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, 2024
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number: 001-35285

Vaxart, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**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 28, 2024, based on the last reported sales price of the Registrant's common stock of $0.67 per share, was $150,839,206. As of March 13, 2025, the registrant had a total of 227,949,245 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") for the year ended December 31, 2024, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections, concerning our business, operations, and financial performance and condition as well as our plans, objectives, and expectations for business operations and financial performance and condition. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as "anticipate," "assume," "believe," "could," "estimate," "expect," "intend," "may," "plan," "should," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this 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 18.

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.

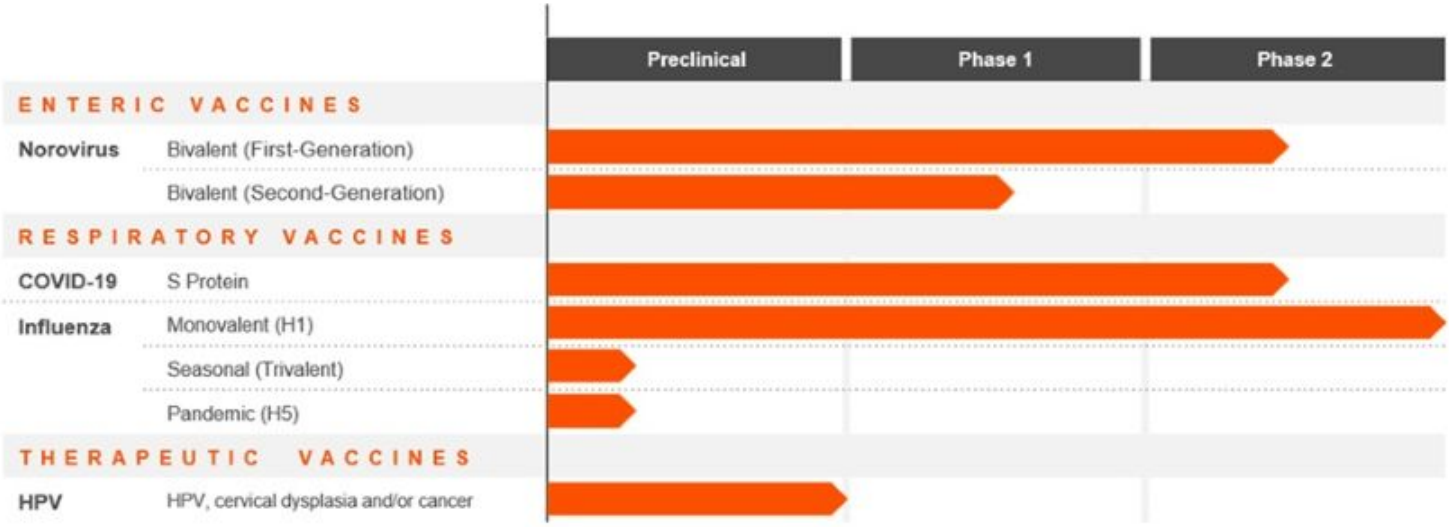
One of the key benefits of our technology is delivery to the gastrointestinal tract, enabling the vaccine to directly enter the mucosal surface of the intestine and activate the immune system of the gut. Mucosal vaccine delivery is believed to enhance protection against mucosal pathogens by generating 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 U.S. 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 Centers for Disease Control and Prevention ("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 first-generation bivalent norovirus vaccine candidate met five of six primary endpoints based on preliminary topline data. The study achieved its primary endpoints of a statistically significant 29% relative reduction in the rate of norovirus infection between the vaccinated and placebo arms, a strong induction of norovirus-specific immunoglobulin A (IgA) and immunoglobulin G (IgG) antibodies, and other immune response endpoints.

Vaccination also led to a 21% relative reduction in norovirus acute gastroenteritis in the vaccine arm compared to placebo, but this was not statistically significant. In prespecified analyses, the study also showed an 85% relative decrease in viral shedding in the vaccine arm compared with placebo and no statistically significant difference in disease severity in the vaccinated cohort compared with placebo. The vaccine candidate was also safe and well tolerated with no vaccine-related serious adverse events.

Based on our norovirus clinical data findings to date, our norovirus oral vaccination induces mucosal and systemic immune responses. Norovirus oral vaccination reduced shedding and infection in a rigorous human challenge model. Based on our machine learning and evaluation of more than 13 different immune parameters, norovirus vaccination protection most tightly associates with making a functional antibody response to norovirus in the serum ("NBAA") and norovirus specific fecal IgA antibodies. Because of the strong induction of mucosal IgA due to the oral vaccination and potential read through into the serum, we believe that this likely means that a functional fecal IgA response is probably critical for protection against norovirus infection.

In the second half of 2024, we received constructive feedback from the U.S. Food and Drug Administration ("FDA") on our data for potential correlates of protection and next steps for our norovirus program. While we believe we have identified a functional antibody response that may be associated with protection for norovirus, the FDA requested new clinical data before proceeding with further review of our potential correlate.

In 2024, we also created new, second-generation norovirus GI.1 and GII.4 constructs. Based on preclinical data, the second-generation norovirus GI.1 and GII.4 constructs are more potent than the first-generation norovirus constructs we previously evaluated in clinical trials.

With advice from advisors and infectious disease experts, we decided to proceed with a Phase 1, open label, dose ranging clinical trial evaluating our second-generation oral norovirus vaccine constructs head-to-head against our first-generation constructs. The trial will measure safety and immunogenicity, including immune parameters that have correlated to protection in our Phase 2 GI.1 norovirus challenge study. The Phase 1 trial initiated in March 2025 and topline data is expected as early as the middle of 2025.

If the Phase 1 trial is successful, the next step, pending a partnership or other funding, would be to conduct a Phase 2 safety and immunogenicity study that could potentially begin as early as the second half of 2025. This Phase 2 trial would be followed by an End of Phase 2 meeting with the FDA. A Phase 3 trial could then begin as early as 2026, pending a successful End of Phase 2 meeting and funding.

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 announced positive top line results in April 2024. Top line results showed antibodies rose in lactating mothers who received the high dose of our bivalent vaccine candidate. Specifically, serum antibodies to norovirus rose on average 5.6 fold in response to the GI.1 virus strain and 4.4 fold in response to the GII.4 virus strain and breast milk antibodies to norovirus rose on average 4.0 fold in response to the GI.1 virus strain and 6.0 fold in response to the GII.4 virus strain. The vaccine was well tolerated with no vaccine-related serious adverse events and no dose-limiting pharmacotoxicity. As a grant recipient from the Bill & 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. One of our first COVID-19 vaccine candidates (rAd-S, known as Vaxart clinical candidate VXA-CoV2-1.1-S) expressed only the spike ("S") protein from the SARS-CoV-2 Wuhan strain. 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 are not proceeding 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 as well as a COVID-19 vaccine candidate that expresses the S protein from the SARS-CoV-2 KP.2 strain. Based on preclinical data, our XBB COVID-19 vaccine candidate is more potent than our prior COVID-19 vaccine constructs.

In January 2024, we were awarded a contract by the U.S. Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Administration for Strategic Preparedness and Response ("ASPR") within the U.S. Department of Health and Human Services ("HHS"), for $9.3 million to fund preparation for a Phase 2b clinical study involving 10,000 patients. Vaxart executed on the deliverables and received all $9.3 million of cash payments related to this contract in 2024. BARDA and Vaxart are currently discussing contract closeout for this contract.

In June 2024, we entered into an agreement (as modified or amended from time to time, the "2024 ATI-RRPV Contract") with Advanced Technology International ("ATI"), the Rapid Response Partnership Vehicle's Consortium Management Firm funded by BARDA. The 2024 ATI-RRPV Contract provides for funding of up to $460.7 million to conduct the Phase 2b study, manufacture a COVID-19 vaccine candidate targeting the KP.2 strain, and acquire an approved mRNA vaccine targeting the KP.2 strain. In February 2025, we entered into Modification No. 5 (the "Modification") to the 2024 ATI-RRPV Contract. The Modification increased the total amount of funding available for payment to approximately $240.1 million. Subsequently, in February 2025, we received written notification directing the Company to stop work on the 2024 ATI-RRPV Contract, with the exception that we may continue effort associated with the per protocol follow-up for the 400-person cohort. The stop work order is in effect for a period of 90 days and, that within a period of 90 days, ATI, as directed by the U.S. Government, will either cancel the stop work order, extend the stop work, or terminate the work covered by the 2024 ATI-RRPV Contract.

The Phase 2b study is a double-blind, multi-center, randomized, comparator-controlled study to determine the relative efficacy, safety, and immunogenicity of Vaxart's oral pill COVID-19 vaccine candidate against an approved mRNA COVID-19 injectable vaccine in adults previously immunized against COVID-19 infection. The study design anticipates enrolling approximately 10,400 healthy adults 18 years and older in the U.S. with approximately 5,200 receiving our COVID-19 vaccine candidate and approximately 5,200 receiving an approved mRNA comparator. The study will strive to enroll participants in line with U.S. demographics, as well as including at least 25% over the age of 65.

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

In the second half of 2024, we initiated and completed enrollment of the sentinel cohort of the Phase 2b study consisting of 400 individuals comparing our XBB COVID-19 vaccine candidate against an approved mRNA XBB comparator. In January 2025, an independent data safety monitoring board ("DSMB") recommended the study to proceed without modifications based on initial safety assessment of 30-day data from the sentinel cohort. Subject to the stop work order described above, if we receive approval from BARDA, we will progress to the next part of the study to enroll approximately 10,000 participants comparing our KP.2 COVID-19 vaccine candidate against an approved mRNA KP.2 comparator.

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 U.S., 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 continue to advance our avian influenza program. We previously published data demonstrating protection in a preclinical model against avian influenza after oral immunization (Clin Vaccine Immunol 2013). We recently created a new avian influenza vaccine candidate to cover the latest clade 2.3.4.4b. We are in the process of conducting several preclinical studies to evaluate the new construct and preparing to manufacture it for clinical use.

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 influenza vaccine candidate.

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 U.S. 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 U.S., 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 U.S., 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, of which we have discontinued independent clinical development. 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. Altesa is conducting a double-blind, randomized, placebo-controlled trial in participants with chronic obstructive pulmonary disease to evaluate the impact of Vapendavir on the development of lower respiratory tract symptoms following rhinovirus challenge.

- Relenza and Inavir are antivirals for the treatment of influenza, marketed by GlaxoSmithKline, plc ("GSK") and Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), respectively. We have earned royalties on the net sales of Relenza and Inavir in Japan. The last patent for Relenza expired in July 2019 and based on information provided by Daiichi Sankyo, the last patent for Inavir expires in August 2036. Sales of these antivirals vary significantly by quarter, because influenza virus activity displays strong seasonal cycles, and by year depending on the intensity and duration of the flu season, the impact COVID-19 has had, and may continue to have, on seasonal influenza, and competition from other antivirals such as Tamiflu and Xofluza.

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.

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. We have also built 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 U.S. and many countries around 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, 2024, 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, 2024, we held more than 45 issued foreign patents 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 as of December 31, 2024, held over 25 foreign patents, including in a number of E.U. countries, Canada, Japan, China, South Korea, Singapore, Australia, Russia, Israel, Indonesia, Vietnam, and South Africa. We also have one application pending in the U.S. and Europe. Patents issuing from these applications will expire in 2035, or later if patent term extension applies.

- ***COVID-19 Vaccine Candidate***. As of December 31, 2024, we have filed provisional applications in the U.S. and have pending applications in the U.S., EPO, Australia, Canada, China, Japan, South Korea, India and South Africa relating to our COVID-19 vaccine candidate. Any patents issuing from these pending applications will expire in 2041/2042, or later if patent term extension applies.

- ***Norovirus Vaccine Tablet Candidates***. As of December 31, 2024, we held two U.S. patents, 18 patents in foreign countries including a number of European countries, Australia, Japan, South Korea, and South Africa, and have pending applications in the U.S., China, Canada, the EPO, the Eurasia Patent Organization, and New Zealand. 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 as of December 31, 2024 relating to our current H1N1 influenza vaccine candidate. These patents will expire in 2030, or later if patent term extension applies.

- As of December 31, 2024, provisional applications relating to improved adenoviral vectors and antibodies to norovirus antigens have been filed.

- ***Inavir***. As of December 31, 2024, we own Japanese patents related to Inavir, which is exclusively licensed to Daiichi Sankyo. Based on information provided by Daiichi Sankyo, the last patent related to Inavir in Japan is set to expire in August 2036, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expired 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 U.S., 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 U.S. 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 U.S. 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 U.S., 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 ("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 U.S., 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 U.S. 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 U.S., 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 U.S. 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.

U.S. 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 U.S., 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 U.S. 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 U.S. 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. In August 2022, the U.S. 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 U.S. 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. It is unknown what form any future changes or any law would take under the incoming Trump administration, and how or whether it may affect our business in the future.

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, 2024, our full-time employee rollforward, excluding interns, was as follows:

	Research and Development	General and Administrative	TOTAL
December 31, 2023	88	21	109
Joined	6	4	10
Terminated	(7)	(7)	(14)
December 31, 2024	87	18	105

We also had 10 full-time equivalent contractors as of December 31, 2024.

We do not have collective bargaining agreements with our employees and 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. We 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 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 U.S. 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, 2024, we had an accumulated deficit of $476.5 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, 2024, we had $51.7 million of cash, cash equivalents and investments. We believe these funds are sufficient to fund our operations into the fourth quarter of 2025. 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 their clinical development stage, 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 vaccines. 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 U.S. and other countries that each have differing regulations. We are not permitted to market our tablet vaccines in the U.S. 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. Clinical studies for our norovirus vaccine candidate and our COVID-19 vaccine candidate have not been completed. 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.

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

In June 2024, we entered into the 2024 ATI-RRPV Contract with Advanced Technology International, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by BARDA. The 2024 ATI-RRPV Contract, as modified and amended to date, provides for a funding ceiling of approximately $460.7 million. In February 2025, we entered into Modification No. 5 (the "Modification") to the 2024 ATI-RRPV Contract. The Modification increased the total amount of funding available for payment to approximately $240.1 million.

We anticipate that a significant portion of the funding to further develop our COVID-19 vaccine candidate will come from the remaining amounts to be received under the 2024 ATI-RRPV Contract. The 2024 ATI-RRPV Contract provides that the government has the right to determine whether to fund the

continued performance of the study after the initial funding. On February 21, 2025, we received written notification from ATI in the form of stop work orders (the "Notices") directing us to stop work on all of our efforts with respect to the 2024 ATI-RRPV Contract, with the exception that we may continue efforts associated with the per protocol follow-up for the 400-person cohort. The Notices stated that the stop work order is in effect for a period of 90 days after the date of the Notices and, that within a period of 90 days, ATI, as directed by the U.S. Government, will either cancel the stop-work order, extend the stop work, or terminate the work covered by the letter.

Even if we were to continue receiving funds under the 2024 ATI-RRPV Contract, the terms of the grant may unfavorably change or the amount of funding may decrease. If the 2024 ATI-RRPV Contract is terminated or suspended, or if there is any government decision not to continue funding or reduction or delay in funding under the 2024 ATI-RRPV Contract, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on no-dilutive terms, terms favorable to us, or at all.

Our 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.

We may fail to produce an effective vaccine that successfully immunizes against norovirus or coronavirus in a timely manner, if at all.

We are pursuing clinical development of vaccine candidates, employing our proprietary oral vaccine platform. While we have begun the Phase 2b clinical trial of our coronavirus vaccine candidate, none of our product candidates has advanced into late-stage clinical trials for the indications that we are pursuing development for. As such, clinical studies of our vaccine candidates may not be completed in a timely manner, and we may not be able to produce an effective vaccine that successfully immunizes against norovirus or coronavirus any time soon, if at all.

Even if we complete our clinical trials as planned and our vaccine candidates successfully demonstrate safety and efficacy, we cannot predict the probability or timing of subsequently obtaining regulatory approval. Regulatory agencies may not complete their review processes in a timely manner, and we may not be able to obtain timely regulatory approval, if at all. Further delays may result if an FDA advisory committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process. Delays or failure to obtain necessary regulatory approvals in time could have a material adverse effect on our business, results of operations and financial condition.

The likelihood and timing of our success further depends on our partners' performance and our ability to maintain relationships with them.

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, 2024, we had $51.7 million of cash, cash equivalents and investments. 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 document 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.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock which could negatively impact the price of our securities and stockholders' ability to sell them.

Our common stock is listed on The Nasdaq Capital Market, which imposes continued listing requirements and rules, including a $1.00 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. There can be no assurance that we will continue to meet these requirements and rules. If we fail to meet the minimum bid price requirement, as described below, or other applicable Nasdaq listing requirements, our common stock could be delisted. 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.

Our common stock traded for less than $1.00 for 30 consecutive trading days, and we received notice of this from the Listing Qualifications Department of The Nasdaq Stock Market on July 2, 2024. Under Nasdaq Listing Rule 5810(c)(3)(A), we were granted a 180-calendar day grace period, or until December 30, 2024, to regain compliance with the minimum bid price requirement. On December 31, 2024, Nasdaq notified the Company in writing that while the Company had not regained compliance with the minimum bid price requirement, it was eligible for an additional 180-day compliance period, or until June 30, 2025, to regain compliance with the minimum bid price requirement. Nasdaq's determination was based on the Company having met the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and on the Company's written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

The minimum bid price requirement would be met if our common stock had a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the additional 180-calendar day grace period. If at any time during this 180-calendar day period the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of ten consecutive business days, the Nasdaq staff stated that it will provide the Company with a written confirmation of compliance and the matter will be closed.

Alternatively, if we fail to regain compliance with Rule 5550(a)(2) prior to the expiration of the second 180-calendar day period, then Nasdaq will notify the Company of its determination to delist the Company's securities, at which point the Company would have an opportunity to appeal the delisting determination to a hearings panel. There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or that the Company will otherwise remain in compliance with the other listing standards for The Nasdaq Capital Market.

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

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 COVID-19, the severe acute respiratory syndrome, the H5N1 strain of avian influenza, the H1N1 strain of swine flu, and the Zika virus.

The occurrence of a pandemic, epidemic, or outbreak of an infectious disease, including, but not limited to, COVID-19, the severe acute respiratory syndrome, the H5N1 strain of avian influenza, the H1N1 strain of swine flu, and the Zika virus, is highly uncertain and cannot be predicted with confidence, including the duration, scope, and severity of such event. These severe conditions may cause us and our business partners to make adjustments, such as temporarily closing down business, limiting business hours, and setting restrictions on travel. In regions where we have concentrations of clinical trial sites or other business activities, our business could be adversely affected by health epidemics, which 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. Any of the forgoing disruptions to our business can result in material adverse effects to our financial condition and results of operations.

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 U.S. 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 U.S., 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 U.S. 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 U.S., the level of reimbursement for our products is likely to be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the U.S. 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, 2024, we had 105 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 document. 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 three 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 U.S.

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 U.S. 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 U.S. 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 COVID-19 and influenza vaccine candidates 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 U.S. 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 U.S. and many countries around 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.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 and or modifications to approved drugs or to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates.

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 U.S. 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 U.S. 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 U.S. 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 ("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 ("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 $10 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, we 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 may build a focused sales, distribution and marketing infrastructure to market our other tablet vaccine candidates in the U.S., 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 U.S. or negotiate a collaborative relationship for the commercialization of our tablet vaccine candidates outside the U.S., 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 U.S. 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 U.S.;
- 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 royalty revenue to be low in the second and third fiscal quarters, since our agreement with HealthCare Royalty Partners III, L.P. (see Note 6 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 August 2036 in Japan, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expired 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 U.S., 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 U.S., 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 U.S. 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 U.S., 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.

On January 20, 2025, President Trump signed an executive order creating an advisory commission, the "Department of Government Efficiency," to reform federal government processes and reduce expenditures. Pressures on and uncertainty surrounding the U.S. federal government's budget, and potential changes in budgetary priorities and spending levels, could adversely affect staffing levels and the funding for the FDA. Disruptions at the FDA and other agencies due to these policies may 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 U.S. 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 U.S., 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 U.S. 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 U.S. and other countries. We seek to protect our proprietary position by filing patent applications in the U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes several significant changes to U.S. 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 ("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 U.S. 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 U.S. 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 U.S., 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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.

While the appeal of the opposition proceeding of a Vaxart European patent in the European Patent Office is completed, we must now obtain approval of the specification conformed to the new claims and it is possible this will be delayed and would delay revalidation of the patent in various European countries. If revalidation of the application was delayed, we may be delayed in asserting the patent to prevent others in Europe from copying some of our product candidates.

We recently concluded the appeal portion of an opposition proceeding of one of our European patents in the European Patent Office ("EPO"). European Patent No. 3307239, which had claims directed to vaccine compositions for norovirus and RSV, 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 appealed this decision and the Board of Appeal upheld the claims to the extent they were directed to norovirus vaccine compositions, but removed claim subject matter as it related to RSV vaccine compositions. Vaxart is awaiting formalities from the Appeal Board and will need to confirm the specification to the new claims. While this is generally a routine practice, it is possible this will be delayed due to bureaucratic delay and/or if the opponent objects to proposed specification amendments. This might delay the ultimate reissue of the EP patent and its revalidation in various European states. It is feasible this may delay Vaxart from asserting the patent in Europe until these formalities are resolved.

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 or cybersecurity breaches.

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.

Our business could be adversely affected by economic downturns, changes in inflation and interest rates, changes in trade policy, natural disasters, political crises, geopolitical events, such as the ongoing military conflict between Russia and Ukraine and the war involving Israel, or other macroeconomic conditions, which may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, changes in inflation and interest rates, and uncertainty about economic stability. For example, during 2022 and 2023, the Federal Reserve raised interest rates multiple times in response to concerns about inflation. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Trade policies and geopolitical disputes and conflicts can result in tariffs, sanctions and other measures that restrict international trade, and may adversely affect our costs of doing business, particularly if these measures occur in regions where our suppliers source components or raw materials. Similarly, the ongoing military conflict between Russia and Ukraine and the war involving Israel have created volatility in the global capital markets and are expected to have further global economic consequences, including disruptions of the global supply chain and energy markets.

Additionally, trade policies and geopolitical disputes and other international conflicts can result in tariffs, sanctions, and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where drug products are manufactured or raw materials are sourced. With the new presidential administration in the U.S. in 2025, additional and higher tariffs and sanctions may be imposed on goods imported from other countries which could increase the cost of goods needed to commercialize our products and continue development of our product candidates. Further, such actions by the U.S. could result in retaliatory action by those countries which could impact our ability to profitably commercialize our products in those jurisdictions in the future. As a result, our business, operations and financial condition could be materially harmed.

Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

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 utilizes machine learning and predictive analytics, which may present flawed, biased, and inaccurate results, and 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), in each case adversely impacting 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, 2024, we concluded that our internal controls and procedures were effective as of December 31, 2024, 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, fires, 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.

Natural disasters, including those resulting from significant climate change, could adversely affect our business and our third-party partners' businesses.

Natural disasters, such as hurricanes, tornadoes, floods, wildfire, and drought may impact our operations or our partners' businesses. Climate change is increasing the frequency, intensity, and duration of these weather events. These natural disasters, including those resulting from significant climate change, could destroy or damage facilities or other properties, disrupt business, increase the probability of power or other outages, or otherwise cause significant economic dislocation in the affected regions. Any of these situations may adversely affect our financial condition and results of operations.

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 has 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 inclusion, 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.

The trend of increased environmental regulation is not linear and can fluctuate depending on the administration and jurisdiction, even within the same county. For example, on January 20, 2025, President Trump issued Executive Orders seeking to rescind prior Executive Orders and agency actions enacted by the Biden Administration. These include revoking Biden-era Executive Orders withdrawing certain offshore waters within the Outer Continental Shelf available for oil and gas exploration and imposing a temporary prohibition of offshore wind leasing in the Outer Continental Shelf. We cannot foresee the potential impact and unintended consequences that future Executive Orders or the changes in enforcement of existing laws, rules, and orders may have on our business. Additionally, although the Trump Administration initially withdrew the U.S. from the Paris Agreement in November 2020, the U.S. reentered the Paris Agreement in February 2021 under the Biden Administration, but the Trump Administration again withdrew from the Paris Agreement on January 20, 2025. Though we are closely following developments in this area and changes in the regulatory landscape in the United States and other jurisdictions, we cannot predict with precision or quantify how or when challenges may arise and ultimately impact our business.

Additionally, in January 2025, President Trump signed a number of Executive Orders focused on diversity, equity, and inclusion ("DEI"), which indicate continued scrutiny of DEI initiatives and potential related investigations of certain private entities with respect to DEI initiatives, including publicly traded companies. If we do not successfully manage expectations across varied stakeholder interests, it could erode stakeholder trust, impact our reputation and constrain our investment opportunities. Such scrutiny of both ESG and DEI related practices could expose us to the risk of litigation, investigations, or challenges by federal or state authorities or result in reputational harm.

Nevertheless, 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, 2024, 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 8. 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

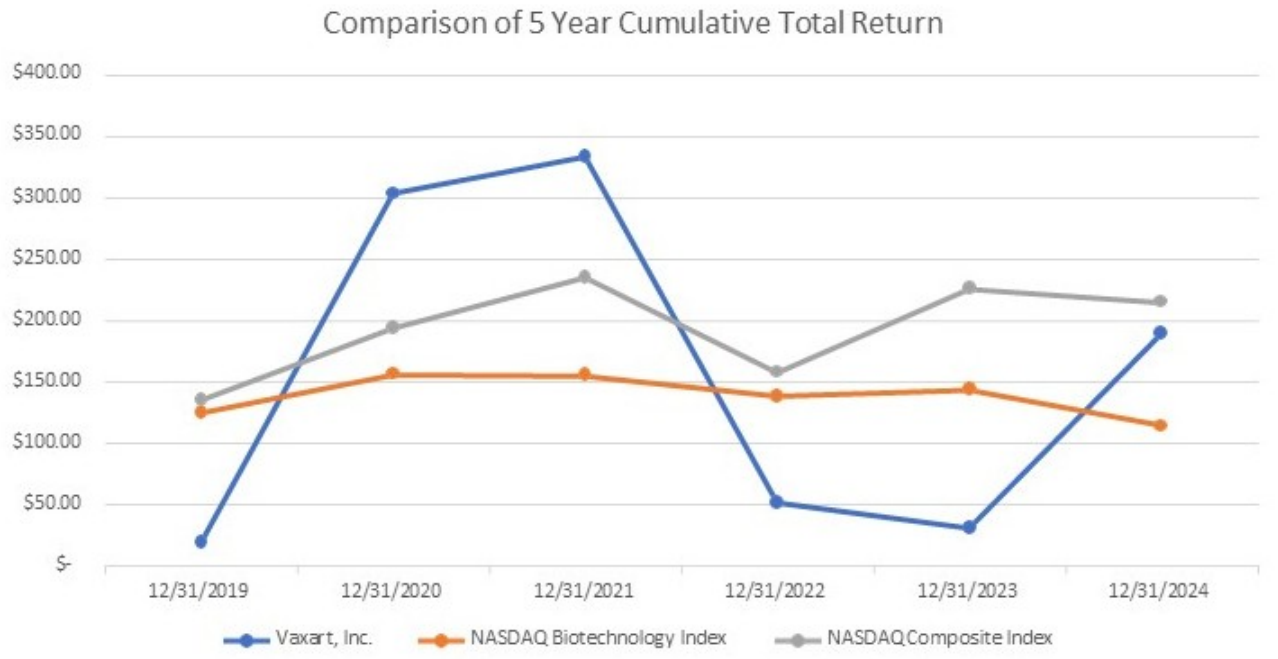
Our common stock is listed on The Nasdaq Capital Market under the symbol "VXRT".

As of March 13, 2025, there were approximately 2,155 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.

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, 2024, 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 14, 2024, for discussion and analysis of results of operations for the year ended December 31, 2023.

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.

Financial Operations Overview

Revenue

Non-Cash Royalty Revenue Related to Sale of Future Royalties

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

We are not obligated to pay HCRP any royalty payment beyond what we are paid by Daiichi Sankyo. The cumulative remaining shortfall amount is the aggregate amount of the shortfall for each annual period, which was $6.0 million as of December 31, 2024. 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.

Revenue from Government Contracts

In January 2024, we were awarded the 2024 ASPR-BARDA Contract by HHS BARDA, with a base and all options value of $9.3 million. Under the 2024 ASPR-BARDA Contract, we received an award to support clinical trial planning activities for a Phase 2b clinical trial that would compare our XBB vaccine candidate to an mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events. Revenue from government contracts recognized on the 2024 ASPR-BARDA Contract was $8.7 million and zero for the years ended December 31, 2024 and 2023, respectively, based on the achievement of certain milestones under the 2024 ASPR-BARDA Contract.

In June 2024, we entered into the 2024 ATI-RRPV Contract. In the second half of 2024, the 2024 ATI-RRPV Contract was modified to increase funding and expand the scope to include the manufacture of a vaccine candidate targeting the KP.2 strain and acquire an approved mRNA vaccine targeting the KP.2 strain. Pursuant to the 2024 ATI-RRPV Contract (as modified or amended from time to time), we may receive funding of up to $460.7 million to conduct a Phase 2b comparative study evaluating our oral pill COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the FDA. As of December 31, 2024, the 2024 ATI-RRPV Contract makes available an aggregate amount of up to $134.2 million, consisting of firm fixed price amounts totaling $67.9 million and reimbursement of costs incurred in trial preparation and execution activities. As of December 31, 2024, the 2024 ATI-RRPV Contract further contemplates additional funding up to $326.5 million if we and HHS BARDA decide to continue with the Phase 2b comparative study. Revenue from government contracts recognized on the 2024 ATI-RRPV Contract was $16.2 million and zero for the years ended December 31, 2024 and 2023, respectively, based on costs incurred and the achievement of firm fixed-price milestones under the 2024 ATI-RRPV Contract. In February 2025, we entered into Modification No. 5 (the "Modification") to the 2024 ATI-RRPV Contract. The Modification increased the total amount of funding available for payment to approximately $240.1 million. On February 21, 2025, we received the "Notices" (discussed above) directing us to stop work on all of our efforts with respect to the 2024 ATI-RRPV Contract, with the exception that we may continue efforts associated with the per protocol follow-up for the 400-person cohort. The Notices stated that the stop work order is in effect for a period of 90 days after the date of the Notices and, that within a period of 90 days, ATI, as directed by the U.S. Government, will either cancel the stop-work order, extend the stop work, or terminate the work covered by the letter.

Grant Revenue

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

Research and Development Expenses

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

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

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

We have incurred significant external costs for CROs that conduct clinical trials on our behalf. 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 for years ended December 31 (in thousands):

	Year Ended December 31,	
	2024	2023
External program costs:		
Norovirus program	$ 3,178	$ 10,570
COVID-19 program	16,883	3,110
Other programs	32	—
Preclinical research	1,909	764
Process development	271	953
Total external costs	22,273	15,397
Internal costs	51,940	52,745
Total research and development costs	$ 74,213	$ 68,142

We expect to incur significant research and development expenses in 2025 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 for years ended December 31 (in thousands, except percentages):

	2024	% Change	2023
Revenue	$ 28,700	289%	$ 7,379
Operating expenses	94,993	5%	90,726
Operating loss	(66,293)	(20)%	(83,347)
Net non-operating (expense) income	(395)	(135)%	1,143
Loss before income taxes	(66,688)	(19)%	(82,204)
Provision for income taxes	260	(0)%	261
Net loss	$ (66,948)	(19)%	$ (82,465)

Total Revenue

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

	2024	% Change	2023
Non-cash royalty revenue related to sale of future royalties	$ 3,842	(2)%	$ 3,920
Revenue from government contracts	24,858	100%	—
Grant revenue	—	(100)%	3,459
Total revenue	$ 28,700	289%	$ 7,379

Non-cash Royalty Revenue Related to Sale of Future Royalties

For the year ended December 31, 2024, non-cash royalty revenue related to sale of future royalties from Daiichi Sankyo was $3.8 million, compared to $3.9 million for the year ended December 31, 2023. We continue to have non-cash royalty revenue as all royalties received in the years ended December 31, 2024 and 2023 were required to be paid to HCRP.

Revenue from Government Contracts

For the year ended December 31, 2024 and 2023, revenue from government contracts was $24.9 million and zero, respectively. The revenue from government contracts consists of the 2024 ASPR-BARDA Contract awarded to us in January 2024 and the 2024 ATI-RRPV Contract awarded to us in June 2024. Revenue from the 2024 ASPR-BARDA Contract was $8.7 million for the year ended December 31, 2024. Revenue from the ATI-RRPV Contract was $16.2 million for the year ended December 31, 2024.

Grant Revenue

We recognized revenue from the BMGF Grant of zero and $3.5 million for the years ended December 31, 2024 and 2023, 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):

	2024	% Change	2023
Research and development	$ 74,213	9%	$ 68,142
General and administrative	20,780	(8)%	22,584
Total operating expenses	$ 94,993	5%	$ 90,726

Research and Development

For the year ended December 31, 2024, research and development expenses were $74.2 million, an increase of $6.1 million, or 9%, compared to $68.1 million for the year ended December 31, 2023. The increase was primarily due to increases in clinical trial expenses related to our COVID-19 vaccine candidate, an increase in manufacturing and preclinical expenses and facilities expenses, offset by a decrease in clinical trial expenses related to our norovirus vaccine candidate and a decrease in stock-based compensation expense and personnel-related costs.

General and Administrative

For the year ended December 31, 2024, general and administrative expenses were $20.8 million, a decrease of $1.8 million, or 8% compared to $22.6 million for the year ended December 31, 2023. The decrease was primarily due to a decrease in personnel-related costs, including stock-based compensation expenses, and directors' and officers' insurance costs, offset by increases in severance costs, recruiting costs and other professional fees.

Non-Operating (Expense) Income

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

	2024	% Change	2023
Interest income	$ 2,543	(4)%	$ 2,652
Non-cash interest expense related to sale of future royalties	(2,969)	105%	(1,447)
Other income (expense), net	31	150%	(62)
Net non-operating (expense) income	$ (395)	(135)%	$ 1,143

For the year ended December 31, 2024, we recorded interest income of $2.5 million, a 4% decrease from the $2.7 million interest income recorded in the year ended December 31, 2023. The decrease is primarily due to lower interest rates in 2024, partially offset by a higher cash, cash equivalents and investments balance.

Non-cash interest expense related to sale of future royalties representing imputed interest on the unamortized portion of the sale of future royalties liability, increased to $3.0 million for the year ended December 31, 2024, from the $1.4 million in 2023, due to an increase in non-cash royalty revenue payable to HCRP.

Provision for Income Taxes

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

	2024	% Change	2023
Foreign withholding tax on royalty revenue	$ 192	(2)%	$ 196
Foreign taxes payable on intercompany interest	65	5%	62
State income taxes	3	0%	3
Provision for income taxes	$ 260	(0)%	$ 261

The provision for income taxes was $260,000 and $261,000 for the years ended December 31, 2024 and 2023, respectively. The tax charge relates to interest on an intercompany loan from a foreign subsidiary and a 5% withholding tax on royalty revenue earned on sales of Inavir in Japan, which is potentially recoverable as a foreign tax credit but expensed because we record a 100% valuation allowance against our deferred tax assets. The amount of income tax expense recorded is directly proportional to Inavir royalties, including the portion that we pass through to HCRP.

Liquidity and Capital Resources

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

In September 2021, we entered into a Controlled Equity Offering Sales Agreement (the "September 2021 ATM"), under which we may offer and sell, from time to time through sales agents, shares of our common stock having an aggregate offering price of up to $100 million. We incurred direct expenses and paid sales commissions of up to 3.0% of gross proceeds from the sale of shares under the September 2021 ATM. In the year ended December 31, 2024, 7,719,641 shares were issued and sold under the September 2021 ATM for gross proceeds of $9.1 million, which, after deducting sales commissions and expenses incurred to date, resulted in net proceeds of $8.8 million. Effective October 18, 2024, the Company terminated the September 2021 ATM and discontinued all offers and sales of common stock thereunder.

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

In January 2024, we were awarded the 2024 ASPR-BARDA Contract with a base and all options value of $9.3 million. Under the 2024 ASPR-BARDA Contract, we received an award to support clinical trial planning activities for a Phase 2b clinical trial that would compare our XBB vaccine candidate to an mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events. The 2024 ASPR-BARDA Contract originally had a period of performance term that was set to expire in July 2024, but we entered into an amendment in July 2024 that extended the period of performance expiration date into October 2024. BARDA and Vaxart are currently discussing contract closeout for the 2024 ASPR-BARDA Contract. As of December 31, 2024, we received approximately $9.3 million of cash payments under the 2024 ASPR-BARDA Contract.

In June 2024, we entered into an underwriting agreement with Oppenheimer & Co. Inc., relating to the issuance and sale by us in an underwritten registered direct offering (the "June 2024 Offering") of 50,000,000 shares of our common stock at a price of $0.80 per share. The gross proceeds to us from such offering were $40.0 million, and after deducting the underwriting discounts and commissions and other offering expenses paid by us, the net proceeds were $37.5 million.

In June 2024, we entered into the 2024 ATI-RRPV Contract. Pursuant to the 2024 ATI-RRPV Contract, we may receive funding of up to $460.7 million to conduct a Phase 2b comparative study evaluating our oral pill COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the U.S. Food and Drug Administration, manufacture a COVID-19 vaccine candidate targeting the KP.2 strain, and acquire an approved mRNA vaccine targeting the KP.2 strain. As of December 31, 2024, we have received $72.0 million of cash payments under the 2024 ATI-RRPV Contract. Subsequent to December 31, 2024, through the filing date of this Annual Report on Form 10-K, we have received $7.2 million under the 2024 ATI-RRPV Contract. On February 21, 2025, we received the Notices directing us to stop work on all of our efforts with respect to the 2024 ATI-RRPV Contract, with the exception that we may continue efforts associated with the per protocol follow-up for the 400-person cohort. The Notices stated that the stop work order is in effect for a period of 90 days after the date of the Notices and, that within a period of 90 days, ATI, as directed by the U.S. Government, will either cancel the stop-work order, extend the stop work, or terminate the work covered by the letter.

As of December 31, 2024, we had approximately $51.7 million of cash, cash equivalents and short-term investments. Our cash, cash equivalents and investments are not sufficient to fund our planned operations for a period of 12 months from the date of issuance of this Annual Report. To continue operations, we expect that we will need to raise further capital, through the sale of additional securities or otherwise. Our future capital requirements and the adequacy of our available funds will depend on many factors, most notably our ability to successfully commercialize our products and services.

We may fund a significant portion of our ongoing operations through partnering and collaboration agreements which, while reducing our risks and extending our cash runway, will also reduce our share of eventual revenues, if any, from our vaccine candidates. We may be able to fund certain activities with assistance from government programs. 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, we expect to have enough cash runway into the fourth quarter of 2025. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, management's plans include further reducing or delaying operating expenses. These conditions raise substantial doubt about our 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 we 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,	
	2024	**2023**
Net cash used in operating activities	$ (44,764)	$ (70,453)
Net cash (used in) provided by investing activities	(21,324)	43,952
Net cash provided by financing activities	56,562	15,243
Net decrease in cash and cash equivalents	$ (9,526)	$ (11,258)

Net Cash Used in Operating Activities

We experienced negative cash flow from operating activities for the years ended December 31, 2024, and 2023, in the amounts of $44.8 million, and $70.5 million, respectively. The cash used in operating activities for the year ended December 31, 2024, was due to cash used to fund a net loss of $66.9 million and an increase in working capital of $3.3 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 $18.9 million. 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.

Net Cash (Used in) Provided by Investing Activities

In the year ended December 31, 2024, we used $20.8 million of cash to purchase investments, net of maturities, and used $0.6 million of cash to purchase property and equipment. 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.

Net Cash Provided by Financing Activities

In the year ended December 31, 2024, we received net proceeds of $37.5 million from the sale of our common stock under the June 2024 Offering, net proceeds of $8.8 million from the sale of our common stock under the September 2021 ATM, net proceeds of $9.9 million from the sale of our common stock under the 2024 Securities Purchase Agreement and $0.5 million from the issuance of common stock and treasury stock under the employee stock purchase plan, partially offset by $0.2 million from common stock acquired to settle employee tax withholding liabilities. 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.

Contractual Obligations and Commercial Commitments

We have the following contractual obligations and commercial commitments as of December 31, 2024 (in thousands):

Contractual Obligation	Total	< 1 Year	1 - 3 Years	3 - 5 Years	> 5 Years
Long Term Debt, HCRP	$ 21,520	$ 4,060	$ 5,520	$ 5,520	$ 6,420
Operating Leases	21,488	4,511	10,238	6,739	—
Purchase Obligations	11,500	11,500	—	—	—
Total	$ 54,508	$ 20,071	$ 15,758	$ 12,259	$ 6,420

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 6 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 7 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.

Share-based payment arrangements. As of December 31, 2024, the unrecognized stock-based compensation cost related to outstanding unvested stock options and RSUs expected to vest was $13.5 million, which we expect to recognize over an estimated weighted average period of 2.1 years. See Note 10 to the Consolidated Financial Statements in Part II, Item 8 for further details on stock-based compensation expense recognized.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our 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 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. The fair value as of December 31, 2024, is being amortized on a straight-line basis over the remaining period of 4.9 years.

Revenue from Government Contracts

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

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

Stock-Based Compensation

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

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

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

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 2024, which are either not applicable to its operations or their adoption is not expected to have a material impact on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Sensitivity

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

Specifically, as of December 31, 2024, we had cash, cash equivalents and short-term investments of approximately $51.7 million, which consist of primarily bank deposits, money market funds and U.S. government securities. All of our investments must satisfy high credit rating requirements at the time of purchase. Such interest-earning instruments carry a degree of interest rate risk, however, because our investments are rated highly and mostly short-term, we believe that our exposure to risk of loss due to interest rate changes is not significant.

Exchange Rate Sensitivity

Our royalty revenue, which is calculated in U.S. dollars, is based on sales in Japanese yen, so a 1% increase in the strength of the U.S. dollar against the yen would lead to a 1% reduction in royalty revenue and related accounts receivable. All our other revenue and substantially all of our expenses, assets and liabilities are denominated in U.S. dollars and, as a result, we have not experienced significant foreign exchange gains or losses recently and do not anticipate that foreign exchange gains or losses will be significant in the near future.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders of

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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and, since inception, has suffered significant operating losses and negative cash flows from operations. The Company's cash, cash equivalents and investments as of December 31, 2024 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. Accordingly, the Company has determined that its planned operations 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 Matter

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.

Prepayments and Accruals Related to Clinical Expenses - Refer to Note 2 to the consolidated financial statements

Critical Audit Matter Description

The Company recognizes costs it incurs for clinical trials 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. Advance payments are recorded as prepaid 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 clinical trial activities and the subjectivity involved in estimating clinical expenses, auditing the prepayments and accruals related to clinical 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 prepayments and accruals of clinical trials included the following, among others:

- We obtained an understanding of the design and implementation of internal controls over the estimation of prepayments and accruals related to clinical trials.
- We obtained and read a sample of research and collaboration 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 clinical trial activities.
- For a selection of agreements and contracts, we compared the amount of accrual or prepayment 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 from the Company's third-party service providers.
- We performed a search for unrecorded clinical trial accruals by testing subsequent cash disbursements.
- We made selections of specific amounts recognized as research and development expense as well as those recognized as prepaid or accrued expenses to evaluate management's estimate of the vendor's progress and performed the following procedures:
    - Performed corroborating inquiries with Company clinical 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 prepayments and accruals.
    - Tested the mathematical accuracy of management's calculation of prepayments and accruals related to clinical trials in the consolidated financial statements.

/s/ WithumSmith+Brown, PC

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

San Francisco, California
March 20, 2025

PCAOB ID Number 100

VAXART, INC. AND SUBSIDIARIES

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 25,229	$ 34,755
Short-term investments	26,494	4,958
Accounts receivable	5,761	3,008
Unbilled receivable from government contracts	6,208	—
Prepaid expenses and other current assets	4,568	2,815
Total current assets	68,260	45,536
Property and equipment, net	8,705	11,731
Prepaid clinical services, long-term	60,116	—
Right-of-use assets, net	20,404	24,840
Intangible assets, net	3,557	4,289
Goodwill	4,508	4,508
Other long-term assets	839	926
Total assets	$ 166,389	$ 91,830
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,963	$ 1,584
Deferred government revenue	65,400	—
Other accrued current liabilities	11,378	5,634
Current portion of operating lease liability	3,077	2,703
Current portion of liability related to sale of future royalties	4,060	3,803
Total current liabilities	90,878	13,724
Operating lease liability, net of current portion	14,449	17,385
Liability related to sale of future royalties, net of current portion	1,698	2,623
Other long-term liabilities	439	293
Total liabilities	107,464	34,025
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred Stock: $0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of December 31, 2024 or 2023	—	—
Common Stock: $0.0001 par value; 350,000,000 and 250,000,000 shares authorized as of December 31, 2024 and 2023; 228,203,822 shares issued and 227,774,275 shares outstanding as of December 31, 2024 and 153,959,853 shares issued and 153,452,833 shares outstanding as of December 31, 2023	23	15
Additional paid-in capital	535,770	467,731
Treasury Stock at cost, 429,547 shares as of December 31, 2024 and 507,020 shares as of December 31, 2023	(350)	(366)
Accumulated deficit	(476,522)	(409,574)
Accumulated other comprehensive income (loss)	4	(1)
Total stockholders' equity	58,925	57,805
Total liabilities and stockholders' equity	$ 166,389	$ 91,830

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,	
	2024	**2023**
Revenue:		
Non-cash royalty revenue related to sale of future royalties	$ 3,842	$ 3,920
Revenue from government contracts	24,858	—
Grant revenue	—	3,459
Total revenue	28,700	7,379
Operating expenses:		
Research and development	74,213	68,142
General and administrative	20,780	22,584
Total operating expenses	94,993	90,726
Operating loss	(66,293)	(83,347)
Other income (expense):		
Interest income	2,543	2,652
Non-cash interest expense related to sale of future royalties	(2,969)	(1,447)
Other income (expense), net	31	(62)
Loss before income taxes	(66,688)	(82,204)
Provision for income taxes	260	261
Net loss	$ (66,948)	$ (82,465)
Net loss per share – basic and diluted	$ (0.33)	$ (0.57)
Shares used to compute net loss per share – basic and diluted	202,137,531	144,819,781
Comprehensive loss:		
Net loss	$ (66,948)	$ (82,465)
Unrealized gain on available-for-sale investments, net of tax	5	298
Comprehensive loss	$ (66,943)	$ (82,167)

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	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances as of January 1, 2023	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 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 loss 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
Issuance of common stock under September 2021 ATM, net of offering costs of $248	7,719,641	1	—	—	8,801	—	—	8,802
Issuance of common stock under the 2024 Securities Purchase Agreement, net of offering costs of $55	15,384,615	2	—	—	9,943	—	—	9,945
Issuance of common stock under the June 2024 Offering, net of offering costs of $2,455	50,000,000	5	—	—	37,540	—	—	37,545
Issuance of common stock upon exercise of stock options	38,030	—	—	—	30	—	—	30
Issuance of common stock under ESPP	502,423	—	—	—	312	—	—	312
Issuance of treasury stock under ESPP	—	—	280,516	230	(88)	—	—	142
Release of common stock for vested restricted stock units	599,260	—	—	—	—	—	—	—
Repurchase of common stock to satisfy tax withholding	—	—	(203,043)	(214)	—	—	—	(214)
Stock-based compensation	—	—	—	—	11,501	—	—	11,501
Unrealized gains on available-for-sale investments	—	—	—	—	—	—	5	5
Net loss	—	—	—	—	—	(66,948)	—	(66,948)
Balances as of December 31, 2024	228,203,822	$ 23	(429,547)	$ (350)	$ 535,770	$ (476,522)	$ 4	$ 58,925

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (66,948)	$ (82,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,850	8,624
Loss on disposal of property and equipment	—	55
Amortization of discount on short-term investments, net	(761)	(659)
Stock-based compensation	11,501	14,132
Non-cash interest expense related to sale of future royalties	2,969	1,447
Non-cash revenue related to sale of future royalties	(3,637)	(737)
Change in operating assets and liabilities:		
Accounts receivable	(2,753)	(2,988)
Unbilled receivable from government contracts	(6,208)	—
Prepaid expenses and other assets	(1,666)	3,561
Prepaid clinical services, long-term	(60,116)	—
Accounts payable	5,273	(2,444)
Deferred grant revenue	—	(2,000)
Deferred government revenue	65,400	—
Accrued and other liabilities	3,332	(6,979)
Net cash used in operating activities	(44,764)	(70,453)
Cash flows from investing activities:		
Purchases of property and equipment	(554)	(1,871)
Proceeds from sale of property and equipment	—	120
Purchases of investments	(64,270)	(27,497)
Proceeds from maturities of investments	43,500	73,200
Net cash (used in) provided by investing activities	(21,324)	43,952
Cash flows from financing activities:		
Net proceeds from issuance of common stock in the June 2024 Offering	37,545	—
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	8,802	1,430
Net proceeds from issuance of common stock through the 2024 Securities Purchase Agreement	9,945	—
Shares acquired to settle employee tax withholding liabilities	(214)	(366)
Proceeds from issuance of common stock upon exercise of stock options	30	17
Proceeds from issuance of common stock under the employee stock purchase plan	312	562
Proceeds from issuance of treasury stock under the employee stock purchase plan	142	—
Net cash provided by financing activities	56,562	15,243
Net decrease in cash and cash equivalents	(9,526)	(11,258)
Cash and cash equivalents at beginning of the period	34,755	46,013
Cash and cash equivalents at end of the period	$ 25,229	$ 34,755

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,	
	2024	**2023**
Supplemental disclosure of non-cash investing and financing activity:		
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ 495
Acquisition of property and equipment included in accounts payable and other accrued current liabilities	$ 106	$ 4

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.

In June 2024, the Company entered into an underwriting agreement with Oppenheimer & Co. Inc., relating to the issuance and sale by the Company in an underwritten registered direct offering of 50,000,000 shares of the Company's common stock, at a price of $0.80 per share. The gross proceeds to the Company from such offering were $40.0 million, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company, the net proceeds were $37.5 million.

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

In September 2021, the Company entered into a Controlled Equity Offering Sales Agreement (the "September 2021 ATM"), pursuant to which it may offer and sell, from time to time through Cantor Fitzgerald & Co. and B. Riley Securities, Inc. (together, the "sales agents"), shares of its common stock having an aggregate offering price of up to $100 million. The Company filed a prospectus supplement with the SEC on September 16, 2021, a subsequent prospectus supplement with the SEC on May 9, 2023 and paid sales commissions of up to 3.0% of gross proceeds from the sale of shares. Effective October 18, 2024, the September 2021 ATM was terminated. Following such termination, the Company may not offer or sell any additional shares of its common stock under the September 2021 ATM or the related prospectus and prospectus supplement. From January 1, 2024 through October 18, 2024, 7,719,641 shares were issued and sold under the September 2021 ATM for gross proceeds of $9.1 million, which, after deducting sales commissions and expenses incurred to date, resulted in net proceeds of $8.8 million.

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 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 financing is from the sale and issuance of common stock in public offerings as well as funding from the Biomedical Advanced Research and Development Authority ("HHS BARDA"), a division of the Administration for Strategic Preparedness and Response ("ASPR") within the United States ("U.S.") Department of Health and Human Services. In the past, we have also obtained funds from the issuance of common stock warrants, secured debt and preferred stock and from collaboration agreements. As of December 31, 2024, the Company had cash, cash equivalents and short-term investments of $51.7 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.

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

Based on management's current plan, the Company expects to have enough cash runway into the fourth quarter of 2025. 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 the Company 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 and Cash Equivalents – 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.

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. The Company does not generally intend to sell the investments and it is more likely than not that the investments will not be required to be sold before recovery of the amortized cost bases, which may be at maturity.

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.

The Company excludes the applicable accrued interest from both the fair value and amortized cost basis of marketable debt securities for purposes of identifying and measuring an impairment. Accrued interest receivable on marketable debt securities is recorded within prepaid expenses and other current assets on the balance sheets. The Company's accounting policy is to not measure an allowance for credit loss for accrued interest receivable and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which is considered to be in the period in which it is determined the accrued interest will not be collected.

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, 2024, and 2023, 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, 2024 and 2023.

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

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

Accounts Receivable and Unbilled Receivable from Government Contracts – Accounts receivable consists of government contract receivables from HHS BARDA for allowable cost-plus-fixed-fees and firm fixed-price, and royalty revenue receivable for sales, net of estimated returns, of Inavir and are reported at amounts expected to be collected in future periods. Unbilled receivable from government contracts consists of government revenue from HHS BARDA, which was earned and not yet billed. 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, 2024 and 2023.

Accounts receivable and unbilled receivable from government contracts are subject to concentration risk whenever a customer has a balance that meets or exceeds 10% of the Company's total accounts receivable balance or has a balance that meets or exceeds 10% of the Company's total unbilled receivable balance. As of December 31, 2024, Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), represented 52% of the Company's total accounts receivable balance, HHS BARDA represented 48% of the Company's total accounts receivable balance and HHS BARDA represented 100% of the Company's total unbilled receivable balance. As of December 31, 2023, Daiichi Sankyo represented 100% of the Company's total accounts receivable balance. As of December 31, 2023, the unbilled receivable balance was zero.

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 are 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 years ended December 31, 2024 and 2023 (see Note 4).

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 zero and $3.5 million revenue from the BMGF Grant for the years ended December 31, 2024 and 2023, respectively. The Company fully recognized revenue from the BMGF Grant during the year ended December 31, 2023.

Revenue from Government Contracts

Under firm fixed-price milestone contracts, the Company recognizes the firm fixed-price revenue as the milestones are substantially complete and the firm fixed-price for the milestone is earned ("firm fixed-price milestone"). Cash received in advance of the completion of a firm fixed-price milestone will be recorded as deferred revenue until the milestone has been substantially completed and earned.

Under cost reimbursable contracts, the Company recognizes revenue as allowable costs are incurred and the fixed fee is earned ("cost-plus-fixed-fee"). Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and approved overhead and indirect costs. Fixed fees under cost reimbursable contracts are earned in proportion to the allowable costs incurred in performance of the work relative to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed, as detailed in Note 5.

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

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.

For the year ended December 31, 2024, one clinical research organization ("CRO") represented 18% of the Company's total research and development costs.

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.

Reclassifications – Prior year data is subject to reclassification to conform to current year presentation.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* requiring public companies to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. The Company adopted ASU 2023-07 during the year ended December 31, 2024. See Note 14 – Segment Reporting for more information.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances the annual income tax disclosures for the effective tax rate reconciliation and income taxes paid. ASU 2023-09 is effective for annual reporting periods beginning after December 15, 2024, with early adoption permitted. The Company is currently assessing the impact ASU 2023-09 will have on the consolidated financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires new disclosures to disaggregate prescribed natural expenses underlying any income statement caption. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently assessing the impact ASU 2024-03 will have on the consolidated financial statement disclosures.

NOTE 3. Fair Value of Financial Instruments

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

Assets and liabilities recorded at fair value on a recurring basis in the 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, 2024 and 2023 (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2024				
Financial assets:				
Money market funds	$ 16,489	$ —	$ —	$ 16,489
U.S. Treasury securities	—	23,805	—	23,805
Commercial paper	—	2,689	—	2,689
Total assets	$ 16,489	$ 26,494	$ —	$ 42,983

	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

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

NOTE 4. Balance Sheet Components

(a) Cash, Cash Equivalents, and Short-Term Investments

Cash, cash equivalents 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, 2024						
Cash at banks	$ 8,740	$ —	$ —	$ 8,740	$ 8,740	$ —
Money market funds	16,489	—	—	16,489	16,489	—
U.S. Treasury securities	23,802	7	(4)	23,805	—	23,805
Commercial paper	2,688	1	—	2,689	—	2,689
Total	$ 51,719	$ 8	$ (4)	$ 51,723	$ 25,229	$ 26,494

	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

As of December 31, 2024 and 2023, all investments were available-for-sale debt securities with remaining maturities of 12 months or less. As of December 31, 2024 and 2023, the Company held 5 and 1 securities, respectively, in an unrealized loss position for 12 months or less. Interest receivable as of December 31, 2024 and 2023, was $0.2 million and $0.1 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 consists of $2.7 million of government contract receivables from HHS BARDA, and $3.0 million royalty receivable totaling $5.7 million as of December 31, 2024, and $3.0 million and less than $0.1 million of accounts receivable for royalties as of December 31, 2023 and 2022, respectively. The Company has provided no allowance for credit losses as of December 31, 2024 and 2023 based on historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that *may* affect a customer's ability to pay.

(c) Unbilled Receivable from Government Contracts

Unbilled receivable, which was earned and not yet billed, consists of government contracts from HHS BARDA of $6.2 million and zero as of December 31, 2024 and 2023, respectively, as detailed in Note 5.

(d) Prepaid Expenses and Other Current Assets

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

	December 31, 2024	December 31, 2023
Prepaid clinical and manufacturing expenses	$ 1,998	$ 984
Prepaid insurance	282	258
Prepaid rent	521	488
Other prepaid	1,449	752
Other current assets	318	333
Prepaid expenses and other current assets	$ 4,568	$ 2,815

As of December 31, 2024, one CRO represented 28% of the Company's total prepaid expenses balance.

(e) Property and Equipment, Net

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

	December 31, 2024	December 31, 2023
Laboratory equipment	$ 13,806	$ 13,448
Office and computer equipment	1,140	1,105
Leasehold improvements	4,107	3,985
Construction in progress	160	24
Total property and equipment	19,213	18,562
Less: accumulated depreciation	(10,508)	(6,831)
Property and equipment, net	$ 8,705	$ 11,731

Depreciation expense was $3.7 million, and $3.8 million for the years ended December 31, 2024 and 2023, respectively. There were no impairments of the Company’s property and equipment recorded for the years ended December 31, 2024 or 2023.

(f) Prepaid Clinical Services, Long-Term

Prepaid clinical services, long-term were $60.1 million and zero as of December 31, 2024 and December 31, 2023, respectively. The long-term prepaid clinical services represent amounts the Company has paid to a single CRO that will be utilized in over one year.

(g) Right-of-Use Assets, Net

Right-of-use assets, net comprises facilities of $20.4 million and $24.8 million as of December 31, 2024 and 2023, respectively. The right of use of additional leased premises in California commenced in 2023, resulting in an additional $3.1 million right-of-use assets recorded in the year ended December 31, 2023.

(h) Intangible Assets, Net

Intangible assets are comprised of developed technology and intellectual property. Intangible assets are carried at cost less accumulated amortization. As of December 31, 2024, developed technology and intellectual property had remaining lives of 4.9 years and 3.0 years, respectively. In each of the years ended December 31, 2024 and 2023, there have been no indicators of impairment.

Intangible assets consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Developed technology	$ 5,000	$ 5,000
Intellectual property	80	80
Total cost	5,080	5,080
Less: accumulated amortization	(1,523)	(791)
Intangible assets, net	$ 3,557	$ 4,289

Intangible asset amortization expense was $0.7 million for each of the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, the estimated future amortization expense by year is as follows (in thousands):

Year Ending December 31,	Amount
2025	$ 732

2026	731
2027	731
2028	727
2029	636
Total	$ 3,557

(i) Goodwill

Goodwill, which represents the excess of the purchase price over the fair value of assets acquired, was $4.5 million for both years ended December 31, 2024 and 2023. For the years ended December 31, 2024 and 2023, there was no change in goodwill. As of December 31, 2024 and 2023, there have been no indicators of impairment.

(j) Accounts Payable

Accounts payable amounts to $7.0 million and $1.6 million as of December 31, 2024 and 2023, respectively. As of December 31, 2024, one CRO represented 67% of the Company's total accounts payable balances.

(k) Deferred Government Revenue

Deferred government revenue represents amounts received from HHS BARDA contracts where the earnings process is not yet complete. The Company will recognize deferred government revenue once the earnings process is complete, in accordance with its revenue recognition policies.

The following table represents the Company's deferred government revenue (in thousands):

	December 31, 2024	December 31, 2023
Balance at beginning of period	$ —	$ —
Revenue recognized	—	—
Amounts collected or invoiced	65,400	—
Balance at end of period	$ 65,400	$ —

Amounts collected or invoiced during the year ended December 31, 2024 primarily relate to amounts received on the 2024 ATI-RRPV Contract (as defined in Note 5) but for which revenue cannot yet be recognized due to contractual milestones not being achieved and the 2024 ASPR-BARDA Contract (as defined in Note 5) budgeted costs that cannot be recognized until project close out.

(l) Other Accrued Liabilities

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

	December 31, 2024	December 31, 2023
Accrued compensation	$ 5,087	$ 4,576
Accrued clinical and manufacturing expenses	5,134	312
Accrued professional and consulting services	623	211
Other liabilities, current portion	534	535
Total	$ 11,378	$ 5,634

As of December 31, 2024, one CRO represented 42% of the Company's total other accrued liabilities balances.

NOTE 5. Revenue

Royalty Revenue Related to Sale of Future Royalties

The Company generates royalty revenue from the sale of Inavir in Japan, pursuant to a collaboration and license agreement that Aviragen entered into with Daiichi Sankyo Company, Limited ("Daiichi Sankyo") in 2009. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza in adults and children, which Daiichi Sankyo markets as Inavir. Under the agreement, the Company currently receives a 4% royalty on net sales of Inavir in Japan. Based on information provided by Daiichi Sankyo, the Company believes the expiration of the last patent related to Inavir is in August 2036, at which time royalty revenue will cease. The Company's royalty revenue is seasonal, in line with the flu season, so the majority of the Company's royalty revenue and non-cash royalty revenue related to the sale of future royalties are earned in the first and fourth fiscal quarters. The royalty revenue related to Inavir recognized for the years ended December 31, 2024 and 2023, was zero. The Company recognized non-cash royalty revenue related to the sale of future royalties of $3.8 million and $3.9 million for the years ended December 31, 2024 and 2023, respectively. Both royalty revenue and the non-cash royalty revenue related to the sale of future royalties are subject to a 5% withholding tax in Japan, for which $0.2 million was included in income tax expense for each of the years ended December 31, 2024 and 2023, respectively, further detailed in Note 6.

Revenue from Government Contracts

The Company recognized revenue from government contracts with HHS BARDA of $24.9 million and zero for the years ended December 31, 2024 and 2023, respectively, consisting of revenue from the 2024 ASPR-BARDA Contract (as defined below) and the 2024 ATI-RRPV Contract (as defined below) described in more detail below. Unbilled receivable from government contracts consists of government revenue from HHS BARDA, which was earned and not yet billed. As of December 31, 2024, the amount of unbilled receivable was $6.2 million and deferred revenue was $65.4 million.

2024 ATI-RRPV Contract

In June 2024, the Company entered into an agreement (as modified or amended from time to time, the "2024 ATI-RRPV Contract") with Advanced Technology International, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by HHS BARDA, which was modified in the second half of 2024 to increase funding and provide for the manufacturing of a vaccine candidate targeting the KP.2 strain and acquire an approved mRNA vaccine targeting the KP.2 strain. As of December 31, 2024, pursuant to the 2024 ATI-RRPV Contract, the Company may receive funding of up to $460.7 million to conduct a Phase 2b comparative study evaluating the Company's oral pill COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the U.S. Food and Drug Administration ("FDA"). As of December 31, 2024, the 2024 ATI-RRPV Contract makes available an aggregate amount of up to $134.2 million, consisting of firm fixed price amounts totaling $67.9 million and reimbursement of costs incurred in trial preparation and execution activities. As of December 31, 2024, the 2024 ATI-RRPV Contract further contemplates additional funding up to $326.5 million if the Company and HHS BARDA decide to continue with the Phase 2b comparative study. The 2024 ATI-RRPV Contract is further detailed in Note 15. The Company accounts for the 2024 ATI-RRPV Contract under Accounting Standards Codification 958-605 and recognizes revenue as the firm fixed-price milestone is earned and allowable cost-plus-fixed-fees are incurred. Reimbursable costs under the 2024 ATI-RRPV Contract primarily include direct labor, subcontract costs, materials, travel, and approved overhead and indirect costs. The 2024 ATI-RRPV Contract contains terms and conditions that are customary for contracts with HHS BARDA of this nature, including the U.S. government having the right to terminate the contract for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work. Revenue from government contracts recognized on the 2024 ATI-RRPV Contract was $16.2 million for the year ended December 31, 2024, based on costs incurred and the achievement of firm fixed-price milestones under the 2024 ATI-RRPV Contract. Deferred government revenue represents amounts that have been received from HHS BARDA and the earnings process is not yet complete. Deferred government revenue in current liabilities was $64.8 million and zero as of December 31, 2024 and December 31, 2023, respectively. The remaining deferred government revenue as of December 31, 2024 will be recognized as revenue once the earnings process is complete, including, but not limited to, the approval from the FDA and HHS BARDA to commence dosing in the 10,000-participant portion of the Phase 2b comparative study.

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

2024 ASPR-BARDA Contract

In January 2024, the Company was awarded a contract (as amended, the "2024 ASPR-BARDA Contract") by HHS BARDA with a base and all options value of $9.3 million. Under the 2024 ASPR-BARDA Contract, the Company received an award to support clinical trial planning activities for a Phase 2b clinical trial that would compare the Company's XBB vaccine candidate to an mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events. The 2024 ASPR-BARDA Contract originally had a period of performance term that was set to expire in July 2024, but the Company entered into an amendment in July 2024 that extended the period of performance expiration date into October 2024. The Company accounts for the 2024 ASPR-BARDA Contract under Accounting Standards Codification 958-605 and recognizes revenue as donor-imposed conditions are met. Revenue from government contracts recognized on the 2024 ASPR-BARDA Contract was $8.7 million for the year ended December 31, 2024, based on the achievement of certain milestones under the 2024 ASPR-BARDA Contract. Deferred government revenue represents amounts that have been received from HHS BARDA and the earnings process is not yet complete. Deferred government revenue in current liabilities was $0.6 million and zero as of December 31, 2024 and December 31, 2023, respectively.

Grant Revenue

In November 2022, the Company accepted a grant (the "BMGF Grant") of $3.5 million 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 is executed and the contract price is fixed or determinable. Revenue from the BMGF Grant was recognized in the period during which the related costs were incurred and the related services rendered, as the applicable conditions under the contract were met. Costs of contract revenue were recorded as

a component of operating expenses in the consolidated statements of operations and comprehensive loss. The Company fully recognized revenue from the BMGF Grant during the year ended December 31, 2023.

NOTE 6. Liabilities Related to Sale of Future Royalties

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

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

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

The following table shows the activity within the liability account during the year ended December 31, 2024 (in thousands):

Total liability related to sale of future royalties, start of year	$	6,426
Non-cash royalty revenue paid to HCRP		(3,637)
Non-cash interest expense recognized		2,969
Total liability related to sale of future royalties, end of year		5,758
Current portion		(4,060)
Long-term portion	$	1,698

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

NOTE 7. Leases

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

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.

As of December 31, 2024, the weighted average discount rate for operating leases with initial terms of more than one year was 9.8% and the weighted average remaining term of these leases was 4.2 years. Discount rates were determined using the Company's marginal rate of borrowing at the time each lease was executed or extended.

The following table summarizes the Company's undiscounted cash payment obligations for its operating lease liabilities with initial terms of more than 12 months as of December 31, 2024 (in thousands):

Year Ending December 31,	Amount
2025	$ 4,511
2026	5,031
2027	5,207
2028	5,389
2029	1,350
Undiscounted total	21,488
Less: imputed interest	(3,962)
Present value of future minimum payments	17,526
Current portion of operating lease liability	(3,077)
Operating lease liability, net of current portion	$ 14,449

The Company is also required to pay for operating expenses related to the leased space, including common area maintenance, taxes and insurance. The operating expenses are incurred separately and were not included in the present value of lease payments. Operating lease expenses for years ended December 31 are summarized as follows (in thousands):

	2024	2023
Operating lease cost	$ 6,214	$ 6,170
Short-term lease cost	40	52
Variable lease cost	1,876	1,864
Sublease income	(74)	—
Total lease cost	$ 8,056	$ 8,086

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

NOTE 8. Commitments and Contingencies

(a) Purchase Commitments

As of December 31, 2024, the Company had approximately $11.5 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 7.

(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. Following discovery, a motion for summary judgment was filed by Armistice and the Armistice-related party defendants to dismiss the complaint. On March 27, 2024, the court granted the motion for summary judgment and dismissed all claims in the complaint in their entirety. On April 11, 2024, the Plaintiff timely filed a notice of appeal of the court's decision to the Second Circuit Court of Appeals, commencing appellate proceedings. In June 2024, Plaintiff filed a motion to the court of appeals to stay the appeal pending efforts to re-instate the complaint in the district court, which was granted by the court of appeals. In July 2024, Plaintiff filed a motion with the district court seeking to set aside the judgment and to re-instate the complaint. On August 15, 2024, the district court denied Plaintiff's motion to set aside the judgment. On September 10, 2024, Plaintiff re-filed its appeal with the Second Circuit Court of Appeals, which is currently pending.

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.

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

NOTE 9. Stockholders' Equity

(a) Preferred Stock

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

(b) Common Stock

As of December 31, 2024, the Company was authorized to issue 350,000,000 shares of common stock, $0.0001 par value per share, which includes an increase of 100,000,000 on June 11, 2024, when the Company's stockholders approved an amendment to the Company's certificate of incorporation to increase the number of authorized shares of common stock from 250,000,000 to 350,000,000 shares. Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of common stock possess all voting power for the election of the Company's directors and all other matters requiring stockholder action. Holders of common stock are entitled to one vote per share on matters to be voted on by stockholders. Holders of common stock are entitled to receive such dividends, if any, as may be declared from time to time by the Company's board of directors 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, 2024, no dividends had been declared by the board of directors.

In June 2024, the Company entered into an underwriting agreement with Oppenheimer & Co. Inc., relating to the issuance and sale by the Company in an underwritten registered direct offering of 50,000,000 shares of the Company's common stock, at a price of $0.80 per share. The gross proceeds to the Company from such offering were $40.0 million, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company, the net proceeds were $37.5 million.

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

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

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

	December 31, 2024	December 31, 2023
Options issued and outstanding	20,405,239	17,938,726
RSUs issued and outstanding	3,016,481	2,126,373
2019 Equity Incentive Plan available for future grant	18,046,374	5,685,806
2024 Inducement Award Plan available for future grant	1,603,750	—
Common stock warrants	140,596	227,434
2022 Employee Stock Purchase Plan	2,362,902	1,065,325
Total	45,575,342	27,043,664

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

(c) Warrants

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

Securities into which warrants are convertible	Warrants outstanding	Exercise Price	Expiration Date
Common Stock	29,150	$ 2.50	March 2025
Common Stock	100,532	$ 3.125	February 2025
Common Stock	10,914	$ 22.99	December 2026
Total	140,596		

On February 27, 2025 and March 3, 2025, 100,532 and 29,150, respectively, of the warrants outstanding as of December 31, 2024, expired unexercised.

NOTE 10. Equity Incentive Plans

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

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

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

A summary of stock option and RSU transactions for the years ended December 31, 2024 and 2023 are as 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, 2023	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
Authorized under 2024 Inducement Plan	3,000,000	—	$ —	—	$ —
Authorized under 2019 Plan Amendment	15,000,000	—	$ —	—	$ —
Granted	(7,258,980)	5,309,437	$ 1.12	1,949,543	$ 1.13
Exercised	—	(38,030)	$ 0.78	—	$ —
Released	—	—	$ —	(599,260)	$ 1.48
Forfeited	1,944,001	(1,483,826)	$ 2.29	(460,175)	$ 1.41
Canceled	1,279,297	(1,321,068)	$ 2.87	—	$ —
Balance at December 31, 2024	19,650,124	20,405,239	$ 2.49	3,016,481	$ 1.19

As of December 31, 2024, there were 20,405,239 options outstanding with a weighted average exercise price of $2.49, a weighted average remaining term of 6.89 years, and an aggregate intrinsic value of $40,000. Of these options, 12,124,318 were vested, with a weighted average exercise price of $3.08, a weighted average remaining term of 5.65 years, and an aggregate intrinsic value of $35,000.

The Company received $30,000 for the 38,030 options exercised in the year ended December 31, 2024, which had an intrinsic value of $7,000. 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, 2024, based on the Company's common stock closing price of $0.66 on December 31, 2024, 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 $17,000 for the 54,720 options exercised in the year ended December 31, 2023, which had an intrinsic value of $31,000.

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

The weighted average grant date fair value of options awarded in the years ended December 31, 2024 and 2023, was $1.01 and $0.78, respectively. Fair values were estimated using the following assumptions:

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	3.7% - 4.4%	3.5% - 4.2%
Expected term (in years)	5.50 - 6.00	5.50 - 6.00
Expected volatility	128.9% - 130.8%	127.8% - 133.8%
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, RSUs and ESPP was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 7,246	$ 8,362
General and administrative	4,255	5,770
Total stock-based compensation	$ 11,501	$ 14,132

As of December 31, 2024, the unrecognized stock-based compensation cost related to outstanding unvested stock options and RSUs expected to vest was $13.5 million, which the Company expects to recognize over an estimated weighted average period of 2.1 years.

On August 4, 2022, the 2022 Employee Stock Purchase Plan (the "2022 ESPP") was approved by the Company's stockholders. The Company initially reserved 1,800,000 shares of the Company's common stock for purchase under the 2022 ESPP, which was increased by 1,800,000 shares through an amendment to the 2022 ESPP adopted by the Company's stockholders on June 11, 2024, to 3,600,000 shares. The 2022 ESPP generally has a six-month offering period comprised of one purchase period. In May 2024, the 2022 ESPP had a one-time modification following the end of the six-month offering period ended May 31, 2024, to commence the follow-on offering period on July 1, 2024 for a five-month offering period. The purchase price of the stock is equal to 85% of the lesser of the market value of such shares at the beginning of the six-month offering period or the end of such offering period. During the year ended December 31, 2024, the Company received $0.5 million and issued 782,939 shares under the 2022 ESPP. 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, 2024, 2,362,902 shares are available and reserved for future issuance under the 2022 ESPP.

Stock-based compensation expense related to the ESPP for the years ended December 31, 2024 and 2023, was $0.2 million and $0.4 million, respectively.

NOTE 11. 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 $23,000 for calendar year 2024 and $22,500 for calendar year 2023. Employees age 50 or over may elect to contribute an additional $7,500 annually for 2024 and 2023.

Employees direct their contributions, which vest immediately, across a series of mutual funds. In the years ended December 31, 2024 and 2023, the Company matched employee contributions up to 3% of each employee's eligible earnings, vesting immediately. The Company's matching contributions totaled $0.5 million and $0.6 million in the years ended December 31, 2024 and 2023, respectively. The costs of administering the Plan totaled $38,000 and $28,000 in the years ended December 31, 2024 and 2023, respectively.

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

NOTE 12. Income Taxes

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

	Year Ended December 31,	
	2024	2023
Current:		
Federal	$ —	$ —
State	3	3
Foreign	257	258
Total Current	260	261
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total Deferred	—	—
Provision for income taxes	$ 260	$ 261

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

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 48,154	$ 47,720
Research and development tax credits	12,949	10,187
Capitalized research and development	27,892	21,676
Sale of future royalties	1,179	1,623
Lease liability	3,682	4,206
Accruals, reserves and other	6,676	4,827
Total deferred tax assets	100,532	90,239
Valuation allowance	(94,119)	(82,500)
Deferred tax assets net of valuation allowance	6,413	7,739
Deferred tax liabilities:		
Intangible assets	(1,999)	(2,308)
Right-of-use assets	(4,309)	(5,216)
Depreciation on property and equipment	(105)	(215)
Total deferred tax liabilities	(6,413)	(7,739)
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,	
	2024	2023
U.S. federal taxes at statutory rate	21.0%	21.0%
State taxes (net of federal benefit)	0.1	0.1
Foreign rate differential	(0.7)	(1.1)
Permanently non-deductible items	(0.1)	—
Tax credits	4.2	2.7
Change in valuation allowance	(17.4)	(19.7)
Prior year true-up	(5.5)	(0.1)
Stock-based compensation	(2.0)	(3.2)
Provision for income taxes	(0.4)%	(0.3)%

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, 2024 and 2023, 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, 2024 and 2023, the Company had net operating loss ("NOL") carryforwards of $221.1 million and $201.1 million for federal purposes, and $8.9 million and $87.5 million for state purposes, respectively. If not utilized, federal net operating losses of $1.7 million will begin to expire in 2025 and $219.4 million will be carried forward indefinitely; state net operating losses of $3.5 million will begin to expire in 2028 and $5.4 million will be carried forward indefinitely.

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

As of December 31, 2024, the Company also has accumulated tax losses of $4.2 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, 2024 and 2023, the Company had research and development tax credit carryforwards for federal purposes of $12.8 million and $9.4 million, respectively, and state research and development tax credit carryforwards of $10.0 million and $8.5 million, respectively. The federal research and development tax credit carryforwards will expire at various dates between 2039 and 2044. 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, 2024 and 2023. The net change in total valuation allowance was an increase of approximately $11.6 million and $16.2 million for the years ended December 31, 2024 and 2023, 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 $8.5 million and $6.6 million as of December 31, 2024 and 2023, 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 balance of total unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning Balance	$ 6,566	$ 4,945
Additions based on tax positions related to the current year	1,977	1,621
Decreases related to prior years' tax positions	(6)	—
Ending Balance	$ 8,537	$ 6,566

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 years ended December 31, 2024 and 2023, 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 2020. 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 2020 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 2005 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 2020 and forward.

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

NOTE 13. 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,	
	2024	2023
Net loss	$ (66,948)	$ (82,465)
Shares used to compute net loss per share – basic and diluted	202,137,531	144,819,781
Net loss per share – basic and diluted	$ (0.33)	$ (0.57)

No adjustment has been made to the net loss in the years ended December 31, 2024 and 2023, as the effect would be anti-dilutive due to the net loss.

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

	Year Ended December 31,	
	2024	2023
Options to purchase common stock	20,659,336	17,270,980
Restricted stock units to purchase common stock	2,828,395	2,931,662
Warrants to purchase common stock	158,262	227,434
Employee Stock Purchase Plan	335,190	402,699
Total potentially dilutive securities excluded from denominator of the diluted earnings per share computation	23,981,183	20,832,775

NOTE 14. Segment Reporting

The Company operates in one reportable segment, which is the discovery and development of oral recombinant protein vaccines, based on its proprietary oral vaccine platform. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by the Chief Executive Officer as chief operating decision maker (the "CODM") in assessing segment performance and deciding how to allocate resources on a consolidated basis.

The CODM uses consolidated net loss to evaluate the Company's spend and monitor budget versus actual results. The monitoring of budgeted versus actual results is used in assessing performance of the segment and in establishing resource allocation across the organization. The measure of segment assets is reported on the consolidated balance sheets as total assets.

Our segment revenue, segment loss, significant segment expenses, and other segment items consist of the following (in thousands):

	Year Ended December 31,	
	2024	2023
Revenue	$ 28,700	$ 7,379
Less:		
Research and development		
External program costs:		
Norovirus program	3,178	10,570
COVID-19 program	16,883	3,110
Other programs	32	-
Preclinical research	1,909	764
Process Development	271	953
Internal research and development costs	51,940	52,745
General and administrative	20,780	22,584
Interest income	(2,543)	(2,652)
Non-cash interest expense related to sale of future royalties	2,969	1,447
Other segment items[A]	(31)	62
Provision for income taxes	260	261
Segment net loss	$ (66,948)	$ (82,465)
Reconciliation of net loss		
Adjustments and reconciling items	-	-
Net loss	$ (66,948)	$ (82,465)

(A) Other segment items included in other income (expense), net.

NOTE 15. Subsequent Events

Appointment of Mr. Kevin Finney to Board of Directors

On January 24, 2025, following a recommendation by the Nominating and Governance Committee of the Board of Directors, the Company's Board appointed Kevin Finney to serve on the Board, effective January 28, 2025, until Mr. Kevin Finney's successor is elected and qualified, or sooner in the event of his death, resignation, or removal. The Board has determined that Mr. Kevin Finney meets the requirements for independence under the applicable listing standards of The Nasdaq Stock Market LLC and the Securities Exchange Act of 1934, as amended. Mr. Kevin Finney was also appointed as a member of the Audit Committee and the Nominating and Governance Committee of the Board.

Modification of 2024 ATI-RRPV Contract

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

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

Stop Work Order Received for the 2024 ATI-RRPV Contract

On February 21, 2025, the Company received written notification from ATI in the form of stop work orders (the "Notices") directing the Company to stop work on all of the Company's efforts with respect to the Project Agreement with ATI, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by HHS BARDA, with the exception that the Company may continue efforts associated with the per protocol follow-up for the 400-person cohort.

The Notices stated that the stop work order is in effect for a period of 90 days after the date of the Notices and, that within a period of 90 days, ATI, as directed by the government, will either cancel the stop-work order, extend the stop work, or terminate the work covered by the letter as provided in Article 13.4 of the Project Agreement.

Reduction in Operating Costs

In the first quarter of 2025, the Company suspended all activities related to the 10,000-participant cohort of its COVID-19 Phase 2b study and implemented additional measures to reduce expenses with specific vendors, consultants, and contractors. The Company also implemented a restructuring plan to better align its workforce with the needs of its business. The restructuring plan led to an approximately 10% reduction of the Company's workforce on an FTE basis.

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

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, 2024.

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, 2024, 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

Item 10. Directors, Executive Officers and Corporate Governance

Listed below are the names of the directors, executive officers, and key employees of the Company, their ages as of the date of this Annual Report, and their positions held with the Company.

Name	Age	Title
Steven Lo	58	President, Chief Executive Officer, and Director
Phillip Lee	38	Chief Financial Officer
Sean Tucker, Ph.D.	57	Senior Vice President and Chief Scientific Officer
Edward B. Berg	61	Senior Vice President and General Counsel
James Cummings, M.D.	59	Chief Medical Officer
Michael J. Finney, Ph.D.	66	Director
Kevin P. Finney	57	Director
Elaine J. Heron, Ph.D.	77	Director
W. Mark Watson	74	Director
David Wheadon, M.D.	67	Director

There are no family relationships among any of our directors or executive officers. Set forth below is a summary of the business experience of each of our directors, executive officers, and key employees identified above:

Steven Lo has served as our President, Chief Executive Officer, Principal Executive Officer, and a member of the board of directors since March 2024. He has over 25 years of experience in healthcare, biotechnology, and pharmaceutical industries, including over 12 years of C-level experience in publicly traded biotech companies. Prior to joining the Company, Mr. Lo served as Chief Executive Officer and a member of the board of directors of Valitor, Inc., a private biotech company, from August 2022 to March 2024. From October 2019 to August 2022, Mr. Lo was the President, Chief Executive Officer, and member of the board of directors of Zosano Pharma Corporation ("Zosano"), a clinical-stage biopharmaceutical company. On June 1, 2022, Zosano filed a voluntary petition for relief under chapter 11 of title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware. From September 2015 to October 2019, he was the Chief Commercial Officer at Puma Biotechnology, Inc., a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. At that company, he built and led business development and the worldwide commercialization of the company's first product. Prior to that, he was Chief Commercial Officer of Corcept Therapeutics Incorporated, where he established the commercial organization to launch the company's first product. Earlier in his career, he spent 13 years at Genentech, Inc., a member of Roche Group, in a variety of leadership roles of increasing responsibility in commercial and drug development. He worked in numerous areas, including oncology, endocrinology and other specialty therapeutics. Mr. Lo started his career in the pharmaceutical industry at AstraZeneca after holding positions in finance and operations at Kaiser Permanente. Mr. Lo obtained a Master of Health Administration from the University of Southern California and a B.S. in Microbiology from the University of California, Davis.

Phillip E. Lee has served as our Chief Financial Officer, Principal Financial Officer, and Principal Accounting Officer since December 2022. Prior to joining Vaxart, Mr. Lee was an executive at Clover Biopharmaceuticals, Ltd., a global biotechnology company developing novel vaccines and biologic therapeutics, and served as Chief Financial Officer from January 2021 to July 2022, Chief Operating Officer from February 2022 to July 2022, and Chief Business Officer from January 2021 to February 2022. From April 2018 to January 2021, he served at 4D Molecular Therapeutics, Inc., a clinical-stage biotherapeutics company harnessing the power of directed evolution for targeted genetic medicines, as Senior Director, Finance and was subsequently promoted to Vice President, Finance in January 2019. From December 2015 to March 2018, he served at Cytokinetics, Inc., a biopharmaceutical company focused on discovering, developing and commercializing muscle activators and muscle inhibitors, as Director, Corporate Finance and Business Analysis and was subsequently promoted to Senior Director, Corporate Finance and FP&A in November 2017. He began his career as an investment banker and served at Centerview Partners LLC from June 2009 to July 2015 in positions of increasing responsibility with his last position being Principal. Mr. Lee received a B.S. in Business Administration and a B.S. in Electrical Engineering and Computer Sciences from the University of California, Berkeley.

Sean Tucker, Ph.D. has served as our Chief Scientific Officer since February 2010, and as Senior Vice President since March 2021. From March 2004 to February 2010, Dr. Tucker served as our Vice President of Research and Director of Immunology. Prior to these roles, Dr. Tucker held numerous scientific and engineering roles at various biotechnology companies. Dr. Tucker received a B.S. in chemical engineering from the University of Washington, an M.S. in chemical engineering from the University of California, Berkeley and a Ph.D. in immunology from the University of Washington.

Edward B. Berg has served as our Senior Vice President and General Counsel since February 2022. Mr. Berg has served in senior legal positions at prominent healthcare companies for most of his more than 30-year career and has represented Fortune 500 and mid-cap companies in biotechnology, pharmaceuticals and life sciences. Prior to Vaxart, he served as VP, Deputy General Counsel for BioMarin Pharmaceutical Inc. from July 2018 to January 2022. Mr. Berg previously served as VP Legal and the head attorney supporting Novartis AG's biosimilar / generic subsidiary, Sandoz US, from June 2016 to June 2018. Mr. Berg's previous roles include Deputy General Counsel, Pharmaceutical Operations for Sanofi-Aventis U.S. LLC and Sanofi NA Pharmaceuticals, and Senior Corporate Counsel, Research & Development at Bristol-Myers Squibb, Inc. He began his career in healthcare as Senior Attorney / Associate Counsel for Merck & Co, Inc. Mr. Berg received a B.A. from Washington University in economics and political science and a law degree from the University of Pennsylvania Law School.

James Cummings, M.D. has served as our Chief Medical Officer since August 2021. Preceding his role at Vaxart, Dr. Cummings served as President of ICON Government and Public Health Solutions, Inc., a global clinical research organization, from January 2018 until September 2021, providing clinical trial and functional services to government and commercial customers, in support of global health. Prior to joining ICON, Dr. Cummings served as Vice President of Clinical Development and Translational Medicine at Novavax, Inc. from September 2015 until January 2018. There he led the development programs for all Emerging and Re-Emerging Infectious Diseases to provide a timely, broad response across the spectrum of emerging infectious diseases. Dr. Cummings retired as a Colonel in the U.S. Army after 26 years of service, during which he acquired a proven track record in vaccine, drug and diagnostics development, and served as Director of the Department of Defense (DoD) Global Emerging Infectious Diseases Surveillance and Response Systems (DoD GEIS) leading Biosurveillance for the US DoD with laboratories and partners in 71 countries and as the consultant to the Army Surgeon General for all medical research and development. A graduate of Georgetown University's School of Medicine, Dr. Cummings trained in Internal Medicine and Infectious Diseases Fellowships at Walter Reed and the National Capital Consortium and has been elected to fellow in the American College of Physicians (FACP), the Infectious Diseases Society of America (FIDSA) and the American Society of Tropical Medicine and Hygiene (FASTMH).

Michael J. Finney, Ph.D. has served as a member of our board of directors since February 2018 and Chair of our board of directors since March 2023. He previously served as a member of Private Vaxart's board of directors since 2007. Since October 2004, Dr. Michael J. Finney has served as the Managing Director of Finney Capital, an investment firm. Since 1986, Dr. Michael J. Finney has served as a founder, executive, director and/or investor in various life sciences companies. Currently, he sits on six private company boards. Dr. Michael J. Finney served as Vaxart's Chief Executive Officer from 2009 to 2011, and as interim Chief Executive Officer from January 16, 2024 to March 17, 2024. Dr. Michael J. Finney received an A.B. in biochemical sciences from Harvard University and a Ph.D. in biology (genetics) from the Massachusetts Institute of Technology.

Kevin Finney has served as a member of our board of directors since January 2025. Mr. Kevin Finney is an experienced biotech executive and director who has held numerous leadership roles in the healthcare industry, leading companies from early stages of development through to commercialization. Since November 2019, Mr. Kevin Finney has served as President, Chief Executive Officer, and Chairman of the board of directors of Autobahn Therapeutics, Inc., a biotechnology company developing a portfolio of neuropsychiatric and neuroimmunologic clinical candidates leveraging its brain-targeting chemistry platform. Since January 2016, Mr. Kevin Finney has also served as vice chairman of the board of directors of Eirion Therapeutics, Inc. Mr. Kevin Finney also served on the board of directors of Anterios Inc. and Taris Biomedical (now a part of Johnson & Johnson). From January 2019 to July 2019, Mr. Kevin Finney served as president and chief operating officer of Abide Therapeutics Inc., where he led the acquisition of Abide by H. Lundbeck A/S in 2019. Mr. Kevin Finney is also a founder of Zavante Therapeutics, Inc. (now known as Nabriva therapeutics PLC) and served as its chief operating officer. As a founding member, Mr. Kevin Finney led the initial financing of Zavante Therapeutics and its operations from inception in June 2015 through its sale in September 2018. Previously, Mr. Kevin Finney was vice president and head of world-wide corporate development at Allergan, Inc., an international specialty pharmaceutical company operating in more than 100 countries worldwide. In this role he led strategic corporate development and was at the center of some of the industry's largest transactions, including Allergan's 2015 acquisition by Actavis. During his tenure at Allergan, the company grew from $3 billion in annual revenue to $7 billion through organic and acquired growth, including substantial growth of the neurology franchise with the flagship product BOTOX®. Mr. Kevin Finney is an experienced biotech executive and director who has held numerous leadership roles in the healthcare industry, leading companies from -early stages of development through to commercialization. Mr. Kevin Finney has a B.A. in Exercise Physiology from California State University, Long Beach, and an MBA from Pepperdine Graziadio Business School.

Elaine J. Heron, Ph.D. has served as a member of our board of directors since August 2022. Dr. Heron has served on the board of directors of BioMarin Pharmaceutical Inc. (Nasdaq: BMRN) since July 2002. From February 2009 to October 2015, Dr. Heron served as Chair and CEO of Amplyx Pharmaceuticals, Inc., a private drug development company acquired by Pfizer, Inc. in April 2021. She currently serves on the boards of Visgenx, Inc., a private early-stage therapeutics company, BlueWhale Bio, Inc., a private early-stage therapeutics company, and Watershed Medical, Inc., a private early-stage therapeutics company. She is also an advisor to Kyto Technology and Life Science, Inc. (OTCQB: KBPH). From July 2001 to October 2008, Dr. Heron was Chair and CEO of Labcyte Inc., a private biotechnology company. Before joining Labcyte Inc., she spent six years in positions of increasing responsibility at the Applied Biosystems Group of Applera Corporation, a biotechnology company, including the position of General Manager and Vice President of Sales and Marketing. Dr. Heron earned a B.S. in chemistry with highest distinction and a Ph.D. in analytical biochemistry from Purdue University and an M.B.A. from Pepperdine University.

W. Mark Watson has served as a member of our board of directors since August 2022. Mr. Watson is a Certified Public Accountant with over 40 years of experience in public accounting and auditing, having spent his entire career from January 1973 to June 2013 at Deloitte Touche Tohmatsu and its predecessor, and his last position was Central Florida Marketplace Leader. He has served as lead audit partner and lead client service partner on public companies ranging from middle market firms to Fortune 500 enterprises. Mr. Watson also served as Chairman of the Board of Directors and Chairman of the Audit Committee of Inhibitor Therapeutics, Inc. and as a director and chair of the Audit Committee of Sykes Enterprises, Inc and BioDelivery Sciences International, Inc. Mr. Watson served as a trustee of Tekla World Healthcare Fund (THW), Tekla Healthcare Opportunities Fund (THW), Tekla Healthcare Investors (HQH), and Tekla Life Sciences Investors (HQL) until the Fall of 2023. Mr. Watson also serves on the Board of Moffitt Cancer Center and as its Audit Committee Chair. As a member of American Institute of Certified Public Accountants and the Florida Institute of Certified Public Accountants. He received his undergraduate degree in Accounting from Marquette University.

David Wheadon, M.D. has served as a member of our board of directors since April 2021. He served as Senior Vice President, Global Regulatory Affairs, Patient Safety and Quality Assurance for AstraZeneca Pharmaceuticals from 2014 to 2019 and as Executive Vice President, Research and Advocacy at the Juvenile Diabetes Research Foundation from 2013 to 2014. From 2009 to 2013, Dr. Wheadon served as Senior Vice President, Scientific and Regulatory Affairs and as a member of the Management Committee of the Pharmaceutical Research and Manufacturers of America ("PhRMA"). Prior to his joining PhRMA, Dr. Wheadon held senior regulatory and clinical development leader roles at Abbott Laboratories and GlaxoSmithKline plc. Dr. Wheadon began his career as a clinical research physician in neuroscience at Eli Lilly & Company. Dr. Wheadon currently serves on the board of directors of Sotera Health, Inc. He formerly served on the board of directors of Assertio Holdings, Inc. (formerly Assertio Therapeutics, Inc.), Karuna Therapeutics, Inc. and Chemocentryx, Inc. Dr. Wheadon holds an A.B. from Harvard College and an M.D. from Johns Hopkins University School of Medicine. He completed his fellowship training in Psychiatry at the Tufts, New England Medical Center.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has, during the past ten years, been involved in any legal proceedings that are required to be disclosed pursuant to the rules and regulations of the SEC.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Specific due dates for these reports have been established, and the Company is required to report any failure to comply therewith during the fiscal year ended December 31, 2024. During the fiscal year ended December 31, 2024, each of Messrs. Lee, Tucker, Berg, and Cummings filed one late Form 4 with respect to one transaction.

To our knowledge, based solely on a review of the reports filed electronically with the SEC during the Company's most recent fiscal year and, where applicable, written representations that no other reports were required, we believe that all other Section 16(a) filing requirements applicable to our executive officers, directors, and greater than 10% beneficial owners were complied with in a timely manner during the fiscal year ended December 31, 2024.

Code of Ethics

We have adopted a Code of Conduct that applies to all officers, directors, and employees, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Conduct is available on the Investors section of our website at *http://www.vaxart.com*. The Code of Conduct is a "code of ethics," as defined in Item 406(b) of Regulation S-K. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. The Company's website address is provided as an inactive textual reference only.

Director Nominations

No material changes have been made to the procedures by which stockholders may recommend nominees to our board of directors.

Audit Committee

The members of our Audit Committee are Mr. Kevin Finney, Dr. Heron, and Mr. Watson. Mr. Watson serves as Chair of the Audit Committee. The board of directors reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of the Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards). The board of directors determined that Mr. Watson qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The board of directors made a qualitative assessment of Mr. Watson's level of knowledge and experience based on a number of factors, including Mr. Watson's over 40 years of experience in public accounting and auditing and status as a Certified Public Accountant.

The primary purpose of the Audit Committee is to discharge the responsibilities of the board of directors with respect to our accounting, financial, and other reporting and internal control practices and to oversee its independent registered accounting firm. Specific responsibilities of the Audit Committee include:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit the Company's financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent auditors, the Company's interim and year-end operating results;
- developing procedures for employees to anonymously submit concerns about questionable accounting, ethical, and auditing matters;
- reviewing policies on risk assessment and risk management;
- reviewing with management the type and presentation of the Company's environmental, social and governance ("*ESG*") disclosures and the adequacy and effectiveness of applicable internal controls related to such disclosures;
- reviewing related party transactions in accordance with the Company's policies and procedures with respect to related party transactions;
- reviewing cyber risk on a quarterly basis and reporting to the board of directors;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes the independent auditor's internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law, as well as all relationships between the independent auditor and the Company or any of its subsidiaries; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit services, other than de minimis non-audit services, to be performed by the independent registered public accounting firm.

Insider Trading Policies and Procedures

The Company has adopted an insider trading policy that applies to any and all transactions by our directors, officers, and other employees, as well as consultants, contractors, advisors, and agents of the Company in our securities. Our insider trading policy prohibits such persons from engaging in speculative trading activities, including hedging transactions (such as zero-cost collars and forward sale contracts) or other inherently speculative transactions with respect to our securities, and from pledging our securities as collateral for any loans. It also prohibits such persons from purchasing or selling our securities while in possession of material nonpublic information and contains restrictions relating to pre-clearance procedures and blackout periods.

We believe our insider trading policy is reasonably designed to promote compliance with applicable U.S. federal securities laws and listing standards applicable to companies listed on The Nasdaq Capital Market.

Item 11. Executive Compensation

This section describes the 2024 compensation program established by the Compensation Committee for our named executive officers. Our named executive officers for 2024 were:

Name	Position
Steven Lo	President and Chief Executive Officer(1)
Michael J. Finney, Ph.D.	Interim Chief Executive Officer(2)
Andrei Floroiu, M.B.A.	Former President and Chief Executive Officer(3)
James Cummings, M.D.	Chief Medical Officer
Sean Tucker, Ph.D.	Senior Vice President and Chief Scientific Officer

(1) Mr. Lo was appointed to serve as President and Chief Executive Officer on March 18, 2024.
(2) Dr. Michael J. Finney served as Interim Chief Executive Officer from January 16, 2024, until Mr. Lo's appointment as President and Chief Executive Officer on March 18, 2024.
(3) Mr. Floroiu resigned as President and Chief Executive Officer of the Company on January 15, 2024.

Compensation Objectives

Our compensation objectives for 2024 are outlined below.

Compensation Objective	Description
Pay-For-Performance	Emphasize performance-based compensation to motivate executives to achieve strong financial, operational and individual performance in a manner that balances short-term and long-term results
Talent Retention	Attract and retain high-caliber executives who can effectively manage our complex global business.
Alignment with Stockholder Interests	Align our executives' interests with those of our stockholders by making stock-based incentives a core element of our executives' compensation.

Pay-for-Performance

The guiding principle of our compensation philosophy is that pay should be linked to performance and that the interests of executives and stockholders should be aligned. That principle is embedded in our compensation program, which is designed to optimize alignment between executive pay and actual results.

As described below, the variable components of our compensation program for 2024 were short-term incentives ("*STI*") and long-term incentives ("*LTI*"). Our STI opportunities were provided under an annual cash bonus plan, the payout of which was dependent on corporate and individual performance. Our LTI opportunities were provided through stock options and restricted stock units.

Say-on-Pay

The Compensation Committee has considered the results of the most recent stockholder advisory vote on executive compensation in determining compensation policies and decisions. The Company received support from our stockholders for our executive compensation program in 2024, with a favorable "say-on-pay" vote at our 2024 annual meeting of approximately 67% of the votes cast. The Compensation Committee viewed this result as confirmation that our compensation program is appropriately structured to support our strategic initiatives and our pay-for-performance commitment.

Market Practices

Competitive Compensation Levels

We believe that each element of our compensation program should remain competitive in order to retain, and, if necessary, attract experienced, high-caliber executives.

When setting 2024 compensation levels for the named executive officers, the Compensation Committee retained Aon Consulting, Inc. ("*Aon*") as its independent compensation consultant, reporting directly to the Compensation Committee and serving at the sole discretion of the Compensation Committee. During its engagement, Aon was asked to review competitive compensation data, including pay mix and compensation levels. The compensation data was derived from several sources, including the companies in a compensation peer group established by the Compensation Committee, upon advice of Aon, and select compensation surveys. Each of these sources is described below.

For 2024, the Compensation Committee generally attempted to structure compensation for named executive officers at approximately the 25th to 50th percentile of the market data. The Compensation Committee, however, retained discretion to adjust specific compensation elements and levels above or below these guidelines in order to respond to market conditions, promotions, new hires, individual performance or other circumstances.

Compensation Peer Group

The Compensation Committee, after obtaining advice from Aon, established the following criteria for the 2024 compensation peer group:

- U.S.-based, publicly traded, pre-commercial biopharmaceutical companies
- Headcount generally between 1/3 and 3x the Company's headcount
- Market capitalization generally between 1/3 and 3x the Company's market capitalization

Based on this criteria, the members of the compensation peer group for 2024 were as follows:

Compensation Peer Group	
Adverum Biotechnologies	Inhibrx Biosciences
Allakos	Inovio Pharmaceuticals
Altimmune	Iteos Therapeutics
ALX Oncology	Jasper Therapeutics
Arcturus Therapeutics	Kezar Life Sciences
Armata Pharmaceuticals	Ocugen
Atea Pharmaceuticals	RAPT Therapeutics
Cidara Therapeutics	Sutro Biopharma
Gossamer Bio	Vor Biopharma

The Compensation Committee also reviews market data from the Radford McLagan Compensation Database, which is provided by Aon.

Elements of Total Direct Compensation

A brief summary of our total direct compensation - consisting of base salary, STI opportunities and LTI opportunities - for our named executive officers is set forth below.

Annual Base Salaries

We provide a base salary to retain and attract key executive talent and to align our compensation with market practices. Base salaries are reviewed and established by the Compensation Committee on a competitive basis each year to align with market levels.

As noted above, Mr. Floroiu resigned as Chief Executive Officer on January 15, 2024, and therefore the Compensation Committee did not approve any adjustment to his base salary for 2024. Dr. Michael J. Finney agreed to serve as Interim Chief Executive Officer upon Mr. Floroiu's resignation and received a base salary at an annualized rate of $595,000. When Mr. Lo was appointed to serve as Chief Executive Officer, effective March 18, 2024, he received an annual base salary of $600,000.

During the annual performance review process in February 2024, the Compensation Committee approved a 3.5% merit increase for each of Dr. Cummings and Dr. Tucker, which increased Dr. Cummings's base salary to $473,616 and Dr. Tucker's base salary to $448,797, in each case effective March 1, 2024. In June 2024, based on the recommendation of Mr. Lo and applicable market factors, the board of directors approved an increase in the annual base salary for Dr. Cummings from $473,616 to $503,000, retroactive to June 1, 2024.

For more information about the 2024 base salaries for each of our named executive officers, please refer to the "Salary" column of the 2024 Summary Compensation Table on page 96.

Short-Term Incentive Compensation

The STI program is designed to motivate our named executive officers to achieve annual business plan objectives and individual goals.

Each year the Compensation Committee establishes a STI award opportunity for our named executive officers. As noted above, Mr. Floroiu resigned as Chief Executive Officer on January 15, 2024, and therefore he did not participate in the 2024 STI program. Dr. Michael J. Finney agreed to serve as Interim Chief Executive Officer upon Mr. Floroiu's resignation, and he participated in the 2024 STI program with an award opportunity equal to 50% of his annual base salary (pro-rated for 2024). When Mr. Lo was appointed to serve as Chief Executive Officer, effective March 18, 2024, he commenced participation in the 2024 STI program with an award opportunity equal to 50% of his annual base salary. The Compensation Committee did not make any changes to the STI award opportunities for Dr. Cummings and Dr. Tucker, which remained at 40% of their annual base salary.

The 2024 STI payout levels were determined by the Compensation Committee based on an overall assessment of corporate performance and individual contributions. The Compensation Committee approved certain corporate goals and objectives at the beginning of the year that generally focused on deliverables with respect to five primary areas: the norovirus program, COVID-19, other programs (including Influenza and HPV Therapeutic programs), manufacturing, and finance. Based on its assessment of overall corporate performance and the individual contributions of each participating executive, and its desire to retain a management team that is essential to our continued success, the Compensation Committee recommended, and the board of directors approved, an overall achievement level of 92% for the 2024 STI program, which funded a bonus pool that was allocated among the named executive officers based on recommendations of the Chief Executive Officer (other than with respect to himself) and final approval by the board of directors.

The amount of the 2024 STI award payable to each named executive officer is set forth in the "Non-Equity Incentive Plan Compensation" column of the 2024 Summary Compensation Table of this proxy statement at page 96.

Long-Term Incentives

The Compensation Committee believes that a competitive LTI program is an important component of total direct compensation because it: (i) enhances the retentive value of our compensation; (ii) rewards executives for increasing our stock price and developing long-term value; and (iii) provides executives with an opportunity for stock ownership to align their interests with those of our stockholders.

As noted above, Mr. Floroiu resigned as Chief Executive Officer on January 15, 2024, and therefore he did not participate in the 2025 LTI program. Dr. Michael J. Finney agreed to serve as Interim Chief Executive Officer upon Mr. Floroiu's resignation, but he did not participate in the 2024 LTI program given his short tenure in that role. When Mr. Lo was appointed to serve as Chief Executive Officer, effective March 18, 2024, he received a grant under the Vaxart, Inc. 2024 Inducement Award Plan consisting of a stock option to purchase 1,000,000 shares that vests one-fourth on the first anniversary of his start date and thereafter in equal monthly installments over the next three years, and a restricted stock unit award covering 250,000 shares that vests in four equal annual installments.

During the annual performance review process in 2024, the Compensation Committee, with the help of Aon, its independent compensation consultant, conducted a review of the LTI award opportunities for our officers. The Compensation Committee recommended, and the board of directors approved, a grant to each of Dr. Cummings and Dr. Tucker, consisting of a stock option to purchase 410,000 shares that vests one-fourth on the first anniversary of the vesting commencement date and thereafter in equal monthly installments over the next three years, and a restricted stock unit award covering 90,000 shares that vests in four equal annual installments.

2024 Trial Launch Bonus Program

In February 2024, the board of directors, upon the recommendation of the Compensation Committee, approved a $1,000,000 bonus pool under a Trial Launch Bonus Program, that would be allocated and payable to each employee selected by the Chief Executive Officer (including Dr. Cummings and Dr. Tucker). Under this program, each of Dr. Cummings and Dr. Tucker were eligible to a pro-rata share of the bonus pool equal to 30% of his annual salary as in effect as of December 31, 2023, if he remained employed through the date that the first 1,000 volunteers in the Phase 2 trial had been dosed. To date, there have been no payouts related to the Trial Launch Bonus Program.

Additional Compensation Arrangements

Severance Benefit Plan

During 2024, each of the named executive officers, other than Dr. Michael J. Finney, participated in the Severance Benefit Plan (the "*Severance Plan*").

Under the Severance Plan, if a participating named executive officer were terminated other than for cause, death or disability, or resigned for good reason, other than in connection with a change in control, he would be entitled to receive (i) continued payment of base salary for six months (twelve months for Mr. Lo), and (ii) the portion of health insurance premiums paid by the Company, prior to the termination, under our group health insurance plans as provided under COBRA, until the end of the applicable salary continuation period (or, if earlier, such time as the named executive officer is eligible for health insurance coverage with a subsequent employer).

If a participating named executive officer were terminated other than for cause, death or disability, or resigned for good reason, either during the three months before or in the twelve months after a change in control, then he would be entitled to receive (in lieu of the benefits described above): (i) lump sum cash severance equal twelve months of base salary, (ii) the portion of health insurance premiums paid by the Company, prior to the termination, under our group health insurance plans as provided under COBRA, until the end of the applicable salary continuation period (or, if earlier, such time as the named executive officer is eligible for health insurance coverage with a subsequent employer), (iii) full vesting of any unvested time-based equity awards, and (iv) a pro-rated target annual bonus for the year of termination.

In exchange for the severance benefits, the participating named executive officers must agree to comply with the Company's standard employee invention assignment and confidentiality agreement, return all company property, and sign a release of claims in favor of the Company.

For purposes of the Severance Plan, the term "cause" generally means (i) engaging in willful or gross misconduct or willful or gross neglect; (ii) the commission of a felony or a crime involving any of the following: moral turpitude, dishonesty, breach of trust or unethical business conduct; or the commission of any crime involving the Company or any of its subsidiaries; (iii) fraud, misappropriation or embezzlement; or (iv) the abuse of illegal drugs or other controlled substances or habitual intoxication while providing services for the Company or any of its affiliates.

The term "good reason" generally means the occurrence of any of the following events without the participant's consent; (i) a material diminution in base salary or target bonus; (ii) a material diminution in authority, duties, or responsibilities; or (iii) a relocation of the principal place of employment or service to a location that increases his or her one-way commute distance by more than 35 miles, subject to applicable notice and cure provisions.

The Severance Plan does not provide a tax gross-up for named executive officers or any other employees in the event they are subject to golden parachute excise taxes on severance or other payments received in connection with a change in control. The Severance Plan promotes retention incentives for our executives by establishing severance protections for participants that are consistent with market levels, while eliminating the need to negotiate individual severance agreements in connection with an executive's termination or at the time of hire. The enhanced benefits available upon a change in control increase our retention incentives by reducing the personal uncertainty that arises from the possibility of a future business combination and promoting objectivity in the evaluation of transactions that are in the best interests of our stockholders.

Mr. Lo

In connection with his appointment as President and Chief Executive Officer, Mr. Lo entered into a letter agreement with the Company, dated as of February 21, 2024. The letter agreement provided for an initial base salary equal to $600,000, a target STI award opportunity equal to 50% of his annual base salary and a grant under the Vaxart, Inc. 2024 Inducement Award Plan consisting of a stock option to purchase 1,000,000 shares that vests one-fourth on the first anniversary of his start date and thereafter in equal monthly installments over the next three years, and a restricted stock unit award covering 250,000 shares that vests in four equal annual installments. The letter agreement also provides that Mr. Lo will participate in the Severance Plan, with a severance multiple equal to twelve months.

Dr. Michael J. Finney

In connection with his appointment as Interim Chief Executive Officer, Dr. Michael J. Finney entered into a letter agreement with the Company, dated as of January 16, 2024. The letter agreement provided for a base salary equal to $595,000, and a target STI award opportunity equal to 50% of his annual base salary (pro-rated for the 2024 fiscal year). Given his short tenure in the potion, Dr. Michael J. Finney did not participate in the LTI program or the Severance Plan.

Mr. Floroiu

In connection with his appointment as Chief Executive Officer of the Company, Mr. Floroiu entered into a letter agreement with the Company, dated as of June 14, 2020. The letter agreement provided for an initial base salary of $400,000 per year, an initial "target" bonus opportunity of 50% of his annual base salary and coverage under the Severance Plan, with his "Non-CiC Severance Period", as defined in the Severance Plan, set at three months and his "CiC Severance Period", as defined in the Severance Plan, set at six months. On May 2, 2023, the board of directors approved an amendment to Mr. Floroiu's offer letter to increase his "Non-CiC Severance Period" to 6 months, and to increase his "CiC Severance Period" to 12 months.

Under his letter agreement, Mr. Floroiu received a stock option on June 15, 2020 to purchase 845,280 shares of the Company's common stock at a strike price equal to the closing price of the Company's common stock on the grant date, which vests as follows: 25% on the first anniversary of the grant date and 75% in equal monthly installments over the three-year period commencing on such first anniversary, with accelerated vesting with respect to 50% of any then-unvested option shares upon the Company's execution of a strategic agreement, as determined by the board, and with accelerated vesting in full in the event of a "change in control". On that same date, Mr. Floroiu received a stock option to purchase 900,000 shares of the Company's common stock at a strike price equal to the closing price of the Company's common stock on the grant date, which vested as follows: (i) one-third if the Company achieves a per share closing price equal to $5.00 or more during any 10-consecutive trading days after the grant date but before November 30, 2020 or such later date as determined by the board (the "*Reference Date*"), (ii) one-third if the Company achieves a per share closing price equal to $7.50 or more during any 10-consecutive trading days after the grant date but before the Reference Date, and (iii) one-third if the Company achieves a per share closing price equal to $10.00 or more during any 10-consecutive trading days after the grant date but before the Reference Date, in each case subject to continued employment. The performance-based stock option has already vested in full. Mr. Floroiu will not receive any non-employee director cash retainers or other compensation under the Company's director compensation program for his services as a director while he is serving as Chief Executive Officer. In addition, the letter

agreement provides that during the period of his employment with the Company and for a period of two years thereafter, Mr. Floroiu will not compete anywhere in the world outside the State of California with the Company to develop, sell, market, or offer to sell products that are competitive with any products being developed or sold by the Company.

On January 31, 2024, the Company entered into a Separation Agreement with Mr. Floroiu in connection with his termination without cause. Pursuant to the separation agreement, the Company agreed to provide Mr. Floroiu with the following payments and benefits: (i) continued base salary for 12 months, (ii) subsidized health insurance premiums for 12 months, (iii) the 2023 bonus, if any, to which he would have been entitled to receive had he remained employed by the Company through the payout date, (iv) reimbursement of up to $5,000 in attorney fees incurred in negotiating the agreement, (v) accelerated vesting of his equity awards that would have vested through September 30, 2024, and (vi) up to two years to exercise his vested stock options after termination of employment. In exchange for these benefits, Mr. Floroiu signed a release of claims in favor of the Company and agreed to certain confidentiality, non-competition, non-solicitation of personnel and customers, non-disparagement and cooperation covenants. The separation benefits were conditioned upon Mr. Floroiu's non-revocation of the release of claims and his compliance with the restrictive covenants.

Dr. Cummings

In connection with his appointment as Senior Vice President and Chief Medical Officer of the Company, Dr. Cummings entered into a letter agreement with the Company, dated as of August 16, 2021. The letter agreement provides for an initial base salary of $400,000 per year, an initial "target" bonus opportunity of 40% of his annual base salary and an initial grant of a stock option covering 300,000 shares (effective when he commenced the consulting services described below). In addition, the letter agreement provided that, prior to his start date, Dr. Cummings would provide certain consulting services to the Company at the direction of the Chief Executive Officer with respect to clinical and regulatory matters (including clinical trial design and regulatory strategies both in the U.S. and abroad), interactions with pan-governmental organizations such as WHO and CEPI, and business development activities. Dr. Cummings received a consulting fee at the rate of $100 per hour for these services and entered into a standard consulting agreement with the Company, which terminated on September 26, 2021, the day prior to the date he commenced employment.

Dr. Tucker

In connection with his appointment as Vice President, Research and Director of Immunology, Dr. Tucker entered into a letter agreement with the Company, dated as of May 20, 2006. The letter agreement provided that, if Dr. Tucker's employment were terminated without "cause", or he voluntarily resigned for "good reason", then one-half of his then outstanding and unvested stock options shall vest and become immediately exercisable, except that if there are fewer than one-half of the option shares unvested at that time, then all remaining unvested option shares would vest and become immediately exercisable. During the term of his employment, Dr. Tucker agreed that he would not render any commercial or professional services of any nature to any person or organization, whether or not for compensation, without the prior written consent of the board of directors. He also agreed not to directly or indirectly engage or participate in any business that is competitive with the Company's business.

Retirement Plan

We maintain a tax-qualified retirement plan that provides eligible employees, including our named executive officers, with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees may defer eligible compensation up to certain tax code limits, which are updated annually. Employees are immediately and fully vested in their own contributions. We make matching contributions to participants in the 401(k) plan annually in arrears in an amount equal to the employee's deferral up to a maximum of 3% of the employee's annual eligible earnings, which are immediately and fully vested. As a tax-qualified retirement plan, contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not taxable to the employees until withdrawn or distributed from the 401(k) plan. The named executive officers did not participate in, or otherwise receive any benefits under any pension plan or nonqualified deferred compensation plan.

2024 Summary Compensation Table

The following table provides information regarding the compensation for services rendered that was earned by our named executive officers during the years ended December 31, 2024 and 2023.

Name and Principal Position	Fiscal Year	Salary	Stock Awards(1)	Option Awards(2)	Non-Equity Incentive Plan Compensation(3)	All Other Compensation(4)	Total
Steven Lo(5)	2024	$ 473,810	$ 290,000	$ 1,044,370	$ 272,000	$ 5,588	$ 2,085,768
President and Chief Executive Officer	2023	$ —	$ —	$ —	$ —	$ —	$ —
Michael J. Finney, Ph.D.(6)	2024	$ 110,521	$ 12,312	$ 66,069	$ 46,364	$ 70,124	$ 305,390
Former Interim Chief Executive Officer	2023	$ —	$ —	$ —	$ —	$ —	$ —
Andrei Floroiu, M.B.A.(5)	2024	$ 81,403	$ 76,700	$ 1,027,902	$ —	$ 745,351	$ 1,931,356
Former President and Chief Executive Officer	2023	$ 568,333	$ 286,833	$ 801,895	$ 198,917	$ 10,866	$ 1,866,844
James Cummings, M.D.	2024	$ 488,087	$ 104,400	$ 428,192	$ 179,700	$ 12,156	$ 1,212,535
Chief Medical Officer	2023	$ 454,667	$ 151,593	$ 428,840	$ 128,128	$ 11,706	$ 1,174,934
Sean Tucker, Ph.D.	2024	$ 446,267	$ 104,400	$ 428,192	$ 164,300	$ 11,872	$ 1,155,031
Chief Scientific Officer	2023	$ 428,267	$ 147,542	$ 428,840	$ 121,414	$ 11,422	$ 1,137,485

(1) Reflects the grant date fair value of time-based restricted stock unit awards computed in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. See Note 10 to the consolidated financial statements included in this Annual Report for a discussion of the relevant assumptions used in calculating value pursuant to FASB ASC Topic 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For Mr. Floroiu, the amounts also include the incremental fair value of restricted stock unit awards, calculated in accordance with FASB ASC Topic 718 as a result of the accelerated vesting of those awards in connection with his termination.

(2) Reflects the grant date fair value of stock option awards for the applicable year computed in accordance with ASC Topic 718. See Note 10 to the consolidated financial statements included in this Annual Report for a discussion of the relevant assumptions used in calculating the grant date fair value pursuant to FASB ASC Topic 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options. For Mr. Floroiu, the amounts also include the incremental fair value of restricted stock unit awards, calculated in accordance with FASB ASC Topic 718 as a result of the accelerated vesting and extended exercisable period of those awards in connection with his termination.

(3) Reflects the bonuses awarded to the named executive officers for the applicable year under the Short-Term Incentive Program.

(4) Reflects an employer match under the Company's 401(k) plan, premiums paid by the Company under the group-term life insurance program, and an employer match under the Health Savings Account as applicable. For Mr. Floroiu, the amounts also include the cash severance benefits that he received in connection with his termination, including (i) continued base salary for 12 months and (ii) subsidized health insurance premiums for 12 months. For Dr. Michael J. Finney, the amounts also include compensation received as a non-employee director during 2024.

(5) On January 15, 2024, Mr. Floroiu resigned as President and Chief Executive Officer of the Company. On March 18, 2024, Mr. Lo was appointed to serve as President and Chief Executive Officer.

(6) Dr. Michael J. Finney, who serves on the board of directors, also served as Interim Chief Executive Officer from January 16, 2024, until Mr. Lo's appointment as President and Chief Executive Officer on March 18, 2024. The amount reported in the "Salary" column reflects the base salary that Dr. Michael J. Finney earned in his role as Interim Chief Executive Officer from January 16, 2024, until March 18, 2024, and the amount reported in the "Non-Equity Incentive Plan Compensation" column reflects the pro-rated bonus that Dr. Michael J. Finney received under the 2024 annual bonus program. The amount reported in the "Stock Awards" and "Option Awards" columns reflect equity retainers that Dr. Michael J. Finney received, and the amounts reported in the "All Other Compensation" column reflect cash retainers that Dr. Michael J. Finney received, in each case for his services as a non-employee director in 2024 (i.e., when he was not serving as Interim Chief Executive Officer) under the Company's Non-Employee Director Compensation Program.

Outstanding Equity Awards as of December 31, 2024

The following table presents, for each of our named executive officers, information regarding outstanding stock options and RSUs held as of December 31, 2024.

	Options Awards					Stock Awards	
Name	Vesting commencement date	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Options exercise price ($)	Options expiration date	Number of shares or units of stock that have not vested	Market value of shares or units of stock that have not vested(1)
Steven Lo	3/18/2024	—	1,000,000(2)	$ 1.16	3/17/2034		
	3/18/2024					250,000(3)	$ 165,000
Michael J. Finney, Ph.D.	6/8/2020	65,700(5)	—	$ 2.39	6/7/2030		
	6/16/2021	15,097(5)	—	$ 7.79	6/15/2031		
	8/4/2022	44,224(5)	—	$ 3.91	8/3/2032		
	6/26/2023	44,224(5)	—	$ 0.74	6/25/2033		
	6/11/2024	—	95,400(4)	$ 0.77	6/10/2034		
	6/12/2024					16,000(4)	$ 10,560
Andrei Floroiu, M.B.A. (6)		(5)					
	6/8/2020	54,720	—	$ 1.71	1/15/2026		
	6/15/2020	900,000(5)	—	$ 2.46	1/15/2026		
	6/15/2020	845,280(5)	—	$ 2.46	1/15/2026		
	6/16/2021	218,750(5)	—	$ 6.27	1/15/2026		
	3/28/2022	343,750(5)	—	$ 5.09	1/15/2026		
	3/17/2023	296,875(5)	—	$ 0.78	1/15/2026		
	3/17/2023	400,000(5)	—	$ 0.78	1/15/2026		
James Cummings, M.D.	8/16/2021	250,000	50,000(2)	$ 8.44	8/15/2031		
	3/28/2022	180,469	82,031(2)	$ 5.09	3/27/2032		
	3/28/2022					21,874(3)	$ 14,437
	3/17/2023	187,917	222,083(2)	$ 0.78	3/16/2033		
	3/17/2023	205,000(5)	—	$ 0.78	3/16/2033		
	3/17/2023					67,500(3)	$ 44,550
	3/18/2024	—	410,000(2)	$ 1.16	3/17/2034		
	3/18/2024					90,000(3)	$ 59,400
Sean Tucker, Ph.D.	7/23/2015	10,067(5)	—	$ 17.49	7/22/2025		
	3/25/2016	7,731(5)	—	$ 12.98	3/24/2026		
	6/14/2017	9,060(5)	—	$ 4.07	6/23/2027		
	2/13/2018	14,000(5)	—	$ 5.17	5/24/2028		
	5/10/2019	84,061(5)	—	$ 0.77	5/11/2029		
	3/24/2020	360,000(5)	—	$ 1.70	3/23/2030		
	3/25/2021	93,750	6,250(2)	$ 6.27	3/24/2031		
	3/28/2022	180,469	82,031(2)	$ 5.09	3/27/2032		
	3/28/2022					21,874(3)	$ 14,437
	3/17/2023	205,000(5)	—	$ 0.78	3/16/2033		
	3/17/2023	187,917	222,083(2)	$ 0.78	3/16/2033		
	3/17/2023					67,500(3)	$ 44,550
	3/18/2024	—	410,000(2)	$ 1.16	3/17/2034		
	3/18/2024					90,000(3)	$ 59,400

(1) Market value of restricted stock units that have not vested was determined by multiplying the number of shares by $0.66, the closing price of our common stock on December 31, 2024.

(2) The option award vests as to 25% of the underlying shares on the first anniversary of the applicable vesting commencement date and in 36 equal monthly installments thereafter.

(3) Represents remainder of an award that vest in four equal annual installments beginning on the first anniversary of the applicable vesting commencement date.

(4) The award fully vests on the earlier of the date immediately preceding the date of the annual meeting of stockholders of the Company held in the year following the vesting commencement date and the first anniversary of the vesting commencement date.

(5) The shares subject to these options are fully vested.

(6) All restricted stock units and options ceased to vest upon Mr. Floroiu's resignation on January 15, 2024. Any unvested equity awards at such time were forfeited.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

While we do not have a formal written policy in place with regard to the timing of awards of options in relation to the disclosure of material nonpublic information, our board of directors and the Compensation Committee do not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Similarly, it is our practice not to time the release of material nonpublic information based on equity award grant dates or for the purpose of affecting the value of executive compensation.

Director Compensation

During 2024, our non-employee directors were compensated in the following manner under our director compensation program.

The Company's director compensation program is designed to enhance our ability to attract and retain highly qualified directors and to align their interests with the long-term interests of its stockholders. The program includes a cash component, which is intended to compensate non-employee directors for their service on our board of directors and an equity component, which is intended to align the interests of non-employee directors and stockholders. Directors who are employees of the Company receive no additional compensation for their service on our board of directors.

The Compensation Committee annually reviews compensation paid to our non-employee directors and makes recommendations for adjustments, as appropriate, to the full board of directors. As part of this annual review, the Compensation Committee considers the significant time commitment and skill level required by each non-employee director in serving on our board of directors and its various committees. The Compensation Committee seeks to maintain a market competitive director compensation program and, with the assistance of its independent compensation consultant, benchmarks our director compensation program against those maintained by the peer group we use to evaluate our executive compensation program.

Under the director compensation program for 2024, our non-employee directors received the following cash compensation for their service on our board of directors and its committees:

- $40,000 annual cash retainer;
- $30,000 for the Chair of the board of directors;
- $20,000 for the chair of the Audit Committee and $10,000 for each of its other members;
- $12,000 for the chair of the Compensation Committee, and $6,000 for each of its other members;
- $10,000 for the chair of the Nominating and Governance Committee, and $5,000 for each of its other members; and
- $15,000 for the chair of the Science and Technology Committee, and $7,500 for each of its other members.

In February 2024, the Compensation Committee approve an additional cash retainer of $20,000 for Mr. Yedid to recognize the significant time that he had spent, in his capacity as a member of the board of directors, assisting and advising the Company on certain strategic transactions, financings and management issues.

In addition, each non-employee director who is initially elected or appointed to the board after the effective date of the program shall automatically be granted on the day of such first election or appointment: (i) a stock option to purchase 190,800 shares of our shares of common stock, and (ii) a RSU award covering 32,000 shares of our common stock (the "*Initial Award*"). Each Initial Award shall vest and become exercisable in substantially equal installments on each of the first three anniversaries of the date of grant, subject to the non-employee director continuing in service on the board through each such vesting date.

A non-employee director who is serving on the board as of the date of any annual meeting after the effective date of the program, and who will continue to serve as a non-employee director immediately following such meeting, shall automatically be granted on the date of such annual meeting: (i) a stock option to purchase 95,400 shares of our common stock, and (ii) a RSU award covering 16,000 shares of our common stock (the "*Annual Award*"), which amounts are pro-rated for new directors to reflect their service since the last annual meeting. Each Annual Award shall vest and become exercisable on the earlier of (x) the first anniversary of the date of grant, or (y) the date immediately prior to the next annual meeting of the Company's stockholders following the date of grant, subject to the non-employee director continuing in service on the board through such vesting date.

Upon a change in control, all outstanding equity awards that are held by a non-employee director shall become fully vested and exercisable.

2024 Director Compensation

The following table provides director compensation information for each of the non-employee directors of the board of directors who served between January 1, 2024, and December 31, 2024. Dr. Michael J. Finney served as Interim Chief Executive Officer from January 16, 2024 until March 18, 2024 and, therefore, his compensation, including compensation received as a non-employee director during 2024, is included in the Summary Compensation Table.

Name	Fees earned or paid in cash	Stock Awards	Option Awards	Total
Elaine J. Heron, Ph.D.	$ 65,398	$ 12,312	$ 66,069	$ 143,779
W. Mark Watson	$ 64,500	$ 12,312	$ 66,069	$ 142,881
David Wheadon, M.D.	$ 68,595	$ 12,312	$ 66,069	$ 146,976
Robert A. Yedid[1]	$ 80,152	$ 12,312	$ 66,069	$ 158,533

(1) Mr. Yedid resigned as a director on January 28, 2025.

Name	Number of shares underlying RSUs	Number of shares underlying stock options
Elaine J. Heron, Ph.D.	16,000	95,400
W. Mark Watson	16,000	95,400
David Wheadon, M.D.	16,000	95,400
Robert A. Yedid	16,000	95,400

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information as of December 31, 2024, under equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, restricted stock units and rights (a)[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 (a))[3]
Equity compensation plans approved by security holders	22,025,470	$ 2.57	20,409,276
Equity compensation plans not approved by security holders	1,396,250	$ 1.12	1,603,750
Total	23,421,720	$ 2.49	22,013,026

(1) Includes 20,405,239 shares issuable upon the exercise of stock options outstanding under the 2016 Equity Incentive Plan, the 2019 Equity Incentive Plan and the 2024 Inducement Award Plan, and 3,016,481 shares issuable upon the vesting and payment of outstanding time-based restricted stock units outstanding under the 2019 Equity Incentive Plan and the 2024 Inducement Award 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 19,650,124 shares of common stock available for future issuance under the 2019 Equity Incentive Plan and the 2024 Inducement Award Plan, and 2,362,902 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.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information, as of March 14, 2025, with respect to the beneficial ownership of our common stock by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 227,949,245 shares of common stock outstanding as of March 14, 2025. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to the exercise of options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 14, 2025 are counted as outstanding. Unless noted otherwise, the address of all listed stockholder is 170 Harbor Way, Suite 300, South San Francisco, California. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owners	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders		
Sio Capital Management, LLC	11,515,315(1)	5.1%
Named Executive Officers and Directors		
Steven Lo	333,333(2)	*
Andrei Floroiu, M.B.A.	3,266,985(3)	1.4%
James Cummings, M.D.	1,247,102(4)	*
Sean Tucker, Ph.D.	1,613,568(5)	*
Michael J. Finney, Ph.D.	840,085(6)	*
Kevin Finney	—(7)	*
Elaine J. Heron, Ph.D.	120,124(8)	*
W. Mark Watson	160,397(9)	*
David Wheadon, M.D.	168,898(10)	*
Robert A. Yedid(12)	197,975(11)	*
All directors and executive officers as a group (10 individuals)(13)	6,152,070	2.7%

* Less than 1.0%

(1) Based solely on a Schedule 13G filed on February 10, 2025, by Sio Capital Management, LLC ("Sio Capital"). Consists of 11,515,315 shares of common stock held by various investors, for which Sio Capital serves as an investment adviser. Sio Capital may be deemed to beneficially own the 11,515,315 shares of common stock but disclaims beneficial ownership of such shares. The principal business office of Sio Capital is 600 Third Avenue, 2nd Floor, New York, New York 10016.

(2) Consists of 270,833 shares issuable pursuant to stock options exercisable and 62,500 shares issuable pursuant to restricted stock unit vesting within 60 days of March 14, 2025.

(3) Consists of (i) 207,610 shares of common stock held directly by Mr. Floroiu, and (ii) 3,059,375 shares issuable pursuant to stock options exercisable within 60 days of March 14, 2025.

(4) Consists of (i) 192,947 shares of common stock held directly by Dr. Cummings, and (ii) 1,024,010 shares issuable pursuant to stock options exercisable and 30,145 shares issuable pursuant to restricted stock unit vesting within 60 days of March 14, 2025.

(5) Consists of (i) 189,579 shares held directly by Dr. Tucker, (ii) 51,465 shares held jointly by Frances Chang and Dr. Tucker, (iii) 9,060 shares held by Dr. Tucker's spouse, and (iv) 1,333,929 shares issuable pursuant to stock options exercisable and 29,535 shares issuable pursuant to restricted stock unit vesting within 60 days of March 14, 2025.

(6) Consists of (i) 670,840 shares of common stock held directly by Dr. Michael J. Finney, and (ii) 169,245 shares issuable pursuant to stock options exercisable vesting within 60 days of March 14, 2025.

(7) Mr. Kevin Finney does not own any common stock of the Company.

(8) Consists of (i) 19,649 shares of common stock held directly by Dr. Heron, and (ii) 100,475 shares issuable pursuant to stock options exercisable vesting within 60 days of March 14, 2025.

(9) Consists of (i) 57,208 shares of common stock held directly by Mr. Watson, and (ii) 103,189 shares issuable pursuant to stock options exercisable vesting within 60 days of March 14, 2025.

(10) Consists of (i) 14,750 shares of common stock held directly by Dr. Wheadon, and (ii) 154,148 shares issuable pursuant to stock options exercisable vesting within 60 days of March 14, 2025.

(11) Consists of (i) 18,490 shares of common stock held directly by Mr. Yedid, and (ii) 179,485 shares issuable pursuant to stock options exercisable vesting within 60 days of March 14, 2025.

(12) Mr. Yedid resigned as a director on January 28, 2025.

(13) Does not include Mr. Floroiu, who resigned as President and Chief Executive Officer of the Company and as a member of the board of directors in January 2024, and Mr. Yedid, who resigned as a member of the board of directors in January 2025.

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

Related-Party Transaction Policy and Procedures

We have adopted a written Related Party Transaction Policy that sets forth our policies and procedures regarding the identification, review, consideration and approval or ratification of "related party transactions." For purposes of our policy only, a "related party transaction" is a transaction, arrangement or relationship (including indebtedness or a guarantee of indebtedness) or any series of similar transactions, arrangements or relationships in which we and any "related party" are, were or will be participants involving an amount that exceeds $120,000 and in which any "related party" has a direct or indirect material interest. Certain types of related party transactions are deemed to be pre-approved or ratified, as applicable, including: (i) the payment of compensation by us to our executive officers or directors; and (ii) a transaction where the related party's interest arises solely from the ownership of a class of equity securities of the Company and all holders of that class of equity securities received the same benefit on a pro rata basis. A related party is any executive officer, director, nominee to become a director or more than 5% stockholder of us, including any of their immediate family members, and any entity owned or controlled by such persons. We describe below such transactions or series of similar transactions to which we have been or were a party since January 1, 2023.

Under the policy, where a transaction has been identified as a related party transaction, management must present information regarding the proposed related party transaction to the Audit Committee (or, where Audit Committee approval would be inappropriate, to another independent body of the board of directors) for consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related parties, the benefits to us of the transaction and whether any alternative transactions were available. To identify related party transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related party transactions, the Audit Committee takes into account the relevant available facts and circumstances including, but not limited to (a) the risks, costs and benefits to us, (b) the impact on a director's independence in the event the related party is a director, immediate family member of a director or an entity with which a director is affiliated, (c) the terms of the transaction, (d) the availability of other sources for comparable services or products and (e) the terms available to or from, as the case may be, unrelated third parties or to or from employees generally. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval. The policy requires that, in determining whether to approve, ratify or reject a related party transaction, the Audit Committee consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, the best interests of us and our stockholders, as the Audit Committee determines in the good faith exercise of its discretion.

Certain Related-Person Transactions

Indemnity Agreements

We have entered into indemnity agreements with our executive officers and directors which provide, among other things, that we 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 our Bylaws.

Letter Agreements

We have entered into letter agreements, employment agreements and change in control arrangements with our executive officers. For more information regarding these agreements, see the "Executive Compensation" section of this Annual Report.

On January 31, 2024, we entered into a Separation Agreement with Mr. Floroiu, our former President and Chief Executive Officer. For a description of Mr. Floroiu's separation arrangements, see the "Executive Compensation" section of this Annual Report.

Equity Grants

We have granted stock options to our executive officers and members of our board of directors. For a description of our executive officers' options, see the "Executive Compensation — Outstanding Equity Awards as of December 31, 2024" section of this Annual Report.

Independence of the Board of Directors

As required under The Nasdaq Stock Market ("*Nasdaq*") listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. The board of directors consults with our counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and us, our senior management and our independent auditors, the board of directors has affirmatively determined that all of our current directors, other than Mr. Lo due to his positions as our current President and Chief Executive Officer, are independent within the meaning of the applicable Nasdaq listing standards. In making this determination, the board of directors found that none of the independent nominees for director had a material or other disqualifying relationship with Vaxart.

Item 14. Principal Accounting Fees and Services

WithumSmith+Brown, PC serves as our independent registered public accounting firm.

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2024 and 2023 by our auditors:

	December 31, 2024	December 31, 2023
Audit Fees	$ 730,038	$ 669,361
Audit-Related Fees	$ —	$ —
Tax fees	$ —	$ —
Other Fees	$ —	$ —
Total	$ 730,038	$ 669,361

The Audit Committee has adopted a policy and procedure for pre-approving all audit and non-audit services to be performed by our independent auditors. The policy requires pre-approval of all services rendered by our independent auditors either as part of the Audit Committee's approval of the scope of the engagement of the independent auditors or on a case-by-case basis.

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	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	8-K	001-35285	3.1	June 13, 2024
3.8	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 3.8				
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				
4.12	Amended and Restated Warrant issued to Oxford Finance LLC, dated February 13, 2018	8-K	001-35285	10.2	February 20, 2018
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	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
10.17	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
10.18 #	Severance Benefit Plan and Form of Severance Benefit Plan Participation Notice	8-K	001-35285	10.1	June 6, 2018
10.19 #	2019 Equity Incentive Plan, as amended	8-K	001-35285	10.1	June 21, 2021
10.20 #	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
10.21 #	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
10.22 +	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
10.23	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
10.24 #	Offer Letter, dated May 1, 2006, by and between the Company and Dr. Sean Tucker	10-Q	001-35285	10.2	May 12, 2020
10.25 #	Letter Agreement, dated June 14, 2020, between Vaxart, Inc. and Andrei Floroiu	8-K	001-35285	10.2	June 15, 2020
10.26 +	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
10.27 +	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
10.28 +	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
10.29	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
10.30	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
10.31	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
10.32 #	Offer Letter, dated August 16, 2021, by and between the Company and James Cummings MD	10-Q	001-35285	10.4	November 4, 2021
10.33 #	Offer letter, dated January 18, 2022, by and between the Company and Edward Berg	10-K	001-35285	10.46	February 24, 2022
10.34 #	Non-Employee Director Compensation Program, effective as of April 1, 2022	10-Q	001-35285	10.2	May 9, 2022
10.35 #	Non-Employee Director Compensation Program, effective as of April 1, 2024	10-Q	001-35285	10.1	August 8, 2024
10.36 +	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
10.37 #	2019 Equity Incentive Plan	8-K	001-35285	10.1	June 13, 2024
10.38 #	2022 Employee Stock Purchase Plan	8-K	001-35285	10.2	June 13, 2024
10.39 #	Offer Letter, dated December 5, 2022, by and between the Company and Phillip Lee	10-K	001-35285	10.53	March 15, 2023
10.40 #	Amendment to Letter Agreement dated May 2, 2023, between Andrei Floroiu and Vaxart, Inc.	10-Q	001-35285	10.1	May 4, 2023
10.41 #	Amendment to the Vaxart, Inc. Severance Benefit Plan dated May 2, 2023	10-Q	001-35285	10.2	May 4, 2023
10.42 #	Letter Agreement, dated January 16, 2024, between Vaxart, Inc. and Michael J. Finney	8-K	001-35285	10.1	January 16, 2024
10.43	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-K	001-35285	10.59	March 13, 2024
10.44	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
10.45 #	Separation Agreement, dated January 31, 2024, by and between the Company and Andrei Floroiu	8-K	001-35285	10.1	February 2, 2024
10.46 #	Vaxart, Inc. 2024 Inducement Award Plan	8-K	001-35285	10.1	February 29, 2024
10.47 #	Form of Restricted Stock Unit Award Grant Notice and Award Agreement	8-K	001-35285	10.2	February 29, 2024
10.48 #	Form of Stock Option Grant Notice and Stock Option Agreement	8-K	001-35285	10.3	February 29, 2024
10.49 #	Letter Agreement, between Vaxart, Inc. and Steven Lo	8-K	001-35285	10.1	March 6, 2024
10.50 ^	ATI-RRPV Base Agreement, dated May 6, 2024, between Vaxart Biosciences Inc. and Advanced Technology International (RRPV Consortium Management Firm)	10-Q	001-35285	10.2	August 8, 2024
10.51 ^	ATI-RRPV Project Award Agreement No. 001, dated June 13, 2024, between Vaxart Biosciences Inc. and Advanced Technology International (RRPV Consortium Management Firm)	10-Q	001-35285	10.3	August 8, 2024
10.52 ^	Modification No. 3, dated September 27, 2024, to the ATI-RRPV Project Award Agreement No. 001, dated June 13, 2024, between Vaxart Biosciences Inc. and Advanced Technology International (RRPV Consortium Management Firm)	10-Q	001-35285	10.3	November 13, 2024
10.53 *^	Modification No. 4, dated December 20, 2024, to the ATI-RRPV Project Award Agreement No. 001, dated June 13, 2024, between Vaxart Biosciences Inc. and Advanced Technology International (RRPV Consortium Management Firm)				
10.54 ^	Modification No. 5, dated February 7, 2025, to the ATI-RRPV Project Award Agreement No. 001, dated June 13, 2024, between Vaxart Biosciences Inc. and Advanced Technology International (RRPV Consortium Management Firm)	8-K	001-35285	10.1	February 10, 2025
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	10-K	001-35285	19.1	March 14, 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	10-K	001-35285	97.1	March 14, 2024
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

^ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted as (i) the Company has determined the omitted information is not material and (ii) the Company customarily and actually treats the omitted information as private or confidential

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/ STEVEN LO
Steven Lo
President and Chief Executive Officer

Date: March 20, 2025

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Steven Lo 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/ STEVEN LO Steven Lo	President and Chief Executive Officer *(Principal Executive Officer)*	March 20, 2025
/s/ PHILLIP LEE Phillip Lee	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 20, 2025
/s/ MICHAEL J. FINNEY Michael J. Finney, Ph.D.	Chairman of the Board	March 20, 2025
/s/ KEVIN FINNEY Kevin Finney	Director	March 20, 2025
/s/ ELAINE J. HERON Elaine J. Heron, Ph.D.	Director	March 20, 2025
/s/ W. MARK WATSON W. Mark Watson	Director	March 20, 2025
/s/ DAVID WHEADON David Wheadon M.D.	Director	March 20, 2025

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) 350,000,000 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 Equiniti Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

Exhibit 10.53

December 20, 2024

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

Attention: [***]

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

Reference: RRPV Base Agreement No. 2024-606

Dear [***]:

In accordance with the terms and conditions of the referenced RRPV Base Agreement, Modification No. 04 hereby amends the Project Award No. 01 as follows:

DESCRIPTION OF MODIFICATION

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

4. PROJECT AGREEMENT CEILING
The total estimated ceiling for this Project Awardee is **$460,697,900** *(this is an increase of $4,578,621)* broken out as follows:

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

Fixed Amount (Milestone 2 Only)	$[***]
Fixed Amount (CMC / KP.2 Manufacturing)	$[***]
Total Fixed Cost	**$**[***]

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

	ESTIMATED EXPENDITURE
Estimated Expenditure	**$**[***] *(this is an increase of $*[***]*)*
Fixed Fee	**$**[***] *(this is an increase of $*[***]*)*
Total Expenditure and Fixed Fee Cost	**$**[***] *(this is an increase of $*[***]*)*

The United States Government (USG) and Vaxart agree that the current award amount will be **$460,697,900**. Billable costs for the duration of the agreement will not exceed the total amount of **$460,697,900** as any additional effort would require additional funds from the USG. Additional funds can be requested and may be approved provided Vaxart has an acceptable technical justification. However, Vaxart acknowledges that any costs above an agreed upon contract ceiling amount of $[***], to include potential indirect rate adjustments, will be the sole responsibility of Vaxart.

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

5. Incremental Funding
The total amount of funding currently allotted to this Project Award and available for payment is **$134,173,944** *(this is an increase of $37,658,328)* for those milestones marked as authorized within the Statement of Work's Milestone Payment schedule. Any work performed in excess thereof shall be at the Project Awardee's risk. The Project Awardee shall notify the CMF if at any time the Project Awardee has reason to believe that the costs accrued in the next [***] ([***]) days will exceed [***] percent ([***]%) of the current total authorized funding. Such notice should specify the estimate of additional funds required, along with the associated remaining tasking and timeframe. The Project Awardee is not obligated to continue performance under this Project Award (including actions under the Termination clause of the RRPV Base Agreement) or otherwise incur costs in excess of the amount identified in this clause.

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

3) Attachment A, Statement of Work, of the Project Award is hereby replaced in its entirety as attached herein.

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

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

Vaxart Biosciences Inc
By: /s/[***]
Name: [***]
Title: [***]

Advanced Technology International
By: /s/[***]
Name: [***]
Title: [***]

Date: 12/20/2024

Date: 12/20/2024

Attachment A
Statement of Work
(Incorporated via Modification No. 04. Attachment A is replaced in its entirety.

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

1.0 Introduction / Background

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

This project will compare Vaxart's updated COVID-19 vaccine candidate to an mRNA comparator to evaluate efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and adverse events.

2.0 Scope / Project Objective

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

Phase 1: Clinical Trial Execution for Phase 2b Clinical Trial
Vaxart shall execute a Phase 2b clinical trial in approximately 10,000 individuals comparing Vaxart's vaccine candidate and an mRNA vaccine comparator for efficacy, immune induction, and safety. The clinical trial will begin with a sentinel cohort of 400 individuals using Vaxart's XBB vaccine and an mRNA XBB comparator.

Specifically, Vaxart will:

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

Concurrently, Vaxart will manufacture new KP.2 lots to support a 10,000 subject follow-on trial as described under Task Area 5 (1.5), CMC, below.

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

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

3.0 Requirements

Phase 1: Clinical Trial Execution for Phase 2b Clinical Trial (WBS 1)
Vaxart shall execute a Phase 2b clinical trial in approximately 10,000 individuals comparing Vaxart's vaccine candidate and an mRNA vaccine comparator for efficacy, immune induction, and safety. The clinical trial will begin with a sentinel/safety cohort of 400 individuals using Vaxart's XBB vaccine and an mRNA XBB comparator.

Task Area #1 – Program Management (WBS 1.1)
Vaxart's program management activities will follow procedures described in the Project Management Institute Project Management Book of Knowledge ("PMBOK©"). These activities align with requirements established by BARDA. Consistent with those requirements, the primary objective to program management is to ensure that the activities and outputs that result are delivered on time, within scope and budget, and meet applicable quality standards.

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

- The Principal Investigator (PI) for the project will work with Vaxart's program management team and will be responsible for the technical and contractual deliverables of the program. The Vaxart Program Team (VPT), which includes representatives from BARDA, will conduct weekly progress meetings through the period of performance. In addition, the VPT will conduct monthly performance reviews in accordance with the USG contract/communication plan requirements. (WBS 1.1.1)
- The Program Manager and Principal Investigator will have responsibility for deliverables from the Subcontractors. Each of the Subcontractors will be managed day-to-day by the program management team and the appropriate Vaxart Technical Lead. A Subcontract Management Plan will be submitted to BARDA within [***] business 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. (WBS 1.1.2)
- The PI and program management team are the leads and with the entire Project Teams input, have responsibility for Risk Identification and Mitigation. Included in this section is the generation of a Risk Management Plan (RMP) and Security Plan within [***] business 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. (WBS 1.1.3)
- Vaxart will perform and report on program performance as directed by BARDA. Included in this activity is program cost accounting and invoicing. (WBS 1.1.4)
- Vaxart will maintain a quality management system to ensure that all activities carried out in accordance with the standards applicable to medical devices and pharmaceutical activities for clinical studies. Vaxart will use a Quality Assurance Surveillance Plan (QASP) with the key subcontractors in the program. The QASP, an element of Quality Management, will describe the methods used to monitor subcontractor performance, establish documentation/reporting requirements, and Vaxart's interactions with the subcontractor. The QASP is a means for evaluating whether the subcontractor is meeting the performance standards/quality levels identified in the project work plan and the contractor's quality control plan, and to ensure that the deliverables meet Vaxart's commitment to BARDA in the program. (WBS 1.1.5)
- As part of Vaxart's overall program management activities including subcontractor, risk and quality management activities will travel to sites as necessary to oversee the project. (WBS 1.1.6)
- Specific deliverables for WBS 1.1 subtasks are delineated in Section 4.0 Deliverables

Task Area #2 – Analytical (WBS 1.2)

Vaxart's analytical activities encompass those activities to be performed to collect, test, and report on samples taken from subjects in the Phase 2b trial. The lead-in cohort samples will be stored for analysis, pending an agreed upon plan from BARDA/ATI.

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

- Serum samples will be collected from all subjects according to the schedule detailed in the synopsis. Samples will be shipped from the clinical sites to a central repository. Samples from the central repository will be shipped to the CRO contracted by BARDA to measure serum antibody responses. (WBS1.2.1.1)PBMC samples will be taken from greater than 1,000 subjects, according to the timeline plan detailed in the protocol. These will be processed using the BARDA protocol of PBMC isolation. Samples will be shipped with a liquid N2 dry shipper to a central repository and provided to the CRO contracted by BARDA to measure to measure T cell responses to SARS-Cov-2 S protein. Additionally, 200 subjects (0 and 7 days post vaccination) enrolled in the study will be collected and processed using the Vaxart protocol for isolation. These samples will be used for assessing mucosal memory and mucosal homing markers in Phase 2. (WBS 1.2.1.3)

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

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

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

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

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

- Statistician with significant immune correlate analysis will develop an analysis plan to examine the relative importance of the correlates. (WBS 1.2.4.1)
- At the end of the study, the data will be compiled on the various immune parameters, and correlates of protection analyzed against both symptomatic and asymptomatic infection. If more analysis of secondary endpoints is needed, additional samples may be added in the analysis. (WBS 1.2.4.2)
- Vaxart will employ machine learning to refine the understanding risk factors and immune correlates are steps. (WBS 1.2.4.3)

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

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

Task Area #3 – Clinical (WBS 1.3)

Vaxart's clinical efforts encompasses all activities and tasks to be performed in the execution of the phase 2b clinical trial for study execution with a sentinel/safety group of 400 participants**,** complete safety review of Day 1 – 31 for that cohort and to activate additional sites and resume screening to support enrollment for 10,000 participants. **.**

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

- A comprehensive set of documents that provide critical information about the study and ensure regulatory compliance will be prepared. These documents include the study protocol, informed consent forms, investigator's brochure, case report forms, institutional review board (IRB) approvals, clinical trial agreements, financial disclosure forms, any adverse events, and additional safety-related reporting forms, and monitoring plans. (WBS 1.3.1.1)
- Site contract negotiation will be completed. This will include finalization of details including site payment, indemnification, intellectual property rights, publication rights, and data ownership. (WBS 1.3.1.2)
- Site budget negotiation will be completed. This will include finalization of the budget for activities such as participant recruitment, study visits, data collection, site personnel costs, and any additional expenses related to the trial. (WBS 1.3.1.3)
- Regulatory binders will be compiled and sent to clinical sites participating in the trial. These include study protocol, investigator's brochure, informed consent forms, IRB approvals, financial disclosure forms, and other regulatory submissions. (WBS 1.3.1.4)
- Site initiation visits (SIVs) will be conducted to ensure that the research site is ready to initiate the study. During SIVs, representatives from the sponsor or contract research organization (CRO) will meet with the site staff to review study procedures, data collection methods, and regulatory requirements. (WBS 1.3.1.5). BARDA representative(s) will be invited at SIVs and IMVs with appropriate notice to allow for coordination with all parties.
- Investigational product, as well as the mRNA comparator, will be shipped to investigative sites. Based on the site's enrollment needs, the sponsor or contract research organization (CRO) will generate drug shipment orders. These orders specify the quantity of investigational product required. The orders are then processed through an Interactive Web Response System (IWRS), which helps manage and track drug supplies supported by automated re-supply triggers. The IWRS assigns unique randomization numbers and treatment codes to participants, ensuring blinded allocation. The drug is then packaged, labeled, and shipped to the investigative sites following regulatory and logistical requirements. The site receives the shipment, confirms its integrity, and maintains appropriate storage and accountability records for the investigational product throughout the trial. (WBS 1.3.1.6***).***
    - The shipment of IP for the initial 400 sentinel participants will be closely managed by Vaxart. The remaining unused XBB material can be disposed per written agreement with BARDA.
- All other required laboratory and essential supplies will be shipped to investigative sites. These supplies can include items such as laboratory kits, specimen collection materials, study-specific laboratory tests, shipping containers, and labeling materials. The CRO ensures the timely provision of these supplies, often in accordance with the study protocol and specific requirements outlined by the sponsor. (WBS 1.3.1.7)

Vaxart will enroll eligible participants first in the sentinel safety cohort (400) followed by the 10,000 cohort. Vaxart will ensure participants are randomized and assigned to a treatment group. (WBS 1.3.2)

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

OMB/FDA/US Census Categories	2020/2023 US Census Data*	Planned Enrollment	Actual Enrollment
Subgroup Population			
Sex			
Female	50.5%		
Male	49.5%		
Total	***100%***	***100%***	***100%***
Ethnicity			
Hispanic or Latino	19.5%		
Not Hispanic or Latino**	N/A		
Total	***N/A***	***100%***	***100%***
Race			
American Indian or Alaska Native	1.3%		
Asian	6.4%		
Black or African American	13.7%		
Native Hawaiian or Other Pacific Islander	0.3%		
White	75.3%		
Two or More Races***	3.1%	N/A	N/A
Total	***100%***	***100%***	***100%***
Age			
18-64 years	60.6%	75%	
≥ 65 years	17.7%	25%	
Total	***N/A***	***100%***	***100%***
High Risk for Severe COVID****	75.4%		
# Proposed Sites			

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

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

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

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

Diversity Plan includes proposed targets to achieve the deliverable and also includes how PBMCs will be collected from a diverse population. Post enrollment of 2500, 5000 and 7500 participants, the parties will meet to ensure alignment with the goals of the diversity plan. Plans to continue or adjust strategy for diverse enrollment will be discussed and agreed to at that time, if necessary. BARDA reserves the right to issue a stop work order if alignment is not reached.

- Potential participants will undergo pre-screening including an initial evaluation to determine their eligibility (WBS 1.3.2.1)
- Various efforts to identify and enroll an eligible and diverse participant population will be undertaken. These may include developing targeted recruitment strategies and advertisements to reach the intended participant population. Participant recruitment vendors may be engaged to assist with recruitment campaigns, utilizing various channels such as online platforms, social media, print media, and community outreach. BARDA, ASPR, and HHS logos are not allowable in any source of materials for recruitment (WBS 1.3.2.2)
- Enrollment data will be provided daily, in a format and to a location agreed to by BARDA. to ensure that study enrollment is tracking study goals, including diversity goals. Strategies will be implemented to correct any enrollment lag or diversity imbalances identified.
- If necessary, trial participants' past medical or surgical history to confirm eligibility into the study will be requested. (WBS 1.3.2.3)
- Participant informed consent will be obtained. (WBS 1.3.2.4)
- Screening visits will be performed. (WBS 1.3.2.5)
- Sites and investigators will verify participant eligibility for clinical trials by conducting a thorough evaluation. (WBS 1.3.2.6)
- Participants will be randomized using the Interactive Web Response System (IWRS) which will assign unique identification numbers and determines treatment allocation based on the randomization schedule. (WBS 1.3.2.7)
- Dosing data will be updated into EDC within 24 hours to support the daily data dashboard reporting. All other data will be updated into EDC within 48 hours.

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

- Study visits will be performed as per the clinical trial protocol. Site visits will involve scheduling the visit, preparing study materials, administering assessments, and addressing study participants' questions. Investigators oversee the visit, conducting physical examinations, reviewing data, making treatment decisions, and ensuring protocol adherence. (WBS 1.3.3.1)
- Safety monitoring will be conducted throughout as per the clinical trial protocol. The safety monitoring process during study visits will include AE reporting, safety assessments, protocol adherence, and proactive pharmacovigilance measures. Study coordinators will systematically collect information on adverse events (AEs) or any untoward medical occurrences experienced by participants during or after the study visit. AEs can range from mild side effects to serious adverse reactions. These events will be documented, assessed for severity and causality, and reported to the appropriate regulatory authorities and the trial sponsor as per the established reporting timelines and guidelines. (WBS 1.3.3.2)
    - As recommended by the FDA, a Drug Safety Monitoring Board (DSMB) will convene and review safety data of the initial 400 participants in the sentinel cohort after they complete Day 31 (Visit 3). The raw data and the DSMB recommendation will then be submitted to BARDA and the FDA.
- Biosamples will be collected as per the clinical trial protocol. Trained healthcare professionals will conduct phlebotomy to draw blood, and participants provide urine samples as required. After collection, the biosamples will be processed, labelled and stored until shipping. Biosamples will be transported to designated laboratories using specialized containers that maintain required temperatures. The collection of PBMC (Peripheral Blood Mononuclear Cell) samples involves a specialized process to obtain these immune cells from the blood for research purposes. Trained healthcare professionals will perform venipuncture to draw blood from the participant. The sample will be processed, labeled and then cryopreserved or immediately used for various immune-based assays or research investigations. (WBS 1.3.3.3)

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

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

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

- Query resolution activities will include identification and rectification of discrepancies or missing information in study data. Data managers or clinical research associates (CRAs) review the data for inconsistencies and raise queries to the site personnel or data entry personnel to seek clarification or corrections. These queries are documented and communicated to the site, and the site responds with the necessary information to resolve the query. (WBS 1.3.5.1)
- A statistical analysis plan (SAP) will be developed and finalized prior to database unblinding. The effort will begin with defining the trial's

primary and secondary objectives, study endpoints, and the statistical methods to be employed. The SAP outlines the data handling procedures, data transformations, and imputation methods for missing data. Additionally, it specifies the statistical tests and models to be used, sample size calculations, and adjustments for multiple comparisons. The SAP also addresses subgroup analyses, sensitivity analyses, and any predefined interim analysis if applicable. (WBS 1.3.5.2)

- Programming specifications for biostatistical analysis will be developed. This effort involves collaboration between biostatisticians and programmers and will result in final programming specifications are established, ensuring robust and reliable data analysis for the clinical trial. (WBS 1.3.5.3)
- Method validation will be completed to ensure the statistical methods used for data analysis are appropriate, accurate, and reliable. (WBS 1.3.5.4)
- PI attestation will be completed. During this process, the PI reviews and confirms the appropriateness and accuracy of the statistical methods used for data analysis. The PI then provides a formal attestation, verifying that the statistical methods are aligned with the study objectives, are appropriate for the data collected, and comply with regulatory requirements. (WBS 1.3.5.5)
- Tables, figures and listings will be generated. Once approved, the TFLs are included in the clinical study report (CSR) and submitted to regulatory authorities as part of the trial documentation, providing a comprehensive representation of the trial's results and data. (WBS 1.3.5.6)
- A topline data report will be prepared. This report will summarize and presents key findings and results from a clinical trial in a concise and high-level manner. This report focuses on the primary objectives and key secondary endpoints of the trial, providing a snapshot of the trial's outcomes without delving into detailed analyses or subgroup findings. (WBS 1.3.5.7)

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

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

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

Task Area #4 – Regulatory (WBS 1.4)
Vaxart will prepare FDA submissions, keep track of relevant legislation, advise on legal and scientific requirements and limitations, and provide regulatory support for the evaluation of data for this study.

- In compliance with FDA regulations, Vaxart will prepare and submit for this study Annual Reports, Certificate of Analysis, Protocol(s), and pharmacovigilance documents. These submissions will be submitted under US FDA IND 27602 - VXA- CoV2-***3***.1-S, an oral SARS-CoV-2 vaccine E1-/E3-deleted replication defective recombinant adenovirus 5 with dsRNA adjuvant. (WBS 1.4.1)
- In compliance with FDA regulations, Vaxart will submit all required annual regulatory submissions within [***] of the anniversary date of our approved IND 27602. This report will contain new information collected over the past year pertaining to the safety, effectiveness, and labeling of our vaccine in this study. (WBS 1.4.2)
- Vaxart will notify the appropriate regulatory authorities regarding the safety of the vaccine. The safety of the vaccine will be evaluated through the reporting of solicited symptoms of reactogenicity for one (1) week following each study drug administration. Because the vaccine contains a double stranded RNA (dsRNA) adjuvant, MAAEs will be collected through one (1) year post last dose to address the theoretical potential for induction of autoimmune or auto-inflammatory diseases, as is standard for this class of vaccines. ***Participants*** will also be monitored for exposure to SARS-CoV2 and symptomatic SARS-CoV2 infection (COVID-19). (WBS 1.4.3)

Task Area #5 – CMC (WBS 1.5) - Trial Material Manufacturing, Acquisition, Packaging & Distribution
Vaxart will complete all activities and GMP documentation, ensuring that clinical trial material will be ready to support the 400-participant sentinel study (XBB) and the 10,000 participant Ph2b head-to-head clinical trial with an mRNA comparator targeting the KP.2 COVID variant.

Vaxart Trial Material Manufacturing & Packaging (1.5.1)

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

Comparator & Placebo Acquisition & Kitting (1.5.2)

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

Storage and Distribution of Clinical Trial Materials (1.5.3)

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

PHASE 2: Additional Characterization of Immune Responses
Vaxart will expand on the durability of the immune responses initially characterized by tracking mucosal samples from vaccinated individuals for a year, and assess cross-reactivity over time.

Task Area #1 – Analytical (*WBS 2.1*)

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

- As part of phase 1, additional samples in a small subpopulation of subjects at 3, 6 and 12 months will have been collected. The mucosal (and serum) immune responses of these samples will be measured in order to examine durability, particularly against multiple different coronaviruses as well as new SARS-CoV-2 variants. (WBS **2.**1.1)
- Vaxart will use flow cytometry to determine the changes to the memory pool in the subpopulation of participants using the samples collected in phase 1. B cell clones will be sequenced from the memory pools and used to characterize the diversity of the response based on vaccine and infection history. (WBS 2.1.2)
- Vaxart will analyze antibodies from the task in 2.1.2 and their diversity tested for binding and neutralizing various SARS-COV-2 variants and other coronaviruses. (WBS 2.1.3)

Task Area #2 – Clinical (WBS *2.2)*

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

- Vaxart will complete all required reports including an amended CSR that the discusses the analysis in option 2 will be completed; a full final report describing all the Phase 2 analyses, any additional reports to BARDA and regulatory agencies on the conduct of the trial as required. (WBS *2*.2.1)
- Vaxart will complete site close-out and unused vaccine will be returned or destroyed; and documents will be properly shipped and stored. (WBS 2.2.2)
- Vaxart will undertake essential document reconciliation in which records from the trial will be verified by medical monitors and database experts. Discrepancies will be resolved before finalizing the data. (WBS *2*.2.3)
- Vaxart will employ an Electronic Trial Master File (eTMF) which leverages software and server technology to guide and assist the setup, collection, storage, tracking and archival of essential clinical study documents. (WBS ***2***.2.4)
- Vaxart will prepare an amended clinical study report which will include the additional analysis conducted under Phase 2. (WBS ***2***.2.5)

4.0 Deliverables

1. Meetings

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

2. Technical Reporting: General

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

3. Physical Inventory Deliverables

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

4. Technical Reporting: Clinical Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1	Clinical Trial Protocols	[***]	[***]
4.2	Clinical Trial Documentation[1]	[***]	[***]
4.3	ClinicalTrials.Gov Posting and Results Reporting	[***]	[***]
4.4	Draft and Final Clinical Study Report(s)	[***]	[***]
4.5	Project-Specific First Site Activated for First Subject First Visit	[***]	[***]
4.6	Clinical Report During Active Enrollment Periods[2]	[***]	[***]
4.7	Access to Electronic Systems Used in Trial Conduct	[***]	[***]

4.8	Blinded Safety Reports, Medical Data Listing, CIOMS Report, Pharmacovigilance Database Listing	[***]	[***]
4.9	Specimen Collection for Future Use	[***]	[***]
4.10	Clinical Trial Final Study Package	[***]	[***]
4.11	Data Exchange Package(s) Submitted to Regulatory Agency(s)	[***]	[***]
4.12	Clinical Trial Datasets	[***]	[***]
4.13	Additional Data Package(s)	[***]	[***]

5. Technical Reporting: Quality Assurance

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

6. Advanced R&D Products

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

7. Regulatory Deliverables

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

5. Milestones

MS #	Task #	Description	Due Date	Government Funds	Authorized
PHASE 1					
	1.1	**Project Management**	[***]		
1	1.1	Project Kick Off	[***]	$[***]	Y
2		CRO Initiation. Subcontract Execution: [***]	[***]	$[***]	Y
3	1.1	PM Plans	[***]	$[***]	Y
4	1.1.1	Weekly Meetings - 110 total ($[***] ea)	[***]	$[***]	Y
5	1.1.1	Weekly Meetings - 10 total ($[***] ea)	[***]	$[***]	Y
5.1	1.1.1	Weekly Meetings – 12 additional ($[***] ea)	[***]	$[***]	Y
6		PM Meetings at Vaxart	[***]	$[***]	Y
7		PM Meetings at Vaxart	[***]	$[***]	Y
8		PM Meetings at Vaxart	[***]	$[***]	
9		PM Meetings at Vaxart	[***]	$[***]	
10		PM Meetings at Vaxart	[***]	$[***]	
11		PM Meetings at Vaxart	[***]	$[***]	
11.1		PM Subcontract – Latham	[***]	$[***]	Y
11.2		PM Subcontract – Latham	[***]	$[***]	Y
11.3	1.1.3	Risk Management	[***]	$[***]	Y
12	1.1.4	Monthly Cost Accounting/Invoicing	[***]	$[***]	
12.1		2 Invoices	[***]	$[***]	Y
12.2		3 Additional Invoices	[***]	$[***]	Y
12.3		Financial Management & Reporting	[***]	$[***]	Y
12.4		Accounting Subcontract – Latham	[***]	$[***]	Y
12.5		Accounting Subcontract – Latham	[***]	$[***]	Y
13	1.1.1	Monthly Technical & Business Reports	[***]	-	
	1.2	**Analytical**			
	1.2.1	**Serum & T Cells**			
14		Start Up Meeting	[***]	$[***]	Y
15		Log Samples	[***]	$[***]	Y

16		Complete Sample Shipment	[***]	$[***]
17		Results Tabulated & Sent to Vaxart	[***]	$[***]
	1.2.2	**Mucosal Analysis**		
18		Start Up	[***]	$[***]Y
18.1		Initial Start Up	[***]	$[***]Y
19		Order & Receive Materials	[***]	$[***]Y
20		Controls & Qualification Complete	[***]	$[***]Y
21		Complete Nasal Analysis	[***]	$[***]
22		Complete Saliva analysis	[***]	$[***]
23		Complete additional analysis	[***]	$[***]
	1.2.3	**Infection & Efficacy**		
24		Start Up	[***]	$[***]Y
24.1		Task Kick-Off	[***]	$[***]Y
25		Lab Kit Replenishment	[***]	$[***]
25.1		Lab Kit Replenishment– first shipment	[***]	$[***]Y
26		Site to Central Lab Shipment	[***]	$[***]
26.1		Site to Central Lab Shipment – first shipments	[***]	$[***]Y
27		Central Lab: 3 shipments / 6 months	[***]	$[***]
28		Statistical Analysis	[***]	$[***]
29		Analysis Complete	[***]	$[***]
30		Phase 2b Relative Efficacy & Infectious Report	[***]	-
	1.2.4	**Correlates**		
31		Machine Learning & Programming	[***]	$[***]
32		Statistical Analysis	[***]	$[***]
33		Verification / Analysis Complete	[***]	$[***]
34		Correlates of Protection Report	[***]	$[***]
	1.3	**Clinical**		
	1.3.1	**Site Start Up**	[***]	
35		Essential Documents Complete	[***]	$[***]Y
35.1		Essential Documents 50% Complete	[***]	$[***]Y
36		Site Contracts Complete	[***]	$[***]Y
37		Regulatory Binders Complete	[***]	$[***]Y
37.1		Regulatory Binders Draft	[***]	$[***]Y
38		Site Initiation Visits	[***]	
38.1		SIV – Initial Sites	[***]	$[***]Y
38.2		SIV – Additional Sites 1	[***]	$[***]Y
38.3		SIV – Additional Sites 2	[***]	$[***]
39		IP Shipments to Sites	[***]	$[***]
39.1		IP Shipment to Sites – Initial Sites	[***]	$[***]Y
40		Lab & Other Supplies to Sites	[***]	$[***]Y
40.1		Lab & Other Supplies to Sites – Initial Sites	[***]	$[***]Y
41		Study Meetings/Training	[***]	$[***]Y
41.1		Study Meetings/Training – Initial Sites	[***]	$[***]Y
	1.3.2	**Enrollment**		
42		Pre-screening	[***]	$[***]Y
43		Screening	[***]	$[***]Y
44		Randomization	[***]	$[***]
44.1		Randomization – 400 subjects	[***]	$[***]Y
	1.3.3	**Clinical Conduct**		
45		1st Person In	[***]	-
46		Biosample Collection	[***]	$[***]
46.1		Biosample Collection – 400 subjects	[***]	$[***]Y
47		Interim Analysis	[***]	$[***]
48		Source Data Verification	[***]	$[***]
48.1		SDV – 400 subjects	[***]	$[***]Y
49		Sites Supplies Management	[***]	
49.1		Site Supplies Management through 1/31/2025	[***]	$[***]Y
49.2		Site Supplies Management from 2/1/2025	[***]	$[***]
50		First 2500 Participants Dosed	[***]	$[***]
50.1		Second 2500 Participants Dosed	[***]	$[***]
50.2		Third 2500 Participants Dosed	[***]	$[***]
50.3		Final 2500 Participants Dosed	[***]	$[***]
51		Conclusion of Follow Up	[***]	$[***]
52		Unblinded Monitoring	[***]	
52.1		Unblinded Monitoring through 1/31/2025	[***]	$[***]Y
52.2		Unblinded Monitoring from 2/1/2025	[***]	$[***]
	1.3.4	**Site Monitoring**		
53		Routine Monitoring Visit - 2-3 Visits Per Site (360 visits)		
54		Routine Monitoring Visits, Quarter 1	[***]	$[***]Y
55		Routine Monitoring Visits, Quarter 2	[***]	$[***]Y
56		Routine Monitoring Visits, Quarter 3	[***]	$[***]
57		Routine Monitoring Visits, Quarter 4	[***]	$[***]

58		Routine Monitoring Visits, Quarter 5	[***]	$[***]
59		Routine Monitoring Visits, Quarter 6	[***]	$[***]
60		Routine Monitoring Visits, Quarter 7	[***]	$[***]
61		Routine Monitoring Visits, Quarter 8	[***]	$[***]
62		Routine Monitoring Visits, Quarter 9	[***]	$[***]
63		Routine Monitoring Visits, Quarter 10	[***]	$[***]
64		Routine Monitoring Visits, Quarter 11	[***]	$[***]
65		Routine Monitoring Visits, Quarter 12	[***]	$[***]
	1.3.5	**Data Management / Statistics**		
66		Statistical Analysis Plan	[***]	$[***]Y
66.1		SAP – Initial Work	[***]	$[***]Y
67		Programming Specification, Dvlpt, & Review	[***]	$[***]Y
67.1		Set up of TLF shells for 1st DSMB review	[***]	$[***]Y
67.2		Stats reprogramming for kit size change, 5 blocks vs 10 blocks	[***]	$[***]
68		Method Validation	[***]	$[***]Y
69		TFL Generation	[***]	
69.1		TLF Generation for DSMB Review	[***]	$[***]Y
69.2		TLF Generation for remaining trial	[***]	$[***]
	1.3.6	**Database Lock**	[***]	
70		Soft Lock	[***]	$[***]
71		Hard Lock	[***]	$[***]
		Data Safety Monitoring Board		
72		DSMB Meetings (6/14/2024-11/23/2026)		
73		DSMB Meeting	[***]	$[***]Y
74		DSMB Meeting	[***]	$[***]Y
75		DSMB Meeting	[***]	$[***]Y
76		DSMB Meeting	[***]	$[***]
77		DSMB Meeting	[***]	$[***]
78		DSMB Meeting	[***]	$[***]
79		DSMB Meeting	[***]	$[***]
80		DSMB Meeting	[***]	$[***]
81		DSMB Meeting	[***]	$[***]
82		DSMB Meeting	[***]	$[***]
		BARDA Update Meetings		
83		Year 1 Meeting - BARDA	[***]	$[***]
84		Year 2 Meeting - BARDA	[***]	$[***]
85		Year 3 Meeting - BARDA	[***]	$[***]
		Reporting		
86		Annual Report 1	[***]	-
87		Annual Report 2	[***]	-
88		Annual Report 3	[***]	-
	1.4.	**Regulatory (6/2024-7/1/2027)**	[***]	
89	1.4.2	FDA Annual Report 1	[***]	$[***]Y
90	1.4.2	FDA Annual Report 2	[***]	$[***]
91	1.4.2	FDA Annual Report 3	[***]	$[***]
92	1.4.1	Regulatory Interactions - Quarter 1	[***]	$[***]Y
93		Regulatory Interactions - Quarter 2	[***]	$[***]Y
94		Regulatory Interactions - Quarter 3	[***]	$[***]Y
95		Regulatory Interactions - Quarter 4	[***]	$[***]Y
96		Regulatory Interactions - Quarter 5	[***]	$[***]
97		Regulatory Interactions - Quarter 6	[***]	$[***]
98		Regulatory Interactions - Quarter 7	[***]	$[***]
99		Regulatory Interactions - Quarter 8	[***]	$[***]
100		Regulatory Interactions - Quarter 9	[***]	$[***]
101		Regulatory Interactions - Quarter 10	[***]	$[***]
102		Regulatory Interactions - Quarter 11	[***]	$[***]
103		Regulatory Interactions - Quarter 12	[***]	$[***]
	1.5	CMC / KP.2 Manufacturing		
104	1.5.1.1	Manufacturing Start - **FFP**	[***]	$[***]Y
105	1.5.1.2	Research Virus Bank manufacturing	[***]	
		KP.2 Bulk Drug Substance manufacture, test, and release		
106	1.5.1.3.1	Lot A - **FFP**	[***]	$[***]Y
107	1.5.1.3.2	Lot B	[***]	
		KP.2 GMP Drug Product manufacture, test, and release		
108	1.5.1.4.1	Lot A - **FFP**	[***]	$[***]Y
109	1.5.1.4.2	Lot B - **FFP**	[***]	$[***]Y
110	1.5.1.5	Stability Studies	[***]	
111	1.5.1.6	Labeling, Packaging and Shipment to Depot (Vaxart KP.2 Product) - **FFP**	[***]	$[***]Y
112	1.5.2.1	Technical Management of Non-Vaxart Trial Material Acquisition, Packaging & Distribution	[***]	$[***]Y

113.1	1.5.2.2.1	Acquisition of mRNA Comparator (First 3,750 PFS)	[***]	$[***]Y
113.2	1.5.2.2.1	Acquisition of mRNA Comparator (Additional 3,750 PFS)	[***]	$[***]
114	1.5.2.2.2	Acquisition of Saline	[***]	$[***]Y
115	1.5.2.2.3	Acquisition of Ancillary Kits	[***]	$[***]Y
116.1	1.5.2.3.1	Kitting of mRNA Comparator (First 3,750 PFS)	[***]	$[***]Y
116.2	1.5.2.3.1	Kitting of mRNA Comparator (Additional 3,750 PFS)	[***]	$[***]
117	1.5.2.3.2	Kitting of Saline	[***]	$[***]Y
118	1.5.3.1	Storage	[***]	$[***]Y
119	1.5.3.2	Distribution to Clinical Sites	[***]	$[***]Y
		PHASE 2		
120		Kick Off / Program Initiation	[***]	$[***]
121		Materials & Supplies Acquisition	[***]	$[***]
122	1.1.1	Sample Processing	[***]	$[***]
123	1.1.1	Durability Sample Analysis	[***]	$[***]
124	1.1.1	Flow Analysis	[***]	$[***]
125	1.1.2	Sequence Memory Cells	[***]	$[***]
126	1.1.3	Produce Clones	[***]	$[***]
127	1.1.3	Complete Clone Analysis	[***]	$[***]
128	1.2	Phase 2 Final Report	[***]	-
129		Final Technical and Business Status Report	[***]	-
			Total	$[***]
			Contract Type	**CPFF/FFP**

6. Data Rights

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

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

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

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, 333-188111, 333-143238, 333-277944 and 333-280669) of Vaxart, Inc. of our report dated March 20, 2025, 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, 2024 and 2023 which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

San Francisco, California

March 20, 2025

Exhibit 31.1

CERTIFICATION

I, Steven Lo, 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 20, 2025

By: /s/ STEVEN LO

Steven Lo
President and Chief Executive Officer
(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 20, 2025

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), Steven Lo, President and Chief Executive Officer of Vaxart, Inc. (the "Company"), and Phillip Lee, Chief Financial Officer of the Company, each hereby certifies that, to his knowledge:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2024, 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 20, 2025

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

Date: March 20, 2025

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.