equity award or other derivative security; (c) the sale of any shares issued on the exercise of stock options or other equity award elections made under 401(k) plans to (i) increase or decrease the percentage of periodic contributions that will be allocated to the Company's securities, (ii) make an intra-plan transfer of an existing account balance into or out of the Company's securities, (iii) borrow money against a 401(k) plan account if the loan will result in a liquidation of all or some of the Company's securities in the account, and (iv) pre-pay any loan if the pre-payment will result in an allocation of loan proceeds to the Company's securities; (d) elections to participate in or increase participation in an employee stock purchase plan and to a participant's sale of the Company's securities purchased pursuant to such plan; (e) elections to participate in or increase participation in any dividend reinvestment plan, voluntary purchases of the Company's securities that result from additional contributions a participant chooses to make under such plan, and a participant's sale of the Company's securities purchased pursuant to such plan; and (f) gifts.

IX. POST-TERMINATION TRANSACTIONS

If you are aware of material nonpublic information when you terminate employment or services, you may not engage in transactions in our securities until that information has become public or is no longer material. In addition, if you are subject to a blackout period at the time of your termination of employment or services, the restrictions on engaging in transactions in our securities will not cease to apply until the expiration of such blackout period.

X. UNAUTHORIZED DISCLOSURE

Maintaining the confidentiality of our information is essential for competitive, security and other business reasons, as well as to comply with securities laws. You should treat all information you learn about Vaxart or its business plans in connection with your employment as confidential and proprietary to us. Inadvertent disclosure of confidential or inside information may expose us and you to significant risk of investigation and litigation. Nothing in this policy prevents reporting of violations to regulatory agencies.

The timing and nature of our disclosure of material information to outsiders is subject to legal rules, including the SEC's Regulation FD, the breach of which could result in substantial liability to you, us and our management. Accordingly, it is important that responses to inquiries about us by the press, financial analysts, investors or others in the financial community be made on our behalf only through authorized individuals.

XI. PERSONAL RESPONSIBILITY

You should remember that **the ultimate responsibility for adhering to this policy and avoiding improper trading rests with you.** If you violate this policy, Vaxart may take disciplinary action, including dismissal for cause.

XII. ADDITIONAL INFORMATION FOR DIRECTORS AND SECTION 16 OFFICERS

Officers and directors have additional obligations under the federal securities laws, most notably the obligations to report their share ownership and transactions, and to forfeit the profits on any purchases and sales of Company stock within a six-month period under Section 16(b) of the Securities Exchange Act of 1934. Short sales by such persons are also prohibited under Section 16(c).

Upon becoming an officer or director, a person must report the person's holdings of equity securities of the Company on a Form 3, and any transaction in such securities (including purchases, sales, gifts, award or exercise of stock options) must be reported to the SEC within two business days on a Form 4. Late filing of these reports must be reported by the Company in its periodic reports filed with the SEC. Consequently, it is critical that such transactions be reported to the Company's Compliance Officers immediately so that proper reports can be timely prepared and filed.

While the Company may assist you in the assessing your obligations under Section 16 and coordinate the filing of your Section 16 reports, **such legal responsibilities and obligations are ultimately yours**.

Officers, directors and other affiliates should also be prepared to file Forms 144, if necessary, at the time of any sale.

You should also understand that compliance with the obligations described above does not excuse violation of the laws against trading on material inside information which apply to any single transaction regardless of whether or not it is reported on Form 4 or subject to the recapture of profits under Section 16(b).

XIII. PENALTIES FOR NONCOMPLIANCE

Penalties for trading on or communicating material nonpublic information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory. If you believe that you may have violated this Policy or any federal or state laws governing insider trading or tipping, or you know of the possibility of any such violation by any person, you must report such matter immediately to a Compliance Officer.

Civil and Criminal Penalties. A person who violates insider trading laws by engaging in transactions in a company's securities when the person has material nonpublic information can be sentenced to a substantial jail term and required to pay a criminal penalty of several times the amount of profits gained or losses avoided.

In addition, a person who tips others may also be liable for transactions by the tippees to whom the person has disclosed material nonpublic information. Tippers can be subject to the same penalties and sanctions as the tippees, and the SEC has imposed large penalties even when the tipper did not profit from the transaction.

The SEC can also seek substantial civil penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Company and/or management and supervisory personnel. These control persons may be held liable for up to the greater of $1 million or three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek penalties from a company and/or its management and supervisory personnel as control persons.

Controlling Person Liability. If we fail to take appropriate steps to prevent illegal insider trading, we may have “controlling person” liability for a trading violation and be subject to civil penalties of up to the greater of $1 million and three times the profit gained or loss avoided as well as a criminal penalty of up to $25 million. The civil penalties can extend personal liability to our directors, officers and other supervisory personnel if they fail to take appropriate steps to prevent insider trading.

Company-Imposed Penalties. Failure to comply with this policy may also subject you to sanctions imposed by Vaxart, including dismissal for cause, whether or not your failure to comply with this policy results in a violation of law. Any exceptions to this policy, if permitted, may only be granted by a Compliance Officer and must be provided before any activity contrary to the above requirements takes place.

XIV. ASSISTANCE

Your compliance with this policy is of the utmost importance both for you and Vaxart. If you have any questions about this policy or its application to any proposed transaction, you may obtain additional guidance from any Compliance Officer. Do not try to resolve uncertainties on your own, as the rules relating to insider trading are often complex, not always intuitive and carry severe consequences.

Adopted by the Board of Directors on March 12, 2024.

CERTIFICATION

I hereby certify that:

1. I have read and understand the Insider Trading and Securities Law Compliance Policy of Vaxart, Inc. (the "Policy"). I understand that the Compliance Officers are available to answer any questions I have regarding the Policy.

2. I will comply with the Policy for as long as I am subject to the Policy.

Print name: _____
Signature: _____
Date: _____

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name	Jurisdiction
Vaxart Biosciences, Inc.	Delaware
Biota Holdings Pty, Ltd.	Australia
Biota Scientific Management Pty, Ltd.	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-270671, 333-239751 and 333-228910) and Form S-8 (Nos. 333-267984, 333-257245, 333-239727, 333-231013, 333-225475, 333-215141 and 333-143238) of Vaxart, Inc. of our report dated March 14, 2024, which includes an explanatory paragraph regarding Vaxart, Inc.'s ability to continue as a going concern, relating to the consolidated financial statements of Vaxart, Inc. as of and for the years ended December 31, 2023 and 2022, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

San Francisco, California

March 14, 2024

Exhibit 31.1

CERTIFICATION

I, Michael J. Finney, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. I am 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. I have disclosed, based on my 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: March 14, 2024

By: /s/ MICHAEL J. FINNEY

Michael J. Finney, Ph.D.
Interim Chief Executive Officer and Chair of the Board of Directors
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Phillip Lee, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. I am 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. I have disclosed, based on my 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: March 14, 2024

By: /s/ PHILLIP LEE

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

Exhibit 32.1

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), Michael J. Finney, Interim Chief Executive Officer and Chairman 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 Annual Report on Form 10-K for the period ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "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 Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: March 14, 2024

By: /s/ MICHAEL J. FINNEY
Michael J. Finney, Ph.D.
Interim Chief Executive Officer and Chair of the Board of Directors
(Principal Executive Officer)

Date: March 14, 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-K 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-K), irrespective of any general incorporation language contained in such filing.

VAXART, INC.
COMPENSATION RECOVERY POLICY
(Adopted as of October 2, 2023)

1. Introduction. Vaxart, Inc. (the "Company") has adopted this Compensation Recovery Policy (the "Policy"), which provides for the recovery of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws. This Policy is intended to comply with Section 10D of the Securities Exchange Act of 1934 (the "Exchange Act"), the rules of the Securities and Exchange Commission (the "Commission") promulgated thereunder and the listing requirements of The Nasdaq Capital Market, or such other national securities exchange on which the Company's securities may be listed from time to time (the "Exchange").

2. Covered Executive Officers. This Policy applies to the Company's current and former executive officers, as determined by the Company in accordance with Section 10D of the Exchange Act (the "Executive Officers"). This Policy does not apply to Incentive Compensation (defined below) received by an Executive Officer (a) prior to beginning services as an Executive Officer, or (b) if that person did not serve as an Executive Officer at any time during the performance period for such Incentive Compensation.

3. Recovery in General; Applicable Restatements

a. If the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including a required accounting restatement to correct an error in previously issued financial statements that (i) is material to the previously issued financial statements, or (ii) would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "Restatement"), the Compensation Committee (the "Committee") of the Board of Directors (the "Board") of the Company shall cause the Company to recover reasonably promptly, and subject to the exceptions set forth below, any erroneously awarded Incentive Compensation (as defined in Section 4 below) received by each Executive Officer during the three completed fiscal years immediately preceding the date on which the Company is required to prepare such a Restatement (including, where required under Section 10D of the Exchange Act, any transition period resulting from a change in the Company's fiscal year).

b. For purposes of clarity, a "Restatement" shall not be deemed to include changes to the Company's financial restatements that do not involve the correction of an error resulting from material non-compliance with financial reporting requirements, as determined in accordance with applicable accounting standards and guidance.

c. For purposes of this Policy, the date that the Company is required to prepare a Restatement shall be the earlier of (i) the date that the Board of committee thereof (or if Board or committee action is not required, the officer(s) of the Company authorized to take such action) concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement; or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare a Restatement.

d. For purposes of this Policy, Incentive Compensation shall be deemed to be "received" by an Executive Officer in the Company's fiscal period during which the applicable Financial Reporting Measure (as defined in Section 4 below) specified in the Incentive Compensation award is attained, even if the payment or grant of the Incentive Compensation occurs after the end of that period.

4. Incentive Compensation. For purposes of this Policy, "Incentive Compensation" means any compensation that is granted, earned or vested based wholly or in part on the attainment of a Financial Reporting Measure (as defined below). For purposes of this Policy, "Financial Reporting Measures" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures, regardless of whether such measures are presented within the Company's financial statements or included in a filing with the Commission. Financial Reporting Measures include stock price and total shareholder return.

5. Erroneously Awarded Compensation: Amount Subject to Recovery

a. The amount to be recovered from an Executive Officer pursuant to this Policy in the event of a Restatement shall equal the amount of Incentive Compensation received by the Executive Officer that exceeds the amount of Incentive Compensation that otherwise would have been received had it been determined based on the restated amounts, computed without regard to any taxes paid.

b. Where the amount of erroneously awarded Incentive Compensation is not subject to mathematical recalculation directly from the information in the Restatement (as in the case of Incentive Compensation based on stock price or total shareholder return), the Committee shall determine such amount based on a reasonable estimate of the effect of the Restatement on the applicable Financial Reporting Measure, and the Committee shall maintain documentation of any such estimate and provide such documentation to the Exchange.

6. Exceptions to Recovery. Notwithstanding anything herein to the contrary, the Company need not recover erroneously awarded Incentive Compensation from an Executive Officer to the extent that the Committee determines that such recovery would be impracticable and either: (a) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered (determined by the Committee after making and documenting a reasonable attempt to recover such erroneously awarded compensation, and providing documentation to the Exchange of such reasonable attempt to recover the compensation); or (b) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code and regulations thereunder.

7. Methods of Recovery

a. The Committee will determine, in its absolute discretion and taking into account the applicable facts and circumstances, the method or methods for recovering any erroneously awarded Incentive Compensation hereunder, which method(s) need not be applied on a consistent basis; provided in any case that any such method provides for reasonably prompt recovery and otherwise complies with any requirements of the Exchange and applicable law (including, without limitation, Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A")). By way of example and not in limitation of the foregoing, methods of recovery that the Committee, in its discretion, may determine to use under the Policy may include one or more of the following methods to the extent permitted by applicable law (which rights shall be cumulative and not exclusive): repayment by the Executive Officer in immediately available funds, the forfeiture or repayment of Incentive Compensation, the forfeiture or repayment of time-based equity or cash incentive compensation awards, the forfeiture of benefits under a deferred compensation plan, and/or the offset of all or a portion of the amount of the erroneously awarded Incentive Compensation against other compensation payable to the Executive Officer.

b. To the fullest extent permitted by applicable law (including, without limitation, Section 409A), the Committee may, in its sole discretion, delay the vesting or payment of any compensation otherwise payable to an Executive Officer to provide a reasonable period of time to conduct or complete an investigation into whether this Policy is applicable, and if so, how it should be enforced, under the circumstances.

8. No Indemnification. Notwithstanding the terms of any agreement, policy or governing document of the Company to the contrary, the Company shall not indemnify any Executive Officer against (a) the loss of any erroneously awarded Incentive Compensation, or (b) any claim relating to the Company's enforcement of its rights under this Policy. By signing the Acknowledgement Agreement (defined below), each Executive Officer irrevocably agrees never to institute any claim against the Company or any subsidiary, knowingly and voluntarily waives his or her ability, if any, to bring any such claim, and releases the Company and any subsidiary from any such claim, for indemnification with respect to any expenses (including attorneys' fees), judgments or amounts of compensation paid or forfeited by the Executive Officer in connection with the application or enforcement of this Policy.

9. Administration.

a. This Policy shall be administered by the Committee. The Committee shall have full and final authority to make all determinations under this Policy. In this regard, the Committee shall have no obligation to treat any Executive Officer uniformly and the Committee may make determinations selectively among Executive Officers in its business judgment. All determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company, its subsidiaries, its stockholders and its employees.

b. Notwithstanding the foregoing, the independent members of the Board may reserve to itself any or all of the authority or responsibility of the Committee under this Policy or may act as the administrator of the Policy for any and all purposes. To the extent the independent members of the Board have reserved any such authority or responsibility or during any time that the independent members of the Board are acting as administrator of the Policy, it shall have all the powers of the Committee hereunder, and any reference herein to the Committee (other than in this Section 9(b)) shall include the independent members of the Board.

10. **Policy Not Exclusive**. The remedies specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company.

11. **Effective Date**. This Policy shall apply to any Incentive Compensation that is received by an Executive Officer on or after October 2, 2023.

12. **Amendment; Termination**. To the extent permitted by, and in a manner consistent with applicable law, including the rules of the Commission and the Exchange, the Committee may terminate, suspend or amend this Policy at any time in its discretion.

13. **Governing Law**. To the extent not preempted by federal law, this Policy shall be governed, construed, interpreted and enforced in accordance with the substantive laws of the State of Delaware, without regard to conflicts of law principles.

14. **Severability; Waiver**. If any provision of this Policy is determined to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted by applicable law and shall automatically deemed to be amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law. The waiver by the Company or the Committee with respect to compliance of any provision of this Policy by an Executive Officer shall not operate or be construed as a waiver of any other provision of this Policy, or of any subsequent acts or omissions by an Executive Officer under this Policy.

15. **Filings**. The Committee shall cause the Company to make any filings with, or submissions to, the Commission and the Exchange that may be required pursuant to rules or standards adopted by the Commission or the Exchange pursuant to Section 10D of the Exchange Act.

16. **Acknowledgement by Executive Officers**. The Company shall require each Executive Officer serving as such on or after the effective date of this Policy to sign and return to the Company an acknowledgement agreement in the form attached hereto as Exhibit A (or in such other form as may be prescribed by the Committee from time to time) (the "Acknowledgement Agreement"), pursuant to which the Executive Officer will affirmatively agree to be bound by, and to comply with, the terms and conditions of this Policy; provided that an Executive Officer's failure or refusal to sign or return an Acknowledgement Agreement as provided herein shall not waive the Company's right to enforce the Policy against such Executive Officer.

* * * * *

ACKNOWLEDGEMENT AGREEMENT

VAXART, INC.
COMPENSATION RECOVERY POLICY

I, the undersigned, agree and acknowledge that I am fully bound by, and subject to, all of the terms and conditions of the Vaxart, Inc. Compensation Recovery Policy (as it may be amended, restated, supplemented or otherwise modified from time to time, the "Policy"). In the event of any inconsistency between the Policy and the terms of any employment agreement to which I am a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern. In the event it is determined by the Committee that any amounts granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement, including, upon demand, repaying to the Company fully and promptly (in immediately available funds denominated in U.S. dollars or otherwise as specified by the Company pursuant to the Policy) all amounts of erroneously awarded Incentive Compensation. Any capitalized terms used in this Acknowledgment Agreement without definition shall have the meaning set forth in the Policy.

_____ _____

Signature Date

_____

Print Name