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, 2020

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. ☑

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

The aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2020, based on the last reported sales price of the Registrant's common stock of $8.85 per share, was $842,046,746. As of February 24, 2021, the registrant had a total of 117,766,672 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2020. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2020, 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 on Form 10-K 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 on Form 10-K. 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 on Form 10-K.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

This Annual Report on Form 10-K 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 on our business, results of operations, financial condition and the market price of our common stock.

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 on Form 10-K 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. 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.

We are developing prophylactic vaccine candidates that target a range of infectious diseases, including SARS-CoV-2 (the virus that causes coronavirus disease 2019 ("COVID-19")), norovirus (a widespread cause of acute gastro-intestinal enteritis), seasonal influenza and respiratory syncytial virus ("RSV") (a common cause of respiratory tract infections). We have completed human dosing for our Phase 1 clinical trial for our SARS CoV-2 vaccine candidate, that commenced in October 2020 and met its primary and secondary endpoints. Three Phase 1 human studies for our norovirus vaccine candidate have been completed, including a study with a bivalent norovirus vaccine which, as we disclosed in September 2019, met its primary and secondary endpoints. Our monovalent H1 influenza vaccine protected participants against H1 influenza infection in a Phase 2 challenge study.

In addition, we are developing our first therapeutic vaccine targeting cervical cancer and dysplasia caused by human papillomavirus ("HPV"). Pending licensing, partnering or collaboration agreements, our seasonal influenza, RSV and HPV programs are currently on hold.

Vaccines have been essential in eradicating or significantly reducing multiple devastating infectious diseases, including polio, smallpox, mumps, measles, diphtheria, hepatitis B, influenza, HPV and several others. According to a MarketsandMarkets research report titled "Vaccines Market - Global Forecast to 2023", the global market for vaccines is expected to reach $50.42 billion by 2023 from $36.45 billion in 2018, at a compound annual growth rate of 6.7%.

We believe our oral tablet vaccine candidates offer several 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 COVID-19, influenza, norovirus and RSV, 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. For example, according to the U.S. Centers for Disease Control and Prevention (the "CDC"), in the 2018/2019 seasonal influenza season, only approximately 49% of the U.S. population was vaccinated against influenza, with particularly low vaccination rates among adults between ages 18 and 49.

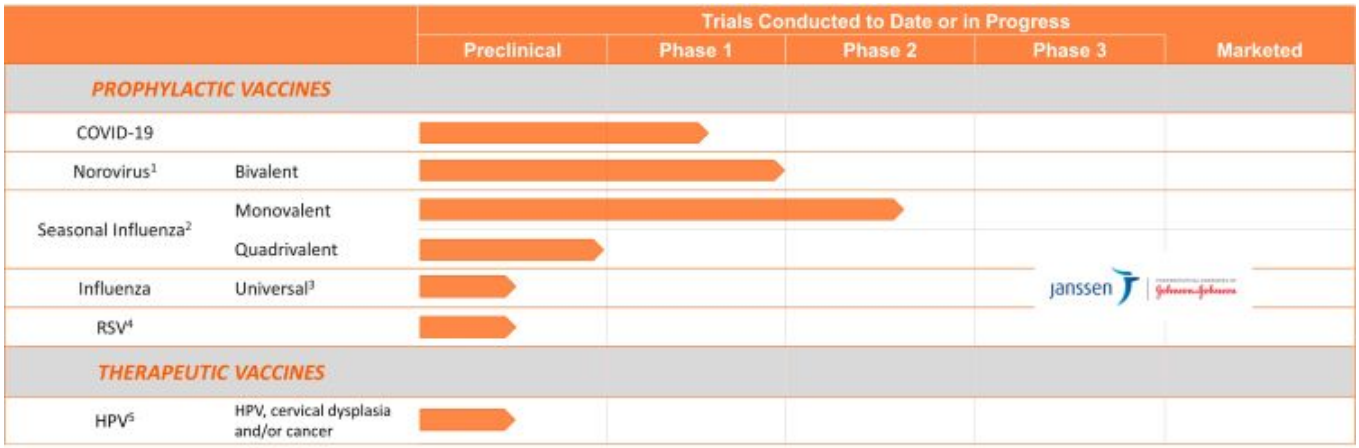
Business Update Regarding COVID-19

The COVID-19 outbreak has presented a substantial public health and economic challenge around the world and is affecting employers, employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 outbreak will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

To date, we have been able to continue our operations and do not anticipate any material interruptions in the foreseeable future. However, we are continuing to assess the potential impact of the COVID-19 pandemic and the development of other competing COVID-19 vaccines on our business and operations, including our expenses, supply chain and clinical trials. Our office-based employees have been mostly working from home since mid-March 2020 and will continue to do so until we believe it is safe to return to the workplace. Our partners have mostly continued to operate their facilities at or near normal levels. While we currently do not anticipate any interruptions in our operations, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our operations and/or the operations of our third-party suppliers and partners. Any recovery from negative impacts to our business and related economic impact due to the COVID-19 outbreak may also be slowed or reversed by a number of factors, including the recent emergence of coronavirus strains with mutated S proteins.

Our Product Pipeline

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



1. Bivalent GI.1 - GII.4 Norovirus vaccine generated IgA ASC response rates of 78 – 86% for GI.1 and 90 – 93% for GII.4. Program restarted with second dosing.
2. Monovalent H1 flu vaccine completed phase 2 Proof of Concept efficacy study. Quadrivalent flu Phase 1 on hold pending partnering process.
3. Janssen collaboration. Janssen has an option to negotiate an exclusive license.
4. RSV program to be partnered with new antigen partner, pending which the program is on hold.
5. HPV therapeutic pre-IND feedback received. Program presently on hold.

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

- ***Coronavirus Vaccine.*** We are developing an oral tablet vaccine to protect against SARS-CoV-2 infection, the virus that causes COVID-19. Vaxart generated multiple vaccine candidates based on the published genome of SARS-CoV-2 and evaluated them in preclinical models for their ability to generate both mucosal and systemic immune responses. Of particular interest will be the mucosal immune responses, as coronavirus is primarily an infection of the respiratory tract. We believe the logistical advantages of an oral vaccine that is administered using a convenient room temperature-stable tablet could be of critical benefit when rolling out a major public health vaccination campaign. Given the recent emergence of coronavirus strains with mutated S proteins compared to the original strain, serum antibodies from injected vaccines may not adequately protect against these novel mutant strains over time. A vaccine that is able to create cross-reactive T cells against conserved epitopes may have significant advantages.

  According to the CDC, in late 2019 an outbreak of COVID-19, caused by the virus SARS-CoV-2, began in Wuhan, China. The disease spread rapidly and person-to-person transmission has been widely documented. Stay-at-home orders or similar mandates were issued in all 50 states in the U.S. and throughout Europe and restrictions on certain activities, especially those involving large gatherings of people, remain in place, with regional variations. By February 24, 2021, more than 112 million COVID-19 cases had been identified in over 200 countries and territories worldwide, including the United States, where the CDC had reported over 28 million infections and 501,000 deaths.

  On September 14, 2020, we announced that the U.S. Food and Drug Administration (the “FDA”) had permitted our Investigational New Drug (“IND”) application to proceed. On October 13, 2020, we announced that a Phase 1 study had commenced and on February 3, 2021, we announced preliminary results.

  The Phase 1 study utilized an open-label, dose-ranging design to evaluate the safety and immunogenicity of Vaxart’s tablet adenoviral-vector based COVID-19 vaccine (“VXA-CoV2-1”), which expresses a SARS-CoV-2 antigen and dsRNA adjuvant, when administered orally to healthy adult volunteers. Under the Phase 1 protocol 35 participants were enrolled (October - November 2020) and received either a low dose (n=20) or mid dose (n=15) of the vaccine VXA-CoV-2. Five subjects in the low dose group received a boost four weeks after their initial vaccination. Study subjects were followed for safety and immunogenicity for four weeks following their last vaccination, and then entered a safety follow-up period which will last for one year following their last vaccination.

  Male and female volunteers who were between the ages of 18 to 54 years with body mass index (“BMI”) between 17 and 30 kg/m^2 inclusive at screening, who are at low risk of exposure to SARS-CoV-2, screened negative for SARS-CoV-2 infection at the time of screening and were in general good health, were eligible to participate in this study. Post confirmation of eligibility, five sentinel subjects were enrolled into Cohort 1 and immunized with the low dose ($1x10^{10}$ infectious units (“IU”) ± 0.5 log increase / reduction (“log”)) VXA-CoV2-1 oral vaccine.

  The primary objective was to determine the safety of our VXA-CoV2-1 oral vaccine delivered by enteric tablet. Safety and tolerability were evaluated through the detection and documentation of solicited symptoms of reactogenicity (seven days post each vaccination), unsolicited Adverse Events (“AEs”) (through 28 days post last vaccination, or Day 29; Day 57 for Cohort 1), Serious Adverse Events (“SAEs”), Medically Attended Adverse Events (“MAAEs”), including evidence of COVID-19, and vaccine enhanced disease (through Day 360). Clinical laboratory (blood chemistry, hematology, and urinalysis) results, physical examination, and vital signs results were also assessed.

Solicited symptoms were reported by 40% of study participants (15 out of 35 subjects), with more subjects reporting symptoms in the mid dose (67%) versus the low dose (20%). The most commonly reported solicited symptoms were nausea (14%) and headache (14%), followed by diarrhea (11%) and malaise/fatigue (11%). Most reported solicited symptoms were mild in severity and resolved without the need for medical treatment; additionally, no subjects discontinued due to a solicited AE.

A total of nine unsolicited AEs were reported by six subjects during the active study period (through Day 57). All unsolicited AEs were mild in severity and resolved without the need for medical treatment. Subjects are currently within the safety follow-up period of between four and five months post initial vaccinations. No serious AEs have been reported to date.

The secondary objective of this study was to determine the immunogenicity of the vaccine. The vaccine was immunogenic, and immune responses against SARS-CoV-2 were observed in approximately 85% of subjects. In particular, increases in Th1 cytokines and markers were observed in the T cells that recognize the SARS-CoV-2 S and N proteins in the clinical trial. Cytotoxic T cells, those that express the surface marker CD8, at day eight had a high percentage of cells that made IFNg, TNFa, and/or CD107a in response to stimulation with the S protein, with substantial increases compared to the first day of the study. B cell plasmablasts increased in subjects post immunization, as well as upregulation of the mucosal homing receptor and surface IgA on those B cells in a dose dependent manner. While no neutralizing antibody responses were observed in the serum of subjects, preliminary analysis showed that increases in IgA responses to the S protein, the receptor binding domain, and the N protein could be found in some subjects and several different compartments including nasal and saliva samples. Given the dose dependent manner in which the B cells of interest were activated, future studies of this candidate will focus on dose ranging and boosting to increase the mucosal immune responses to SARS-CoV-2.

The first-generation vaccines seem to have varying levels of efficacy to emerging strains of Covid-19. The current selective pressure of strain adaptation has been in an environment of very low levels of a vaccinated public and strain change may increase in speed as the vaccinated population grows.

There was significant vaccine hesitancy reported before the vaccines were offered to the public, in some countries more than 50% of the population stated they would not take a Covid-19 vaccine. This vaccine hesitancy seems to be waning a little as more people are being vaccinated without serious Adverse Events and may end up being similar to rates of vaccine hesitancy for other vaccines such as the influenza vaccine.

We expect this to remain a public market vaccine opportunity for the foreseeable future. However, because of the impact to the freedom of movement for the public and the economic fallout, the overall market needs for doses may be many times higher than the global market for seasonal influenza vaccines because there may be higher demand by working adults then we see for seasonal influenza vaccine.

- ***Norovirus Vaccine.*** We are developing an oral tablet vaccine for norovirus, a leading cause of acute gastroenteritis in the United States and Europe. Because norovirus infects the small intestine, we believe that our vaccine, which is designed to generate mucosal antibodies locally in the intestine in addition to systemic antibodies in the blood, has the potential to protect against norovirus infection. Clinical evidence that vaccines based on our platform technology can protect against infection is described under “Clinical Trial Update” in the “Seasonal Influenza Vaccine” section below. The program has been restarted with the addition of a second dose more than 12 months post first vaccination in subjects who participated in the Phase 1b norovirus trial.

  Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis among people of all ages in the United States. Each year, on average, norovirus causes 19 to 21 million cases of acute gastroenteritis and contributes to 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults. Typical symptoms include dehydration, vomiting, diarrhea with abdominal cramps, and nausea. In a study by the CDC and Johns Hopkins University, published in 2016, the global economic impact of norovirus disease was estimated at $60 billion, $34 billion of which occurred in high income countries including the United States, Europe and Japan. An update by the lead authors estimated the burden in the U.S. alone to be $10.5 billion in 2018. Virtually all norovirus disease is caused by norovirus GI and GII genotypes, and we are developing a bivalent vaccine designed to protect against both. We anticipate the vaccine will be an annual, one-time administration ahead of the winter season when norovirus incidence is at its peak, like the influenza season.

  Clinical Trial Update. In 2019, we completed the active phase of a Phase 1 clinical trial with our bivalent oral tablet vaccine for the GI.1 and GII.4 norovirus strains. Both the oral norovirus GI.1 and GII.4 vaccines had no SAEs reported. Most solicited and unsolicited AEs were mild in severity, and there were no significant differences observed between the vaccine and placebo treatment groups.

  Vaxart’s bivalent vaccine demonstrated robust immunogenicity in Phase 1 testing, with an IgA ASC response rate of 78% for the GI.1 strain and 93% for the GII.4 strain for the bivalent cohort of the study, and 86% and 90%, respectively, for the two monovalent cohorts of the study. There was no interference observed in the bivalent arm of the study.

  As previously disclosed, we suspended our norovirus program in late 2019. In October 2020 we recently restarted clinical development with our norovirus vaccine candidate. The next step in the clinical development program is administering a second dose to a subset of participants in the Phase 1b bivalent study. Additionally, a Phase 1b dose ranging study in elderly adult subjects aged 55 to 80 years old is currently in the start-up phase with enrollment expected to be initiated in April 2021. After this Phase 1b elderly study, we plan to initiate a Phase 2 safety and dose confirmation study with our bivalent norovirus vaccine in 2021. A Phase 2 challenge study may also be considered, and could be conducted in parallel with, before or after the Phase 2 dose confirmation study. The Phase 2 dose confirmation study would be followed by a Phase 3 efficacy study in subjects age 18 and over, after an End of Phase 2 Meeting to gain FDA concurrence.

- ***Seasonal Influenza Vaccine.*** Influenza is a major cause of morbidity and mortality in the U.S. and worldwide and, according to the CDC, only 49% of eligible U.S. citizens were vaccinated in 2018/2019, with particularly low vaccination rates among adults between ages 18 and 49. We believe our oral tablet vaccine has the potential to provide protective efficacy for influenza and increase flu vaccination rates.

  Influenza is one of the most common global infectious diseases, causing mild to life-threatening illness and even death. An estimated 350 million cases of seasonal influenza occur annually worldwide, of which three to five million cases are considered severe, causing 290,000 to 650,000 deaths per year globally. During the flu season of 2018/2019 there were 34,200 flu related deaths in the U.S. alone, according to the CDC. Very young children and the elderly are at the greatest risk. In the United States, between 5% and 20% of the population contracts influenza, 226,000 people are hospitalized with complications of influenza, and between 3,000 and 49,000 people die from influenza and its complications each year, with up to 90% of the influenza-related deaths occurring in adults older than 65. The total economic burden of seasonal influenza has been estimated to be $87.1 billion, including medical costs which average $10.4 billion annually, while lost earnings due to illness and loss of life amount to $16.3 billion annually.

  We believe our tablet vaccine candidate has the potential to address many of the limitations of current injectable egg-based influenza vaccines, because: our tablet vaccine candidates are designed to create broad and durable immune responses, which may provide immunity and protect against strain variants; our vaccine is delivered as a room temperature-stable tablet, which we believe would provide a more convenient method of administration to enhance patient acceptance, and should simplify distribution and administration; and, by using recombinant methods, we believe our tablet vaccine may be manufactured more rapidly than vaccines manufactured using egg-based methods and should eliminate the risk of allergic reactions to egg protein.

  Clinical Trial Update. In September 2018, we completed a $15.7 million contract with the U.S. Government through the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority ("HHS BARDA") under which a Phase 2 challenge study of our H1N1 flu vaccine candidate was conducted. Previously, we had announced that, in healthy volunteers immunized and then experimentally infected with H1 influenza, our H1 influenza oral tablet vaccine reduced clinical disease by 39% relative to placebo. Fluzone, the market-leading injectable quadrivalent influenza vaccine, reduced clinical disease by 27%. Our tablet vaccine also showed a favorable safety profile, indistinguishable from placebo.

  On October 4, 2018, we presented data from the study demonstrating that our vaccine elicited a significant expansion of mucosal homing receptor plasmablasts to approximately 60% of all activated B cells. We believe these mucosal plasmablasts are a key indicator of a protective mucosal immune response and a unique feature of our vaccines. This data also provided evidence that our vaccines may protect through mucosal immunity, the first line of defense against mucosal infections such as flu, norovirus, RSV and others, a potential key advantage over injectable vaccines for these indications.

  At this time, we aim to finance development and commercialization of our seasonal quadrivalent influenza oral tablet vaccine through third-party collaboration and licensing arrangements and/or non-dilutive funding. In the future, we may also consider equity offerings and/or debt financings to fund the program. Pending a licensing, partnering or collaboration agreement, the seasonal flu program is currently on hold.

  In addition to our conventional seasonal flu vaccine, we entered into a research collaboration agreement with Janssen Vaccines & Prevention B.V. ("Janssen") to evaluate our proprietary oral vaccine platform for the Janssen universal influenza vaccine program. Under the agreement, we produced non-GMP oral vaccine containing certain proprietary antigens from Janssen and tested the product in a preclinical challenge model. The study has been completed and we have submitted a report to Janssen. Janssen has an option to negotiate an exclusive worldwide license to our technology encompassing the Janssen antigens.

- ***RSV Vaccine.*** RSV is a major respiratory pathogen with a significant burden of disease in the very young and in the elderly.

  Based on the positive results of our cotton rat study, we believe our proprietary oral vaccine platform has the potential to be the optimal vaccine delivery system for RSV, offering potential advantages over injectable vaccines. We will seek to develop a tablet RSV vaccine by licensing one or more RSV protein antigens that have demonstrated protection against RSV infection in clinical studies, or by partnering with a third party with RSV antigens that can be delivered with our platform. Pending a licensing, partnering or collaboration agreement, the RSV program is currently on hold.

- ***HPV Therapeutic Vaccine.*** Our first therapeutic oral vaccine candidate targets HPV-16 and HPV-18, the two strains responsible for 70% of cervical cancers and precancerous cervical dysplasia.

  Cervical cancer is the fourth most common cancer in women worldwide and in the United States with about 13,000 new cases diagnosed annually in the United States according to the National Cervical Cancer Coalition.

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

  In October 2018, we filed a pre-IND meeting request for our first therapeutic vaccine targeting HPV16 and HPV18 with the FDA, and we subsequently submitted a pre-IND briefing package. We received feedback from the FDA in January 2019. The HPV program is currently on hold while the Company is focusing its efforts on the COVID-19 vaccine.

Additional Objectives

- ***Develop Other Tablet Vaccine Candidates Based on Our Proprietary Platform.*** Our technology platform employs a modular approach using the Ad5 vector-adjuvant construct with disease-specific antigens and can be used to create new tablet vaccine candidates for a wide range of infectious diseases. We may consider exploring additional infectious diseases including Chikungunya, Hepatitis B and Herpes Simplex Virus 2 ("HSV-2"). In addition, we intend to leverage our vaccine formulation expertise to develop oral formulations suitable for pediatric populations.

- ***Further Strengthen Our Intellectual Property Portfolio***. We intend to continue to strengthen our patent portfolio by filing and prosecuting current and future patent applications in the United States and international jurisdictions. In addition, we have established proprietary formulation and tableting capabilities.

- ***Maximize the Commercial Value of Our Tablet Vaccine Candidates***. We believe that we own worldwide rights for the research, development, manufacturing, marketing and commercialization of our tablet vaccine candidates for seasonal influenza and norovirus. We aim to develop additional vaccine candidates based on our oral vaccine platform. We may seek partners to maximize the commercial opportunity of some or all of our tablet vaccine candidates.

Anti-Virals

- Through the Merger, we acquired two royalty earning products, Relenza and Inavir. We also acquired three Phase 2 clinical stage antiviral compounds, which we have discontinued.

- Relenza and Inavir are antivirals for the treatment of influenza that are marketed by GlaxoSmithKline, plc ("GSK") and Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), respectively. We have earned royalties on the net sales of Relenza and Inavir in Japan. The last patent for Relenza expired in July 2019 and the last patent for Inavir expires in December 2029. Sales of these antivirals vary significantly from quarter to quarter due to the seasonality of flu, and from one year to the next depending on the intensity of the flu season and competition from other antivirals such as Tamiflu. Importantly, on February 23, 2018, Xofluza, a new drug to treat influenza developed by Shionogi & Co., Ltd. ("Shionogi"), was approved in Japan. The drug has gained significant market share, substantially reducing sales of Inavir.

Our Tablet Vaccine Platform

Vaccines based on our proprietary VAAST platform are designed to generate broad local and systemic immune responses, which may offer important advantages in addressing a wide range of infectious diseases.

Platform Components

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

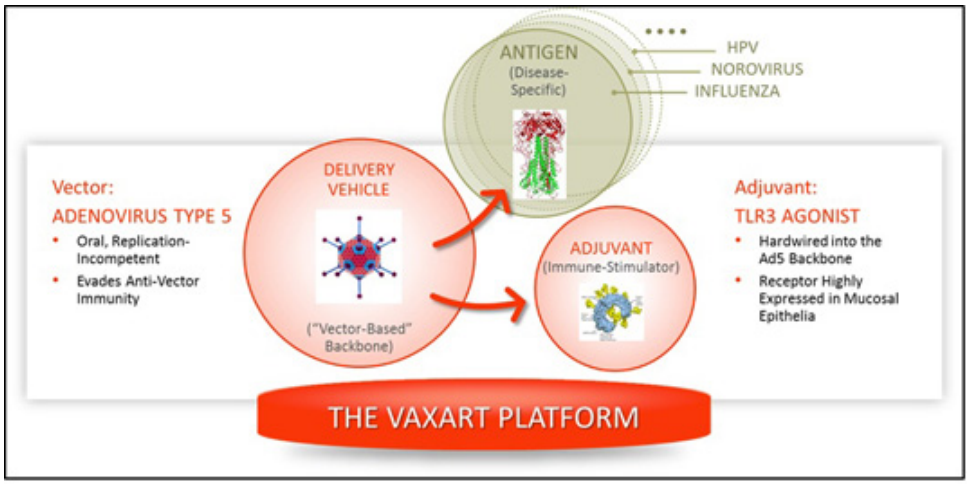
- A vector, which is a virus used as a carrier to deliver DNA coding for vaccine antigens and an adjuvant selected to activate the immune system of the gut. Specifically, we use non-replicating adenovirus type 5 ("Ad5"), which delivers the DNA for both the antigen and adjuvant to the cells of the small intestine, where both the antigen and adjuvant are co-expressed.

- A protein antigen, which is a viral or bacterial protein that stimulates an immune response to the targeted pathogen. We use a different antigen for each of our current clinical vaccine candidates.

- An adjuvant, which is a substance that enhances the immune-stimulating properties of the vaccine. We use a Toll-like receptor 3 ("TLR3") agonist, which was selected specifically for its ability to activate the immune system of the gut.

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

Fig. 2. Our VAAST Platform.



Caption. Vector-Adjuvant-Antigen Standardized Technology Platform

Our Platform. *Combination of the vector-based delivery system, with antigen and adjuvant expressed by the vector.*

Adenovirus 5 Vector

Ad5 is an extensively studied and well-characterized vector. 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 will reduce regulatory risk, given that it is known to regulatory authorities.

Recombinant Antigen

Our vector contains cloning space where DNA encoding for any recombinant antigen can be inserted. In the vaccine programs pursued to date, we have chosen recombinant antigens that are known to be key targets of the immune system with the ability to generate protection against the corresponding pathogen. The Ad5 vector-adjuvant gene cassette allows for a modular approach.

Adjuvant

We use a short section of double-stranded RNA (“dsRNA”) as an adjuvant to enhance the immunogenicity of our tablet vaccine candidates. dsRNA is a TLR3 agonist and is recognized by the innate immune system as a signal that an undesired viral replication is ongoing, triggering it to mount an immune response in defense. dsRNA is one of the few signals available for use in the intestine as the natural large reservoir of bacteria (the “microbiome”) makes it difficult to use bacteria- related signals. We chose this adjuvant because of its ability to complement the non-replicating adenovirus when administered orally, and because very few pathways of immune system recognition signals occur in the small intestine. Importantly, our adjuvant is expressed within a cell, not provided as a separate component, resulting in a localized response.

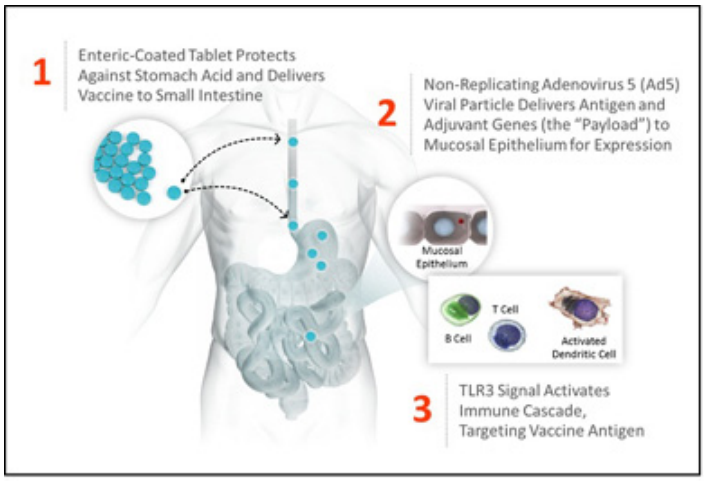
Enteric-Coated Tablet

While tablets are typically used to deliver small molecules to the intestine, we have designed our tablets to deliver the much larger adenovirus particles. We hold intellectual property related to the composition and formulation of our tablet vaccine candidates. Our tablet manufacturing does not require sterile fill and finish processing, such as for injectables, but rather uses standard tableting equipment.

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 the acidic environment in the stomach. The coating is designed to dissolve in the neutral pH environment of the small intestine which we are targeting to generate an optimal immune response. Once the coating has dissolved, 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 antigen protein and adjuvant are expressed, or manufactured, by the cells. The adjuvant is molecular in nature and always produced within the exact same intestinal cells that also produce the antigen. Importantly, the production of antigens delivered using our approach is identical to that of the actual pathogen when it invades the mucosa. In addition, we believe that delivering the replication incompetent Ad5-vectored vaccine via tablet directly to the gut avoids neutralization by blood or muscle tissue-based immune cells.

Fig. 3. Our Oral Recombinant Vaccine Platform.



Caption. 1. Enteric-coated tablet is administered. The tablet coating protects the active ingredient from stomach acid degradation. 2. When the tablet reaches the small intestine, it releases the active ingredient, the viral vector, that can then transfect the epithelial cells in the mucosal epithelium and deliver the genes for the two payloads (antigen and adjuvant). 3. Expression of the antigen and adjuvant in the epithelial cells then leads to the TLR3 signaling cascade that can activate B and T cells.

Immune cells come in contact with proteins, and if the protein elicits an immune recognition signal, the immune cell becomes activated. This eventually leads to an immune response, producing either memory cells or large quantities of antibodies that bind to a key antigen. The expressed antigen and adjuvant of its platform, like other vaccines, cause induction of B and T cells specific for the antigen. Induction is believed to begin when an immature dendritic cell (specialized immune cell) absorbs an epithelial cell expressing both the antigen and adjuvant that were delivered by the Ad5 vector. Upon induction, dendritic cells migrate to the regional lymph nodes where they interact with recirculating naive B and T cells. The dendritic cell presents pieces of the antigen on its surface to stimulate T cells, and some of the antigen drains into the lymph node to stimulate B cells. Upon recognizing its specific antigen, small B or T cells stop migrating and enlarge. These then multiply in a clonal fashion and eventually recirculate to the tissues. B cells secrete antibodies that recognize the antigen and T cells find cells that have antigen presented on their surface and either kill the presenting cell or stimulate a local inflammatory response. A successful vaccination occurs if the B cells and T cells can form either memory cells (cells specialized to respond quickly to the protective antigen upon subsequent exposure) or enough antibody to a key antigen is made in large quantity to block infection.

The Significance of Mucosal Immunity and T Cell Responses

The immune system has developed defenses against pathogens by creating a special class of immune effectors, such as mucosal antibodies that are 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. However, there remain many infections, such as norovirus and RSV for which no vaccines exist. These and other pathogens may need greater immune responses outside of serum antibodies. Organisms that cause these infections largely evade the antibody immune response generated by serum antibodies in the blood because the pathogenic organism can pass through cells that line the open, mucosal membranes without coming into direct contact with blood. Alternatively, the serum antibodies are unable to penetrate the cells infected by the pathogen.

Injectable vaccines available today typically do not induce mucosal immune responses, and subunit vaccines do not typically induce strong killer T cell immune responses, which are required to produce an effective level of immunization against several difficult pathogens. Administering vaccines through non-mucosal routes often leads to poor protection against mucosal pathogens primarily because such vaccines do not generate memory lymphocytes that migrate to mucosal surfaces. Although mucosal vaccination induces mucosa homing memory lymphocytes, we believe no complete mucosal recombinant oral vaccines are commercially available. Live attenuated vaccines can pose safety risks, whereas killed pathogens or molecular antigens are usually weak immunogens when applied to intact mucosa. Moreover, the immune mechanisms of protection against many mucosal infections are poorly understood.

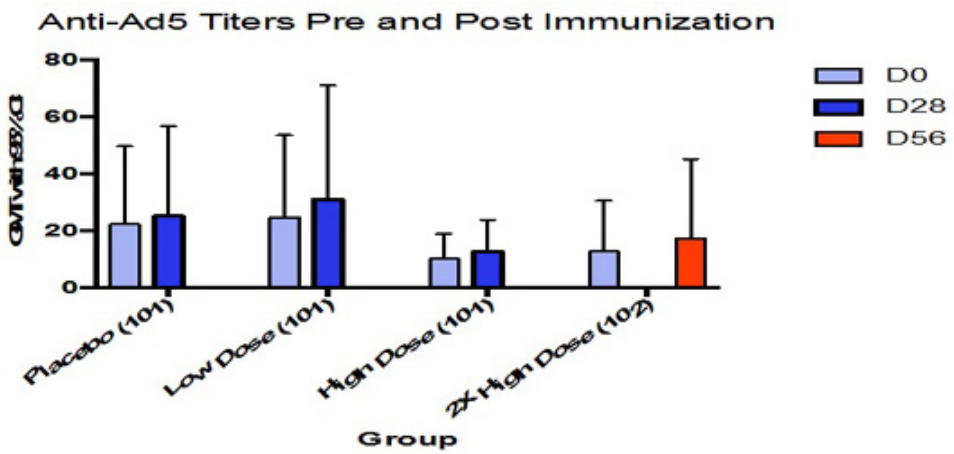
One of the key benefits of our technology is delivery to the gastrointestinal tract, enabling the vaccine to directly enter the mucosal surface of the intestine and activate the immune system of the gut. Mucosal vaccine delivery is believed to enhance protection against mucosal pathogens by generating immunity at the very 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. Besides robust mucosal and systemic antibody responses, we observed potent and poly-functional T cell responses in our human clinical trials, demonstrating that our tablet vaccine candidates efficiently activate both B and T cells.

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.

Anti-vector responses have been studied in our H1 influenza Phase 1 and Phase 2 studies, as well as in the two norovirus Phase 1 studies. In the first H1 influenza oral tablet vaccine study in 12 subjects, there were no significant rises in the neutralizing antibody titers to Ad5 following immunization. A challenge study was recently performed using the same H1 flu oral tablet vaccine in more than 60 subjects. This study found a 2.2 geometric fold rise in neutralizing antibody titers to Ad5, compared to a rise of 1.1-fold in the placebo group. Finally, the rise in vaccine anti-vector immune responses were monitored in the two Phase 1 norovirus vaccine studies, study #101 and study #102. There were no significant increases in the neutralizing anti-Ad5 antibody titers following either one or two doses of vaccine, even at the high dose (see figure below).

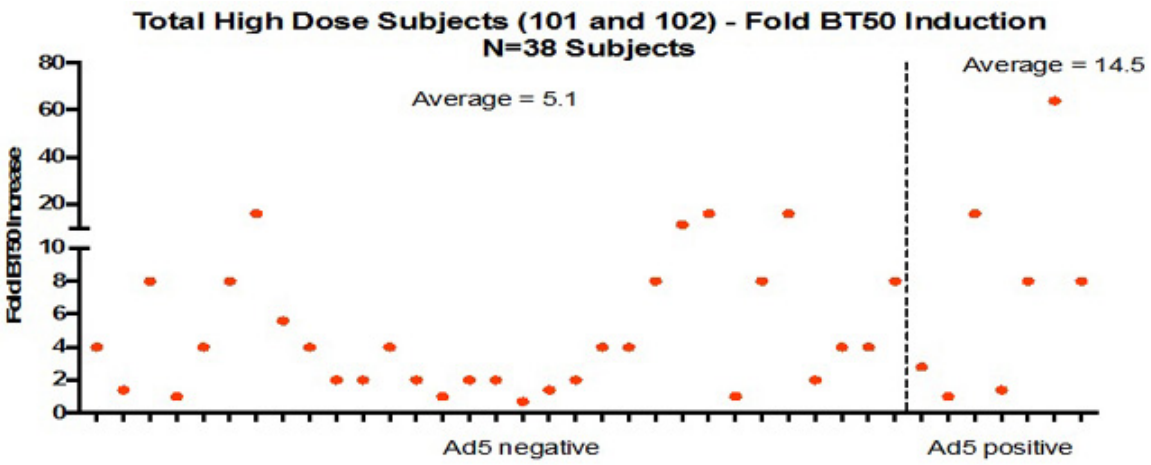
Fig. 4. Anti-vector titers pre- and post-immunization.



Caption. In the single dose 101 study, anti-vector titers were measured 28 days after the only dose. In the two-dose 102 study, these were measured 28 days after the second dose. No significant increase in Ad5 titers were observed in any group in the two studies.

In addition, in all studies to date, immune responses to the antigen of choice appeared to be independent from the recipient's pre-existing anti-Ad5 immune status. In studies with our Ad5 vectored H1 influenza oral tablet vaccine, the pre-existing antibody titers to Ad5 had no effect on the ability of the vaccine to induce a neutralizing antibody response (by hemagglutinin inhibition or microneutralization assay) to influenza. In the two recently completed Phase 1 studies with our Ad5 vectored norovirus GI.1 oral tablet vaccine, the ability of the vaccine to generate a rise in antibody titers to norovirus or specifically blocking titers to norovirus virus-like particles ("VLP") (BT50 assay), was not reduced in subjects with pre-existing anti-Ad5 antibody titers. These results are shown below. In conclusion, performance of our Ad5 vectored vaccine delivered orally does not appear to be adversely affected by the pre-existing serum antibody status of the recipient.

Fig. 5. Anti-vector immunity had no effect on the ability of the norovirus vaccine to induce BT50 titers.



Caption. Subjects in the high dose groups were divided based on the preexisting anti-Ad5 titers on day 0. Those with titers ≥ 100 were considered Ad5 positive, those <100 were considered Ad5 negative. The fold increase in BT50 titers for each subject were plotted. Average increase in the BT50 titers for the Ad5 positive group were not lower than the BT50 Ad5 negative group.

Our Covid-19 Program

Market Overview

Vaccines for COVID-19 have been purchased at large scale by governments for mass distribution within countries. In addition, non-government organizations ("NGOs") and the World Health Organization have set-up purchasing organizations such as COVAX to purchase on behalf of countries without domestic manufacturing and/or with limited resources to make pre-purchase agreements. This central government purchasing is most likely to continue for the next few years. Many of the more affluent countries such as the United States and Canada, have made pre-purchase agreements for doses equating to many times their population. The first wave of vaccines has been effective in Phase 3 trials against the first strain of COVID-19 however distribution and administration issues have been slower than anticipated because of the storage and handling requirements for these vaccines.

The first-generation vaccines seem to have varying levels of efficacy to emerging strains of COVID-19. The current selective pressure of strain adaptation has been in an environment of very low levels of a vaccinated public and strain change may increase in speed as the vaccinated population grows.

There was significant vaccine hesitancy reported before the vaccines were offered to the public, in some countries more than 50% of the population stated they would not take a COVID-19 vaccine. This vaccine hesitancy seems to be waning as more people are vaccinated without SAEs and may end up being similar to rates of vaccine hesitancy for other vaccines such as the influenza vaccine.

We expect this to remain a public market vaccine opportunity for the foreseeable future, however, because of the impact to the freedom of movement for the public and the economic fallout, the overall market for doses may be many times higher than the global market for seasonal influenza vaccines because there may be higher demand by working adults.

Variability of the circulating strains of SARS-CoV-2

SARS-CoV-2 is an RNA virus that naturally evolves genetic mutations over time producing numerous viral variants. Since December of 2019 coordinated global efforts have traced the emergence of SARS-CoV-2 variants, and identified frequent genetic mutations occurring in multiple countries. Viral variants rapidly emerging in many regions of the world, have several genomic changes leading to significant shifts in amino acid sequence and protein structure. During the second half of 2020, three divergent SARS-CoV-2 variants quickly spread through populations in the United Kingdom (B.1.1.7), South Africa (B.1.351) and Brazil (P.1). These particular variants have alterations in key regions of the outer S protein which is utilized by the virus to infect human cells through a receptor called ACE2. Structural changes in the receptor binding portion of the S protein in these variants have been shown to enhanced viral transmission, possibly leading to higher viral loads and worse disease outcomes. Currently, most vaccine strategies under development or approved for emergency use by the FDA, employ the S protein as a vaccine antigen to elicit antibodies responses to block the SARS-CoV-2 virus from entering cells. All existing vaccine formulations comprise of the S protein are derived from the original strain, which may not elicit cross protective antibody responses that block new viral variants from binding to the receptor and entering cells. Recent data from a Johnson & Johnson Phase 3 trial, showed that 28 days after vaccination 66% of participants in Latin America and 57% in South Africa were protected from the circulating strains. The Oxford-AstraZeneca vaccine campaign in Africa has recently been halted due to efficacy being only 25% against the dominant circulating strain. While laboratory experiments indicate that Moderna and Pfizer-BioNTech vaccines are effective against the U.K. variant B.1.1.7, it seems unlikely that substantial cross-protection will extend to P1 or B.1.351 mutants. These results indicate as novel S protein variants continue to emerge current vaccination approaches will need to be updated to offer immune protection against new SARS-CoV-2 mutants.

Our COVID-19 Vaccine Candidate

Our vaccine candidate (rAd-S-N, known as Vaxart clinical candidate, VXA-CoV2-1) expresses two different genes from the SARS-CoV-2 virus, the spike protein and the nucleoprotein ("N"). The N protein is more conserved among the coronavirus family of viruses, and inclusion in our vaccine candidate was done in order to create a T cell target even if new and emerging strains of SARS-CoV-2 had substantial mutations in the S protein, thereby reducing the ability of the vaccine to create protective immune responses that recognize the S from these strains. Our candidate was chosen in spring of 2020 based on preclinical results in mice showing that the construct had the ability to elicit antibody and T cell responses in mice, as well as mucosal IgA against SARS-CoV-2 in lungs.

Preclinical Results

In order to evaluate efficacy of our COVID-19 vaccine, we conducted a hamster challenge study at Lovelace Biomedical (Albuquerque, NM). Hamsters are a good model of SARS-CoV-2 infection because they can be infected via the intranasal route, and can get clinical symptoms such as weight loss, labored breathing, and ruffled fur. They also get lung problems similar to humans. Microcomputed tomographic imaging of hamsters given SARS-CoV-2 revealed severe lung injury that shared characteristics with SARS-CoV-2−infected human lung, including severe multi-lobular ground glass opacity, and regions of lung consolidation. A study by Janssen reported results showing that their vaccine can prevent disease in the same animal model.

Our topline results showed that two oral administrations of VXA-CoV2-1 (rAd-S-N) at 1e9 IU could substantially protect hamsters from weight loss associated with infection (Fig. N1A), protect against the lung weight gain associated with lung CoV-2 mediated damage (Fig. N1B), and substantially protect against high viral titers in the lungs five days post challenge (Fig. N1C). Oral vaccination with VXA-CoV2-1 reduced the viral titers in the lungs four to five logs (Fig. N1C). Histopathological comparisons between the lungs of untreated animals and VXA-CoV2-1 oral immunized animals showed substantial differences. All untreated animals had mostly moderate (six of eight animals) to marked (two of eight animals) mixed cell inflammation, minimal (one of eight animals) to moderate (two of eight animals) epithelial hypertrophy/hyperplasia in centriacinar areas, mostly minimal (five of eight animals) to mild (three of eight animals) alveolar hemorrhage, and mild (eight of eight animals) epithelial hypertrophy/hyperplasia in the bronchi. All animals that received two doses of the vaccine VXA-CoV2-1 had minimal mixed cell inflammation. There was no evidence of epithelial hypertrophy/hyperplasia in centriacinar areas, alveolar hemorrhage or epithelial hypertrophy/hyperplasia in the bronchi of these animals. Control vaccination by intranasal (i.n.) delivery of VXA-CoV2-1 also induced a similar level of protection as oral delivery.

The vaccine induced antibody responses in the serum of animals, with both binding Immunoglobulin G ("IgG") antibodies to S1, as well as neutralizing antibodies measured after oral or intranasal immunization (Fig. N2). Neutralizing antibody titers were measured using the surrogate neutralizing assay (Genscript). The IgG ELISA titers to S increased after boosting the animals in the fourth week of the study.

Fig. N1

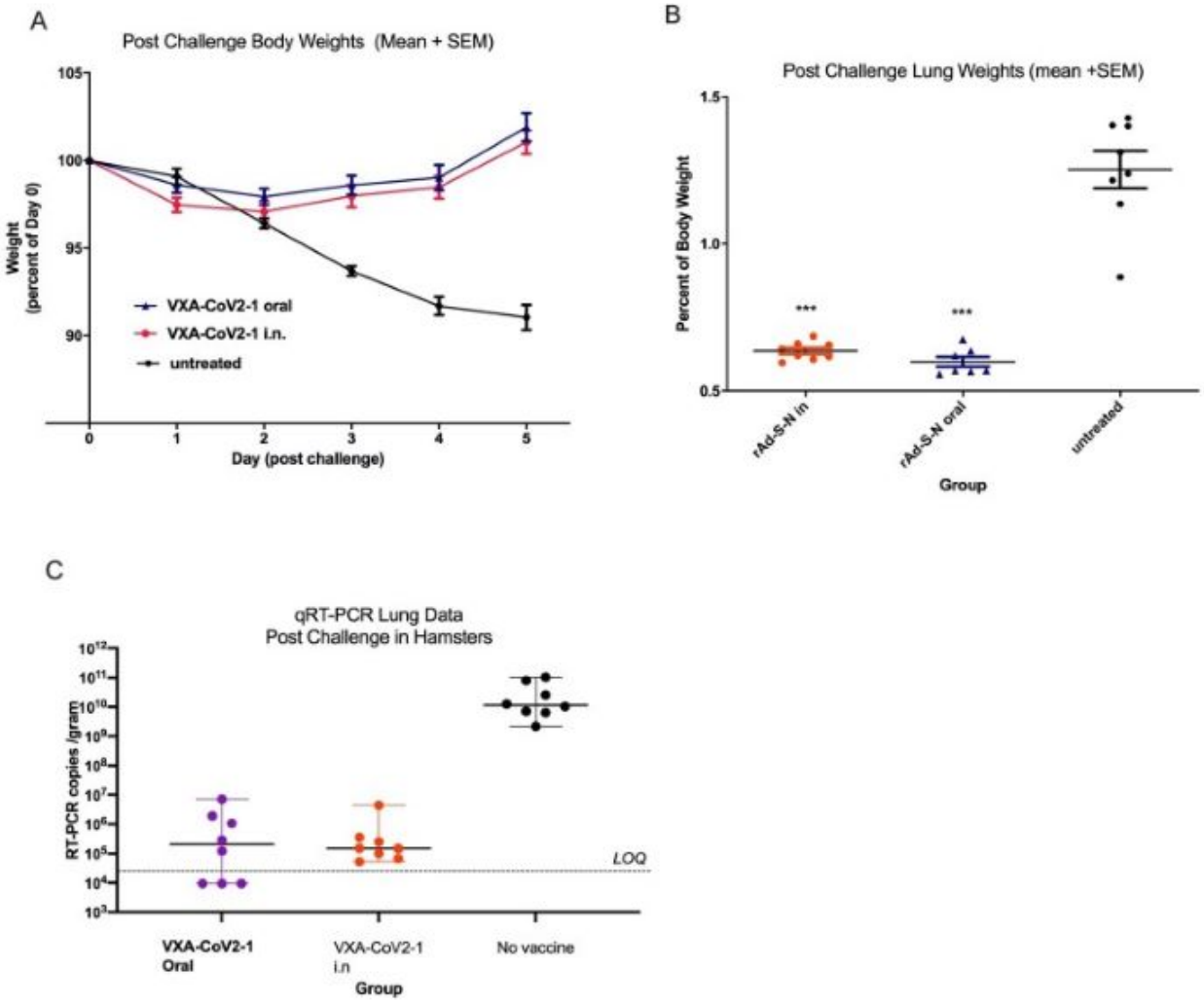


Figure N1. *Hamsters were immunized on weeks 0 and 4, and challenged intranasally with SARS-CoV-2 on week 8. rAd-S-N was given at 1e9 IU per hamster (either orally or by i.n.). Untreated animals were given no vaccine, but challenged at the same time as the vaccine groups. N=8 per group. A. Animals were monitored for weight for 5 days following challenge. Mean (+/- SEMs) are shown for each group. B. Lung weights on day 5 were taken and normalized by the actual animal weight to calculate a percent of body weight. Mean (+/- SEMs) are shown for each group. *** p<0.001 by one way ANOVA with Dunnett's Multiple Comparison's Test. All groups compared to untreated. C. Lung SARS-CoV-2 titers as measured by qRT-PCR on day 5 post challenge. Samples with undetectable values were set to ½ the Limit of Quantitation.*

Fig. N2

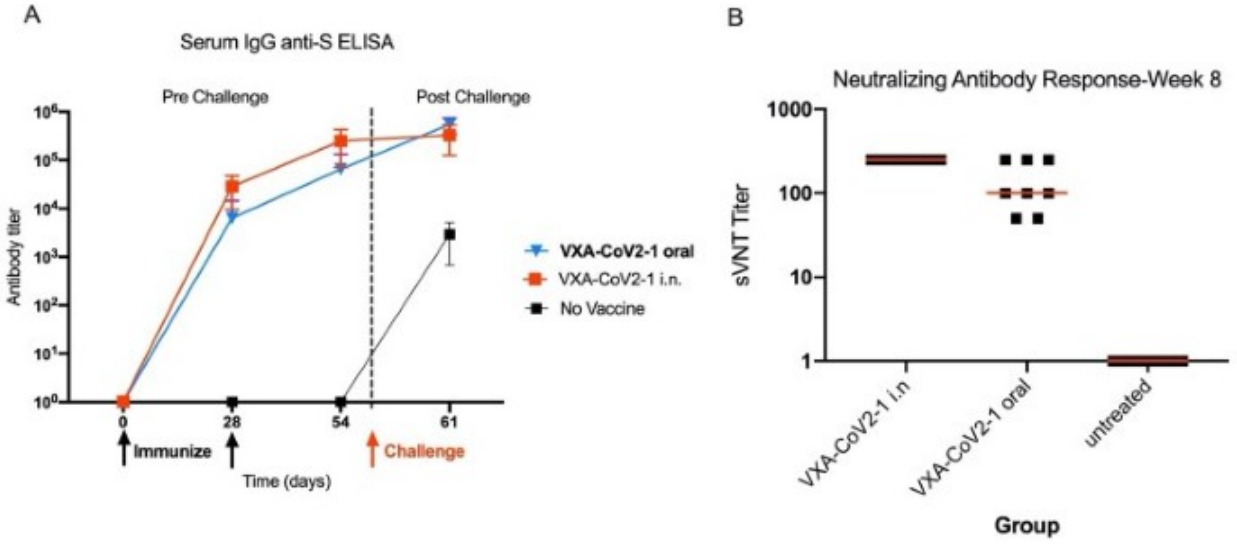


Figure N2*. Antibody responses in serum after 1 or 2 doses of vaccine given at weeks 0 and 4. Post challenge at week 8. A. IgG serum ELISA antibody titers to the S1 protein over time. B. Neutralizing antibody responses (sVNT) at week 8.*

Clinical Trial
Phase 1 - VXA-COV2-101

The Phase 1 study utilized an open-label, dose-ranging design to evaluate the safety and immunogenicity of Vaxart's tablet adenoviral-vector based vaccine (VXA-CoV2-1), which expresses a SARS-CoV-2 antigen and dsRNA adjuvant, when administered orally to Healthy Adult Volunteers. Under the Phase 1 protocol 35 participants were enrolled (October - November 2020) and received either a low dose (n=20) or mid dose (n=15) of the vaccine VXA-CoV-2. Five subjects in the low dose group received a boost 4 weeks after their initial vaccination. Study subjects were followed for safety and immunogenicity for 4 weeks following their last vaccination, and then entered a safety follow-up period which will last for 1 year following their last vaccination.

Male or female volunteers who were between the ages of 18 to 54 years with body mass index (BMI) between 17 and 30 kg/m^2 at screening, inclusive who are at low risk of exposure to SARS-CoV-2, screened negative for SARS-CoV-2 infection at the time of screening and were in general good health, without significant medical illness, based on medical history, physical examination, vital signs, and clinical laboratories (complete blood count, chemistry, and urinalysis) as determined by the investigator in consultation with the medical monitor and sponsor were eligible to participate in this study. Post confirmation of eligibility, 5 sentinel subjects were enrolled into Cohort 1 and immunized with the low dose ($1x10^{10}$ IU ± 0.5 log) VXA-CoV2-1 oral vaccine.

The primary objective was to determine the safety of a SARS-CoV-2 (VXA-CoV2-1) oral vaccine delivered by enteric tablet. Safety and tolerability were evaluated through the detection and documentation of solicited symptoms of reactogenicity (7 days post each vaccination), unsolicited AEs (through 28 days post last vaccination (Day 29); Day 57 for Cohort 1), SAEs, MAAEs, including evidence of COVID-19, and vaccine enhanced disease (through Day 360). Clinical laboratory (blood chemistry, hematology, and urinalysis) results, physical examination, and vital signs results were also assessed.

Safety Results

Solicited symptoms were reported by 40% of study participants (15 out of 35 subjects), with more subjects reporting symptoms in the mid dose (67%) versus the low dose (20%). The most commonly reported solicited symptoms were nausea (14%) and headache (14%), followed by diarrhea (11%) and malaise/fatigue (11%). Most reported solicited symptoms were mild in severity and resolved without the need for medical treatment; additionally, no subjects discontinued due to a solicited AE.

Solicited Symptoms and Adverse Events

Solicited Symptoms Days (1 – 8)	Low Dose (n=20)	Mid Dose (n=15)
No. (%) with Solicited Symptoms	4 (20.0)	10 (66.7)
Gastrointestinal Symptoms		
Diarrhea	0	4 (26.7)
Nausea	0	5 (33.3)
Vomiting	0	0
Abdominal Pain	1 (5.0)	2 (13.3)
General Symptoms		
Malaise/Fatigue	2 (10.0)	2 (13.3)
Myalgia (Muscle Pain)	1 (5.0)	1 (6.7)
Anorexia	0	2 (13.3)
Headache	3 (15.0)	2 (13.3)
Fever	0	1 (6.7)

- Most Solicited Symptoms mild and transient; few moderates @ Days 2 to 6

A total of nine unsolicited AEs were reported by six subjects during the study active period (through Day 57). All unsolicited AEs were mild in severity and resolved without the need for medical treatment. Subjects are currently within the safety follow-up period four to five months post initial vaccinations. No SAEs have been reported to date.

Immunogenicity Results

T cell Polarization and T cell Induction. As part of the anti-viral immune response, T cells are important as they can act as specific 'killers' that can seek out and destroy viral infected cells to control infection and prevent severity of disease. Vaccination with a SARS-CoV-2 vaccine (such as with VXA-CoV2-1) should induce an increase in T cells that recognize SARS-CoV-2 infected cells. However, T cells can produce either a protective (Th1) or an allergic response (Th2) upon activation. A primary immunological endpoint in this clinical study was to measure the polarization of the SARS-CoV-2 specific T cells, whether it was towards a protective Th1 response or an allergic Th2 response. This was measured using a restimulation assay where peripheral blood mononuclear cells ("PBMCs") taken both pre- and post-vaccination were cultured with SARS-CoV-2 peptides from either the spike protein (S) or Nucleoprotein (N) and the Th1/Th2 responses were measured. 26 pairs of PBMC samples from day one and day eight were able to be assessed from the study, pre and post a single dose; the remaining samples were not either not available or of poor quality to assess. No significant increase of Th2 responses, defined as IL5/IL4/IL13 released from CD4 T cells, was observed to either the Spike (S) or Nucleoprotein (N) in any of the subjects measured, with 0/26 having a twofold increase at day eight post vaccination and with the average percent increase on day eight in response to N was 0.09/0.02/0.04 percent and to S was 0.02/0.09/0.1 for IL5/IL4/IL13 respectively (Fig. N3c).

The majority of subjects had an increase in Th1 responses, defined as IFNg/TNFa/CD107a, particularly from CD8+ T cells in response to S peptides. In response to S peptides, 13 of 26 (50%) subjects had a twofold or higher increase in Th1 cytokine release, or in the case of CD107a, expression from CD8 T cells and 17 of 26 (65%) had a 1.5-fold or higher increase. 19 of 26 (73%) subjects had any measurable CD8 T cell response above baseline. Average percent increase on d8 above pre-vaccinated baseline was 1.5/4.6/1.95 for IFNg/TNFa/CD107a respectively. Five of 26 (19%) of subjects had CD4 T cells that had a twofold or higher increase, with 14 of 26 (54%) having any measurable CD4 T cell response above baseline. The average percent increase of CD4 T cells was 0.6/1.0/0.9 for IFNg/TNFa/CD107a respectively. In response to N peptides nine of 26 (35%) had a twofold or higher increase of Th1 responses from CD8 T cells over pre-vaccinated baseline, with 11 of 26 (42%) having a measurable CD8 T cell response. Only one of 26 had a Th1 CD4 T cell response to N that was twofold or higher, with nine of 26 (35%) having some measurable CD4 T cell response to N. The average % increase in CD8 was 0.1/0.2/0.6 and in CD4 was 0.08/0.08/0.2 for IFNg/TNFa/CD107a respectively. The high magnitude Th1 CD8 T cell response to S without discernible Th2 response suggests that vaccinating subjects with VXA-CoV2-1 increased the protective anti-viral responses without the potential adverse events occurring from Th2 responses.

Fig. N3

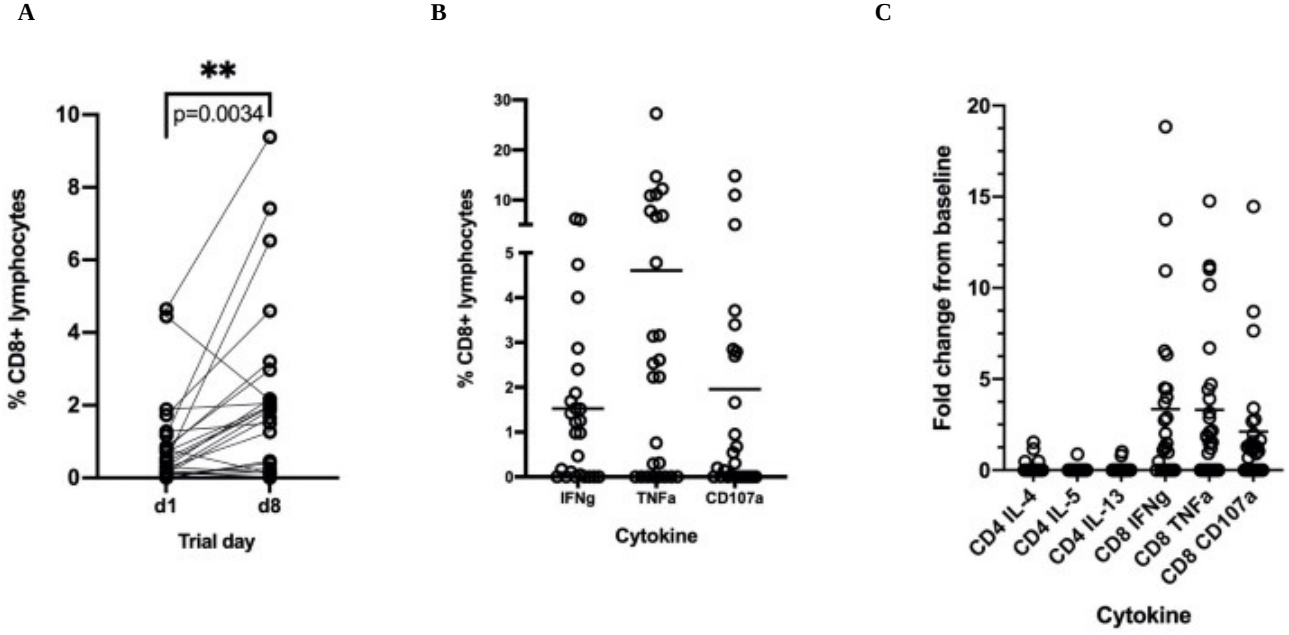


Figure N3. *T cell polarization and characterization. A. Increase in IFN-γ producing CD8 T cells post immunization on day 8 versus day 1. Paired T test was used to compare frequencies before and after vaccination. B. IFNγ, TNFα, and CD107a percent of CD8 T cells increase over background post immunization. C. Polarization toward Th1 responses versus Th2 responses in subjects immunized by VXA-CoV2-1.*

B cell responses. The major goal of vaccination is to induce an immune response that mediates protection from infection or disease. B lymphocytes, also known as B cells, play an important role towards this goal by producing antibodies that can specifically recognize and inhibit infectious agents. B cells can produce antibodies in different forms, each type with distinct characteristics and roles. B cells with the isotype A ("IgA") antibodies are the ones preferentially secreted at mucosal surfaces, such as the respiratory tract, where they prevent foreign substances from entering the body. The ability of our candidate vaccine to promote specific B cells capable of making high levels of antibodies (called 'plasmablasts') was tested using both flow cytometry-based measurements and an antibody-secreting cell (ASC) assay by ELISPOT. Flow cytometry allows measurement of proteins expressed by the cells, either on the surface or inside the cell. We explored immune cell populations in the peripheral blood. This analysis revealed a significant expansion in the overall plasmablast population 8 days after vaccination ($p<0.0001$, Wilcoxon test) with 69% of vaccinees in this study showing a twofold or higher increase in the frequencies of these antibody-secreting cells when compared to baseline levels (Figures N4A-B). Further investigation indicated upregulation of both IgA and the mucosal homing receptor b7 on the surface of circulating plasmablasts post vaccination, particularly in the higher dose cohort ($p=0.0261$, Mann-Whitney test), thus suggesting vaccine-induced migration of this IgA-producing B cell population to mucosal tissues (Figure N4c). Contextually, the ELISPOT assay also confirmed a strong production of IgA-secreting ASC on day 8 after vaccination (fourfold median increase over day 1 levels), additionally highlighting the ability for these cells to recognize and bind the S1 domain of the SARS-CoV-2 S protein (Figure N4d).

Fig. N4

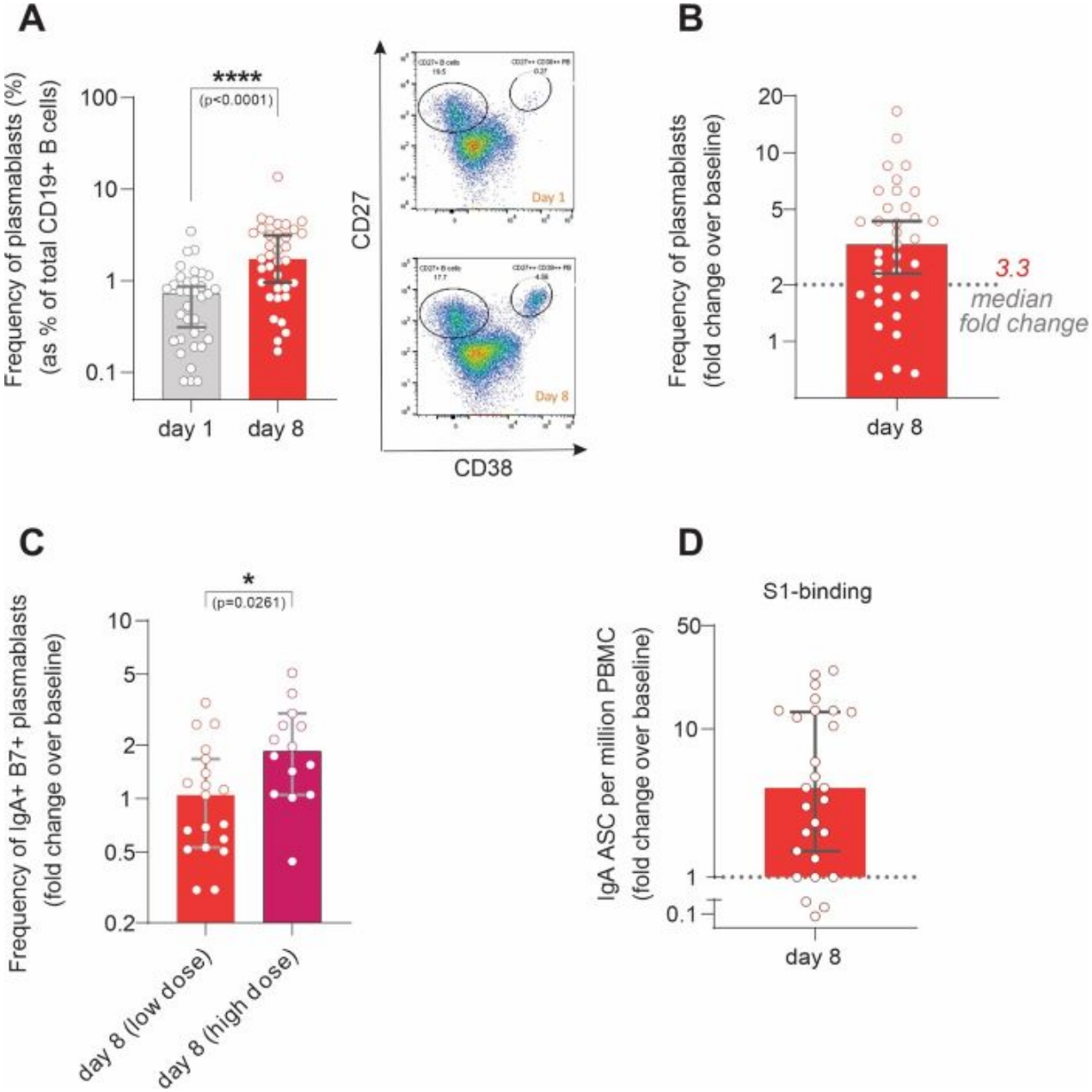


Figure N4. *A. Frequency of CD27++ CD38++ plasmablasts in peripheral blood before (day one) and after (day eight) vaccination as measured by flow cytometry. Bars represent median values, while error bars correspond to 95% confidence intervals. Wilcoxon test was used to compare frequencies before and after vaccination; B. Fold change (day eight compared to day one) in plasmablast frequencies. A total of 24 of 35 subjects (69%) showed a twofold or higher increase (with a 3.3 median fold change increase overall); C. Fold change (day eight compared to day one) of IgA- and B7-expressing plasmablasts in low and high dose vaccine cohorts. Mann-Whitney test was used to compare frequencies between the two different dose groups; D. Fold change (day eight compared to day one) in the number of IgA-positive antibody-secreting cells (ASC) reactive against the S1 domain of S.*

Antibody Responses. Serum samples were measured for neutralizing antibodies. No neutralizing antibodies were found in the serum at day 29 (and day 56 for the five subjects given two low doses). Increases in IgG responses were measured in the serum of only a few subjects. Local immune responses at the site of infection are of particular interest due to their ability to block viral entry, and IgA is considered to be the first line of defense at most mucosal tissues. To measure the immune response in the mucosa, nasal and saliva samples were taken. Sera samples were taken as well, as serum can also contain IgA. Levels of IgA antibodies were measured using a multiplex assay on the Meso Scale Discovery platform that measures antibodies to SARS-CoV-2 S protein, N protein and the Spike Receptor Binding Domain ("RBD"). This platform allows capture of antibodies specific for multiple antigens at once using a lower sample volume than a traditional ELISA format. In a preliminary analysis, a twofold or more increase above pre-vaccination samples in SARS-CoV-2 specific IgA found in the various compartments was detected in 18 of 35 subjects (52%) 29 days post vaccination. 11 of 35 (32%) had a twofold or above response to S protein, 13 of 35 (37%) had a twofold or above response to N protein, 16 of 35 (46%) had a twofold or above response to RBD, with 14 of 35 (40%) having a twofold or above response to two or more antigens. In Cohort 1, where subjects had two doses, four of five (80%) had SARS-CoV-2 IgA responses twofold or above and five of five (100%) had responses 1.5-fold or above in one or more compartments. These results include all subjects. Because samples that may lack any IgA in them are unlikely to show specific antibody responses, future work will normalize samples by the total amount of IgA and discard samples without any IgA from the analysis.

Fig. N5

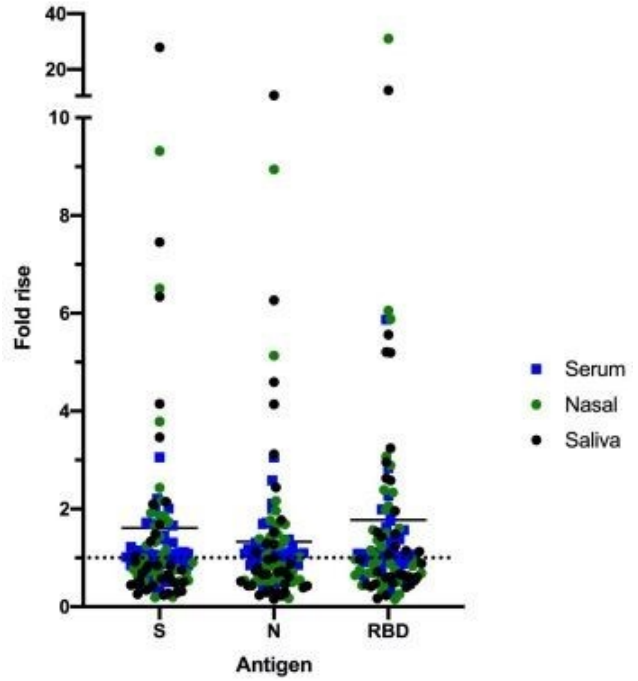


Figure N5. *Fold rise in IgA in serum, nasal and saliva samples.*

MesoScale Discovery (MSD) SARS-CoV-2 V-plex plates were used to measure spike (S), nucleoprotein (N) and receptor binding domain (RBD) in serum, nasal and saliva samples. Sera was measured at a dilution of 1:100, nasal and saliva samples measured at a dilution of 1:10. Fold rise was calculated by the division of day 8 over day 1 (baseline) MSD arbitrary units.

Phase 2a Study VXA-COV2-201: Dose Optimization in Adults

We plan to commence a Phase 2a study in the second quarter of 2021 utilizing an open-label, dose-ranging design to evaluate the safety and immunogenicity of Vaxart's tablet adenoviral-vector based vaccine (VXA-CoV2-1), which expresses a SARS-CoV-2 antigen and dsRNA adjuvant, when administered orally to healthy adult volunteers is currently being planned. Under this Phase 2a protocol 48 participants will be enrolled to receive either a low dose (n=16), mid dose (n=16) or a high dose (n=16) of the vaccine VXA-CoV-2. The study will be enrolled in six cohorts of eight subjects each, three cohorts will be aged 18 to 55 years old and three cohorts will enroll older adults aged 56 to 75 years old. All subjects will receive a boost four weeks after their initial vaccination. Study subjects will be followed for safety and immunogenicity for four weeks following their last vaccination, and then entered a safety follow-up period which will last for one year following their last vaccination. The proposed study design is shown in the table below:

Table 1. VXA-COV2-201 Dose Proposal

Treatment Group	Dose (±0.5 log)	Population (yrs.)	No. of Doses
Cohort 1	$1x10^{10}$ I.U. (Low)	18-55	2
Cohort 2	$3x10^{10}$ I.U. (Medium)	18-55	2
Cohort 3	$1x10^{11}$ I.U. (High)	18-55	2
Cohort 4	$1x10^{10}$ I.U. (Low)	56-75	2
Cohort 5	$3x10^{10}$ I.U. (Medium)	56-75	2
Cohort 6*	$1x10^{11}$ I.U. (High)	56-75	2
***** *Cohort 6 enrollment will commence after Day 8 visits in all other cohorts have been completed and safety data are reviewed by the data monitoring committee.*			

After signing an informed consent, participants will undergo screening assessments to determine study eligibility over a 30-day screening period. Screening assessments will include a SARS-CoV-2 rapid antibody or antigen test. On Day 1, eligible participants will be enrolled sequentially to receive their first oral vaccination according to their assigned cohort. During the active study period, participants will record daily symptoms of reactogenicity for one week post each vaccination, administered on Day 1 and Day 29 using a Solicited Symptom Diary. They will return to the site to have safety assessments and samples collected for evaluation of immunogenicity periodically during the study period.

At Day 29, participants will have pre-vaccination safety assessments to determine eligibility to continue with the second vaccination (negative pregnancy test, absence of acute illness or new medical condition). All participants who receive both vaccine administrations (Day 1 and Day 29) will enter the follow-up period after Day 57, and will be monitored for SAEs, MAAEs and for exposure to and/or symptomatic COVID-19 through Month 13/End of Study (EOS) visit. In addition, these participants will be evaluated for immunogenicity.

The primary objective in this study will be to determine the safety and tolerability of a SARS-CoV-2 (VXA-CoV2-1) oral vaccine delivered by enteric tablet which will be evaluated through the detection and documentation of solicited symptoms of reactogenicity (seven days post each vaccination), unsolicited AEs (through 28 days post last vaccination (Day 29); Day 57 for Cohort 1), SAEs, MAAEs, including evidence of COVID-19, and vaccine-activated enhanced disease. Clinical laboratory (blood chemistry, hematology, and urinalysis) results, physical examination, and vital signs results will also be assessed. Secondary endpoints will include assessment of long-term safety (through Day 390), and assessment of immunogenicity with a repeat-dose vaccination schedule in healthy adults at three dose levels.

Our Norovirus Program

Market Overview

Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis among people of all ages in the United States. Each year, on average, norovirus causes 19 to 21 million cases of acute gastroenteritis, and contributes to 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults. Typical symptoms include dehydration, which is the most common complication, vomiting, diarrhea with abdominal cramps, and nausea. A study conducted by the CDC and Pittsburg School of Medicine in 2012 estimated that the total economic burden of norovirus in the United States was $5.5 billion. 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 leisure and business travelers. In a study published by Johns Hopkins University and the CDC in 2016, the total global economic burden of norovirus was estimated at $60 billion, $34 billion of which occurred in high income countries including the United States, Europe and Japan. 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 $10.5 billion annually and in a January 2021 publication in the American Journal of Preventive Medicine the potential cost savings afforded by of a norovirus vaccine were estimated to be $500 per year in children under five and $75 per year in adults aged 65 and older. There are currently no approved vaccines or therapies to prevent or treat norovirus infection.

Our Norovirus Vaccine Candidate

We plan to develop a VP1-based bivalent oral tablet vaccine that protects 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 in the intestine against norovirus locally in the intestine, such as our tablet vaccine candidate which is delivered directly to the gut, may provide optimal protection against infection.

Preclinical Results

We have conducted multiple preclinical studies of our norovirus vaccine candidate in mice and ferrets. Overall, as compared with injectable VP1 protein vaccine, our norovirus vaccine candidate generated comparable levels of serum antibody and superior levels of mucosal antibody to the VP1 injectable protein vaccine.

Clinical Trials

We have completed two Phase 1 studies with our monovalent tableted norovirus GI.1 oral tablet vaccine, and one Phase 1b study with our bivalent tableted vaccine (co-administration of GI.1 and GII.4 vaccines). In all three studies, the primary endpoint was safety and the secondary endpoint was immunogenicity. In the bivalent study we also evaluated potential interference with co-administration.

Study 101. Placebo Controlled Study

In the Phase 1 study designed to evaluate the norovirus vaccine (VXA-GI.1-NN), 66 healthy adults were randomized in three groups, with 23 subjects receiving a single low dose of 1 x 10^{10} IUs, 23 subjects receiving a single high dose of 1 x 10^{11} IU, and 20 subjects receiving the matching placebo control.

Safety Results. 101 Study

Solicited Events. In the first seven days following study drug administration, 35 study subjects had at least one SAE reported with 25 of 46 (54%) subjects in the VXA-GI.1-NN vaccine groups and 10 of 20 (50%) of subjects in the placebo group (See table below). All the solicited AEs reported (n=46) were grade 1 or 2 in severity with the majority being mild events (44 grade 1 and two grade 2 events). The percentage of subjects with any solicited symptoms was similar among treatments (See table below). Diarrhea and headache were the most common solicited symptoms following VXA-GI.1-NN administration, both reported by 15 (33%) subjects in the treated groups. Headache and nausea were reported evenly across treatments, including placebo. The only solicited symptom demonstrating a statistically significant difference from placebo was diarrhea ($p = 0.0275$), reported by 11 subjects in the high dose group. Nine of the 11 subjects reported mild severity diarrhea, while two subjects reported moderate severity episodes following the high dose vaccine. Onset of diarrhea (verbatim term “loose stools”) ranged from day 1 to day 6 following vaccine administration, and most episodes resolved within one day. At no point did any of the loose stools impact normal activity such as work or school, and none required treatment with anti-diarrheal medications or rehydration therapy. In summary, the vaccine appeared well-tolerated without causing any dose limiting toxicities.

Table 2. Norovirus Study 101 Solicited Systems – Number and Percent of Subjects Reporting Treatment Emergent Adverse Events (“TEAEs”).

Solicited Adverse Events*(1)	**Placebo N=20**	**Low Dose N=23**	**High Dose N=23**
Number of Subjects with Any Symptoms	10 (50%)	11 (48%)	14 (61%)
Gastrointestinal disorders			
Abdominal pain	2 (10%)	5 (22%)	0 (0%)
Diarrhea	3 (15%)	4 (17%)	11 (48%)
Nausea	4 (20%)	4 (17%)	3 (13%)
General disorders and administration site conditions			
Malaise	2 (10%)	1 (4%)	3 (13%)
Nervous system disorders			
Headache	8 (40%)	8 (35%)	7 (30%)

(1) Solicited symptoms were collected from subjects for seven days following immunization.

Unsolicited Events. A total of 83 unsolicited TEAEs, were reported by 33 of the 66 subjects within the first 28 days post dosing, with slightly more placebo subjects 12/20 (60%) reporting adverse events than low dose 11/23 (48%) or high dose vaccinated subjects 10/23 (44%). Headache was the most common adverse event reported in all treatment arms. Most TEAEs were mild or moderate in severity. The site investigator considered 28 TEAEs possibly related, 42 unlikely related, and 13 not related.

Study 102. Dose and Schedule Optimization

The open-label, dose optimization study was designed to evaluate the norovirus GI.1 monovalent vaccine (VXA-GI.1-NN) in 60 subjects given multiple doses with some differences in schedule for the lower dose groups. The first three groups enrolled (N=15 each) used low doses of 1 x 10^{10} infectious units (IU). Group A received two doses of VXA-GI.1-NN on days 0 and 7, group B received three doses on days 0, 2, and 4, and group C received two doses on days 0 and 28. The fourth group, group D (N=15), evaluated two high doses of 1 x 10^{11} IU given on days 0 and 28. The vaccine study was an open labeled study, and enrolled sequentially from group A to group D. The primary endpoint of the study was to evaluate the safety of all dosing regimens and the secondary endpoint was to compare immunogenicity between groups by BT_{50} titers and antibody secreting cells (ASC) counts.

Safety Results. 102 Study

In the first seven days following study drug administration, there were 27 subjects reporting adverse events, distributed across the groups with the highest number of reporting adverse events in group C (11 of 15) and the lowest in group D (3 of 15). The most common adverse event reported was headache, reported in 21 subjects out of 60. Group C reported the highest number of headaches, and adverse events overall. This group was given two low dose vaccines 28 days apart. This was not observed in group D, a vaccine group given the exact same dosing schedule, but receiving two tenfold higher doses of vaccine.

Table 3. Norovirus Study 102 Solicited Symptoms – Number and Percent of Subjects Reporting TEAEs.

Solicited Adverse Events	Group A N=15	Group B N=15	Group C N=15	Group D N=15
Total Number Reporting an Adverse Event	5 (33.3%)	8 (53.3%)	11 (73.3%)	3 (20%)
GASTROINTESTINAL DISORDERS				
Diarrhea	0	1 (7%)	5 (33%)	1 (7%)
Abdominal Pain	1 (7%)	0	3 (20%)	1 (7%)
Nausea	1 (7%)	2 (13%)	2 (13.3%)	0
Abdominal Pain, Upper	0	1 (7%)	0	0
GENERAL DISORDERS				
Malaise	2 (13%)	0	2 (13%)	1(7%)
Feeling Hot	0	1 (7%)	0	0
NERVOUS SYSTEM DISORDERS				
Headache	4 (27%)	7 (47%)	9 (60%)	1 (7%)

Group A: Low Dose - Day 0, 7 **Group B:** Low Dose - Day 0, 2, 4
Group C: Low Dose - Day 0, 28 **Group D:** High Dose - Day 0, 28

Solicited symptoms were collected from subjects for seven days following immunization.

Study 103. Placebo Controlled Study

In this Phase 1 study (VXA-NVV-103) designed to evaluate the bivalent norovirus vaccine administration (VXA-GI.1-NN and VXA-GII.4-NS), 80 healthy adults were randomized into one of four treatment groups. Treatment Group 1 had an open-label sentinel group of five subjects who were enrolled prior to initiation of the subsequent treatment groups. The five sentinel subjects received the monovalent GII.4 vaccine and were monitored for safety and immunogenicity. Randomization was 1:1:2:1 for Treatment Groups 1 through 4, respectively. Patients received the complete investigational dose of 5×10^{10} IU within the monovalent vaccine treatment arms and $1x\ 10^{11}$ IU in the bivalent treatment arm or placebo tablets.

Safety Results. 103 Study

Solicited Symptoms. In the first seven days following study drug administration, 37 study subjects had at least one solicited adverse event reported with 33/65 (51%) subjects in the VXA-NNV-103 vaccine groups and 4/15 (27%) of subjects in the placebo group (See Table 3). Most subjects reported solicited symptoms that were mild in intensity. Five subjects reported solicited symptoms of Grade 3 severity. The percentage of subjects with any solicited symptoms was similar among treatments (See table below). Diarrhea and malaise were the most common solicited symptoms following vaccine administration, reported by subjects in all three active treated groups (20%-27% subjects). The incidence of diarrhea was higher across the vaccine treated subjects compared to placebo. The incidence of nausea and headache was highest in Bivalent GII.4/GI.1 group compared to other groups. The incidence of malaise/fatigue was higher across the vaccine treated subjects compared to placebo. Myalgia and fever were reported only in the vaccine treated subjects. In summary, both vaccines were safe when given as a monovalent vaccine or in combination as a bivalent vaccine. The most common symptoms were mild diarrhea and mild malaise both reported in about 20% of vaccine recipients. There were no deaths, serious adverse events, adverse events of special interest, new onsets of chronic illness, or subject discontinuations due to TEAEs in this study.

Table 4. Norovirus Study 103 Solicited Systems – Number and Percent of Subjects Reporting TEAEs.

Adverse Events*	Monovalent GII.4 (N=20) n (%)	Monovalent GI.1 (N=15) n (%)	Bivalent GII.4/GI.1 (N=30) n (%)	Placebo (N=15) n (%)
Number of Subjects with Any Symptoms	9 (45%)	8 (53%)	16 (53%)	4 (27%)
Gastrointestinal disorders				
Abdominal pain	3 (15.0)	1 (6.7)	4 (13.3)	2 (13.3)
Diarrhea	4 (20.0)	3 (20.0)	6 (20.0)	1 (6.7)
Nausea	3 (15.0)	1 (6.7)	6 (20.0)	2 (13.3)
Vomiting	1 (5.0)	0 (0.0)	2 (6.7)	0 (0.0)
General disorders and Nervous system disorders				
Malaise	4 (20.0)	4 (26.7)	6 (20.0)	1 (6.7)
Myalgia (Muscle Pain)	2 (10.0)	2 (13.3)	2 (6.7)	0 (0.0)
Anorexia	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)
Headache	2 (10.0)	2 (13.3)	7 (23.3)	2 (13.3)
Fever	1 (5.0)	2 (13.3)	1 (3.3)	0 (0.0)

Solicited symptoms were collected from subjects for seven days following immunization

Unsolicited Events. A total of 14 subjects reported a TEAE. The incidence of TEAEs was highest in the placebo group (33.3%) compared with the monovalent GI.1 group (26.7%), monovalent GII.4 group (15.0%), and the bivalent GII.4/GI.1 group (6.7%). The incidence of study vaccine related TEAEs was highest in the monovalent GI.1 group (20%) compared with the placebo group (13.3%), monovalent GII.4 group (5.0%), and the bivalent GII.4/GI.1 group (3.3%). One subject in the monovalent GII.4 group reported an SAE of Hyperemesis Gravidarum which was deemed by the site investigator to be unrelated to study drug.

Safety Summary from the Three Studies.

186 subjects were treated with Vaxart norovirus vaccines in the three Phase 1 studies. The vaccine was well tolerated, with no severe adverse events that were attributable to the vaccine reported in any study. The most common solicited adverse event was headache (27.5%), but this was relatively similar to the 28.6% of subjects in the placebo group. In two of the studies there was a higher incidence of diarrhea (20.5%) reported in the vaccine treatment groups versus the placebo group (11.4%). However, in the high dose group in the 102 study, there was only one subject (6.7%) reporting diarrhea even after receiving two administrations of vaccine at the highest dose. These results in total suggest that there were no dose dependent effects that impacted safety.

Immunogenicity Results-Study 101

BT50 Titers. The primary immunological endpoint was to measure antibody titers by an assay that assessed the ability of antibodies to block interaction of a norovirus VLP to histogroup blood antigen (HGBA). This assay is known as the BT50 (for 50% inhibition of blocking titer) assay. BT50 titers were assessed using Le^b synthetic glycan as the coating antigen. Titers rose in the vaccine recipients, and at all timepoints (Figure 6). By the Le^b BT50 assay, 14/23 (61%) of the subjects in the low dose group, and 18/23 (78%) in the high dose group, had at least a two-fold rise. One subject in the placebo group had a greater than two-fold rise. On Day 28, the geometric mean titer (GMT) for the low dose vaccine group was 59.0, a 2.3-fold geometric mean fold rise ("GMFR") over the initial GMT of 26.2 at baseline. The GMT for the high dose vaccine group was 98.5, a 3.8-fold GMFR over the initial GMT of 25.8 at baseline. The high dose group was significantly increased over placebo on day 28 (P=0.0003). Complete results are given in the table below.

GMT for Leb BT50 assays

Table 5. Study 101, Least Squared Geometric Mean Titer (LSGMT) for Leb BT50 assay.

HBGA	Leb			
Group	D0 LSGMT (95 CI)	D28 LSGMT (95 CI)	LSGMR	p value*
Low	26.2 (16.6-41.2)	59.0 (33.0-105.4)	2.3	0.0459
High	25.8 (18.3-36.2)	98.5 (64.4-150.7)	3.8	0.0003
Placebo	24.6 (15.3-39.3)	27.4 (17.0-44.2)	1.1	Reference
	Overall significance			0.0017

**Significance by Mann-Whitney vs. placebo; overall significance by Kruskal-Wallis Test.*

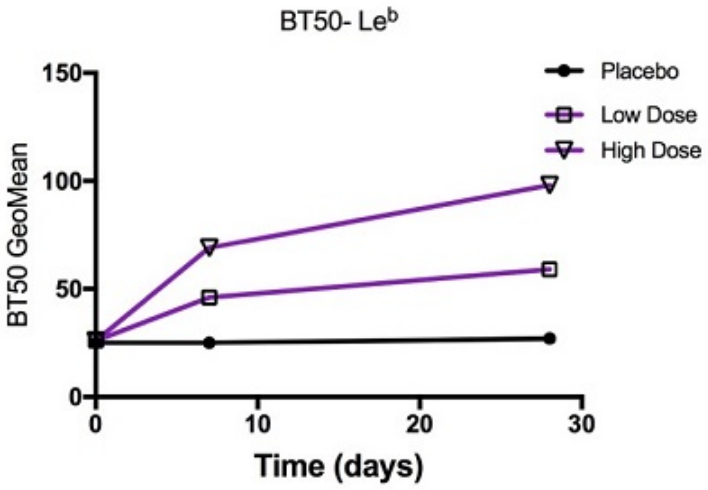
Antibody Secreting Cell (ASC). The ability of the vaccine to induce norovirus specific B cells in the peripheral blood was measured by ASC assay. This assay essentially counts the number of B cells that emerge after immunization and recognize norovirus in the peripheral blood. The number that circulate in the blood pre-immunization is very low, so the assay is a meaningful way to evaluate the vaccine specific effects. In the low dose group, 16 of 23 (70%) of subjects responded and in the high dose group, 19 of 23 (83%) of subjects responded on day seven for both IgA and IgG ASCs (Figure 7). Background ASCs were generally negligible on day 0. For the high dose vaccine treated group, an average of 561 IgA ASCs and 278 IgG ASCs each per 1 x 10^6 peripheral blood mononuclear cells ("PBMC"), were found on day 7. For the low dose vaccine treated group, an average of 372 IgA ASCs and 107 IgG ASCs were found on day 7. The placebo group had no responders with an average of 3.3 spots for IgA ASCs and 2.2 spots for IgG ASCs per 1 x 10^6 PBMC on day 7. The treated groups were significantly different than placebo in terms of the ability to elicit an IgG or an IgA ASC response at day 7 ($P<0.0001$, Mann-Whitney). There was no statistical difference in the number of spots for IgA and IgG ASCs between the high and low dose groups ($P=0.21$ for IgA, $P=0.28$ for IgG).

Enzyme-linked immunosorbent assay (ELISA) IgA and IgG. Serum antibody responses were measured by IgG and IgA ELISA, and the changes in titers at EC50 between days 0 and 28 were calculated for each subject. Most subjects had an increase in antibody titers post immunization. The average change in EC50 for the low dose group was 16 and 7.1-fold in IgA and IgG, respectively. Similarly, the average change in the EC50 for the high dose group were 9 and 5.4-fold for IgA and IgG, respectively. The changes in each subject's EC50 are plotted, separated by group (Figure 8).

Memory Cells. Memory cells are long-lived cells that are important for the rapid induction of immunity following infection. A goal of most vaccines is to safely induce immunological memory to protect people from actual infection. Antigen specific memory B cells were investigated after culturing PMBCs with polyclonal stimulators. VP1 specific IgG memory B cells were higher than IgA memory B cells in the day 0 samples (Figure 9). Post immunization, the response at day 7 was higher for IgA memory B cells, with a GMFR of 15.3 for IgA versus 6.5 for IgG between day 0 and 7, before declining again at day 28. In the low dose group, the GMFR was 7.4 for IgA and 3.7 for IgG was observed between days 0 and 7. This decline from day 7 to day 28 may have resulted from homing of circulating B cells from the peripheral blood to the intestinal lymphoid tissues via expression of high levels of the mucosal homing receptor, $\alpha 4\beta 7$. In the high dose group at day 7, 20/23 (87%) IgA and 19/23 (83%) for IgG showed ≥ 2-fold increase over day 0. In the low dose group at day 7, 18/23 (78%) for IgA and 13/23 (57%) for IgG showed ≥2-fold increase over day 0.

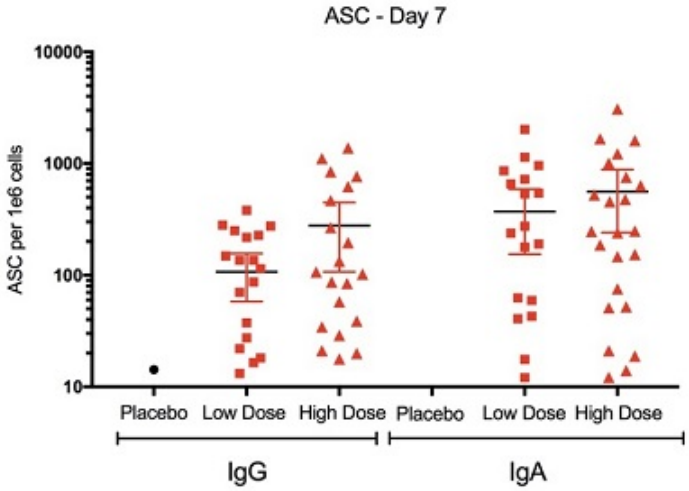
Fecal and Saliva IgA. Norovirus VP1 specific mucosal IgA was explored directly by looking at fecal and saliva samples. Because the quantity of IgA is highly variable within these samples, total IgA was also measured and the ratio between VP1- specific IgA/total IgA for each sample was examined. Samples with IgA levels below the detection limit were excluded from analysis. The increase in the ratio of specific IgA to total IgA was measured between baseline and day 28 (and baseline and day 180 for fecal IgA). In the high dose group, 9 of 19 (47%) fecal samples were responders with a four-fold rise or greater IgA response at day 28, and 9 of 21 (43%) at day 180 (Figure 10). The average fold increases in specific IgA/total IgA ratio were 17.2 and 9.7. These results are significantly higher than the placebo group where 2/18 (11%) and 0/16 (0%) were found to have fourfold or better increases on days 28 and 180 ($P=0.029$ and $P=0.0049$ respectively), with average increases of 1.8 and 1.0 (Figure 10). The low dose group had a similar response as the high dose, with 7 of 20 (35%) and 5 of 16 (31%) with fourfold or greater increases on days 28 and 180 respectively. The number of responders trended higher than placebo on day 28, but the difference was statistically significant on day 180 ($P=0.13$ and 0.043). The low dose group had a 36.2-fold increase on day 28, and a 5.6-fold increase on day 180 (Figure 10). Fewer subjects had detectable increases in the specific IgA to total IgA ratios in saliva samples of treated subjects at day 28 (Figure 11). The average increase in the specific IgA/total IgA ratio was 2.0 for the low dose, 2.9 for the high dose group, and 1.2 for the placebo group. The high dose and low dose groups had each had four subjects with a fourfold rise in the specific response, versus none for the placebo group. These results demonstrate that the vaccine can induce antibody responses that are measured in the mucosa, particularly in the intestinal mucosa, which is the site of norovirus infection.

Fig. 6. Geometric Mean Titers vs. Time.



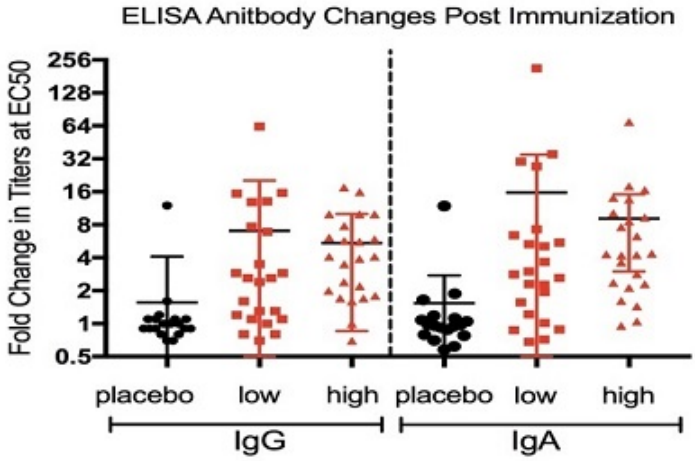
Caption. Geomean Serum BT50 Titers over time for Leb.

Fig. 7. ASC Titers on Day 7 post immunization.



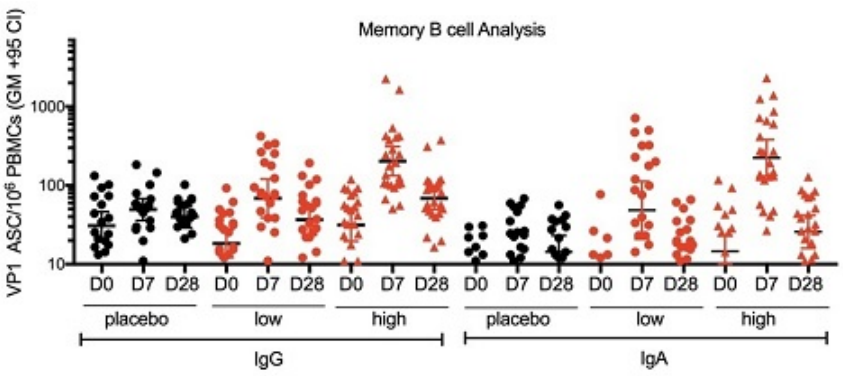
Caption: ASC counts on day 7 for both IgG and IgA responses to norovirus VLP. This assay measures antigen specific B cells in the peripheral blood that occur post vaccination.

Fig. 8. ELISA antibody changes post immunization.



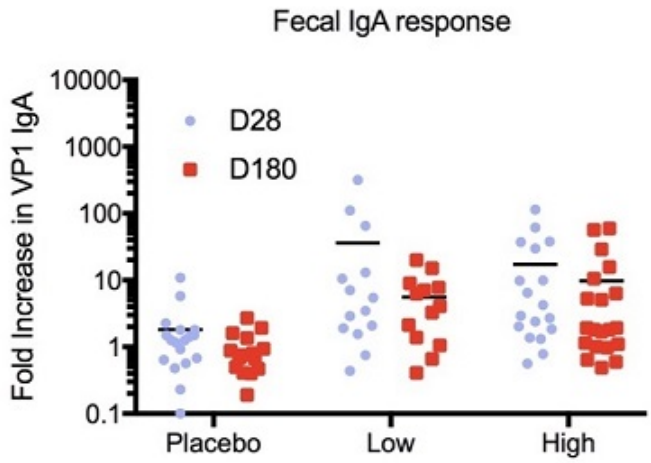
Caption. Change in IgA or IgG ELISA titers post immunization between days 0 and 28 for all subjects divided by treatment group. Each symbol represents an individual subject. The long horizontal line represents the mean, with the smaller lines the 95% confidence interval.

Fig. 9. Memory Cell Responses pre- and post-immunization.



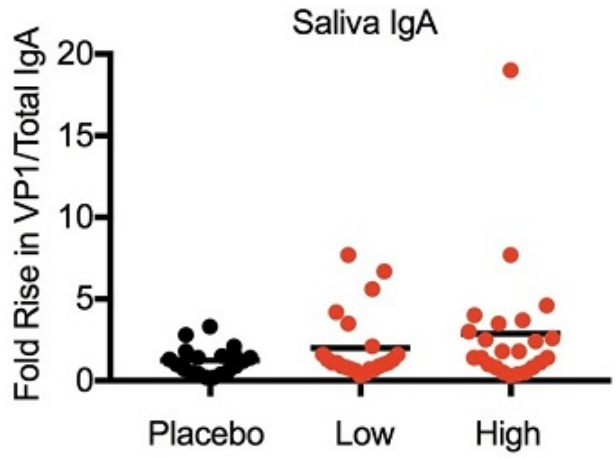
Caption: Norovirus VP1 specific memory B cell counts were plotted for each time point. Each symbol represents an individual subject. The long horizontal line represents the geometric mean.

Fig. 10. Fold Induction in Norovirus Specific Fecal IgA Responses Post Immunization.



Caption. Fecal responses to the vaccine, with fold increase in specific IgA/total IgA for each subject (divided by group and each timepoint) plotted. Average increase is the black bar.

Fig. 11. Fold Rise in Norovirus Specific Responses in Saliva.



Caption. Saliva IgA responses were measured. The plot shows fold rise of specific IgA/ total IgA post immunization. Responses were compared between days 0 and 28.

Immunological Results - 102 Study

BT50 Titers. The objective of the study was to compare schedules and dosing for the ability to elicit immune responses, particularly by evaluating BT50 titers. BT50 titers were assessed at multiple times points, given that multiple doses were given. In the high dose group, 12 of 15 subjects had a 2-fold or greater increase in BT50 titers after the first dose and 14 of 15 subjects (92%) had a 2-fold or greater increase in BT50 titers after 2 doses. The GMT titer rose from 21.3 on day to 85.1 on day 28 for a 3.8 GMFR. The GMT at day 56 were measured to be 75.8, a GMFR of 3.6 over the baseline values. Other groups given lower doses of vaccine had lower response rates. Groups A and C had higher increases in the titers compared to Group B, although this is not statistically significant. An ANCOVA model was used to determine the statistical significance of the increases in GMFR. Least-squares ("LS") geometric mean titers ("LSGMTs") and LS geometric mean fold rises ("LSGMFRs") were calculated by exponentiating the LSMs from the ANCOVA model, which included log-transformed post baseline titer or log-transformed change from baseline titer as a dependent variable, cohort as a factor, and baseline log-titer as a covariate. The significance in the different groups to increase the GMFR (test is LSGMFR=0), was found to be P=0.0008, 0.1224, 0.0004, and <0.0001 for groups A through D respectively at day 56. This means all groups had statistically significant increases in the GMT except for group B, which had a more modest increase in the titers.

102 Study. BT50 Titers, Leb

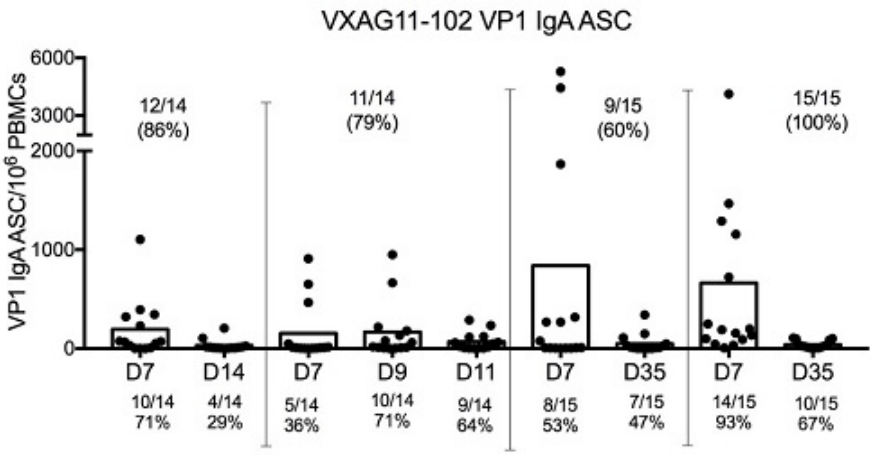
Table 6. Study 102, Geometric Mean Titer **(**GMT) for Le^b BT50 assay roger.

Group	Description	DO GMT	D28 (or D36)	GMFR	GMT D56	GMFR D56
A	**Low, 2X, 7 days apart**	32.2	64.5	2.0	66.0	2.0
B	**Low, 3X, 2 days apart**	31.5	51.2	1.6	42.5	1.4
C	**Low, 2X, 28 days apart**	29.4	66.0	2.2	64.5	2.2
D	**High, 2X, 28 days apart**	21.3	85.1	3.8	75.8	3.6

ASCs. Additional immunological analysis was performed by comparing the ASC responders between groups. The high dose group had 14 out of 15 subjects respond to the vaccine, with an average IgA ASC count of 698 per $1X10^6$ cells. Following a second dose, the subject that didn't respond the first time had a significant increase in ASC counts so all 15 subjects (100%) were able to elicit an ASC response following two doses. As typical, subjects that had a high number of ASC counts after the first immunization had a low response after the 2nd dose. The low dose groups were compared by examining the overall response rate, since the dosing and the analysis were performed at different intermediate timepoints. Group A had the highest overall response rate where 12/14 subjects (86%) were able to induce meaningful ASC responses after one or two doses. Slightly lower responders were observed in group B, where only a few subjects had a response after the first dose, but more subjects responded after additional vaccine doses. Group C had the most variable responses of any group. The average number of spots was 839 per $1X10^6$ cells after the first dose, but this was the result of several subjects having extremely high numbers of spots (three subjects had greater than 1500 per $1X10^6$), mixed with many subjects that didn't respond at all.

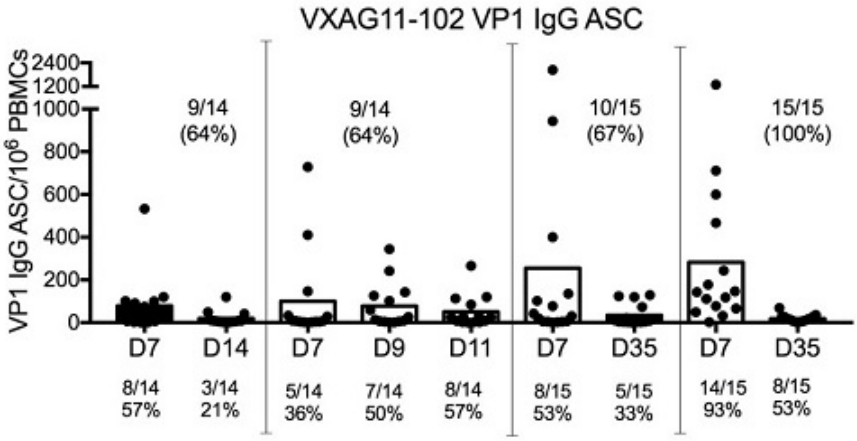
By Fisher's Exact test, the high dose group induced a higher number of responders than group C p=0.02), but only trended higher than groups A and B (0.22, 0.07). Similar results were observed for the IgG ASC responses, with slightly lower values on average.

Fig. 12. IgA ASC Counts for the 102 study.



Caption. The different groups were assessed for IgA ASC counts at each time point taken for each group. Because there were different dosing regiments for each group, there were different timepoints assessed. Response rates at each timepoint are indicated by a fraction and a percentage below each timepoint. The overall response rate (the total number of subjects that responded at any time point) is given near the top of each group. For example, in the last group, 15/15 (100%) subjects responded at either D7 or D35.

Fig. 13. IgG ASC Counts for the 102 Study.



Caption. The different groups were assessed IgG ASC counts at each time point taken for each group. Because there were different dosing regiments for each group, there were different timepoints assessed. Response rates at each timepoint are indicated by a fraction and a percentage below each timepoint. The overall response rate (the total number of subjects that responded at any time point) is given near the top of each group. For example, in the last group, 15/15 (100%) subjects responded at either D7 or D35.

Immunogenicity Results - Study 103

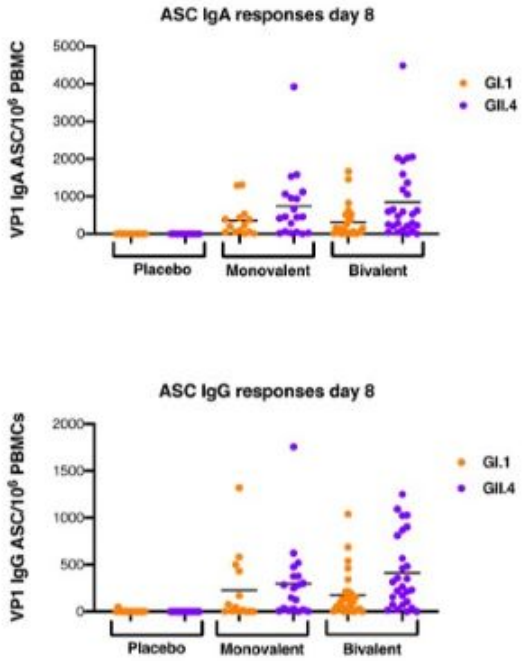
BT50 Titers. There was a significant increase in the titers of serum GI.1 HBGA blocking antibodies by BT50 at Day 29 in the Monovalent GI.1 and Bivalent GII.4/GI.1 from Day 1 values. There was a significant increase in the GMT of serum GII.4 HBGA blocking antibodies by BT50 at Day 29 in the Monovalent GII.4 and Bivalent GII.4/GI.1 from Day 1 values. Serum assays such as the BT50 showed a two- to three-fold increase in titer and a 50% seroconversion rate. No significant differences in the GMT of serum GI.1 HBGA blocking antibodies by BT50 were seen between the Monovalent GI.1 and Bivalent GII.4/GI.1 groups. No significant differences in the GMT of Serum GII.4 BT50 GMT were seen between the Monovalent GII.4 and Bivalent GII.4/GI.1 groups.

Antibody Secreting Cell (ASC). The ability of the vaccine to induce norovirus specific B cells in the peripheral blood was measured by ASC assay. This assay essentially counts the number of B cells that emerge after immunization and recognize norovirus in the peripheral blood. The number that circulate in the blood pre-immunization is very low, so the assay is a meaningful way to evaluate the vaccine specific effects.

The average counts of ASC GI.1 IgG were similar across treatment groups on Day 1. However, on Day 8, statistically significant increases in the average counts of ASC GI.1 IgG were seen in the Monovalent GII.4 group ($p=0.0002$), Monovalent GI.1 group ($p=0.0019$), and the Bivalent GII.4/GI.1 group ($p<0.0001$) compared with placebo. No significant differences in the average counts of ASC GI.1 IgG were seen between the Monovalent GI.1 and Bivalent GII.4/GI.1 groups ($p=0.4172$). The number of subjects with the ASC responses was highest in the Bivalent GII.4/GI.1 group (81.5%) compared with the Monovalent GI.1 group (57.1%), Monovalent GII.4 group (47.4%), and placebo group (6.7%).

The average counts of ASC GII.4 IgG were similar across treatment groups on Day 1. However, on Day 8, statistically significant increases in the average counts of ASC GII.4 IgG were seen in the Bivalent GII.4/GI.1 group ($p<0.0001$) and Monovalent GII.4 group ($p<0.0001$) compared with placebo. No significant differences in the average counts of ASC GII.4 IgG were seen between the Monovalent GII.4 and Bivalent GII.4/GI.1 groups ($p=0.2694$). Number of subjects with response was highest in the Bivalent GII.4/GI.1 group (92.6%) compared with Monovalent GII.4 group (84.2%) and Monovalent GII.4 group (14.3%).

Fig. 14. Plot of ASC GI.1 and GII.4 IgA and IgG response on Day 8 by Dose Group (PP Population).



Caption. The different groups were assessed for IgA and IgG ASC counts in the peripheral blood on Study Day 8 (seven days post immunization). Individual subjects were assessed for both GII.4 (purple) and GI.1 (orange) and plotted as a dot, with the average response for the group shown with a solid black line. These results show that the bivalent group could induce IgA and IgG responses to both GI.1 and GII.4, compared to the placebo group where no significant ASC responses were observed. Further, the monovalent and bivalent groups had similar average responses, demonstrating a lack of interference when the two vaccine strains were given together.

Norovirus Oral Tablet Vaccine Clinical Development Pathway

Phase 1 Bivalent Norovirus Trial Booster. The Phase 1 trial is designed to assess the safety and immunogenicity of a booster norovirus vaccine. The active portion of the bivalent Phase 1 trial was completed in the course of 2019, and topline results were reported in the third quarter of 2019. A booster dose for a subset of subjects is planned for early 2021 to further evaluate safety and immunogenicity of the norovirus vaccine.

Phase 1 Norovirus Age Escalation Trial. The Monovalent Phase 1 age escalation trial is designed to assess the safety and immunogenicity of the norovirus vaccine in an older population.

Phase 2 Norovirus GI.1 Strain Challenge Study. We may conduct a challenge study with our monovalent GI.1 norovirus vaccine candidate dependent on the availability of resources and vaccine.

Phase 2 Efficacy and Safety Trial. This trial will be designed to assess the safety, immunogenicity and possibly the efficacy of the bivalent vaccine in an expanded population of adults ranging in age from 18 to 49 years and step up to adults age 50 to 64, and 65 and older.

Path to Approval. After completing the Phase 2 trial, we anticipate requesting an end-of-Phase 2 meeting with the FDA to discuss the design of a pivotal Phase 3 trial that would support licensure.

Additional Age Groups

- ***Older Adults, Elderly Population***. Following successful completion of the bivalent Phase 1 trial in healthy adults age 18 to 49, we are ready to conduct sequential Phase 1 and Phase 2 clinical trials in healthy adults age 50 to 64 years and age 65 and older, designed to support the safety and immunogenicity of our tablet vaccine candidate for these age groups. Following these studies, we expect to engage in discussions with the FDA to determine the requirements for a Phase 3 pivotal study or studies, and licensure.

- ***Pediatric Population***. Our current tablet vaccine candidates are 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 proprietary liquid 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. 9-17 years, 5-8 years, 2-4 years, 6 weeks-2 years).

Our Seasonal 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 at least 350 million cases of seasonal influenza occur annually worldwide, of which 3 million to 5 million cases are considered severe, causing 290,000 to 650,000 deaths per year globally. Very young children and the elderly are at greatest risk from death. In the United States, between 5% and 20% of the population contracts influenza, 226,000 people are hospitalized with complications of influenza, and between 3,000 and 49,000 people die from influenza and its complications each year, with up to 90% of influenza-related deaths occurring in adults older than 65.

According to a CDC commissioned-report based on 2003 population figures, in the United States seasonal influenza costs an average of over 600,000 life-years lost, 3.1 million hospitalized days, and 31.4 million outpatient visits annually. The total economic burden of seasonal influenza has been estimated to be $87.1 billion, including medical costs which average $10.4 billion annually, while lost earnings due to illness and loss of life amount to $16.3 billion annually.

The CDC generally recommends that individuals 6 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. During the 2017/2018 influenza season, approximately 137 million doses of the influenza vaccine were delivered in the United States. Differentiated flu vaccines in the U.S. market continue to demonstrate the ability to ask for premium prices based on the additional value they provide to public health. According to a 2017 Datamonitor Healthcare report the seasonal influenza vaccines market within the United States and five major European markets (France, Germany, Italy, Spain and the UK) will increase from $2.7 billion in the 2016/17 season to $3.4 billion in the 2025/26 season. We believe, worldwide, the primary drivers of market growth include increasing awareness, increasing vaccination coverage in emerging countries, rising government support for immunization against seasonal influenza, pricing increases due to product differentiation and increased focus on the production and advancement of vaccination treatments.

Limitations of Current Seasonal Influenza Vaccines

Despite the number of cases of influenza diagnosed in the United States, according to the CDC, in the 2018/2019 seasonal influenza season, only approximately 49% of the total U.S. population was vaccinated against influenza, with particularly low vaccination rates among adults between ages 18 and 49. According to the CDC, less than 35% of adults between ages 18 and 49 were vaccinated during the 2018/2019 influenza season. We believe the low vaccination rates among this population are largely attributed to the following limitations of injectable vaccine administration:

Limitations for Providers

- longer manufacturing, shipping and handling time for suppliers;
- cold storage requirement throughout the logistics chain;
- the need for healthcare professional oversight during and after the vaccination procedure;
- potential for needle injuries; and
- medical waste.

Limitations for Users

- inconvenience and time commitment required to obtain vaccine at a clinic or pharmacy;
- fear of needles;
- pain at injection site; and
- potential for allergic reactions to the egg component of the vaccine.

Our Seasonal Influenza Vaccine Candidate

We are developing a tablet vaccine candidate for the immunization of healthy adults against seasonal influenza. Our seasonal influenza vaccine candidate is being designed to cover the four-strain, or quadrivalent, seasonal influenza vaccine consisting of two circulating influenza A lineage viruses as well as two circulating influenza B lineage viruses, matching the seasonally updated recommendations by the FDA. We envision formulating our tablet vaccine candidate as one tablet per strain, or four tablets in total for the quadrivalent 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 three correctly matched vaccine tablets. Alternatively, we have the option to formulate all four 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.

We believe our tablet vaccine candidates have the potential to address many of the limitations of current injectable, egg-based seasonal influenza vaccines. First, our tablet vaccine candidates are designed to create broad and durable immune responses, which may provide more effective immunity and protect against additional strain variants. Second, by providing a more convenient method of administration to enhance patient acceptance and simplify distribution and administration. Finally, by using recombinant methods, we believe our tablet vaccine candidates may be manufactured more rapidly than vaccines manufactured using egg-based methods, eliminate the risk of allergic reactions to egg protein, and alleviate issues caused by egg-adaptation of a mammalian virus.

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.

Phase 1 Trial, VXA02-001, H1N1 Influenza Vaccine Candidate, 10^9 and 10^{10} IU Doses

The first Phase 1 H1N1 trial was conducted at doses of 1 x 10^9 and 1 x 10^{10} IU. Two doses were given one month apart. The tablet vaccine candidate generated a favorable safety and tolerability profile. The trial also demonstrated robust T cell responses and modest hemagglutination inhibition assay (“HAI”) responses, each dependent on the dosage level.

Phase 1 Trial VXA02-003, H1N1 Influenza Vaccine Candidate, 10^{11} IU Dose

The second H1N1 trial was a tablet vaccine trial at a dose of 1 x 10^{11} IU, delivered in a single administration. We observed a favorable safety and tolerability profile at this dose level. An HAI seroconversion rate of 75% was measured in the vaccine group, compared to 0% in the placebo group. 92% of subjects had a four-fold increase in Micro Neutralization (“MN”) titer after the single administration of tablets. Both the HAI seroconversion rate and the MN responses were substantially higher than the respective rates that we observed at lower doses in Trial VXA02-001. The side effects of the vaccine or placebo in the first seven days following administration were mild with no serious adverse effects. In the first seven days following administration, there were eight total solicited AEs reported in the vaccine and placebo groups (four in each group). All these AEs were grade 1 in severity. The most frequent AE was headache (two in placebo, and one in the vaccine group). There were no SAEs and no new onsets of chronic illnesses related to the adjuvant recorded during the entire one year follow up period of the study.

The table below summarizes the trial design and results (serum antibody responses) of our two placebo-controlled Phase 1 H1N1 clinical trials.

Table 7. Overview: H1 Influenza Phase 1 Placebo-Controlled Studies.

TRIAL NO./ # SUBJECTS	TRIAL DESIGN	STUDY GROUPS DOSE/SCHEDULE	KEY IMMUNOGENICITY FINDINGS
Phase 1 Trial VXA02-001 N = 36	Dose-escalation, placebo-controlled, double-blind with enteric-coated capsules	10^9, 10^{10} IU of VXA-A1.1 (H1) vaccine or placebo on Day 0 and Day 28, administered in tablet form	10^9 dose level: • No HAI seroconversion 10^{10} dose level: • 27% HAI seroconversion • 64% MN (4X rise)
Phase 1 Trial VXA02-003 N = 24	Placebo-controlled, double-blind, with enteric-coated tablets	10^{11} IU VXA-A1.1 (H1) vaccine or placebo on Day 0, single administration in table form	• 75% HAI seroconversion • 92% MN (4X rise)

Phase 1 Trial. Influenza B

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 age 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).

H1N1 Influenza Phase 2 Challenge Study Funded by 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 BARDA was subsequently increased to $15.7 million and the term was extended until September 2018.

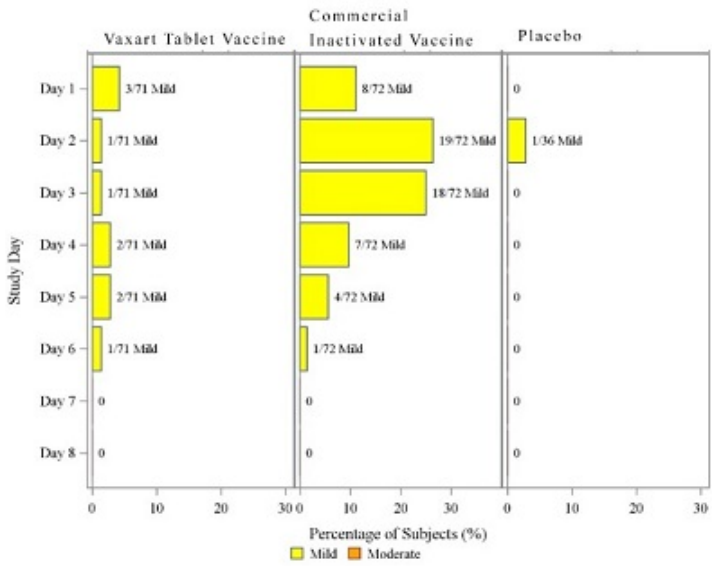
In this Phase 2 study, volunteers were randomized into three groups. One group received our oral H1N1 influenza tablet vaccine candidate, a second group received a commercially licensed inactivated influenza vaccine by intramuscular injection, and a third group received placebo. Three months following 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 is 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 months after dosing.

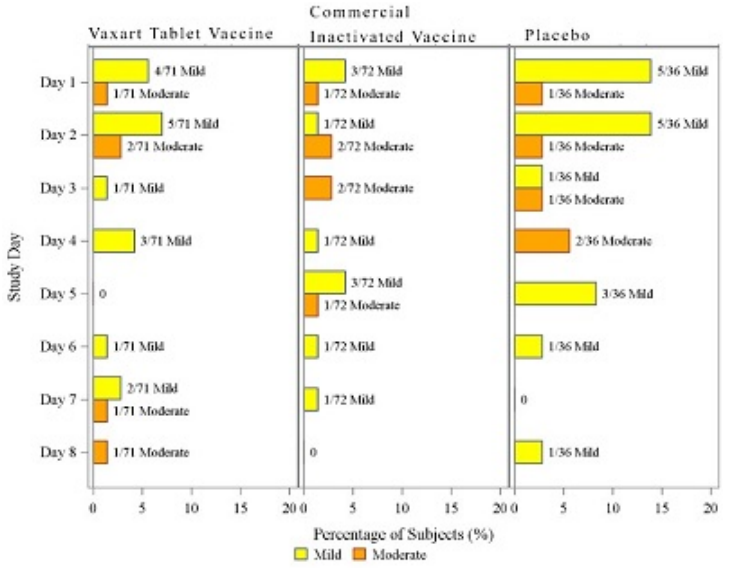
- ***Safety.*** The side effects of the vaccines and placebo in the first seven days following administration were generally mild. In the first seven days following administration, the solicited adverse events reported in the vaccine and placebo groups were mostly grade 1 in severity, and none were above 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. The graphs below show the distribution and severity over time of local and systemic (Figures 14 and 15) solicited adverse events.

Fig. 15. Maximum Severity of Solicited Local Symptoms.



Caption. Solicited local symptoms were collected for seven days following immunization. The severity of solicited symptoms is indicated for each treatment group over time. All events were mild.

Fig. 16. Maximum Severity of Solicited Systemic Symptoms.



Caption. Solicited systemic symptoms were collected for seven days following immunization. The severity of solicited symptoms is indicated for each treatment group over time.

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. The ability to show clinical efficacy in humans is a major step forward for our oral influenza product. These results are summarized in the table below.

Table 8. 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 – Flu-PRO symptom Scores

There were no statistically significant differences between the commercial inactivated influenza vaccine and our tablet vaccine for the Flu-PRO questionnaire, a validated patient recorded outcome tool used in influenza clinical trials in the community. However, our vaccine trended lower for overall symptom severity. Subjects in the VXA-A1.1 group showed a lower overall median Flu-PRO score (2.0 [0, 72]) than the QIV group (5.0 [0, 59]) or the placebo group (5.0 [0, 52]).

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 5 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 8).

Table 9. 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%.*

Immunogenicity

HAI responses. HAI measures the ability of serum antibodies that can disrupt binding of influenza virus to red blood cells. Historically, HAI correlates to protection for injected influenza vaccines. HAI responses were measured 30 days following immunization to determine the number and percentage of volunteers that seroconverted. In our tablet vaccine group, 32% of volunteers achieved seroconversion. In the commercial inactivated influenza vaccine group 84% of volunteers achieved HAI seroconversion at 30 days post vaccination. This difference was statistically significant ($P < 0.001$, Fisher's Exact test). There were no subjects in the placebo group who achieved seroconversion at 30 days post vaccination. Since 32% of subjects seroconverted in the Vaxart tablet vaccine group achieved HAI seroconversion, but 71% of subjects were protected from illness following influenza challenge, HAI seroconversion appeared not to be a reliable indicator of protection for the Vaxart vaccine. The table below summarizes the HAI data. The GMT, GMFR, percentage of volunteers who had a fourfold rise in their HAI and the percentage of subjects who seroconverted are reported.

Table 10. Hemagglutination Antibody Inhibition (HAI) Geometric Mean Titer (GMT) and Geometric Mean Fold Rise (GMFR) Results Post Dosing with 95% Confidence Intervals by Strain, Study Day and Treatment Group.

Full Analysis Set - Vaccination Phase							
	Baseline (Pre-Dosing)		30 Days Post Dosing				
Treatment Group	N	GMT (95% CI)	N	GMT (95% CI)	GMFR (95% CI)	% 4-Fold Rise (95% CI)	% Seroconversion (95% CI)
Strain: A/California/7/2009							
Vaxart Tablet Vaccine	70	11.13 (9.55, 12.96)	69	29.99 (23.72, 37.93)	2.72 (2.18, 3.39)	36.2 (25.0, 48.7)	31.9 (21.2, 44.2)
Commercial Inactivated Influenza Vaccine	72	9.84 (8.33, 11.63)	70	273.13 (182.15, 409.54)	27.50 (19.44, 38.90)	90.0 (80.5, 95.9)	84.3 (73.6, 91.9)
Placebo	35	10.49 (8.37, 13.15)	35	10.40 (8.15, 13.29)	0.99 (0.88, 1.11)	0.0 (0.0, 10.0)	0.0 (0.0, 10.0)

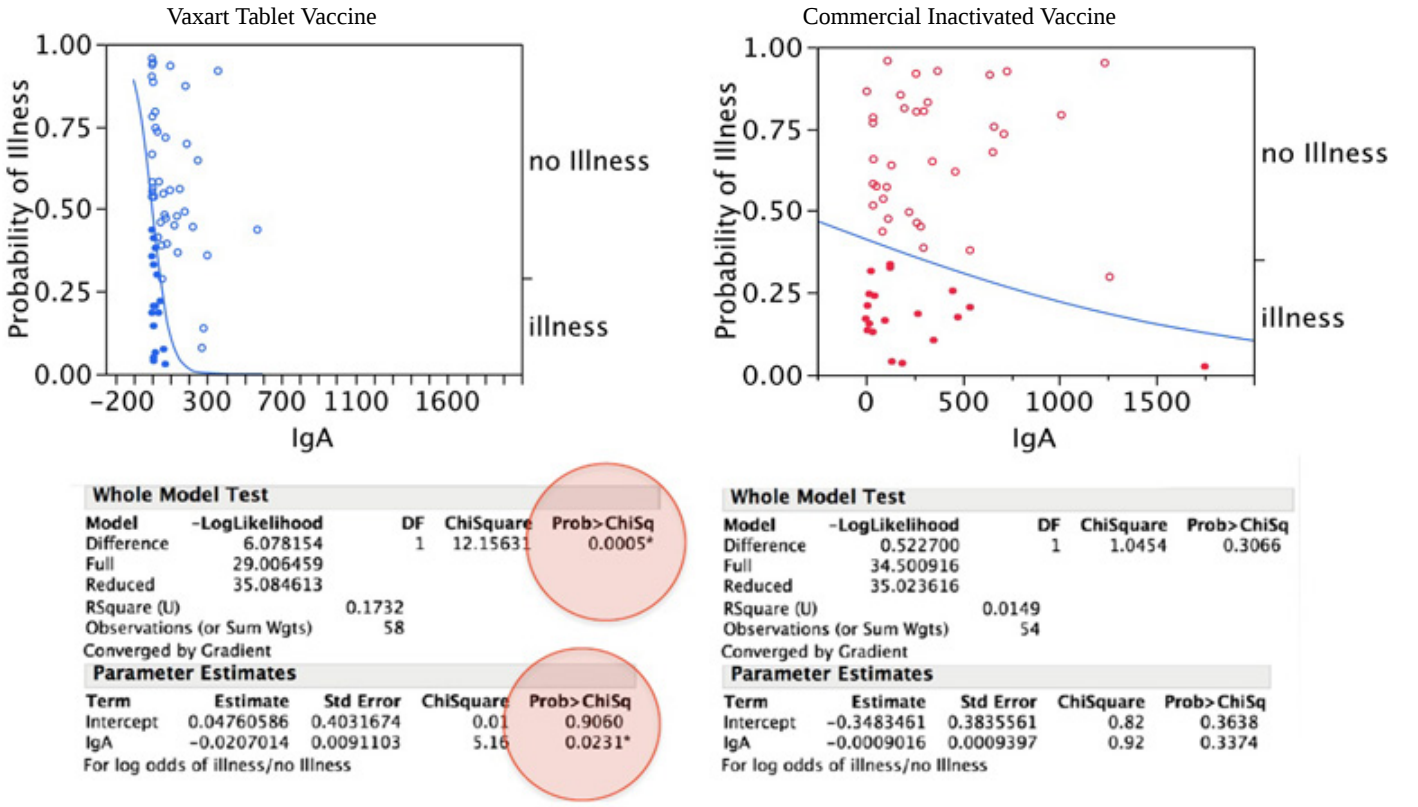
IgA Antibody Secreting Cells. B cells specific for influenza HA (IgA antibody secreting cells or IgA ASCs) were measured at baseline and eight days following immunization in order to determine the B cell responses to the vaccines. At eight days following vaccination, subjects in the commercial inactivated influenza vaccine group had significantly higher mean numbers of spots per 10^6 cells ($p<0.001$, Wilcoxon test) and significantly higher percentages of subjects with greater than 8 spots per 10^6 cells ($p<0.001$, Fisher exact). At Day 8, the commercial inactivated influenza vaccine group had mean spots 286 per 10^6 cells compared to mean spots of 116 per 10^6 cells for the Vaxart tablet vaccine. Additionally, the commercial inactivated influenza vaccine group had a 96% response rate compared to 71% in the Vaxart tablet vaccine group. The table below summarizes these data.

Table 11. ASC Response for IgA and IgG Assays by Study Day and Treatment Group – Vaccination Phase.

		Vaccination Phase							
		Baseline (Pre-Dosing)				Day 8 (Post-Dosing)			
Assay	Treatment Group	N	Mean	Median [Range]	At Least 8 Spots n (%)	N	Mean	Median [Range]	At Least 8 Spots n (%)
IgA ASC	Vaxart Tablet Vaccine	70	2.0	0.0 [0, 18]	6 (8.6)	70	116.0	32.0 [0, 3251]	50 (71.4)
	Commercial Inactivated Influenza Vaccine	71	1.5	0.0 [0, 13]	8 (11.3)	71	286.4	153.0 [3, 1753]	68 (95.8)
	Placebo	36	2.8	0.0 [0, 26]	6 (16.7)	36	16.3	1.0 [0, 256]	8 (22.2)

Correlation of IgA ASCs with Illness for the Vaxart Tablet Vaccine. As stated above, the absolute mean number of ASCs was higher for the commercial inactivated influenza vaccine group (286 spots per 10^6 cells) than for the Vaxart tablet vaccine (116 spots per 10^6 cells). However, when a comparison was made between the two vaccines of the ratio of IgA ASCs in volunteers that were not ill divided by volunteers that were ill following challenge, the Vaxart tablet vaccine group had a ratio of 4.7, compared to a ratio of 1.4 for the commercial injected vaccine. In a logistics fit model with illness compared to non-illness as the outcome, and IgA ASC as the independent variable, the model showed that the Vaxart tablet vaccine IgA ASC could predict ill versus non-ill, but the logistics fit model for the commercial inactivated influenza vaccine could not ($p=0.0005$ for our vaccine, $p=0.3066$ for the commercial injected vaccine for whole logistic model). These data suggest that IgA ASC is important for protection against influenza for our oral vaccine, but not for injected commercial vaccines. These data also suggest that there are ***qualitative*** differences between B cells induced post immunization by different methods. We are actively exploring these qualitative differences.

Fig. 17. IgA ASCs Correlate with Illness for Vaxart Tablet Vaccine.



Caption. Logistic fit regression analysis demonstrates a statistically significant fit for the Vaxart Tablet Vaccine for IgA ASCs and illness. The correlation between higher ASCs and a lower rate of illness is observed. The same model fit is not observed with the commercial inactivated vaccine.

This work was funded in whole or in part with Federal funds from HHS, Office of the Assistant Secretary for Preparedness and Response and BARDA.

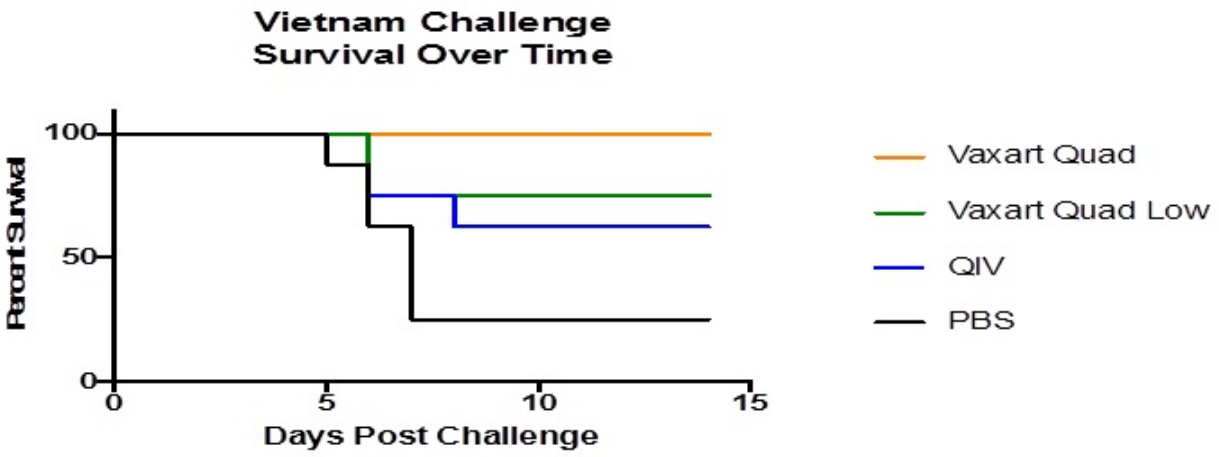
Preclinical Results

We have completed several animal challenge studies for influenza. In an H1N1 influenza challenge study, mice immunized orally with our tablet vaccine candidate were protected against sickness and death compared to unimmunized, control animals. Similarly, our oral H5N1 vaccine candidate protected ferrets and mice against a lethal avian influenza challenge compared to unimmunized animals when the vaccine construct expressed an avian influenza HA construct.

Cross Protection of Vaxart Quadrivalent Seasonal Flu Vaccine against Avian Flu in Ferret Challenge Model

A more recent ferret challenge experiment was completed in 2017 to compare an oral quadrivalent vaccine that we designed with the commercial vaccine Fluzone for protection against a virulent avian influenza strain. There are no components of seasonal influenza vaccines that are matched to the HA made by avian influenza virus, so the virus represents a severe case of vaccine mismatched to virus. Our quadrivalent vaccine was made by mixing four recombinant adenoviruses, each expressing a different HA that matches the HAs in the commercial vaccine, not the HA of the challenge. Two different doses were evaluated; the high dose was used at 1:10 of a Vaxart human dose (Vaxart Quad) and the low dose (Vaxart Quad Low) was used at 1:100 of the human dose. The Fluzone group (QIV) was given at 1:10 of the human dose to directly compare to the Vaxart quadrivalent high dose group. Vaxart animals and the negative control (PBS) animals were given vaccine delivered by endoscope. The QIV animals were intramuscularly injected. Animals were vaccinated on days 0 and 28. Animals were challenged on day 56 with approximately $10^{2.69}$ TCID50/mL of wild type A/Vietnam/1203/2004 (A/VN). Results show that the Vaxart quadrivalent vaccines were able to protect against mismatched A/VN, trending better than Fluzone. The high dose group was able to protect all ferrets against death whereas the low dose Vaxart group protected 75% of ferrets.

Fig. 18. Survival in ferrets vaccinated with seasonal influenza and challenged with H5N1 Vietnam.



Caption. The percent survival was measured for each group at each time point. The Vaxart Quad vaccine group were 100% protected against mismatched avian influenza over the 14 days that survival was assessed. The other groups were not as well protected.

This work was funded in whole or in part with federal funds from HHS BARDA.

Seasonal Influenza Clinical Development Strategy and Pathway

We aim to partner with and/or to obtain funding from the U.S. federal government to finance the development and commercialization of our seasonal quadrivalent influenza oral tablet vaccine. In the future, we may also consider equity offerings and/or debt financings to fund the program.

Our Human Papillomavirus (HPV) Therapeutic Vaccine Candidate

In previous clinical studies with our H5 influenza vaccine candidate, we observed robust T-cell responses that appeared to compare favorably with published results of other flu vaccines, including an adjuvanted vaccine as well as an attenuated live viral vaccine. Specifically, our vaccine generated high levels of polyfunctional cytotoxic CD4 and CD8 cells, T-cells that are likely required to obtain a therapeutic benefit in chronic viral infection and cancer. It was based on these observations that we embarked on the development of our first therapeutic vaccine, targeting HPV -associated dysplasia and cervical cancer.

Medical Need, Commercial Opportunity

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 – HPV16 and HPV18 – responsible for 70% of cervical cancers and precancerous cervical lesions. Cervical cancer is the fourth most common cancer in women worldwide, and about 13,000 new cases are diagnosed annually in the United States according to the National Cervical Cancer Coalition. Studies have indicated a high lifetime probability of any HPV infection by both men and women in the United States, with some estimates indicating at least 80% of women and men acquire HPV by age 45. The CDC estimates 80 million U.S. citizens are currently infected with HPV, representing 25% of the population, with about 14 million new infections per year. A report by BCC Research expects the global cervical cancer drug and diagnostic market to exceed $15 billion by 2018.

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, or CIN, which can progress to invasive cancer over time. More than 400,000 women are diagnosed with CIN annually in the United States, with an annual incidence estimate for CIN1 and CIN2/3 at 1.6 and 1.2 per 1,000 women, respectively.

There are currently no approved therapeutic vaccines to treat HPV infection or cancer. Current treatment options for women infected with HPV (see below) 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

Our plan is to develop a bivalent HPV vaccine against HPV 16 and 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 HPV16 and our HPV18 vaccine candidates. Specifically, mice given our HPV16 or HPV18 vaccines induced T cell responses to HPV as measured by IFN gamma ELISPOT. In addition, our HPV16 vaccine has demonstrated tumor growth suppression as well as increased survival in a robust HPV tumor model in mice. We believe that our HPV vaccine has several advantages over current treatment options for both CIN and cervical cancer. Current treatment options for CIN are invasive and can lead to serious contraindications for pregnancy. In addition, surgical treatments for CIN do not treat the underlying HPV, but rather remove infected tissue. As a result, current CIN treatment options have a significant failure rate which can increase the risk for progression to cervical cancer. Our vaccines have demonstrated a favorable safety and tolerability profile in clinical subjects dosed to date. Current treatment options for cervical cancer, such as chemotherapy and radiation treatment, have multiple side effects such as hair loss, loss of appetite, and severe nausea.

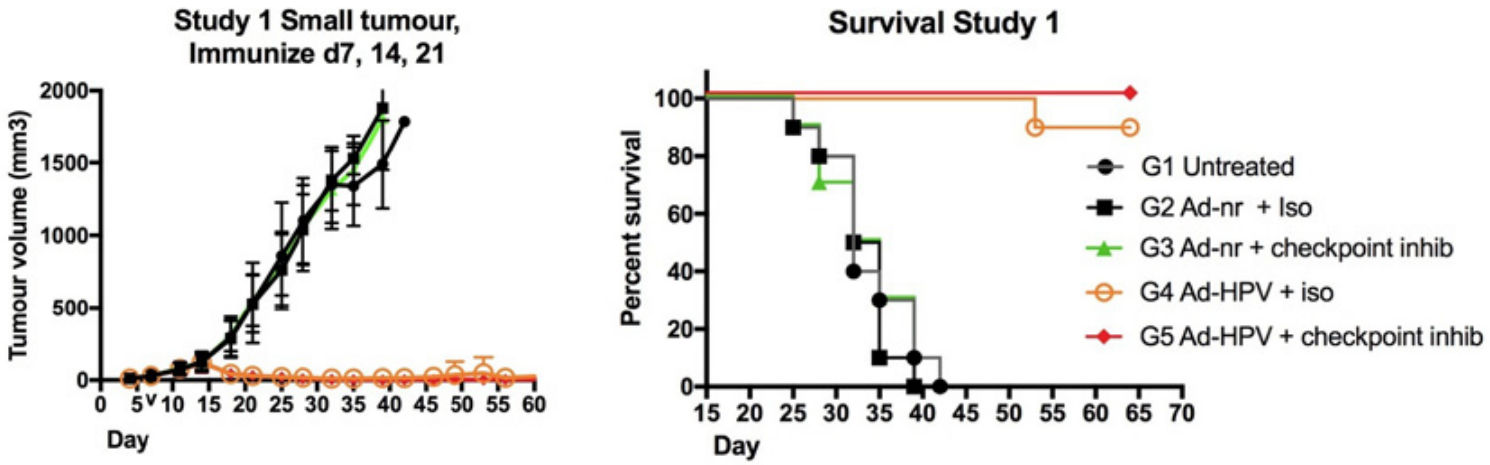
T cells responses to HPV-16 can shrink solid tumors derived from transformed HPV

The ability of T cell responses to HPV-16 to produce a therapeutic response was tested in a solid tumor growth model. TC-1 cells (an HPV-16 transformed cell-line) were injected subcutaneously into the hind flank of B6 mice and allowed to grow for several days before mice were immunized with vaccine or controls. In study 1, mice were immunized on days 7, 14, and 21. For groups 4 and 5, the vaccine expressed the HPV16 antigens E6/E7 (Ad-HPV). A checkpoint inhibitor (an antibody to PD-1) was used along with the vaccine in group 5, and an isotype control (Iso) to the checkpoint inhibitor was used in group 4. A recombinant rAd vector identical to Ad-HPV, but which doesn't express the HPV antigens (Ad-nr), was used in groups 1 or 2 to control for non-specific effects. Untreated animals were not given any vaccine.

The results in study 1 showed that Ad-HPV groups were able to the stop tumor growth and even shrink the tumor. This occurred whether the checkpoint inhibitor was used or not. The checkpoint inhibitor alone was not able to stop tumor progression, and eventually all these animals perished. Other control animals without Ad-HPV didn't survive as well. The use of the checkpoint inhibitor with the Ad-HPV vaccine trended slightly better for survival (10/10 versus 9/10 survived), but this was not significant.

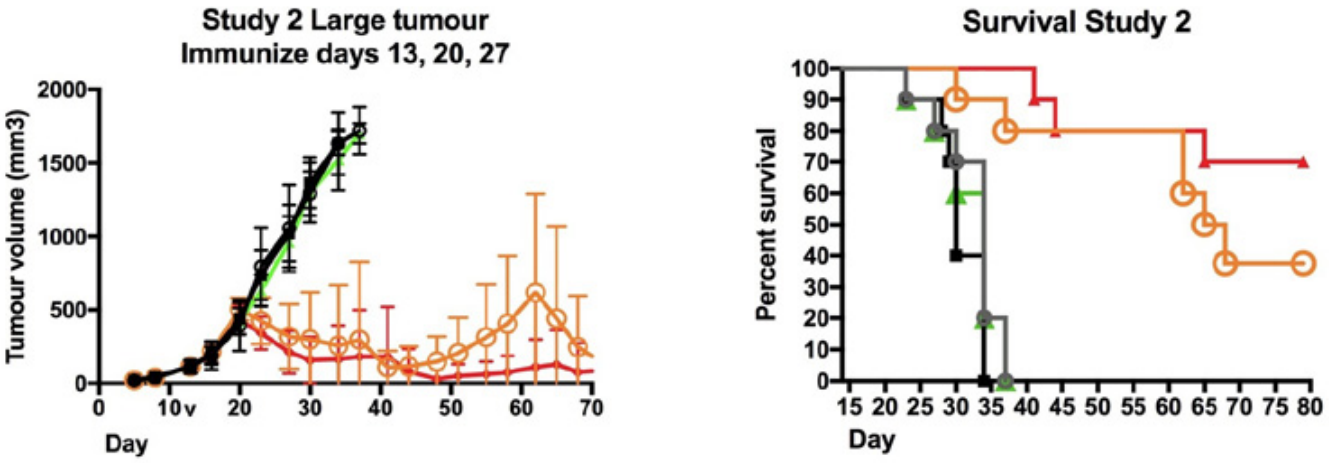
In study 2, the TC-1 tumor was transplanted as before, but allowed to grow longer before immunization occurred. Immunizations occurred on days 13, 20, and 27. In this study, mice that received the Ad-HPV vaccine plus the checkpoint inhibitor were able to control the tumor, up through day 40 before a few mice started to perish. More than 70% of animals in this group survived through the end of the experiment on day 80. Ad-HPV immunized mice in the absence of the checkpoint inhibitor were also able to substantially control the tumor through 60 days (33 days after the last immunization), before several additional animals perished. No control groups in the absence of the Ad-HPV were able to control any of the tumors, and all mice perished before day 40.

Fig. 19. Small Tumor Vaccine Study.



Caption. In the small tumor vaccine study (Study 1), tumors were allowed to grow for seven days before beginning the immunization schedule. Animals given the Vaxart HPV vaccine (Ad-HPV) were protected against tumor growth and survived better. This was the case whether or not a checkpoint inhibitor was used.

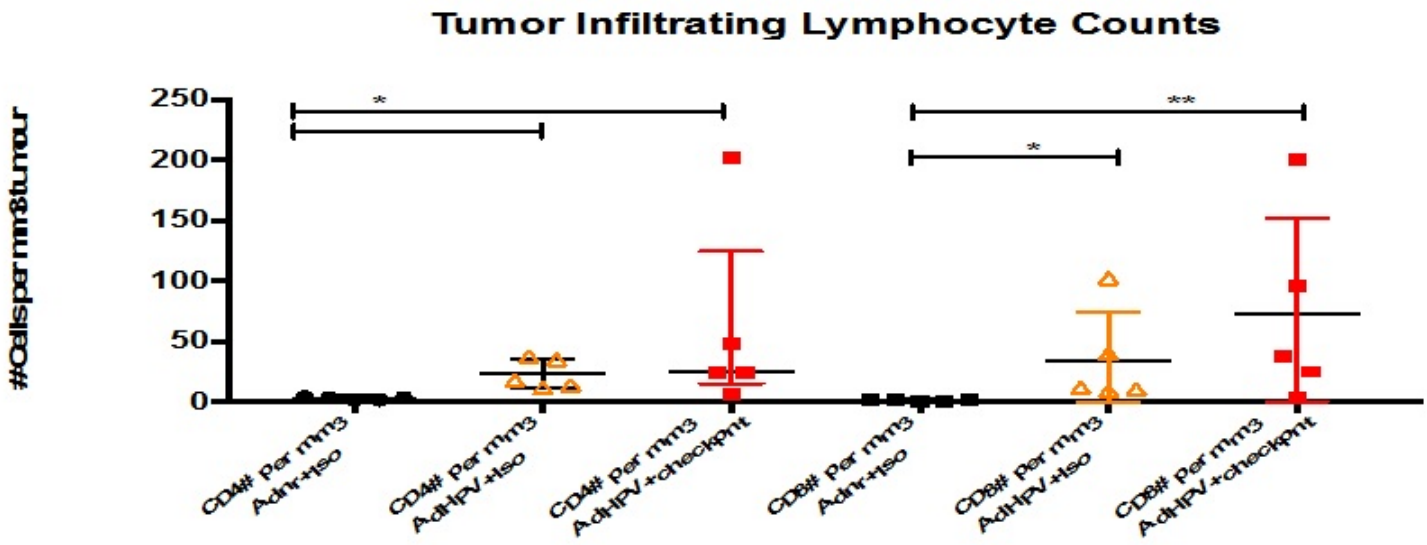
Fig. 20. Large Tumor Vaccine Study.



Caption. In the large tumor vaccine study (Study 2), tumors were allowed to grow for 13 days before the vaccines were given. Again, animals given the Ad-HPV were better protected against tumor growth. The addition of the checkpoint inhibitor improved survival.

The T cells induced post immunization in the tumor model were believed to traffic back to the solid tumor to attack and destroy the cancer cells. This was tested in an additional tumor model experiment. Tumors were transplanted as before, and immunizations were performed on days 13 and 21. Tumors were harvested from the experiment on day 24, and flow cytometry was used to enumerate the T cells infiltrating the tumors. The HPV16 vaccine groups (with either the checkpoint inhibitor or an isotype control antibody) had T cell infiltrates of both CD4 and CD8 positive T cells. The CD8 T cell numbers from the Ad-HPV groups were significantly better than control treated animals in terms of infiltrating lymphocytes. The CD4 T cells were significantly better in the Ad-HPV + checkpoint group, and trended higher in the Ad-HPV + isotype control group.

Fig. 21. The Ad-HPV vaccine induces T cells that migrate to the tumors.



Caption. The number of CD4 and CD8 T cells found within the tumor were analyzed by flow cytometry. The Ad-HPV groups were found to elicit T cells that transited to the tumor, with the Ad-HPV plus checkpoint inhibitor creating slightly more T cell transit than the Ad-HPV vaccine alone.

Near Term HPV Vaccine Development Strategy

Preclinical

The next steps in the vaccine development are to complete the nonclinical studies, which may include a toxicology study using Good Laboratory Practices ("GLPs") to support an IND filing for this vaccine. The exact nature of these studies will be determined in consultation with the FDA.

Clinical

We will propose to test the vaccine in subjects with cervical dysplasia related to HPV16 or HPV18, and to evaluate the ability of the vaccine to clear HPV infection, reduce the cervical dysplasia score, and induce T cells known to be important in the clearance of HPV. T cells will be measured by flow cytometry as well as by IFN-g ELISPOT. 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.

General

Currently, all HPV development is on hold while the Company is focusing its efforts on the COVID-19 vaccine.

Other Indications

We currently have preliminary data in animal models for indications such as RSV, Chikungunya, Hepatitis B and HSV-2.

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 through December of 2017, we relied on third-party contract manufacturers to manufacture clinical cGMP bulk drug substance for our influenza and norovirus 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. During the fourth quarter of 2019, a decision was made to discontinue all activities related to in-house bulk manufacturing and revert to relying on third-party contract manufacturers, so the Company terminated all of its manufacturing staff. Following a reassessment due to the COVID-19 pandemic, we resumed small scale in-house manufacturing in 2020.

In July 2019 we entered into a relationship with Lonza Houston, Inc. ("Lonza") to manufacture bulk norovirus GI.1 and GII.4 vaccine under cGMP. In late 2019, Company suspended the Lonza manufacturing agreement, pending the outcome of the norovirus partnering discussions. Vaxart settled all of its remaining obligations under its agreement with Lonza by paying $2.3 million in September 2020.

In March 2020, we entered into an agreement with Emergent BioSolutions Inc. for the development and manufacture of SARS-CoV-2 vaccine. In May 2020, we entered into an agreement with Kindred Biosciences, Inc. ("KindredBio") for the manufacture of our SARS CoV-2 vaccine. In September 2020 we executed two statements of work with KindredBio for the bulk manufacture of our SARS-CoV-2 and norovirus vaccines. In addition, in October 2020 and January 2021 we executed agreements with Attwill Vascular Technologies, LP ("Attwill") for manufacturing, including lyophilization of drug substance at a larger scale.

Vaccine Tablet Manufacturing (Drug Product)

From inception through December of 2017, we contracted with third-party contract manufacturers for the manufacture, labeling, packaging, storage and distribution of our drug product. During 2016, we established drug product manufacturing capabilities at our corporate headquarters. Our facility is licensed by the State of California Department of Public Health Food and Drug Branch to manufacture drug product for clinical trials. In addition, in January 2021 we executed an agreement with Attwill for further drug product manufacturing (tableting and coating) at a larger scale.

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 facility, 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.

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. The major global non-recombinant injectable vaccine competitors include Astellas Pharma Inc., Abbott Laboratories, AstraZeneca UK Limited, Baxter International Inc., Research Foundation for Microbial Diseases of Osaka University, Seqirus-bioCSL Inc., GSK, Sanofi S.A. (“Sanofi”), Pfizer Inc., and Takeda Pharmaceutical Company Limited (“Takeda”). Non-recombinant intranasal competition includes MedImmune, Inc. (“MedImmune”), and potentially others. Recombinant injectable competitors include Sanofi, Medicago and Novavax, Inc. (“Novavax”). Many other groups are developing new or improved flu vaccine or delivery methods.

Norovirus Vaccine Candidate

There is currently no approved norovirus vaccine for sale globally. We believe that Takeda is developing a norovirus vaccine that would be delivered by injection. There may be other development programs that we are not aware of.

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”), Advaxis, Genexine, and several others.

Coronavirus Vaccine Candidate

Pfizer-BioNTech, Moderna and Johnson & Johnson have already developed a COVID-19 vaccine approved for emergency use in the United States and elsewhere, and many more, including several that have progressed further than us, including Oxford-AstraZeneca, Sanofi, Inovio, Takara Bio and Novavax, are in various stages of development.

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 the proprietary technology, inventions and improvements that are commercially important to our business, including 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, 2020, we hold three U.S. patents with granted 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, 2020, we hold more than 50 issued foreign patents and one pending foreign patent application related to our platform technology and/or our vaccine candidates. These patents will expire in 2027, or later if patent term extension applies.

- ***Tablet Vaccine Formulation***. We own considerable know-how and hold foreign patents in China, Singapore, Russia and South Africa. We also have pending applications in the United States and around the world related to our tablet vaccine formulation technology. Patents issuing from these applications will expire in 2035, or later if patent term extension applies.

- ***COVID-19 Vaccine Candidate***. As of December 31, 2020, we have filed provisional applications in the United States relating to our COVID-19 vaccine candidate. Any patents issuing from these applications will expire in 2041, or later if patent term extension applies.

- ***Influenza, Norovirus and RSV Vaccine Candidates***. As of December 31, 2020, we hold a patent in South Africa, the European Union, and a number of countries therein, and have pending applications in the United States and around the world relating to our norovirus and RSV vaccine candidates. Any patents issuing from these applications will expire in 2036, or later if patent term extension applies. We have been issued 13 foreign patents related to our current H1N1 influenza vaccine candidate. These patents will expire in 2030, or later if patent term extension applies.

- ***Relenza***. As of December 31, 2020, we no longer own any Relenza patents, the last Japanese patent related to Relenza, which was exclusively licensed to GSK, having expired in July 2019.

- ***Inavir***. As of December 31, 2020, we own Japanese patents related to Inavir, which is exclusively licensed to Daiichi Sankyo. The last patent related to Inavir in Japan is set to expire in December 2029, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expires in 2024, at which time generic competition may enter the market, potentially decreasing or eliminating the royalties received.

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

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

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

Trade Secrets

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

Government Regulation and Product Approval

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

U.S. Product Development Process

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

- completion of nonclinical laboratory tests and animal studies according to GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice ("GCP"), and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a Biologics License Application ("BLA") for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

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

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

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

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

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

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

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

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

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

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

U.S. Review and Approval Processes

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

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

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

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

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

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

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

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

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

Post-Approval Requirements

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

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

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

Other U.S. Healthcare Laws and Compliance Requirements

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

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

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

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

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

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

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

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

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

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

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

Coverage, Pricing and Reimbursement

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

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

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

US Healthcare Reform

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

Foreign Regulation

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

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 team includes Ph.D.-level scientists with expertise in mucosal immunology, T cells, viral vectors and virology. As of December 31, 2020, we had 28 full-time employees of whom 20 were engaged in research and development ("R&D") and eight were engaged in finance, human resources, administration, business and general management (collectively, "G&A"). We also had 21 consultants supporting these functions. We do not have collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Our human capital resources objectives include identifying, recruiting, retaining, and incentivizing our existing and new employees. We maintain an equity incentive plan, the principal purposes of which are 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. 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.

In addition, as a result of the COVID-19 pandemic, we have taken steps to protect the health and safety of our employees by generally adopting a work from home policy in line with directives from the State of California and the applicable local governments, and guidance from the CDC. On-site activities have been restricted to certain essential facility and laboratory support functions and various safety protocols have been implemented.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K, including our 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 on Form 10-K 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

- Our business may be adversely affected by the ongoing coronavirus pandemic.
- We have a limited operating history and have generated only 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 coronavirus and norovirus 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.
- We are presently subject to multiple legal proceedings and may be subject to additional legal proceedings.
- Our development of a COVID-19 vaccine candidate is at an early stage, and we may be unable to produce an effective vaccine that successfully immunizes humans against SARS-CoV-2 in a timely manner, if at all.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

- The regulatory pathway for coronavirus vaccines is evolving and 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

- We rely on third-party contract manufacturers for the manufacture of our products.
- If third-party contract manufacturers, upon whom we may have to rely to formulate and manufacture our product candidates, 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 Our Business, Financial Position and Capital Requirements

Our business may be adversely affected by the ongoing coronavirus pandemic.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. This virus continues to spread globally and efforts to contain the spread of COVID-19 have intensified. The outbreak and any preventative or protective actions that governments or we may take in respect of COVID-19 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 COVID-19 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 COVID-19 and the actions to contain COVID-19 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 COVID-19 or other infectious diseases 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.

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 have a limited operating history and have generated only 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 longer operating history or 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 treatment of coronavirus, norovirus, seasonal influenza, respiratory syncytial virus, or RSV, cervical cancer and dysplasia caused by human papillomavirus, or HPV, and other infectious diseases, and to obtain the necessary regulatory approvals.

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

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

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

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

We expect overall research and development expenses to increase significantly for any of our tablet vaccines, including those for the prevention of coronavirus, norovirus, influenza and RSV infection, 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, 2020, we had an accumulated deficit of $148.9 million.

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

None of our product candidates are in late-stage clinical development or approved for commercial sale and we may never be able to develop marketable tablet vaccine candidates. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our tablet vaccine candidates for coronavirus and norovirus. We are committing financial resources to the development of a COVID-19 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 COVID-19 vaccine development. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of our coronavirus and norovirus tablet vaccine. These tablet vaccines may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of tablet vaccine candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market our tablet vaccines in the United States until we receive approval of a Biologics License Application (“BLA”) from the FDA, or in any foreign countries until we receive the requisite approval from such countries. To date, we have only completed Phase 1 clinical trials for our bivalent norovirus tablet vaccine candidate. As a result, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of our tablet vaccines for many reasons, including:

- We may not be able to demonstrate that our tablet vaccine is safe and effective to the satisfaction of the FDA;
- the FDA may not agree that the completed Phase 1 clinical trials of the norovirus vaccine satisfy the FDA’s requirements and may require us to conduct additional testing;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of one or more of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials;
- the FDA may not find the data from our preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of our tablet vaccines outweigh the safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;

- if our NDA or BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA may require development of a risk evaluation and mitigation strategy as a condition of approval;

- the FDA may identify deficiencies in our manufacturing processes or facilities; and

- the FDA may change its approval policies or adopt new regulations.

Our development of a COVID-19 vaccine candidate is at an early stage. We may be unable to produce an effective vaccine that successfully immunizes humans against SARS-CoV-2 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. In response to the global outbreak of COVID-19, in January 2020 we announced that we had initiated a program to develop a coronavirus vaccine candidate based on our Vector-Adjuvant-Antigen Standardized Technology ("VAAST") proprietary oral vaccine platform. In addition, on October 13, 2020, we announced that the first subject has been dosed in our Phase 1 study of VXA-CoV2-1, a non-replicating Ad5 vector oral tablet COVID-19 vaccine candidate. Our development of the vaccine is at an early stage, and we may be unable to produce an effective vaccine that successfully immunizes humans against SARS-CoV-2 in a timely manner, if at all.

We have also entered into an agreement with certain manufacturing partners to help develop and manufacture our experimental oral COVID-19 vaccine. If we are unsuccessful in maintaining our relationships with these and other critical third parties, our ability to develop our oral COVID-19 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 COVID-19 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 COVID-19 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. To date, our manufacturing partners have manufactured clinical supply for our planned clinical investigations. The number of doses of our potential vaccine that we are able to produce is dependent on the ability of our contract manufacturers 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.

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 COVID-19, and this may have the effect of increasing the number of competitors and/or providing advantages to known competitors. We are aware of a substantial number of companies, individuals and institutions working to develop a vaccine against or treatment for COVID-19, many of which have substantially greater financial, scientific and other resources than us, and another party may be successful in producing a vaccine against COVID-19 or an effective treatment before we do. The rapid expansion of development programs directed at COVID-19 may also generate a scarcity of manufacturing capacity among contract research organizations that provide cGMP materials for development and commercialization of biopharmaceutical products.

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 coronavirus, norovirus, seasonal influenza, RSV 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, 2020, we had $126.9 million of cash and cash equivalents. Since then, we have received net proceeds of $65.8 million from the sale of common stock under the Open Market Sale Agreement with Jeffreys LLC and Piper Sandler & Co. (the "Open Market Sale Agreement") and $1.6 million from the exercise of common stock warrants.

Although we believe these funds are sufficient to fund our operations under our current operating plan well into 2022 and possibly beyond, 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, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.

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

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

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

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

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

In addition, public statements by us, government agencies, the media or others relating to the coronavirus outbreak (including regarding efforts to develop a coronavirus 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.

An ownership change under Section 382 of the Code subjects the Company and all of its subsidiaries to limitations on the use of U.S. net operating loss carryforwards and certain other tax attributes. Since the ownership change that occurred in February 2018 due to the Merger, we have identified further changes in April 2019, September 2019 and May 2020, and further ownership changes in the future would subject us to further limitations.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the corporation's U.S. net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds 50% over a three-year period. Similar rules may apply under state and foreign tax laws. Ownership changes occurred for the Company and all of its subsidiaries in February 2018, April 2019, September 2019 and May 2020; accordingly, our U.S. net operating loss carryforwards and certain other tax attributes are subject to limitations on their use. Additional ownership changes in the future would result in further limitations on the combined organization's ability to use net operating loss carryforwards generated in the intervening period. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on our cash flow and results of operations.

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

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

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

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

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

We rely on our executive officers and the other principal members of the executive and scientific teams, particularly our President and Chief Executive Officer, Andrei Floroiu and our Chief Scientific Officer, Sean N. Tucker, Ph.D. 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, 2020, we had 28 full-time 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.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true, complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

We could face risks related to the potential outcomes of the investigation by the U.S. Attorney's office and/or SEC informal inquiry, including potential fines, penalties, damages or other remedies that could be imposed on us, substantial legal costs and expenses, significant management distraction, and potential reputational damages that we could suffer as a result of adverse findings.

In July 2020, the U.S. Attorney's Office for the Northern District of California provided a grand jury subpoena to the Company seeking information pertaining to the Company's participation in, and disclosure of, an Operation Warp Speed-funded ("OWS") non-human primate study of the Company's oral COVID-19 vaccine and certain corporate, financing and stock transactions. In October 2020, the Company was informed that the investigation was being transferred to the Office of the U.S. Attorney for the Eastern District of New York and the Fraud Section of Main Justice (collectively, "DOJ"), and that the Office of the U.S. Attorney for the Northern District of California required no further response or action from the Company. In November 2020, the Company received a grand jury subpoena from DOJ that seeks substantially the same information as the earlier subpoena from the Northern District of California. In August 2020, the Enforcement Division of the SEC requested that the Company provide, on a voluntary basis, certain documents and information relating to the Company's participation in the aforementioned OWS-funded nonhuman primate study. The SEC has advised us that this informal, non-public fact-finding inquiry should not be construed as an indication that we or anyone else has violated the law or that the SEC has any negative opinion of any person, entity or security. The Company is cooperating with the SEC and DOJ and has provided them both with information and documents. We do not intend to comment further on these matters until they are closed or further action is taken by the SEC or the DOJ that, in our judgment, merits further comment or public disclosure. We could face risks related to the potential outcomes of these inquiries, including legal costs and expenses, potential regulatory action, penalties, damages or other remedies that could be imposed on us, management distraction, and potential reputational damage that we could suffer as a result of potential adverse findings.

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. At present, there are three analysts covering our stock. We have no control over these analysts. 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. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which could cause our trading volume and share price to decline.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

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

To date, VXA-CoV2-1 has moved rapidly through the FDA regulatory review process. 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 VXA-CoV2-1. 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 candidate. Discussions with FDA regarding the design of the anticipated Phase 2 and 3 studies for VXA-CoV2-1 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 VXA-CoV2-1. 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 VXA-CoV2-1, we would be able to commercialize VXA-CoV2-1 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 VXA-CoV2-1 is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide VXA-CoV2-1 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 slow-downs 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.

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 7 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 four 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 four influenza strains into one vaccine tablet. In addition, increasing the potency of the vaccine tablets or combining the influenza strains necessary to create a quadrivalent 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 and RSV 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 and seasonal influenza are still in early-stage clinical development. Both 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 seasonal influenza, norovirus and RSV 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 seasonal influenza, norovirus and RSV may not be predictive of the results of subsequent clinical trials. Furthermore, the FDA may impose additional requirements to conduct preclinical studies to advance the HPV therapeutic vaccine candidates which could delay initiation of Phase 1 studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

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

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

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

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

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

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

COVID-19 could adversely impact our preclinical studies and clinical trials.

Since the initial report of a novel strain of coronavirus, SARS-CoV-2, in China in December 2019, COVID-19 has spread to multiple countries, including the United States. We have active and planned preclinical studies and clinical trial sites in the United States. On October 13, 2020, we announced that the first subject has been dosed in our Phase 1 study of VXA-CoV2-1, a non-replicating Ad5 vector oral tablet COVID-19 vaccine candidate.

As COVID-19 continues to spread around the globe, we will likely experience disruptions that could severely impact our planned and ongoing preclinical studies and clinical trials, including preclinical and clinical studies and manufacturing of VXA-CoV2-1 and clinical trials of our vaccine candidate for the GI.1 and GII.4 norovirus strains. Effects on our preclinical studies and clinical trial programs include, but are not limited to:

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

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

The global outbreak of COVID-19 continues to rapidly evolve. The extent to which COVID-19 may impact our preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

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

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

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

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

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

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

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

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

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

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

- develop and commercialize tablet vaccine candidates that are superior to other vaccines in the market;
- demonstrate through our clinical trials that our tablet vaccine candidates are differentiated from existing and future therapies;
- attract qualified scientific, vaccine development and commercial personnel;
- obtain patent or other proprietary protection for our tablet vaccine candidates;
- obtain required regulatory approvals;

- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and

- successfully develop and commercialize, independently or with collaborators, new tablet vaccine candidates.

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

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

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

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

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

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

We believe our seasonal influenza vaccine candidate will compete directly with approved vaccines in the market, which include non-recombinant and recombinant products that are administered via injection or intranasally. The major non-recombinant injectable vaccine competitors include Astellas Pharma Inc., or Astellas, Abbott Laboratories, AstraZeneca UK Limited, Baxter International Inc., Research Foundation for Microbial Diseases of Osaka University, Seqirus-bioCSL Inc., GlaxoSmithKline plc, or GSK, Sanofi S.A., or Sanofi, Pfizer Inc., or Pfizer, and Takeda Pharmaceutical Company Limited, or Takeda. Non-recombinant intranasal competition includes MedImmune, Inc., or MedImmune, and potentially others. Recombinant injectable competitors include Sanofi and Novavax, Inc., or Novavax. Many other groups are developing new or improved flu vaccine or delivery methods.

There is currently no approved norovirus vaccine for sale globally. While we are not aware of all of our competitors' efforts, we believe that Takeda is also developing a virus-like particle-based norovirus vaccine that would be delivered by injection.

There is currently no approved RSV 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. In addition, many other companies are developing products to prevent disease caused by RSV using a variety of technology platforms, including monoclonal antibodies, small molecule therapeutics, as well as various viral vector and VLP based vaccine technologies. While we are not aware of all of our competitors' efforts, we believe that several companies are in various stages of developing an RSV vaccine including Pfizer, Merck and Co., Inc., GSK, Johnson & Johnson, Bavarian Nordic, Astellas, MedImmune, Novavax, and Sanofi, as well as the National Institute of Allergy and Infectious Diseases, an institute under the U.S. National Institutes of Health, and possibly others.

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., or Inovio, Advaxis, Genexine, and possibly others.

There is currently no fully-approved SARS-CoV-2 vaccine for sale globally; however, Pfizer-BioNTech, Moderna and Johnson & Johnson have already developed a COVID-19 vaccine approved for emergency use in the United States and elsewhere, and many more, including several that have progressed further than us, including Oxford-AstraZeneca, Sanofi, Inovio, Takara Bio and Novavax, are in various stages of development, some of which have already received approval for emergency use in some European countries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on manufacturing such tablet vaccine candidate;
- restrictions on the labeling or marketing of a tablet vaccine candidate;
- restrictions on tablet vaccine distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the tablet vaccine candidate from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of such tablet vaccine candidate;
- fines, restitution or disgorgement of profits or revenues;

- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such tablet vaccine candidate;
- tablet vaccine candidate seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- the civil False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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

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

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

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

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

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

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

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

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

- decreased demand for any tablet vaccine candidates that it may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue; and
- the inability to commercialize any products we may develop.

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

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

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

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

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

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

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

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

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

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

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

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

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- tablet vaccination shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

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

Influenza is seasonal in nature with sales of current vaccines occurring primarily in the first and fourth quarters of the calendar year. In addition, outbreaks of norovirus and RSV 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 and, until the royalty agreement expired in July 2019, Relenza, which are marketed by our licensees. Although the royalty rates paid to us by our licensees are fixed at a proportion of the licensees' net sales of these products, our periodic and annual revenues from these royalties have historically been variable and subject to fluctuation based on the seasonal incidence and severity of influenza. It is the seasonality of influenza, which occurs mainly in the winter months, that causes our revenue to be low in the second and third fiscal quarters, since our agreement with HealthCare Royalty Partners III, L.P. (see Note 7 to our 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.

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

In addition, all of our Relenza patents have expired, with the last substantial intellectual property related to the Relenza patent portfolio having expired in July 2019 in Japan. Further, we sold a portion of our Inavir royalties to HealthCare Royalty Partners III, L.P. in April 2016. We cannot predict with any certainty what our royalty revenues are likely to be in any given year.

If safety, tolerability, resistance, drug-drug interactions, competing products or efficacy concerns should arise with Inavir, our future royalty revenue may be reduced, which would adversely affect our financial condition and business.

We currently earn royalty revenue from Inavir and, until the royalty agreement expired in July 2019, Relenza, which are marketed by our licensees. Data supporting the marketing approvals and forming the basis for the safety warnings in the product labels for these products were obtained in controlled clinical trials of limited duration in limited patient populations and, in some cases, from post-approval use. As these marketed products are used over longer periods of time and by more patients, some with underlying health problems or taking other medicines, new issues such as safety, tolerability, resistance or drug-drug interaction issues could arise, which may require our licensees to provide additional warnings or contraindications on their product labels, or otherwise narrow the approved indications. Further, additional information from ongoing research or clinical trials of these products that raise any doubts or concerns about their efficacy may arise, or competing products may be introduced and limit the market penetration of our product candidates. If serious safety, tolerability, resistance, drug-drug interaction, efficacy, competing products, or any other concerns or issues arise with respect to Inavir and Relenza, sales of these products could be impaired, limited or abandoned by our licensees or by regulatory authorities, in which case our royalty revenue would decrease.

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

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

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

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

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

We are aware of a number of companies marketing or developing various classes of anti-infective product candidates or products for the treatment of patients infected with HPV and RSV 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.

Effective treatments of RSV infections in pediatrics, the elderly, and the immunocompromised are very limited. Currently, only Virazole (ribavirin) is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to RSV. We are aware that the following compounds are under development to treat RSV infections: Gilead's presatovir, Johnson & Johnson's JJ-53718678 (ALS-8176), Ablynx's ALX-0171 and Ark Biosciences' AK0529. The only approved drug for the prevention of RSV infections in high-risk infants is MedImmune's palivizumab (Synagis), a monoclonal antibody. There are several vaccines and antibody products designed to prevent RSV infections in clinical development. Among the clinical stage product candidates in development are Novavax's RSV F vaccine, GSK's GSK3003898A vaccine, GSK's GSK3389245A vaccine, Bavarian Nordic's BN RSV vaccine, MedImmune's MEDI ÄM2-2 vaccine and MedImmune's monoclonal antibody MEDI8897.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently on December 22, 2018, 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

If third-party contract manufacturers, upon whom we may have to rely to formulate and manufacture our product candidates, 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We 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.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for our stockholders.

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

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

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

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

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

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

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

Our computer systems and those of our service providers, including our CROs, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including earthquakes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our or their operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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, since our public float exceed $700 million on June 30, 2020, our independent registered public accounting firm is required to attest annually to the effectiveness of our 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, 2020, we concluded that our internal controls and procedures were effective as of December 31, 2020, 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 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.

Our headquarters is 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. Our corporate headquarters and other facilities are 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 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.

Item 1B. Unresolved Staff Comments

None**.**

Item 2. Properties

We do not own any real property. Our leased facilities as of December 31, 2020, are as follows:

Location	Square Feet	Primary Use	Lease Terms
South San Francisco, CA	58,080 sq ft	Laboratory and office	Five leases expiring between July 2021 and September 2025
Alpharetta, GA	11,788 sq ft	Office	Lease expires February 2021; entire office subleased

Leased facilities in South San Francisco include one embedded lease for 13,736 square feet used for outsourced manufacturing. We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings

The information included in "Note 11. Commitments and Contingencies—(c) Litigation" to the Consolidated Financial Statements in Part II, Item 8 is incorporated by reference into this Item.

We may also from time to time be involved in legal proceedings arising in connection with our business. Based on information currently available, we believe that the amount, or range, of reasonably possible losses in connection with any pending actions against us in excess of established reserves, in the aggregate, is not material to our 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 February 24, 2021, there were approximately 6,497 holders of record of our common stock.

Securities Authorized for Issuance Under Equity Compensation Plans

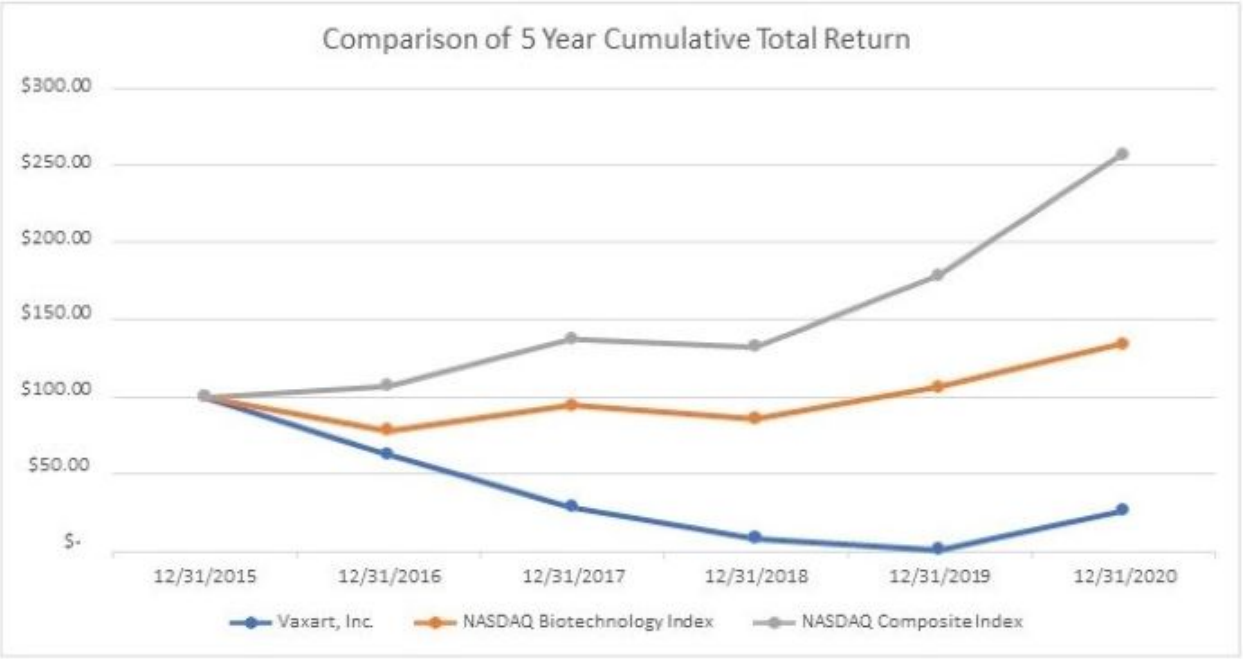
The following table contains information as of December 31, 2020, under equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	6,813,033	$	2.70	1,230,863
Equity compensation plans not approved by security holders	—	$	—	—
Total	6,813,033	$	2.70	1,230,863

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, 2015, through December 31, 2020, 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 all 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. Selected Financial Data

The following selected consolidated financial data for the fiscal years ended December 31, 2020, 2019 and 2018 should be read in conjunction with our consolidated financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K. The statements of operations data for the years ended December 31, 2020, 2019 and 2018 and the balance sheet data as of December 31, 2020 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2017 and 2016 and the balance sheet data as of December 31, 2018, 2017 and 2016 have been derived from our audited consolidated financial statements that are not included elsewhere in this Annual Report on Form 10-K. Data prior to the Merger on February 13, 2018, reflects Vaxart Biosciences, Inc., whereas subsequent to that date it includes data from the company then named Aviragen Therapeutics, Inc. Our historical results are not necessarily indicative of results that may be expected for any future period.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Total revenues	$ 4,046	$ 9,862	$ 4,159	$ 5,839	$ 8,147
Operating expenses:					
Research and development	19,863	14,540	17,275	12,355	17,634
General and administrative	15,202	6,187	6,681	3,499	3,234
Impairment of intangible assets	—	—	1,600	—	—
Costs of exit from leased premises	—	—	359	—	—
Restructuring charges and (reversals)	(849)	4,920	—	—	—
Total operating expenses	34,216	25,647	25,915	15,854	20,868
Operating loss	(30,170)	(15,785)	(21,756)	(10,015)	(12,721)
Other income and (expenses)	(1,812)	(2,370)	3,858	433	(3,641)
Loss before provision for income taxes	(31,982)	(18,155)	(17,898)	(9,582)	(16,362)
Provision for income taxes	238	490	109	—	—
Net loss	(32,220)	(18,645)	(18,007)	(9,582)	(16,362)
Series B and C preferred dividend	—	—	(339)	(2,878)	(2,886)
Net comprehensive loss attributable to common stockholders	$ (32,220)	$ (18,645)	$ (18,346)	$ (12,460)	$ (19,248)
Net loss per share – basic and diluted	$ (0.36)	$ (0.86)	$ (2.90)	$ (91.65)	$ (141.96)
Shares used to compute net loss per share – basic and diluted	88,296	21,570	6,316	136	136
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	126,870	13,526	11,506	2,986	13,073
Total assets	152,582	37,032	35,227	4,523	15,886
Total liabilities	29,178	24,080	23,989	43,245	45,527
Accumulated deficit	(148,881)	(116,661)	(97,989)	(79,982)	(70,400)
Stockholders' Equity (Deficit)	123,404	12,952	11,238	(38,722)	(29,641)

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 on Form 10-K, 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 on Form 10-K, particularly in Item 1A – "Risk Factors." The forward-looking statements made in this Annual Report on Form 10-K are made only as of the date hereof.

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. 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.

We are developing prophylactic vaccine candidates that target a range of infectious diseases, including SARS-CoV-2 (the virus that causes coronavirus disease 2019 ("COVID-19")), norovirus (a widespread cause of acute gastro-intestinal enteritis), seasonal influenza and respiratory syncytial virus ("RSV") (a common cause of respiratory tract infections). We have completed human dosing for our Phase 1 clinical trial for our SARS CoV-2 vaccine candidate that commenced in October 2020 and met its primary and secondary endpoints. Three Phase 1 human studies for our norovirus vaccine candidate have been completed, including a study with a bivalent norovirus vaccine which, as we disclosed in September 2019, met its primary and secondary endpoints. Our monovalent H1 influenza vaccine protected participants against H1 influenza infection in a Phase 2 challenge study. In addition, we are developing our first therapeutic vaccine targeting cervical cancer and dysplasia caused by human papillomavirus ("HPV").

As we previously disclosed, we are no longer prioritizing internal manufacturing and plan to rely primarily on third party manufacturers for the current Good Manufacturing Practice ("cGMP") manufacturing of our candidate vaccines. In addition, we are focusing our efforts on partnering opportunities utilizing the vaccine programs currently in our pipeline, including the bivalent norovirus vaccine program, our seasonal flu vaccine, and the Universal Influenza vaccine collaboration with Janssen Vaccines & Prevention B.V. Finally, we are focusing on the development of a coronavirus vaccine candidate utilizing our proprietary oral vaccine platform. Pending licensing, partnering or collaboration agreements, our seasonal influenza, RSV and HPV programs are currently on hold.

Through our merger with Aviragen Therapeutics, Inc., or Aviragen, we acquired two royalty-earning products, Relenza and Inavir. We also acquired three Phase 2 clinical stage antiviral compounds, which we have discontinued.

Merger with Aviragen

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. Immediately prior to the Merger, all Private Vaxart's convertible promissory notes and convertible preferred stock were converted into common stock, following which each share of common stock was converted into approximately 0.22148 shares of common stock.

Immediately following the completion of the Merger, we effected a reverse stock split at a ratio of one new share for every eleven shares of our common stock outstanding, or the Reverse Stock Split. All share, equity security and per share amounts are presented to give retroactive effect to the Reverse Stock Split. Immediately after the Merger and the Reverse Stock Split there were approximately 7.1 million shares of common stock outstanding. In addition, immediately after the Merger, Private Vaxart's stockholders, warrantholders and optionholders owned approximately 51% of the common stock of the combined company and the stockholders and optionholders of Aviragen immediately prior to the Merger owned approximately 49% of the common stock of the combined company (on a fully diluted basis).

Financial Operations Overview

Revenue

Revenue from Customer Service Contracts

We have been earning revenue from a fixed price service contract, as amended, for a total of $617,000, which we completed in the first three months of 2021.

Revenue from Government Contract

The government contract with the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority ("HHS BARDA"), as modified, was a cost-plus-fixed-fee contract, under which we were reimbursed for allowable direct contract costs plus allowable indirect costs and a fixed-fee totaling $15.7 million from September 2015 through September 30, 2018. Activities were completed in 2018 and no future revenue is expected from this contract.

Royalty Revenue

We earn royalty revenue on sales of Inavir and, until the patent expired, earned royalty revenue on sales of Relenza (both treatments for influenza) through our licensees Daiichi Sankyo Company, Limited and GlaxoSmithKline, plc, respectively, under royalty agreements with expiry dates in December 2029 and July 2019, respectively, based on fixed percentages of net sales of these drugs.

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"). We pay HCRP the first $3 million plus 15% of the next $1 million of royalties earned in annual periods ending on March 31. At the time of the Merger, the estimated future benefit to HCRP was remeasured at fair value and was estimated to be $15.9 million, which we account for as a liability and amortize using the effective interest method over the remaining estimated life of the arrangement. Even though we do not 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.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, including the development of our tablet vaccine platform, and the manufacturing, 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;
- manufacturing materials, analytical and release testing services required to produce vaccine candidates used primarily 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 incur significant external costs for manufacturing our tablet vaccine candidates, and for CROs that conduct clinical trials on our behalf. We capture these expenses for each vaccine program. We do not allocate external costs incurred on preclinical research or process development to specific programs.

The following table shows our period-over-period research and development expenses, identifying external costs that were incurred in each of our vaccine programs and, separately, on preclinical research and process development (in thousands):

	Year Ended December 31,		
	2020	2019	2018
External program costs:			
COVID-19 program	$ 6,659	$ —	$ —
Norovirus program	549	3,765	2,578
RSV and HPV programs	—	21	53
Teslexivir and vapendavir programs	7	63	1,902
Influenza program, funded by BARDA	—	—	749
Preclinical research and process development	1,899	807	285
Total external costs	9,114	4,656	5,567
Internal costs	10,749	9,884	11,708
	$ 19,863	$ 14,540	$ 17,275

We expect that research and development expenses will increase in 2021 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, 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, which include the operations of Aviragen for periods after February 13, 2018 (in thousands, except percentages):

	Year Ended December 31,				
	2020	% Change	2019	% Change	2018
Revenue	$ 4,046	(59)%	$ 9,862	137%	$ 4,159
Operating expenses	34,216	33%	25,647	(1)%	25,915
Operating loss	(30,170)	91%	(15,785)	(27)%	(21,756)
Other income and (expenses)	(1,812)	(24)%	(2,370)	(161)%	3,858
Loss before provision for income taxes	(31,982)	76%	(18,155)	1%	(17,898)
Provision for income taxes	238	(51)%	490	350%	109
Net loss	$ (32,220)	73%	$ (18,645)	4%	$ (18,007)

Total Revenues

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

	2020	% Change	2019	% Change	2018
Revenue from customer service contracts	$ 198	(51)%	$ 406	N/A	$ —
Revenue from government contract	—	N/A	(20)	N/A	1,344
Royalty revenue	2,962	(33)%	4,446	232%	1,340
Non-cash royalty revenue related to sale of future royalties	886	(82)%	5,030	241%	1,475
Total revenue	$ 4,046	(59)%	$ 9,862	137%	$ 4,159

Revenue from Customer Service Contracts

We earned revenue from customer service contracts of $198,000 and $406,000 in the years ended December 31, 2020 and 2019, respectively. This revenue was recognized from a fixed price contract executed in July 2019, as amended, for a total of $617,000, which we have now completed, enabling us to recognize the remaining $13,000 as revenue in the three months ending March 31, 2021. There were no comparable contracts in 2018.

Revenue from Government Contract

We recognized revenue of $1.3 million during the year ended December 31, 2018, of which $20,000 was reversed during the year ended December 31, 2019. As of December 31, 2020, the cumulative revenue recorded from inception under the HHS BARDA contract represents $20,000 less than the maximum amount billable under the contract as presently modified. The active phase of the contract occurred in 2016 and 2017. In 2018 activities were wound down and completed and no future revenue is expected from this contract.

Royalty Revenue

For the year ended December 31, 2020, royalty revenue decreased by $1.5 million, or 33%, compared to the year ended December 31, 2019, which represented an increase of $3.1 million, or 232%, compared to the year ended December 31, 2018. Royalty revenue in the year ended December 31, 2018, excludes comparable revenue of $3.5 million earned in the pre-Merger period, which more than accounts for the increase in 2019.

Royalty revenue was earned on sales of Relenza and Inavir, both treatments for influenza, which were acquired in the Merger and is based on fixed percentages of net sales of these drugs in the period. Relenza revenue ceased in 2019 and all our 2020 Inavir royalty revenue was earned in the first quarter. We recognize royalty revenue from sales of Inavir only after the first $3 million net of 5% withholding tax in years ending on March 31 has been recognized as non-cash royalty revenue related to sale of future royalties. We expect our royalty revenue in 2021, if any, will be significantly lower than in 2020, partly because we expect the increase in social distancing and mask wearing due to the COVID-19 pandemic will cause the number of influenza infections to decrease in the year ending March 31, 2021.

Non-cash Royalty Revenue Related to Sale of Future Royalties

For the year ended December 31, 2020, non-cash royalty revenue related to sale of future royalties was $886,000, compared to $5.0 million for the year ended December 31, 2019 and $1.5 million for the year ended December 31, 2018. Non-cash royalty revenue of up to $3.3 million may be earned in each year ending on March 31. In 2018, we only recognized $1.5 million related to the year ended March 31, 2019, since all non-cash royalty revenue related to the year ended March 31, 2018, was earned in the pre-Merger period. In 2019, we recorded $1.7 million related to the year ended March 31, 2019, plus $3.3 million related to the year ending March 31, 2020. In the year ended December 31, 2020, we recognized the $34,000 not recognized in 2019 for the year ending March 31, 2020, and $852,000 related to the year ending March 31, 2021, so we expect non-cash royalty revenue related to sale of future royalties to increase in the year ending December 31, 2021.

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):

	2020	% Change	2019	% Change	2018
Research and development	$ 19,863	37%	$ 14,540	(16)%	$ 17,275
General and administrative	15,202	146%	6,187	(7)%	6,681
Impairment of intangible assets	—	N/A	—	(100)%	1,600
Costs of exit from leased premises	—	N/A	—	(100)%	359
Restructuring charges and (reversals)	(849)	N/A	4,920	N/A	—
Total operating expenses	$ 34,216	33%	$ 25,647	(1)%	$ 25,915

Research and Development

For 2020, research and development expenses increased by $5.3 million, or 37%, compared to 2019. The increase was principally due to preclinical, manufacturing and clinical expenses related to our COVID-19 vaccine candidate, partially offset by lower costs of manufacturing and clinical trials for our norovirus vaccine candidate and lower depreciation and amortization expense.

For 2019, research and development expenses decreased by $2.7 million, or 16%, compared to 2018. The decrease was principally due to the absence of the teslexivir clinical trials and costs incurred under the HHS BARDA contract, along with decreases in preclinical research, personnel, non-restructuring severance and intangible asset amortization costs, partially offset by increases in manufacturing and clinical trial costs related to our norovirus vaccine tablets.

We expect that research and development expenses will increase in 2021 as we will incur significant expenses for manufacturing and clinical trials related to our COVID-19 vaccine candidate.

General and Administrative

For 2020, general and administrative expenses increased by $9.0 million, or 146%, compared to 2019. The principal reasons for the increase in 2020 are increased legal fees, higher stock-based compensation costs, additional D&O insurance costs, severance expenses for our former Chief Executive Officer and increased costs incurred in upgrading our accounting systems and in line with our corporate growth.

For 2019, general and administrative expenses decreased by $494,000, or 7%, compared to 2018. The decrease was principally due to reductions in legal fees and other costs associated with becoming a public company.

Impairment of Intangible Assets

Impairment of intangible assets represents the write-off in 2018 of the in-process research and development related to teslexivir that we acquired in the Merger. Since the Phase 2 trial completed in May 2018 did not achieve the primary efficacy endpoint and we suspended development activities, we now consider this asset to be fully impaired.

Costs of Exit from Leased Premises

Costs of exit from leasehold premises in 2019 comprise both our lease loss accrual and our write-down of leasehold improvements and furniture at our leased premises in Alpharetta, Georgia. Since this facility had surplus capacity, we subleased these premises, commencing in November 2018, for the remainder of the lease term for less than we are presently paying. Accordingly, we recorded an exit charge consisting of loss on lease obligations for the net discounted future cash flows for rental and associated costs at the cease-use date of $253,000 and a property and equipment impairment charge of $106,000.

Restructuring Charges and (Reversals)

In 2019, in connection with our December restructuring, we accrued costs of $3.2 million representing the amount we were invoiced by Lonza Houston, Inc. ("Lonza") after the suspension of our norovirus manufacturing work order, representing the maximum amount potentially payable to Lonza. We also accrued $0.4 million for severance and legal expenses and impaired $1.3 million of property and equipment and right-of-use assets, mainly related to manufacturing assets. In 2020, we incurred further costs, principally legal fees, of $0.1 million and we paid $2.3 million in full settlement with Lonza, enabling us to reverse $0.9 million of the 2019 accrual. We do not expect to incur any further charges related to this restructuring.

Other Income and (Expenses)

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

	2020	% Change	2019	% Change	2018
Bargain purchase gain	$ —	N/A	$ —	(100)%	$ 6,760
Interest income	75	(50)%	149	157%	58
Interest expense	—	(100)%	(315)	(62)%	(821)
Non-cash interest expense related to sale of future royalties	(1,874)	(10)%	(2,073)	12%	(1,859)
Gain (loss) on sale of equipment	—	(100)%	1	N/A	(11)
Loss on revaluation of financial instruments	—	N/A	—	(100)%	(3)
Loss on debt extinguishment	—	(100)%	(100)	N/A	—
Foreign exchange loss, net	(13)	(59)%	(32)	(88)%	(266)
Net non-operating income and (expenses)	$ (1,812)		$ (2,370)		$ 3,858

For 2020 we recorded net non-operating expenses of $1.8 million, compared to net non-operating expenses of $2.4 million in 2019 and net non-operating income of $3.9 million in 2018.

The principal source of non-operating income in 2018 was a bargain purchase gain of $6.8 million, representing the excess of our valuation of the fair value of net assets acquired over the fair value of the common stock issued to acquire them in the Merger.

Interest expense was $315,000 in 2019, decreasing from $821,000 in 2018 due to the absence of an expense of $295,000 related to Private Vaxart's convertible promissory notes being outstanding for the 43 days prior to the Merger and the lower balance payable on our note due to Oxford Finance LLC, the remaining balance of which was repaid in November 2019, for which we incurred a one-time charge of $100,000 for debt extinguishment. As a result, we incurred no interest expense in 2020.

Non-cash interest expense related to sale of future royalties, which relates to accounting for sums that will become payable to HCRP for royalty revenue earned from Inavir as debt, was $2.1 million in 2019, higher than the $1.9 million in 2020 when the outstanding balance due to HCRP had been paid down, and higher than the $1.9 million in 2018 which related to the shorter post-Merger period.

The foreign exchange loss of $266,000 in 2018 relates to the revaluation of cash and receivables denominated in Australian dollars and British pounds because of the strengthening U.S. dollar. In 2019 and 2020 we held minimal cash and receivables denominated in foreign currency and the loss decreased commensurately.

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):

	2020	% Change	2019	% Change	2018
Foreign withholding tax on royalty revenue	$ 183	(58)%	$ 435	326%	$ 102
Foreign taxes payable on intercompany interest	52	(2)%	53	1,225%	4
State income taxes	3	50%	2	(33)%	3
Provision for income taxes	$ 238	(51)%	$ 490	350%	$ 109

The majority of the provision for income taxes in the years ended December 31, 2020, 2019 and 2018, respectively, represents withholding tax on royalty revenue earned on sales of Inavir in Japan, which is potentially recoverable as a foreign tax credit but expensed because we record a 100% valuation allowance against our deferred tax assets. The amount of income tax expense recorded is directly proportional to Inavir royalties, including the portion that we pass through to HCRP, and was low in 2018 because the majority of Inavir sales in the first calendar quarter arise in the first six weeks, so most of the revenue in the 2018 period was earned pre-Merger. In addition, we incurred charges relating to interest on an intercompany loan from a foreign subsidiary and for state income taxes in the United States.

Liquidity and Capital Resources

From its inception until the Merger, Private Vaxart's operations were financed primarily by net proceeds of $38.9 million and $29.4 million from the sale of convertible preferred stock and the issuance of convertible promissory notes, respectively, all of which were converted into Aviragen common stock in the Merger, and $4.9 million from the issuance of secured promissory notes to Oxford Finance, of which the remaining balance of $2.5 million as of September 30, 2019, was repaid in full on November 4, 2019. Vaxart gained $25.5 million in cash from Aviragen in the Merger, of which $4.9 million was used to pay Aviragen's Merger-related costs. Since the Merger, through December 31, 2020, we have received net proceeds of $156.8 million from the sale of common stock, pre-funded warrants and common stock warrants and the exercise of pre-funded warrants and common stock warrants from equity financings in March, April and September 2019 and March, July and October 2020 (see Note 1 to the Consolidated Financial Statements in Part II, Item 8 for further information regarding our offerings).

As of December 31, 2020, we had $126.9 million of cash and cash equivalents. Since then, we have received net proceeds of $65.8 million from the sale of common stock under the Open Market Sale Agreement, (the "Sales Agreement") and $1.6 million from the exercise of common stock warrants. There is approximately $167 million in net proceeds still available to us under the Sales Agreement.

We believe our existing funds (including funds already received in 2021) are sufficient to fund us well into 2022 and possibly beyond. To continue operations thereafter, we expect that we will need to raise further capital, through the sale of additional securities or otherwise. Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. As of December 31, 2020, we had no commitments for capital expenditures. 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 product candidates. We may be able to fund certain activities with assistance from government programs including HHS BARDA. We may also need to fund our operations through equity and/or debt financing. The sale of additional equity would result in additional dilution to our stockholders. Incurring debt financing 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.

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; 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,		
	2020	2019	2018
Net cash used in operating activities	$ (23,750)	$ (13,090)	$ (14,548)
Net cash (used in) provided by investing activities	(1,220)	(850)	26,212
Net cash provided by (used in) financing activities	138,314	15,960	(1,729)
Net increase in cash and cash equivalents	$ 113,344	$ 2,020	$ 9,935

Net Cash Used in Operating Activities

We experienced negative cash flow from operating activities in 2020, 2019 and 2018 in the amounts of $23.8 million, $13.1 million and $14.5 million, respectively. The cash used in operating activities in 2020 was due to cash used to fund a net loss of $32.2 million, partially offset by adjustments for net non-cash income related to depreciation and amortization, stock-based compensation, non-cash interest expense related to sale of future royalties and non-cash revenue related to sale of future royalties totaling $5.6 million and a decrease in working capital of $2.8 million. The cash used in operating activities in 2019 was due to cash used to fund a net loss of $18.6 million, partially offset by net non-cash expenses related to depreciation and amortization, gain on sale of equipment, impairment charges, stock-based compensation, non-cash interest expense, loss on debt extinguishment, non-cash interest expense related to sale of future royalties and non-cash revenue related to sale of future royalties totaling $4.2 million and a decrease in working capital of $1.3 million. The cash used in operating activities in 2018 was due to a net loss of $18.0 million, partially offset by $1.0 million of adjustments for net non-cash income related to the bargain purchase gain, depreciation and amortization, loss on sale of equipment, impairment charges, stock-based compensation, loss on revaluation of financial instruments, non-cash interest, amortization of note discount, non-cash interest expense related to sale of future royalties and revenue related to sale of future royalties and $2.5 million provided by a change in working capital, principally due to the receipt of accounts receivable of $14.7 million acquired in the Merger.

Net Cash (Used in) Provided by Investing Activities

We used $1.2 million, $850,000 and $707,000 in the years ended December 31, 2020, 2019 and 2018, respectively, to purchase property and equipment. In addition, in 2020 we received cash of $3,000 for the sale of equipment and in 2018 we received cash of $25.5 million in the Merger and $1.4 million from maturities of short-term investments, net of purchases and paid $21,000 for fractional shares of common stock in the Merger.

Net Cash Provided by (Used in) Financing Activities

In 2020, we received $9.2 million from the sale of common stock and common stock warrants in a registered direct offering in March, $97.0 million from the sale of common stock under an at-the-market facility in July, $4.9 million from the sale of common stock under an Open Market Sale Agreement that began in October, $26.0 million from the exercise of common stock warrants, $602,000 from the exercise of stock options and net proceeds of $652,000 from the disgorgement of related party short-swing profits. In 2019, we received $2.5 million from the sale of common stock in a registered direct offering in March, $8.1 million from the sale of common stock, pre-funded warrants and common stock warrants in an underwritten public offering in April, $7.8 million from the sale of common stock, pre-funded warrants and common stock warrants in an underwritten public offering in September, $1.2 million from the exercise of pre-funded warrants and $180,000 from the exercise of common stock warrants, partially offset by repayment of principal of $3.8 million on the secured promissory note payable to Oxford Finance. We used $1.5 million in 2018 to repay principal on the secured promissory note payable to Oxford Finance and $214,000 to repay principal on a short-term note, partially offset by $13,000 received upon the exercise of stock options.

Contractual Obligations and Commercial Commitments

We have the following contractual obligations and commercial commitments as of December 31, 2020 (in thousands):

Contractual Obligation	Total	< 1 Year	1 - 3 Years	3 - 5 Years	> 5 Years
Long Term Debt, HCRP	$ 23,455	$ 2,779	$ 6,218	$ 5,812	$ 8,646
Operating Leases	8,772	2,633	3,386	2,753	—
Purchase Obligations	24,581	11,481	13,100	—	—
Total	$ 56,808	$ 16,893	$ 22,704	$ 8,565	$ 8,646

Long Term Debt, HCRP. Under an agreement executed in 2016, we are obligated to pay HCRP the first $3 million plus 15% of the next $1 million of royalty revenues that we earn for sales of Inavir in each year ending on March 31. See Note 7 to the Consolidated Financial Statements in Part II, Item 8 for further details.

Operating leases. Operating lease amounts include future minimum lease payments under all our non-cancellable operating leases with an initial term in excess of one year. See Note 8 to the Consolidated Financial Statements in Part II, Item 8 for further details.

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

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements in the periods presented.

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 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 balance sheets and within research and development expense in the consolidated statements of operations and comprehensive loss. These costs can be a significant component of our research and development expenses.

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

Intangible Assets

Intangible assets acquired in the Merger were recorded at their estimated fair values of $20.3 million for developed technology related to Inavir which is being amortized on a straight-line basis over the estimated period of future royalties of 11.75 years, $1.8 million for the developed technology related to Relenza which was fully amortized over the remaining royalty period of 1.3 years, and $1.6 million for in-process research and development related to teslexivir which was considered indefinite-lived until it was assessed as impaired in the three months ended June 30, 2018. These valuations were prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams, which are highly subjective.

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 2020, none of which have had, or are expected to have, a material impact on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Sensitivity

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. All our cash is denominated in U.S. dollars and held either in bank accounts or money market funds that presently earn very little interest. Interest rates are sufficiently low that we believe a 1% increase in the borrowing base rate would result in a negligible increase, if any, in the interest we could earn on our cash deposits.

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. All our other revenue and substantially all of our expenses, assets and liabilities are denominated in U.S. dollars and, as a result, we have not experienced significant foreign exchange gains recently and do not anticipate that foreign exchange gains or losses will be significant in the near future.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Vaxart, Inc.
South San Francisco, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Vaxart, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2020, 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 at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the 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.

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 separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

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

Critical Audit Matter Description

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

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

Given the number of ongoing preclinical study and clinical trial activities and the subjectivity involved in estimating clinical trial and manufacturing expenses, auditing the accrued clinical and manufacturing expenses involved especially subjective judgment.

How the Critical Audit Matter Was Addressed in the Audit

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

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

/s/ *OUM & Co. LLP*

San Francisco, California
February 25, 2021

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

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Vaxart, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Vaxart, Inc. and subsidiaries (the Company) as of December 31, 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for the year ended December 31, 2018, and the related notes (collectively, 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, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has experienced losses and negative cash flows from operations since its inception, has an accumulated deficit, and has debt obligations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. 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 audit. 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 audit 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. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ *KPMG LLP*

We served as the Company's auditor from 2014 to 2019.

San Francisco, California
February 6, 2019

VAXART, INC. AND SUBSIDIARIES

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 126,870	$ 13,526
Accounts receivable	334	3,619
Prepaid expenses and other current assets	1,327	453
Total current assets	128,531	17,598
Property and equipment, net	1,480	210
Right-of-use assets, net	6,838	1,990
Intangible assets, net	15,361	17,093
Other long-term assets	372	141
Total assets	$ 152,582	$ 37,032
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,133	$ 852
Current portion of operating lease liability	2,052	841
Liability related to sale of future royalties, current portion	2,779	2,916
Other accrued current liabilities	4,799	4,565
Total current liabilities	11,763	9,174
Operating lease liability, net of current portion	5,156	1,472
Liability related to sale of future royalties, net of current portion	12,150	13,416
Other long-term liabilities	109	18
Total liabilities	29,178	24,080
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred Stock: $0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of December 31, 2020 or 2019	—	—
Common Stock: $0.0001 par value; 150,000,000 shares authorized; 110,271,093 and 48,254,994 shares issued and outstanding as of December 31, 2020 and 2019, respectively	11	5
Additional paid-in capital	272,274	129,608
Accumulated deficit	(148,881)	(116,661)
Total stockholders' equity	123,404	12,952
Total liabilities and stockholders' equity	$ 152,582	$ 37,032

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,		
	2020	**2019**	**2018**
Revenue:			
Revenue from customer service contracts	$ 198	$ 406	$ —
Revenue from government contract	—	(20)	1,344
Royalty revenue	2,962	4,446	1,340
Non-cash royalty revenue related to sale of future royalties	886	5,030	1,475
Total revenue	4,046	9,862	4,159
Operating expenses:			
Research and development	19,863	14,540	17,275
General and administrative	15,202	6,187	6,681
Impairment of intangible assets	—	—	1,600
Costs of exit from leased premises	—	—	359
Restructuring charges and (reversals)	(849)	4,920	—
Total operating expenses	34,216	25,647	25,915
Operating loss	(30,170)	(15,785)	(21,756)
Other income and (expenses):			
Bargain purchase gain	—	—	6,760
Interest income	75	149	58
Interest expense	—	(315)	(821)
Non-cash interest expense related to sale of future royalties	(1,874)	(2,073)	(1,859)
Gain (loss) on sale of equipment	—	1	(11)
Loss on revaluation of financial instruments	—	—	(3)
Loss on debt extinguishment	—	(100)	—
Foreign exchange loss, net	(13)	(32)	(266)
Loss before provision for income taxes	(31,982)	(18,155)	(17,898)
Provision for income taxes	238	490	109
Net loss	(32,220)	(18,645)	(18,007)
Series B and C preferred dividend	—	—	(339)
Net comprehensive loss attributable to common stockholders	$ (32,220)	$ (18,645)	$ (18,346)
Net loss per share – basic and diluted	$ (0.36)	$ (0.86)	$ (2.90)
Shares used to compute net loss per share – basic and diluted	88,295,762	21,569,523	6,316,065

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

VAXART, INC. AND SUBSIDIARIES

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances as of January 1, 2018	1,221,064	$ —	138,492	$ —	$ 41,260	$ (79,982)	$ (38,722)
Issuance of common stock upon conversion of convertible promissory notes, related parties	—	—	1,571,702	—	35,577	—	35,577
Issuance of common stock upon conversion of convertible preferred stock	(1,221,064)	—	1,918,543	—	—	—	—
Reclassification of warrant to equity	—	—	—	—	70	—	70
Issuance of common stock upon reverse merger	—	—	3,510,439	1	31,767	—	31,768
Issuance of common stock upon exercise of stock options	—	—	2,013	—	13	—	13
Stock-based compensation	—	—	—	—	539	—	539
Net loss	—	—	—	—	—	(18,007)	(18,007)
Balances as of December 31, 2018	—	$ —	7,141,189	$ 1	$ 109,226	$ (97,989)	$ 11,238
Cumulative effect of adoption of new leases standard	—	—	—	—	—	(27)	(27)
Balances as of January 1, 2019, as adjusted	—	$ —	7,141,189	$ 1	$ 109,226	$ (98,016)	$ 11,211

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		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances as of January 1, 2019, as adjusted	7,141,189	$ 1	$ 109,226	$ (98,016)	$ 11,211
Issuance of common stock in March 2019, net of offering costs of $560	1,200,000	—	2,440	—	2,440
Issuance of common stock warrants to placement agents' designees in March 2019	—	—	100	—	100
Issuance of common stock, pre-funded warrants and common stock warrants in April 2019, net of offering costs of $1,579	925,455	—	7,741	—	7,741
Issuance of common stock warrants to underwriters' designees in April 2019	—	—	333	—	333
Issuance of common stock, pre-funded warrants and common stock warrants in September 2019, net of offering costs of $1,459	26,124,828	3	7,239	—	7,242
Issuance of common stock warrants to underwriters' designees in September 2019	—	—	497	—	497
Issuance of common stock upon exercise of pre-funded warrants	12,265,455	1	1,225	—	1,226
Issuance of common stock upon exercise of common stock warrants	598,067	—	180	—	180
Stock-based compensation	—	—	627	—	627
Net loss	—	—	—	(18,645)	(18,645)
Balances as of December 31, 2019	48,254,994	$ 5	$ 129,608	$ (116,661)	$ 12,952
Issuance of common stock and common stock warrants in March 2020, net of offering costs of $1,278	4,000,000	—	8,722	—	8,722
Issuance of warrants to placement agents' designees in March 2019	—	—	453	—	453
Issuance of common stock under ATM in July 2020, net of offering costs of $2,966	12,503,806	1	97,033	—	97,034
Issuance of common stock under ATM during the three months ended December 2020, net of offering costs of $563	692,651	—	4,900	—	4,900
Issuance of common stock upon exercise of common stock warrants	44,404,966	5	25,946	—	25,951
Issuance of common stock upon exercise of options	414,676	—	602	—	602
Disgorgement of short-swing profits, net of costs	—	—	652	—	652
Stock-based compensation	—	—	4,358	—	4,358
Net loss	—	—	—	(32,220)	(32,220)
Balances as of December 31, 2020	110,271,093	$ 11	$ 272,274	$ (148,881)	$ 123,404

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,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net loss	$ (32,220)	$ (18,645)	$ (18,007)
Adjustments to reconcile net loss to net cash used in operating activities:			
Bargain purchase gain	—	—	(6,760)
Depreciation and amortization	2,710	3,596	3,203
(Gain) loss on sale of equipment	—	(1)	11
Impairment of intangible assets	—	—	1,600
Impairment of property and equipment and right-of-use assets	—	1,272	106
Stock-based compensation	4,358	627	539
Loss on revaluation of financial instruments	—	—	3
Non-cash interest expense	—	88	448
Amortization of note discount	—	—	18
Loss on debt extinguishment	—	100	—
Non-cash interest expense related to sale of future royalties	1,874	2,073	1,859
Non-cash revenue related to sale of future royalties	(3,277)	(3,482)	(18)
Change in operating assets and liabilities:			
Accounts receivable	3,285	(1,823)	13,500
Prepaid expenses and other assets	(1,108)	855	(873)
Accounts payable	1,207	(62)	(3,784)
Accrued liabilities	(579)	2,312	(6,393)
Net cash used in operating activities	(23,750)	(13,090)	(14,548)
Cash flows from investing activities:			
Purchase of property and equipment	(1,223)	(850)	(707)
Proceeds from sale of equipment	3	—	—
Cash acquired in reverse merger	—	—	25,525
Cash paid for fractional shares in merger	—	—	(21)
Purchases of short-term investments	—	—	(573)
Proceeds from maturities of short-term investments	—	—	1,988
Net cash (used in) provided by investing activities	(1,220)	(850)	26,212
Cash flows from financing activities:			
Net proceeds from issuance of common stock in registered direct offering	9,175	2,540	—
Net proceeds from issuance of common stock through at-the-market facilities	101,934	—	—
Net proceeds from issuance of common stock, pre-funded warrants and common warrants in April 2019 underwritten offering	—	8,074	—
Net proceeds from issuance of common stock, pre-funded warrants and common warrants in September 2019 underwritten offering	—	7,739	—
Proceeds from issuance of common stock upon exercise of pre-funded warrants	—	1,226	—
Proceeds from issuance of common stock upon exercise of common stock warrants	25,951	180	—
Proceeds from issuance of common stock upon exercise of stock options	602	—	13
Disgorgement of short-swing profits, net of costs	652	—	—
Repayment of principal on secured promissory note payable to Oxford Finance	—	(3,799)	(1,528)
Repayment of short-term note	—	—	(214)
Net cash provided by (used in) financing activities	138,314	15,960	(1,729)
Net increase in cash and cash equivalents	113,344	2,020	9,935
Cash and cash equivalents at beginning of the period	13,526	11,506	1,571
Cash and cash equivalents at end of the period	$ 126,870	$ 13,526	$ 11,506

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,		
	2020	**2019**	**2018**
Supplemental disclosure of cash flow information:			
Interest paid	$ —	$ 227	$ 356
Supplemental disclosure of non-cash investing and financing activity:			
Issuance of warrants to placement agents' designees	$ 453	$ 100	$ —
Issuance of warrants to underwriters' designees	$ —	$ 830	$ —
Issuance of common stock upon reverse merger, net of cash paid for partial shares	$ —	$ —	$ 31,768
Conversion of convertible promissory notes, related parties into common stock upon reverse merger	$ —	$ —	$ 35,577
Reclassification of convertible preferred stock warrant liability to equity	$ —	$ —	$ 70
Operating lease liabilities arising from obtaining right-of-use assets	$ 5,664	$ 1,929	$ —
Property and equipment acquired as an incentive to enter an operating lease	$ 87	$ —	$ —
Acquisition of property and equipment included in accounts payable	$ 78	$ 4	$ 52
Proceeds due for sale of property and equipment included in prepaid expenses and other current assets	$ —	$ 3	$ —

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 Basis of Presentation

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.

On February 13, 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. All Private Vaxart's convertible promissory notes and convertible preferred stock was converted into common stock, following which each share of common stock was converted into approximately 0.22148 shares of the Company's common stock (the "Conversion"). Except as otherwise noted in these Consolidated Financial Statements, all shares, equity securities and per share amounts of Private Vaxart are presented to give retroactive effect to the Conversion.

Immediately following the completion of the Merger, the Company effected a reverse stock split at a ratio of one new share for every eleven shares of the Company's common stock outstanding (the "Reverse Stock Split"). Except as otherwise noted in these Consolidated Financial Statements, all share, equity security and per share amounts are presented to give retroactive effect to the Reverse Stock Split.

Immediately after the Reverse Stock Split there were approximately 7.1 million shares of the Company's common stock outstanding. Private Vaxart's stockholders, warrantholders and optionholders owned approximately 51% of the fully-diluted common stock of the Company, with Aviragen's stockholders and optionholders immediately prior to the Merger owning approximately 49% of the fully-diluted common stock of the Company. The Company also assumed all Private Vaxart's outstanding stock options and warrants with proportionate adjustments to the number of underlying shares and exercise prices based on an exchange ratio, based on the combined impact of the Conversion and the Reverse Stock Split, of approximately 0.0201346 shares of the Company for each share of Private Vaxart.

On March 20, 2019, the Company completed a registered direct offering (the "March 2019 Offering") of 1,200,000 shares of the Company's common stock. The total gross proceeds from the offering to the Company were $3.0 million. After deducting placement agent fees and offering expenses payable by the Company, the aggregate net proceeds received by the Company totaled $2.5 million. Pursuant to the terms of the engagement letter with the placement agents, the Company paid the placement agents aggregate fees and reimbursable costs of $320,000. In addition, the Company issued the placement agents' designees 84,000 common stock warrants at the closing of the March 2019 Offering, each warrant entitling the holder to purchase one share of common stock for $3.125 at any time within five years of the effective date of the March 2019 Offering. The aggregate fair value of these warrants at issuance was estimated to be $100,000 (see Note 12), which was recorded in offering costs.

On April 11, 2019, the Company completed a public underwritten offering (the "April 2019 Offering") of 925,455 shares of common stock, 8,165,455 pre-funded warrants, and warrants to purchase 10,454,546 shares of common stock (including 1,363,636 common stock warrants issued upon the exercise by the underwriters of their option to purchase such warrants). Each share of common stock with an accompanying common stock warrant was sold for $1.10, and each pre-funded warrant with an accompanying common stock warrant was sold for $1.00, with the amount paid for each accompanying common stock warrant being $0.10. Each pre-funded warrant entitled the holder to purchase one share of common stock for $0.10, was immediately exercisable, subject to certain ownership limitations, and was exercisable at any time until all the pre-funded warrants were exercised in full. Each common stock warrant entitles the holder to purchase one share of common stock for $1.10, is exercisable immediately, subject to certain ownership limitations, and will expire five years from the date of issuance.

Pursuant to the terms of an underwriting agreement, the Company paid the underwriters aggregate commissions and reimbursable costs of $750,000. In addition, the Company issued the underwriters' designees 636,364 common stock warrants at the closing of the April 2019 Offering, each warrant entitling the holder to purchase one share of common stock for $1.375 at any time within five years of their issuance date. The aggregate fair value of these warrants at issuance was estimated to be $333,000 (see Note 12), which was recorded in offering costs.

The total gross proceeds from the April 2019 Offering to the Company were $9.3 million. After deducting underwriting discounts, commissions and offering expenses payable by the Company, the aggregate net proceeds received by the Company were $8.1 million. In addition, as of December 31, 2020, the Company had received a further $0.8 million from the exercise of all 8,165,455 pre-funded warrants, $11.3 million from the exercise of 10,228,580 common stock warrants issued to investors and $0.7 million from the exercise of 524,433 common stock warrants issued to underwriters' designees issued in the April 2019 Offering.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

On September 30, 2019, the Company completed a public underwritten offering (the "September 2019 Offering") of 26,124,828 shares of common stock (including 3,558,161 shares of common stock issued upon the partial exercise by the underwriters of their option to purchase 4,000,000 shares), 4,100,000 pre-funded warrants, and warrants to purchase 30,666,667 shares of common stock (including 4,000,000 common stock warrants issued upon the exercise by the underwriters of their option to purchase such warrants). Each share of common stock with an accompanying common stock warrant was sold for $0.30, and each pre-funded warrant with an accompanying common stock warrant was sold for $0.20, with the amount paid for each accompanying common stock warrant being $0.10. Each pre-funded warrant entitled the holder to purchase one share of common stock for $0.10, was immediately exercisable, subject to certain ownership imitations, and was exercisable at any time until all the pre-funded warrants were exercised in full. Each common stock warrant entitles the holder to purchase one share of common stock for $0.30, is exercisable immediately, subject to certain ownership limitations, and will expire five years from the date of issuance.

Pursuant to the terms of an underwriting agreement, the Company paid the underwriters aggregate commissions and reimbursable costs of $713,000. In addition, the Company issued the underwriters' designees 2,115,738 common stock warrants at the closing of the September 2019 Offering, each warrant entitling the holder to purchase one share of common stock for $0.375 at any time within five years of their issuance date. The aggregate fair value of these warrants at issuance was estimated to be $497,000 (see Note 12), which was recorded in offering costs.

The total gross proceeds from the September 2019 Offering to the Company were $8.7 million. After deducting underwriting discounts, commissions and offering expenses payable by the Company, the aggregate net proceeds received by the Company were $7.7 million. In addition, as of December 31, 2020, the Company had received $0.4 million from the exercise of all 4,100,000 pre-funded warrants, $9.2 million from the exercise of 30,661,667 common stock warrants issued to investors and $0.7 million from the exercise of 1,890,941 common stock warrants issued to underwriters' designees in the September 2019 Offering.

On March 2, 2020, the Company completed a registered direct offering (the "March 2020 Offering") of 4,000,000 shares of the Company's common stock and warrants to purchase 2,000,000 shares of common stock. Each common stock warrant entitles the holder to purchase one share of common stock for $2.50, is exercisable immediately, subject to certain ownership limitations, and will expire five years from the date of issuance. Pursuant to the terms of the engagement letter with the placement agents, the Company paid the placement agents aggregate fees and reimbursable costs of $775,000. In addition, the Company issued the placement agents' designees 280,000 common stock warrants at the closing of the March 2020 Offering, each warrant entitling the holder to purchase one share of common stock for $3.125 at any time within five years of the effective date of the March 2020 Offering. The aggregate fair value of these warrants at issuance was estimated to be $453,000 (see Note 12), which was recorded in offering costs.

The total gross proceeds from the offering to the Company were $10.0 million. After deducting placement agent fees and offering expenses payable by the Company, the aggregate net proceeds received by the Company totaled $9.2 million. In addition, as of December 31, 2020, the Company had received $4.2 million from the exercise of 1,683,416 common stock warrants issued to investors and 10,504 common stock warrants issued to placement agents' designees in the March 2020 Offering.

On June 8, 2020, the Company's shareholders approved an amendment to the Company's certificate of incorporation to change the par value of its common and preferred stock from $0.10 per share to $0.0001 per share and to increase the number of authorized shares of common stock from 100,000,000 to 150,000,000. Except as otherwise noted in these consolidated financial statements, all share, equity security and per share amounts are presented to give retroactive effect to these changes.

On July 13, 2020, the Company completed the sale of 12,503,806 shares for gross proceeds of $100.0 million from an at-the-market facility (the "ATM Program") under a sales prospectus agreement dated July 8, 2020. After deducting sales commissions and expenses, aggregate net cash proceeds under the ATM Program totaled $97.0 million.

On October 13, 2020, the Company entered into the Open Market Sale Agreement, (the "Sales Agreement") pursuant to which it may offer and sell, from time to time through sales agents, shares of its common stock having an aggregate offering price of up to $250 million. The Company incurred direct expenses of approximately $0.3 million in connection with filing a prospectus supplement, dated October 13, 2020, with the SEC, and will pay sales commissions of 4.5% of gross proceeds from the sale of shares. As of December 31, 2020, the Company had sold 692,651 shares for gross proceeds of $5.5 million which, after deducting sales commissions and expenses, resulted in net proceeds to date under the Sales Agreement of $4.9 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.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

NOTE 2. Summary of Significant Accounting Policies

Basis of Presentation – The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

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

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

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.

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.

Concentration of Credit Risk – Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. The Company places its cash, cash equivalents and short-term investments at financial institutions that management believes are of high credit quality. The Company is exposed to credit risk in the event of default by the financial institutions holding the cash and cash equivalents to the extent such amounts are in excess of the federally insured limits. The Company has not experienced any losses on its deposits since inception.

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. The Company generally requires no collateral from its customers.

Accounts Receivable – Accounts receivable arise from the Company's royalty revenue receivable for sales, net of estimated returns, of Inavir and Relenza, and from its contracts with customers and with the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority ("HHS BARDA") (see Note 6), and are reported at amounts expected to be collected in future periods. An allowance for uncollectible accounts will be recorded based on a combination of historical experience, aging analysis, and information on specific accounts, with related amounts recorded as a reserve against revenue recognized. Account balances will be written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The Company has provided no allowance for uncollectible accounts as of December 31, 2020 and 2019.

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 balance sheet 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

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

Intangible Assets – Intangible assets comprise developed technology, intellectual property and, until it was considered fully impaired (see Note 5), in-process research and development. Intangible assets are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over useful lives ranging from 1.3 to 11.75 years for developed technology and 20 years for intellectual property. In-process research and development is considered to be indefinite-lived and is not amortized, but is subject to impairment testing. The Company assessed its in-process research and development as fully impaired in the year ended December 31, 2018 (see Note 5).

Impairment of Long-Lived Assets – The Company reviews its long-lived assets, including property and equipment and intangible assets with finite lives, for impairment whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. When indications of impairment are present and the estimated undiscounted future cash flows from the use of these assets is less than the assets' carrying value, the related assets will be written down to fair value. The Company assessed leasehold improvements and furniture at its leased offices in Alpharetta, Georgia as impaired in the year ended December 31, 2018 (see Notes 5 and 8). The Company also assessed its manufacturing equipment and its right-of-use asset and leasehold improvements at its manufacturing premises as impaired in the year ended December 31, 2019 (see Note 15).

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 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 – Effective January 1, 2019, 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.

Convertible Preferred Stock Warrant Liability – The Company has issued certain convertible preferred stock warrants. These warrants were recorded within other accrued liabilities in the consolidated balance sheets at fair value due to down-round protection features contained in the convertible preferred stock into which the warrants were exercisable. At the end of each reporting period, changes in fair value of the warrants since the prior period were recorded as a component of gain or loss on revaluation of financial instruments within other income and (expenses) in the consolidated statements of operations and comprehensive loss. In the event that the terms of the warrant change such that liability accounting is no longer required, the fair value on the date of such change is released to equity.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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 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.

The Company performed research and development work under its cost-plus-fixed-fee contract with HHS BARDA. 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 HHS BARDA contract 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.

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

Payments to the Company under cost reimbursable contracts, such as this contract, 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.

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

Stock-Based Compensation – The Company measures the fair value of all stock-based awards, including stock options, to employees and, since April 1, 2018, to nonemployees, on the grant date and records the fair value of these awards, net of estimated forfeitures, to compensation expense over the service period. Prior to April 1, 2018, the fair value of awards to nonemployees was measured on the date of performance at the fair value of the consideration received or the fair value of the equity instruments issued, whichever was more reliably measured. The fair value of options 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.

VAXART, INC. AND SUBSIDIARIES

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Net Income (Loss) Per Share Attributable to Common Stockholders – Basic net income (loss) per share is computed by dividing net income (loss), as adjusted for dividends on the Series B and Series C convertible preferred stock in the period, 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 and warrants. The Company uses the treasury-stock method to compute diluted income (loss) per share with respect to its stock options and warrants. For purposes of this calculation, options and warrants 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.

Reclassification

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

Recently Adopted Accounting Pronouncements

The Company did not adopt any new accounting policies in fiscal 2020.

Recent Accounting Pronouncements

In August 2020, the FASB issued Accounting Standards Update (ASU) 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in an Entity's Own Equity (Subtopic 815-40).* In addition to simplifying the accounting for certain debt and equity instruments, none of which the Company presently has outstanding, this standard update provides guidance on how certain instruments should be treated in the computation of earnings per share. The Company plans to adopt the new guidance effective January 1, 2021. Its adoption will have an immaterial impact on the number of shares used in the computation of year-to-date basic and diluted earnings per share.

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

NOTE 3. Business Combination

On February 13, 2018, the Company acquired Aviragen in a reverse merger (see Note 1). On the date of the Merger, Aviragen had in-process research and development as it was conducting a Phase 2 trial, it had previously developed drugs that were licensed to others who brought them to market and it had a workforce that was considered to have the necessary skills, knowledge, and experience to perform a process that, when applied to the in-process research and development, was critical to the ability to convert it into outputs. Based on this evaluation, the Company determined that the Merger should be accounted for as a business combination.

Since the date of the Merger, the results of Aviragen's operations have been included in the consolidated financial statements. As a result of the acquisition, the Company eliminated the majority of its debt and acquired a significant cash balance in exchange for equity securities.

The total purchase price for Aviragen is summarized as follows (in thousands):

Common stock	$ 31,789
Total	$ 31,789

In connection with the Aviragen acquisition, the Company allocated the total purchase consideration to the net assets and liabilities acquired, including identifiable intangible assets, based on their respective fair values at the acquisition date.

The following table summarizes the preliminary allocation of the purchase price to the fair value of the respective assets and liabilities acquired, adjustments made since the acquisition date and the final allocation as of December 31, 2018 (in thousands):

	As of February 13, 2018	2018 Adjustments	As of December 31, 2018
Cash and cash equivalents	$ 25,525	$ —	$ 25,525
Accounts receivable	14,666	—	14,666
Prepaid expenses	446	(10)	436
Property and equipment	170	—	170
Intangible assets:			
Developed technology (1)	22,400	(300)	22,100
In-process research and development (2)	1,600	—	1,600
Total assets	64,807	(310)	64,497
Accounts payable	(3,379)	75	(3,304)
Other current liabilities	(6,351)	(393)	(6,744)
Liability related to sale of future royalties	(16,300)	400	(15,900)
Net assets acquired	38,777	(228)	38,549
Purchase price	(31,789)	—	(31,789)
Bargain purchase gain (3)	$ 6,988	$ (228)	$ 6,760

(1) Developed technology comprises Inavir and Relenza, both influenza vaccines on which the Company is, or was, receiving royalty revenue, which, based on valuations prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams provided by the Company's management, are being, or has been, amortized on a straight-line basis over the estimated periods of future royalties at the time of the acquisition of 11.75 and 1.3 years, respectively.

(2) In-process research and development (see Note 5) related to teslexivir, or BTA074, a direct-acting antiviral that, at the time of the Merger, was being actively developed as a treatment for genital warts. The valuation was prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams provided by the Company's management.

(3) The bargain purchase gain represents the excess of the fair value of tangible and identified intangible assets acquired, less liabilities assumed, over the purchase price.

NOTE 4. Fair Value of Financial Instruments

Fair value accounting is applied for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, 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 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 Company's money market funds are classified within Level 1 of the fair value hierarchy and are valued based on quoted prices in active markets for identical securities. The Company's convertible preferred stock warrant liability was classified within Level 3 of the fair value hierarchy as it was valued by using inputs that are unobservable in the market.

The Company's only recurring financial assets that are measured at fair value were $60,005,000, $15,000 and $15,000 held in money market funds and classified as cash equivalents as of December 31, 2020, 2019 and 2018, respectively, with no recurring financial liabilities held at any of those dates or in either of the years ended December 31, 2020 and 2019. The following table presents a reconciliation of all liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2018 (in thousands):

	Convertible Preferred Stock Warrant Liability	Total
Balance at January 1, 2018	$ 67	$ 67
Issuances	—	—
Revaluation loss included in loss on revaluation of financial instruments	3	3
Settlements	(70)	(70)
Balance at December 31, 2018	$ —	$ —
Total losses included in other income and (expenses) attributable to liabilities still held as of December 31, 2018	$ —	$ —

NOTE 5. Balance Sheet Components

(a) Cash and Cash Equivalents

Cash and cash equivalents comprises the following (in thousands):

	December 31, 2020	December 31, 2019
Cash at banks	$ 66,865	$ 13,511
Money market funds	60,005	15
Cash and cash equivalents	$ 126,870	$ 13,526

(b) Accounts Receivable

Accounts receivable comprises the following (in thousands):

	December 31, 2020	December 31, 2019
Royalties receivable	$ 334	$ 3,438
Customer service contracts – billed	—	181
Accounts receivable	$ 334	$ 3,619

(c) Property and Equipment, Net

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

	December 31, 2020	December 31, 2019
Laboratory equipment	$ 1,759	$ 537
Office and computer equipment	294	132
Total property and equipment	2,053	669
Less: accumulated depreciation	(573)	(459)
Property and equipment, net	$ 1,480	$ 210

Depreciation expense was $114,000, $504,000 and $476,000 for the years ended December 31, 2020, 2019 and 2018, respectively. Property and equipment and leasehold improvements at one of the Company's leased premises in California that were used in the Company's manufacturing operations (see Note 15) were assessed as impaired as of December 31, 2019, and accordingly an impairment charge of $1,152,000 was recorded as a component of restructuring costs within operating expenses. Leasehold improvements and furniture at the Company's leased premises in Georgia, which has been subleased, commencing in November 2018, for less than the rental that the Company is obligated to pay (see Note 8), were assessed as impaired as of September 30, 2018, and accordingly an impairment charge of $106,000 was recorded as a component of costs of exit from leased premises within operating expenses.

(d) Right-of-Use Assets, Net

Right-of-use assets consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Facilities	$ 6,836	$ 1,985
Office equipment	2	5
Right-of-use assets, net	$ 6,838	$ 1,990

The right of use of one of the Company's leased premises in California used in the Company's manufacturing operations (see Note 15) was assessed as impaired as of December 31, 2019, and accordingly an impairment charge of $120,000 was recorded as a component of restructuring costs within operating expenses.

(e) Intangible Assets, Net

Intangible assets comprise developed technology, intellectual property and, until it was considered fully impaired, in-process research and development. Intangible assets are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over useful lives ranging from 1.3 to 11.75 years for developed technology and 20 years for intellectual property. As of December 31, 2020, developed technology and intellectual property had remaining lives of 8.9 and 7.0 years, respectively. Intangible assets consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Purchased technology	$ 20,300	$ 22,100
Intellectual property	80	80
Total cost	20,380	22,180
Less accumulated amortization	(5,019)	(5,087)
Intangible assets, net	$ 15,361	$ 17,093

Intangible asset amortization expense was $1,732,000, $2,320,000 and $2,727,000 for the years ended December 31, 2020, 2019 and 2018, respectively. Following the results of Phase 2 trials in June 2018, the in-process research and development was assessed as fully impaired in the three months ended June 30, 2018, with the $1.6 million acquired in the Merger (see Note 3) being charged to operating expenses.

As of December 31, 2020, the estimated future amortization expense by year is as follows (in thousands):

Year Ending December 31,	Amount
2021	$ 1,732
2022	1,731
2023	1,732
2024	1,732
2025	1,731
Thereafter	6,703
Total	$ 15,361

(f) Other Accrued Liabilities

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

	December 31, 2020	December 31, 2019
Accrued compensation	$ 1,618	$ 903
Accrued clinical and manufacturing expenses	1,772	3,228
Accrued professional and consulting services	777	2
Reserve for return of royalties	—	178
Other	632	254
Total	$ 4,799	$ 4,565

NOTE 6. Revenue

Service Contracts with Customers

Contract Balances. Accounts receivable related to service contracts with customers as of December 31, 2020 and 2019, was nil and $181,000, respectively. Contract assets, representing unbilled receivables where revenue has been recognized in advance of customer billings, as of December 31, 2020 and 2019, was $219,000 and $21,000, respectively, which is included in prepaid expenses and other current assets.

Remaining Performance Obligations. Remaining Performance Obligations (“RPO”) comprise deferred revenue plus unbilled contract revenue. As of December 31, 2020 and 2019, there was no deferred revenue and the aggregate amount of RPO was $13,000 and $211,000, respectively, all of which was unbilled contract revenue which is not recorded on the balance sheet. We expect 100% of the balance as of December 31, 2020, to be recognized as revenue within the next three months. Unbilled contract revenue represents non-cancelable contracts under which the Company has an obligation to perform, for which revenue has not yet been recognized in the financial statements and the fixed amounts billable have not yet been invoiced.

U.S. Government HHS BARDA Contract

In September 2015, HHS BARDA awarded the Company a contract to support the advanced development of a more effective and universal influenza vaccine to improve seasonal and pandemic influenza preparedness. On each of May 25 and July 18, 2017, and June 28, 2018, the Company entered into a Modification of Contract with HHS BARDA, the combined effect being to increase the value of the original $14 million contract by $1.7 million and to extend it through September 30, 2018. The modified contract is a cost-plus-fixed-fee contract, which reimburses the Company for allowable direct contract costs plus allowable indirect costs and a fixed-fee, totaling $15.7 million. The Company recognized revenue of $1,344,000 during the year ended December 31, 2018, of which $20,000 was reversed during the year ended December 31, 2019. As of December 31, 2020, the cumulative revenue recorded from inception under the HHS BARDA contract represents $20,000 less than the maximum amount billable under the contract as presently modified, with no further change orders envisaged.

Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. Indirect rates as well as allowable costs are subject to audit by HHS BARDA on an annual basis. Management believes that revenues recognized to date have 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 adjustments are known and collection is probable. Costs relating to contract acquisition are expensed as incurred. In the three months ended December 31, 2019, the Company reversed $20,000 in revenue that was invoiced late in 2018 to correct prior undercharges but which may never be received, and does not consider any of the revenue recorded as of December 31, 2020, to be at risk of reversal.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

Royalty agreements

Aviragen entered into a royalty-bearing research and license agreement with GlaxoSmithKline, plc ("GSK") in 1990 for the development and commercialization of zanamivir, a neuraminidase inhibitor marketed by GSK as Relenza, to treat influenza. All the Company's Relenza patents have expired, the last remaining intellectual property related to the Relenza patent portfolio, which is solely owned by the Company and exclusively licensed to GSK, having expired in July 2019 in Japan, at which time royalty revenue ceased, although it remained subject to minor adjustments for sales returns and exchange rate differences. Royalty revenue related to Relenza in 2020, 2019, and in the post-Merger period in 2018, was $193,000, $778,000 and $788,000, respectively, representing 7% of net sales in Japan.

The Company also 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. The last patent related to Inavir is set to expire in December 2029 in Japan, at which time royalty revenue will cease. The royalty revenue related to Inavir recognized in 2020, 2019, and in the post-Merger period in 2018, was $2,769,000, $3,668,000 and $552,000, respectively. In addition, the Company recognized non-cash royalty revenue related to sale of future royalties (see Note 7) of $886,000, $5,030,000 and $1,475,000 in 2020, 2019 and 2018, respectively. Both the royalty revenue and the non-cash royalty revenue related to sale of future royalties have been subjected to a 5% withholding tax in Japan, for which $183,000, $435,000 and $102,000 was included in income tax expense in the years ended December 31, 2020, 2019 and 2018, respectively.

NOTE 7. Liabilities Related to Sale of Future Royalties

In April 2016, Aviragen entered into a Royalty Interest Acquisition Agreement (the "RIAA") with 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, HCRP is entitled to the first $3.0 million 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.

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, 2020 (in thousands):

Total liability related to sale of future royalties, start of year	$	16,332
Non-cash royalty revenue paid to HCRP		(3,277)
Non-cash interest expense recognized		1,874
Total liability related to sale of future royalties, end of year		14,929
Current portion		(2,779)
Long-term portion	$	12,150

NOTE 8. Leases

The Company has obtained the right of use for office and manufacturing facilities under six operating lease agreements, one of which has been subleased, and for equipment under an operating lease agreement with an initial term exceeding one year, and under three operating lease agreements with initial terms of one year or less.

The Company obtained the right of use of real estate located in South San Francisco, California, in November 2020 under a lease that terminates on September 30, 2025, with no extension option. The Company also obtained the right of use of real estate 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. The right of use of these premises was assessed as partially impaired as of December 31, 2019 (see Note 15). Further, the Company obtained, via the Merger in February 2018, the right of use of facilities located in Alpharetta, Georgia, that terminates on February 28, 2021, with no extension option. These facilities were subleased for the remainder of the lease term effective November 30, 2018. In addition, the Company has the right of use of two facilities located in South San Francisco, California, under leases that terminate on July 31, 2021, with no extension options, and the right of use of equipment under a lease that terminates in September 2021. Further, the Company has identified an embedded lease for the rental of facilities in Burlingame, California, within a Statement of Work for the manufacture of bulk vaccine product that is expected to be completed early in 2022.

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As of December 31, 2020, the weighted average discount rate for operating leases with initial terms of more than one year was 9.94% and the weighted average remaining term of these leases was 4.07 years. Discount rates were determined using the Company's marginal rate of borrowing at the time each lease was executed or extended.

The following table summarizes the Company's undiscounted cash payment obligations for its operating lease liabilities with initial terms of more than twelve months as of December 31, 2020 (in thousands):

Year Ending December 31,	Amount
2021	$ 2,633
2022	1,801
2023	1,585
2024	1,641
2025	1,112
Undiscounted total	8,772
Less: imputed interest	(1,564)
Present value of future minimum payments	7,208
Current portion of operating lease liability	(2,052)
Operating lease liability, net of current portion	$ 5,156

The Company presently has no finance leases and no future obligations under operating leases for equipment with initial terms of one year or less.

Certain operating lease agreements for facilities include non-lease costs, such as common area maintenance, which are recorded as variable lease costs. Operating lease expenses for the years ended December 31, 2020 and 2019, are summarized as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Lease cost		
Operating lease cost	$ 1,145	$ 959
Short-term lease cost	13	15
Variable lease cost	264	162
Sublease income	(217)	(217)
Total lease cost	$ 1,205	$ 919

Net cash outflows associated with operating leases totaled $1,111,000 and $983,000 in the years ended December 31, 2020 and 2019, respectively.

When the Company subleased its facilities located in Alpharetta, Georgia, for less than it is required to pay under the head lease, it recorded a lease loss charge of $253,000 on the cease-use date in the three months ending December 31, 2018, which, along with the related impairment of property and equipment (see Note 5), was recorded as a component of costs of exit from leased premises within operating expenses.

Liabilities related to costs of exit from leased premises are summarized as follows (in thousands):

Balance as of January 1, 2018	$ —
Costs of exit from leased premises	359
Deferred rent on cease-use date	19
Impairment of property and equipment	(106)
Cash paid, net of receipts	(41)
Accretion charges, included in rent expense	2
Balance as of December 31, 2018	$ 233

Prior to December 31, 2018, rent expense was recognized on a straight-line basis over the noncancelable term of each operating lease and, accordingly, the Company recorded the difference between cash rent payments and the recognition of rent expense as a deferred rent liability, which was included within accrued expenses. Rent expense was $875,000 for the year ended December 31, 2018.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

NOTE 9. Convertible Promissory Notes, Related Parties

On December 10, 2014, the Company entered into a note purchase agreement with certain existing preferred stockholders under which the Company issued convertible promissory notes during December 2014 for total proceeds of $18.4 million.

On November 20, 2015, the Company entered into a second note purchase agreement with certain existing preferred stockholders under which the Company issued convertible promissory notes during November and December 2015 for total proceeds of $11.0 million. These notes were issued with the same terms as the notes issued in 2014.

As the holders of the convertible promissory notes each had an equity ownership in the Company, the convertible promissory notes were considered to be a related-party transaction.

The convertible promissory notes bore interest at a rate of 8.0% per annum.

As of December 31, 2017, the balance of the convertible promissory notes was $35.3 million, comprising principal of $29.4 million plus accrued interest associated with the convertible promissory notes of $6.3 million, offset by unamortized debt discount of $0.4 million. Interest expense related to the convertible promissory notes, including amortization of debt discount, totaled $0.3 million in the year ended December 31, 2018, all related to the 43 days prior to the Merger.

On February 13, 2018, the balance of the convertible promissory notes was $35.6 million, comprising principal of $29.4 million plus accrued interest of $6.6 million, offset by the unamortized debt discount to $0.4 million. On that date, in conjunction with the Merger, the convertible promissory notes were exchanged for 1,571,702 shares of the Company's common stock which, based on the closing stock price of $9.05, had a value of $14.2 million. The difference of $21.4 million was recorded as a capital contribution.

NOTE 10. Secured Promissory Note Payable to Oxford Finance

On December 22, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance, under which the Company borrowed $5.0 million. The $5.0 million loan, which bore interest at the 30-day U.S. LIBOR rate plus 6.17%, was evidenced by a secured promissory note and was repayable over four years, with interest only payable over the first 12 months and the balance fully amortized over the subsequent 36 months. The loan was secured by substantially all the Company's assets, except for intellectual property.

In conjunction with the execution of the Loan Agreement, all the holders of convertible promissory notes signed subordination agreements, under which they agreed to subordinate in favor of Oxford Finance all amounts due under their promissory notes and any security interest in the Company's property. In addition, the holders of the notes agreed that they would not demand or receive any payment until all amounts owed to Oxford Finance under the Loan Agreement had been fully paid in cash. Upon repayment, an additional final payment equal to $325,000 would be due, which was accreted as interest expense over the term of the loan using the effective-interest method.

In connection with the Loan Agreement, the Company issued a warrant to Oxford Finance to purchase 7,563 shares of its Series C convertible preferred stock at an exercise price of $33.11 per share (the "Warrant"). The fair value of the Warrant at the date of issuance was approximately $134,000 which, along with other initial costs, was recorded as debt discount and was amortized as interest expense over the term of the loan using the effective-interest method.

The Warrant provided that if the share price at the next equity financing was less than the Warrant exercise price, then the Warrant would be for the new class of shares, the exercise price would be the new class share price, and the number of shares would be calculated by dividing $250,000 by the new class share price. Due to this anti-dilution protection, the Company determined that the Warrant needed to be recorded as a liability, and therefore estimated the fair value of the Warrant upon issuance and at each balance sheet date, with any changes in the fair value being recorded within loss on revaluation of financial instruments in other income and (expenses) in the consolidated statements of operations and comprehensive loss.

Due to the antidilution protection, following the Merger, the Warrant was amended to allow the holder to purchase 10,914 shares of common stock at an exercise price of $22.99 per share. Since the amended Warrant contains no non-standard antidilution protections or similar features, the fair value of approximately $70,000 on February 13, 2018, was reclassified to equity (see Note 4).

The annual effective interest rate of the note, including the accretion of the final payment and the amortization of the debt discount, was approximately 10.5%. The Company recorded interest expense related to the Loan Agreement of $311,000 and $526,000 during the years ended December 31, 2019 and 2018, respectively, of which $223,000 and $356,000 was paid, respectively. The note was repaid in full on November 4, 2019. At that date, the unamortized deferred financing costs of $98,000 plus $2,000 reimbursed to Oxford Finance for legal fees were expensed as loss on debt extinguishment within other income and (expenses).

NOTE 11. Commitments and Contingencies

(a) Purchase Commitments

As of December 31, 2020, the Company had approximately $24.6 million of non-cancelable purchase commitments, principally for contract manufacturing and clinical services which are expected to be paid within the next eighteen months. In addition, the Company has operating lease commitments as detailed in Note 8.

(b) Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has also entered into indemnification agreements with its directors and officers that require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. 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 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 the Company successfully, and could have a material adverse impact on its business, financial condition and results of operations.

On August 4, 2020, a purported shareholder derivative complaint was filed in the Superior Court of California, San Mateo County, entitled Godfrey v. Latour, et al. An amended complaint was filed on September 4, 2020, and the case was re-named Ennis v. Latour, et al. A second amended complaint was filed on November 25, 2020. The second amended complaint names certain of Vaxart's officers and directors as defendants, asserting claims against them for breach of fiduciary duty, unjust enrichment, and waste and seeking, among other things, an award of unspecified damages, certain equitable relief, and attorneys' fees and costs. The complaint also asserts claims for breach of fiduciary duty, unjust enrichment, and aiding and abetting breach of fiduciary duty against Armistice Capital, LLC ("Armistice"). The claims challenge certain stock options granted to certain of the Company's officers and directors between March 24, 2020 and June 15, 2020 and certain amendments to two warrants held by Armistice, as disclosed on June 8, 2020. The second amended complaint purports to bring the lawsuit derivatively on behalf of and for the benefit of the Company and names the Company as a "nominal defendant" against which no damages are sought. On December 30, 2020, all defendants in the action filed a demurrer with the court addressing the second amended complaint, seeking to have the entire case dismissed.

On September 8, 2020, a purported shareholder derivative complaint was filed in the Chancery Court in the State of Delaware, entitled Galjour v. Floroiu, et al. On October 20, 2020, a purported shareholder derivative and class action complaint, entitled Jaquith v. Vaxart, Inc., was filed in the Court of Chancery of the State of Delaware. The complaints name as defendants certain of Vaxart's current and former directors, asserting claims against them for breach of fiduciary duty, unjust enrichment, and waste and seeking, among other things, an award of unspecified damages, certain equitable relief, and attorneys' fees and costs. The complaints also assert claims against Armistice. The complaints challenge certain stock options granted to certain of the Company's officers and directors between March 24, 2020 and June 15, 2020 and certain amendments made to two warrants held by Armistice, as disclosed on June 8, 2020. Both complaints purport to bring suit derivatively on behalf of and for the benefit of the Company, and the Jaquith complaint also purports to assert a direct claim for breach of fiduciary duty on behalf of a class of Vaxart stockholders. Both complaints name the Company as a "nominal defendant" against which no claims are asserted and no damages are sought. On October 9, 2020, all defendants moved to dismiss the Galjour complaint and to stay the action pending disposition of the Ennis action in California. On November 12, 2020, the Galjour and Jaquith actions were consolidated under the caption *In re Vaxart, Inc. Stockholder Litigation* and the complaint filed in the *Jaquith v. Latour* action was deemed the operative pleading. On January 4, 2021, all defendants filed motions to dismiss, seeking to have the case dismissed.

On September 17, 2020, a purported derivative complaint was filed in the U.S. District Court for the Northern District of California, entitled Stachowski v. Boyd, et al. The complaint names as defendants certain of Vaxart's current directors, asserting claims against them for breach of fiduciary duty and unjust enrichment and seeking, among other things, an award of unspecified damages, certain equitable relief, and attorneys' fees and costs. The complaint also alleges a violation of §14(a) of the Securities Exchange Act of 1934 for allegedly false statements or omissions in the Company's April 24, 2020, proxy statement regarding the Company's options practices. The complaint also asserts a claim for breach of fiduciary duty against Armistice. The claims are based on allegations that certain stock options granted to certain of the Company's officers and directors between March 24, 2020 and June 15, 2020, were allegedly improper and that certain warrants held by Armistice were amended on June 8, 2020, allegedly for no consideration. The complaint purports to bring the lawsuit derivatively on behalf of and for the benefit of the Company and names the Company as a "nominal defendant" against which no claims are asserted and no damages are sought. On November 13, 2020, plaintiffs voluntarily withdrew their claims and the case was dismissed.

Two substantially similar securities class actions were filed in the U.S. District Court for the Northern District of California, the first, titled Himmelberg v. Vaxart, Inc. et al. was filed on August 24, 2020 (the "Himmelberg Action"), and the second action, titled Hovhannisyan v. Vaxart, Inc. et al. was filed on September 1, 2020 (the "Hovhannisyan Action," and together, the "Putative Class Actions"). On September 17, 2020, the court issued an order that the Putative Class Actions were related and would proceed as one consolidated action. On December 9, 2020, the court appointed the lead plaintiffs and lead plaintiffs' counsel and on January 29, 2021, the lead plaintiffs filed their consolidated amended complaint. The consolidated amended complaint names as defendants certain of Vaxart's current and former executive officers and directors, and Armistice. It claims two violations of federal civil securities laws, violation of SEC Rule 10b-5, as against all defendants; violation of Section 20(a) of the Exchange Act, as against all defendants except for Vaxart; and violation of Section 20A of the Exchange Act against Armistice. The consolidated amended complaint alleges that the defendants violated securities laws by misstating and omitting information regarding the Company's development of a norovirus vaccine, the vaccine manufacturing capabilities of a business counterparty, as well as the Company's Operation Warp Speed ("*OWS*") involvement to deceive the investing public and inflate Vaxart's stock price. The consolidated amended complaint seeks to be certified as a class action for similarly situated shareholders and seek, among other things, an uncertain amount of damages and attorneys' fees and costs.

On October 23, 2020, a purported shareholder derivative 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 an Armistice-affiliated Company director as defendants, asserting a violation of Exchange Act Section 16(b) and seeking the disgorgement of short-swing profits obtained in violation thereof. The complaint purports to bring the lawsuit derivatively on behalf of and for the benefit of the Company and names the Company as a "nominal defendant" against which no damages are sought.

On January 8, 2021, a purported shareholder, Phillip Chan, commenced a *pro se* lawsuit in the U.S. District Court for the Northern District of California titled *Chan v. Vaxart, Inc. et al.* (the "*Opt-Out Action*"). This complaint is nearly identical to an earlier version of the complaint filed in the Putative Class Actions, naming the same defendants, certain of Vaxart's current and former executive officers and directors and Armistice, and asserting identical legal claims relating to the same factual allegations. The complaint asserts two violations of federal civil securities laws, violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5, as against all defendants, and violation of Section 20(a) of the Exchange Act, as against the individual defendants. The Opt-Out Action alleges that the defendants violated securities laws by misstating and omitting information regarding the Company's development of a Covid-19 vaccine as well as its OWS involvement to deceive the investing public and inflate Vaxart's stock price.

On February 4, 2021, a purported shareholder, Stephen Barker, commenced a lawsuit in the Delaware Court of Chancery titled *Barker v. Vaxart, Inc. et al*. The complaint names as defendants the Company and its current board of directors. The complaint asserts a single claim for declaratory relief seeking a declaration that one of the Company's bylaws, which requires a supermajority vote to remove a Company director from office, is in violation of Delaware General Corporate Law Section 141(k). It does not seek damages.

The Company's legal costs incurred in its defense against these claims are expensed as incurred.

NOTE 12. Stockholders' Equity

(a) Convertible 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. Prior to February 13, 2018, there were three classes of convertible preferred stock outstanding, all of which were converted into common stock in conjunction with the Merger (see Note 1). Significant provisions of the convertible preferred stock were as follows:

Series C – Shares of series C convertible preferred stock were issued in 2013 for net proceeds of $20.0 million. The holders of Series C convertible preferred stock were entitled to receive non-compounding cumulative dividends, in preference to any dividends payable to holders of Series B and Series A convertible preferred stock or common stock, at an annual dividend rate of 8%. Dividends accumulated from the date of issuance and were payable, whether or not declared, before any dividend on Series B and Series A convertible preferred stock or common stock could be paid or declared. Since no dividends were ever declared, holders were entitled to receive additional shares of common stock on conversion. As of February 13, 2018, when the convertible preferred stock was converted into common stock, accumulated and undeclared dividends for Series C convertible preferred stock were $7.3 million, of which $188,000 related to the pre-Merger period in 2018. On February 13, 2018, in conjunction with the Merger, the Series C convertible preferred stock and the related accumulated dividends were converted into 696,028 and 253,851 shares of common stock, respectively.

Series B – Shares of series B convertible preferred stock were issued between 2009 and 2014 for net proceeds of $16.0 million. The holders of Series B convertible preferred stock were entitled to receive non-compounding cumulative dividends, in preference to any dividends payable to holders of Series A convertible preferred stock or common stock, at the annual dividend rate of 8%. Dividends accumulated from the date of issuance and were payable, whether or not declared, before any dividend on Series A convertible preferred stock or common stock could be paid or declared. Since no dividends were ever declared, holders were entitled to receive additional shares of common stock on conversion. As of February 13, 2018, when the convertible preferred stock was converted into common stock, accumulated and undeclared dividends for Series B convertible preferred stock were $7.6 million, of which $151,000 related to the pre-Merger period in 2018. On February 13, 2018, in conjunction with the Merger, the Series B convertible preferred stock and the related accumulated dividends were converted into 599,259 and 265,340 shares of common stock, respectively.

Series A – Shares of series A convertible preferred stock were issued between 2007 and 2012 for net proceeds of $2.9 million. The holders of Series A convertible preferred stock were entitled to receive noncumulative dividends, in preference to any dividends payable to holders of common stock, if declared by the board of directors. No dividends were ever declared. On February 13, 2018, in conjunction with the Merger, the Series A convertible preferred stock was converted into 104,065 shares of common stock.

(b) Common Stock

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 therefore. 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, 2020, no dividends had been declared by the board of directors.

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

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

	December 31, 2020	December 31, 2019
Options issued and outstanding	6,813,033	1,811,652
Available for future grants of equity awards	1,230,863	295,180
Common stock warrants	1,244,974	43,370,162
Total	9,288,870	45,476,994

(c) Warrants

The Company has the following warrants outstanding as of December 31, 2020, 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	5,000	$ 0.30	September 2024
Common Stock	224,797	$ 0.375	September 2024
Common Stock	225,966	$ 1.10	April 2024
Common Stock	111,931	$ 1.375	April 2024
Common Stock	316,584	$ 2.50	March 2025
Common Stock	269,496	$ 3.125	February 2025
Common Stock	80,286	$ 3.125	March 2024
Common Stock	10,914	$ 22.99	December 2026
Total	1,244,974		

The aggregate fair value at issuance of the warrants issued to the placement agents' designees at the closing of the March 2019 Offering and the March 2020 Offering and to the underwriters' designees at the closing of the April 2019 Offering and the September 2019 Offering (see Note 1) were estimated to be $100,000, $453,000, $333,000 and $497,000, respectively, using the Black-Scholes valuation model and using parameters and assumptions tabulated as follows:

Offering	March 2019	April 2019	September 2019	March 2020
Aggregate valuation on issuance date	$ 100,000	$ 333,000	$ 497,000	$ 453,000
Number of warrants issued	84,000	636,364	2,115,738	280,000
Exercise price	$ 3.125	$ 1.375	$ 0.375	$ 3.125
Closing stock price	$ 2.08	$ 0.89	$ 0.36	$ 2.34
Risk-free interest rate	2.34%	2.31%	1.55%	0.88%
Expected term (In Years)	5.00	5.00	5.00	4.99
Expected volatility	80%	83%	83%	98%
Dividend yield	—%	—%	—%	—%

In the event of a Fundamental Transaction (a transfer of ownership of the Company as defined in the warrant) within the Company's control, the holders of the unexercised common stock warrants exercisable for $0.30, $0.375, $1.10 and $2.50 and those exercisable for $3.125 expiring in February 2025 shall be entitled to receive cash consideration equal to a Black-Scholes valuation, as defined in the warrant. If such Fundamental Transaction is not within the Company's control, the warrantholders would only be entitled to receive the same form of consideration (and in the same proportion) as the holders of the Company's common stock, hence these warrants are classified as a component of permanent equity.

NOTE 13. Equity Incentive Plans

Prior to the Merger, Private Vaxart issued equity awards for compensation purposes to employees, directors and consultants under the Company's 2007 Equity Incentive Plan (the "2007 Plan"). The 2007 Plan expired in July 2017 and no further awards may be made under the 2007 Plan. Each outstanding stock option to acquire shares of Private Vaxart stock, whether vested or unvested, was assumed in the Merger after adjustment for the impact of the Conversion and the Reverse Stock Split.

In November 2016, Aviragen's stockholders approved the 2016 Equity Incentive Plan ("2016 Plan"), under which all outstanding awards under their previous plans became available for issuance under the 2016 Plan if such awards are forfeited or otherwise terminated. Under the 2016 Plan, the Company was authorized to issue incentive stock options ("ISOs"), non-qualified stock options ("NQSOs"), restricted stock ("RSAs") and restricted stock units ("RSUs"). Awards have a maximum term of ten years from the grant date and vest over varying periods, as specified by the Company's board of directors for each grant. Following stockholder approval of the 2019 Equity Incentive Plan (the "2019 Plan"), no further awards are available for grant under the 2016 Plan.

On April 23, 2019, the Company's stockholders approved the adoption of the 2019 Plan, under which the Company is authorized to issue ISOs, NQSOs, stock appreciation rights, RSAs, 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.

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 on June 8, 2020, to 8,000,000 (the "Plan Amendment"), subject to standard adjustments in the event of a stock split, stock dividend or other extraordinary dividend, or other similar change in the Company's common stock or capital structure. Further amendments to the 2019 Plan to increase the share reserve would require stockholder approval. Awards that expire or are canceled generally become available for issuance again under the 2019 Plan. Awards have a maximum term of ten years from the grant date and may vest over varying periods, as specified by the Company's board of directors for each grant.

A summary of stock option transactions in each of the three years ended December 31, 2020, is as follows:

	Shares Available For Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at January 1, 2018	—	304,850	$ 9.50
Assumed on consummation of Merger	291,102	627,106	$ 26.33
Granted	(431,100)	431,100	$ 5.17
Exercised	—	(2,013)	$ 6.49
Forfeited	71,500	(89,903)	$ 5.90
Canceled	269,148	(405,977)	$ 34.64
Balance at December 31, 2018	200,650	865,163	$ 8.13
Authorized under 2019 Plan on Adoption	1,600,000	—	$ —
Removed from 2016 Plan	(223,389)	—	$ —
Granted	(1,791,030)	1,791,030	$ 0.67
Forfeited	483,849	(592,528)	$ 1.57
Canceled	25,100	(252,013)	$ 9.25
Balance at December 31, 2019	295,180	1,811,652	$ 2.74
Authorized under 2019 Plan Amendment	6,400,000	—	$ —
Granted	(5,579,800)	5,579,800	$ 2.66
Exercised	—	(414,676)	$ 1.45
Forfeited	105,910	(105,992)	$ 1.65
Canceled	9,573	(57,751)	$ 10.57
Balance at December 31, 2020	1,230,863	6,813,033	$ 2.70

As of December 31, 2020, there were 6,813,033 options outstanding with a weighted average exercise price of $2.70, a weighted average remaining term of 8.99 years and an aggregate intrinsic value of $22.5 million. Of these options, 6,502,213 were expected to vest, with a weighted average exercise price of $2.68, a weighted average remaining term of 8.97 years and an aggregate intrinsic value of $21.6 million. Of these, 2,886,541 were vested, with a weighted average exercise price of $2.65, a weighted average remaining term of 8.65 years and an aggregate intrinsic value of $9.9 million.

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, 2020, based on our common stock closing price of $5.71, which would have been received by the option holders had all their in-the-money options been exercised as of that date.

The intrinsic value of options exercised in the year ended December 31, 2020, was $2.2 million. There were no options exercised in the year ended December 31, 2019. The intrinsic value of options exercised in the year ended December 31, 2018, was zero.

In March 2020, the Company granted 411,000 performance-based restricted stock unit ("PRSU") awards to employees which would vest upon the achievement of certain performance conditions by December 31, 2020, subject to each employee's continued service relationship with the Company. The related compensation cost, based on the grant date fair value of the Company's common stock of $1.70 multiplied by the number of PRSUs granted, was recognized as an expense ratably over the estimated vesting period when achievement of the performance condition was considered probable. Based on the Company's evaluation of the probability of achieving the performance condition as of September 30, 2020, the Company recognized $632,000 of related expense during the nine months ended September 30, 2020. As of December 31, 2020, the performance condition had not been achieved so these 411,000 PRSUs were canceled and the expense was reversed.

On March 24, 2020, the board of directors of the Company approved the grant of an aggregate of 2,610,000 options with an exercise price of $1.70 per share (the closing price of the Company's common stock on March 24, 2020) (the "March Option Awards"), which vests as to 25% of the underlying shares of common stock on the date of grant and thereafter in twenty-four (24) equal monthly installments from May 1, 2020 until April 1, 2022; provided that the stock options were not exercisable until the approval by the stockholders of the Plan Amendment. On June 8, 2020, the stockholders approved the Plan Amendment and at such time the March Option Awards became exercisable, subject to the vesting schedule noted previously.

On June 15, 2020, the Company awarded 900,000 performance-based options and 845,280 time-based options with an exercise price of $2.46 per share (the closing price of the Company's common stock on the grant date) to its new Chief Executive Officer. Vesting of the time-based options will be 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 a substantial strategic agreement, as determined by the Board, and with accelerated vesting in full in the event of a "Change in Control" (as defined under the 2019 Plan).

Vesting of the performance-based options would occur if the Company achieved a specified closing price during any ten consecutive trading days by November 30, 2020, with one-third based on a closing price of $5.00, one-third based on a closing price of $7.50 and one-third based on a closing price of $10.00, subject to continuing employment. Utilizing a Monte Carlo Simulation and assumptions of the fair value of Common Stock of $2.46, estimated volatility of 105%, a risk-free interest rate of 0.35%, a zero dividend rate and an expected term of 5.23 years, the Company determined the weighted average fair value of these options on the issuance date to be $0.31 per share, or $279,000, which was initially being expensed over the estimated vesting term, assuming vesting occurs by November 30, 2020, for each tranche. The tranches based on closing prices of $5.00, $7.50 and $10.00 vested on July 9, 2020, July 20, 2020 and July 24, 2020, respectively, so the unamortized balance as of June 30, 2020, was expensed in the three months ended September 30, 2020.

Excluding these performance-based options, the weighted average grant date fair value of options awarded in the years ended December 31, 2020, 2019 and 2018, was $2.49, $0.48 and $3.59, respectively. Fair values were estimated using the following assumptions:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	0.40% - 0.88%	1.68% - 2.31%	2.79% - 2.80%
Expected term (in years)	5.22 - 10.00	5.39 - 10.00	5.84 - 6.05
Expected volatility	94% - 111%	83% - 85%	78% - 80%
Dividend yield	—%	—%	—%

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

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 1,563	$ 253	$ 254
General and administrative	2,795	374	285
Total stock-based compensation	$ 4,358	$ 627	$ 539

As of December 31, 2020, the unrecognized stock-based compensation cost related to outstanding stock options that are expected to vest was $8.2 million, which the Company expects to recognize over an estimated weighted average period of 2.31 years.

NOTE 14. Related Party Transactions

In April 2020, the Company recorded a net amount of $652,000 related to the disgorgement of stockholder short-swing profits under Section 16(b) of the Securities Exchange Act of 1934, as amended. The Company recognized these related party proceeds as an increase to contributed capital on the consolidated balance sheet.

NOTE 15. Restructuring Charges and (Reversals)

Restructuring liabilities primarily consisted of the estimated future obligations for contract suspension costs and severance and benefits obligations. These restructuring liabilities, all of which were paid in the year ending December 31, 2020, were recorded in either accounts payable or other accrued liabilities in the consolidated balance sheets.

The Company approved a reduction-in-force during the year ended December 31, 2019, for which it accrued severance and benefits charges, all of which were paid in the three months ended March 31, 2020. The Company also accrued the maximum amount potentially payable under a manufacturing work order which it suspended. Following negotiations with the vendor, the Company paid $2,252,000 in September 2020 in full settlement and reversed the remainder of the balance accrued. Further, the Company recorded impairment charges against property and equipment and right-of-use assets formerly used for manufacturing covering the period in which no benefits were expected to be derived, and incurred legal fees and accretion costs in connection with the restructuring. In the year ended December 31, 2020, the Company recorded costs for legal fees and for accretion related to the manufacturing premises. The Company does not expect to incur any further charges related to this restructuring.

Cumulative restructuring costs incurred and a reconciliation of the change in related liabilities during the years ended December 31, 2019 and 2020, is as follows (in thousands):

	Suspension of Contract	Severance Benefits	Impairment Charges	Other	Total
Cumulative cost incurred as of December 31, 2020	$ 2,252	$ 368	$ 1,272	$ 179	$ 4,071
Reconciliation of liabilities:					
Balance at January 1, 2019	$ —	$ —	$ —	$ —	$ —
Period charges	3,223	368	1,272	57	4,920
Settlements	—	—	(1,272)	—	(1,272)
Balance at December 31, 2019	3,223	368	—	57	3,648
Period charges	—	—	—	122	122
Period reversals	(971)	—	—	—	(971)
Settlements	(2,252)	(368)	—	(179)	(2,799)
Balance at December 31, 2020	$ —	$ —	$ —	$ —	$ —

NOTE 16. 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 $19,500 for calendar year 2020, up from $19,000 for 2019 and $18,500 for 2018. Employees age 50 or over may elect to contribute an additional $6,500 annually, up from $6,000 for 2019 and 2018.

Employees direct their contributions, which vest immediately, across a series of mutual funds. In the years ended December 31, 2020, 2019 and 2018, the Company matched employee contributions up to 3% of each employee's eligible earnings, vesting immediately. The Company's matching contributions totaled $96,000, $140,000 and $124,000 in the years ended December 31, 2020, 2019 and 2018, respectively. The costs of administering the Plan totaled $10,000, $14,000 and $9,000 in the years ended December 31, 2020, 2019 and 2018, respectively.

NOTE 17. Income Taxes

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

	Year Ended December 31,		
	2020	2019	2018
Current:			
Federal	$ —	$ —	$ —
State	3	2	3
Foreign	235	488	106
Total Current	238	490	109
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total Deferred	—	—	—
Provision for income taxes	$ 238	$ 490	$ 109

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

	December 31, 2020	December 31, 2019	December 31, 2018
Deferred tax assets:			
Net operating loss carry-forwards	$ 14,161	$ 6,924	$ 43,822
Research and development tax credits	2,497	1,591	3,357
Capitalized research and development	4,534	4,773	2,326
Sale of future royalties	7,178	7,486	8,383
Lease Liability	1,695	492	—
Accruals, reserves and other	1,327	1,253	714
Total deferred tax assets	31,392	22,519	58,602
Valuation allowance	(21,952)	(13,365)	(48,626)
Deferred tax assets net of valuation allowance	9,440	9,154	9,976
Deferred tax liabilities:			
Intangible assets	(7,832)	(8,730)	(9,976)
Right-of-use assets	(1,608)	(424)	—
Total deferred tax liabilities	(9,440)	(9,154)	(9,976)
Net deferred tax assets	$ —	$ —	$ —

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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,		
	2020	2019	2018
U.S. federal taxes at statutory rate	21.0%	21.0%	21.0%
State taxes (net of federal benefit)	2.9	0.4	0.6
Foreign rate differential	(0.7)	(2.6)	3.1
Global intangible low-taxed income	—	—	(8.8)
Permanently non-deductible items	2.2	(3.7)	(2.5)
Tax credits	2.8	1.7	2.1
Change in valuation allowance	(26.8)	194.2	(20.4)
Tax attributes write-off due to change in control	0.5	(208.3)	—
Prior year true-up	(2.5)	(0.9)	—
NOL and credit adjustments	—	—	(3.8)
Bargain purchase gain	—	—	8.1
Other	(0.1)	(4.5)	—
Provision for income taxes	(0.7)%	(2.7)%	(0.6)%

The Company's actual tax expense differed from the statutory federal income tax expense using a tax rate of 21% for the year ended December 31, 2019, primarily due to the write-off of tax attributes due to a change in control. In addition, in each of the years ended December 31, 2020, 2019 and 2018, significant reasons for the difference between the actual tax rate and the federal rate of 21% were the write-off of tax attributes 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, 2020, 2019 and 2018, the Company had a net operating loss ("NOL") carryforwards of $51.6 million, $18.0 million and $92.3 million for federal purposes, and $26.8 million, $1.6 million and $76.9 million for state purposes, respectively. If not utilized, these carryforwards will begin to expire in 2024 for federal, and 2028 for state purposes. The reductions in carryforwards in 2019 were primarily due to a change in ownership.

As of December 31, 2020, the Company also has accumulated tax losses of $6.8 million for Australia available for carry forward against future earnings, which under relevant tax laws do not expire but may not be available under certain circumstances. As of December 31, 2020, the Company's foreign subsidiaries have no positive accumulated earnings. As such, no federal or state income taxes have been provided on the losses of its foreign subsidiaries. If in the future there are positive earnings generated from the Company's foreign subsidiaries, the Company will evaluate whether to record any applicable federal and state income taxes on such earnings.

As of December 31, 2020, 2019 and 2018, the Company had federal research and development tax credit carryforwards of $0.9 million, $0.1 million and $3.0 million, respectively and state research and development tax credit carryforwards of $3.4 million, $2.7 million and $2.3 million, respectively, before offset for unrecognized tax benefits, to offset future income tax liabilities. The federal research and development tax credits will expire in 2039, if not utilized, while the state research and development tax credit can be carried forward indefinitely.

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's losses and credit carryforwards may be subject to these limitations. The Company has completed an analysis covering the period from February 13, 2018, through December 31, 2020, to determine if such ownership changes have occurred and concluded it was more likely than not that there were changes in ownership, including a change on September 30, 2019, which resulted in an annual limitation of $62,000, and on May 15, 2020, for which the annual limitation is $3.2 million. Due to the existence of the 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 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 its net deferred tax assets as of December 31, 2020, 2019 and 2018. The net change in total valuation allowance was an increase of approximately $8.6 million for the year ended December 31, 2020, a decrease of approximately $35.3 million for the year ended December 31, 2019 and an increase of approximately $25.7 million for the year ended December 31, 2018. The decrease in 2019 is primarily due to the reduction in NOL and tax credit carryforwards that were triggered by the change in ownership on September 30, 2019.

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 $1.3 million as of December 31, 2020, none of which would impact the effective tax rate, if recognized, because the benefit would be offset by an increase in the valuation allowance.

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

	Year Ended December 31,		
	2020	2019	2018
Beginning Balance	$ 851	$ 1,582	$ 1,404
Additions based on tax positions related to the current year	431	159	181
Decreases related to prior years' tax positions	(1)	(890)	(3)
Ending Balance	$ 1,281	$ 851	$ 1,582

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, 2020, 2019 and 2018, 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. and Australia, as well as with various U.S. states. The Company is subject to tax audits in all jurisdictions in which it files income tax returns. Tax audits by their very nature are often complex and can require several years to complete. There are currently no tax audits that have commenced with respect to income tax returns in any jurisdiction.

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

NOTE 18. 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,		
	2020	2019	2018
Net loss	$ (32,220)	$ (18,645)	$ (18,007)
Series B and C preferred dividend	—	—	(339)
Net loss attributable to common stockholders	$ (32,220)	$ (18,645)	$ (18,346)
Shares used to compute net loss per share, basic and diluted	88,295,762	21,569,523	6,316,065
Net loss per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (0.86)	$ (2.90)

No adjustment has been made to the net loss attributable to common stockholders as the effect would be anti-dilutive due to the net loss.

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

	Year Ended December 31,		
	2020	2019	2018
Options to purchase common stock	4,409,806	1,583,575	839,396
Warrants to purchase common stock	14,773,425	17,579,945	9,658
Warrant to purchase convertible preferred stock	—	—	891
Series B and C convertible preferred stock outstanding, including cumulative dividends	—	—	213,760
Series A convertible preferred stock outstanding	—	—	12,260
Convertible promissory notes, related party (as converted)	—	—	185,159
Total potentially dilutive securities excluded from denominator of the diluted earnings per share computation	19,183,231	19,163,520	1,261,124

NOTE 19. Quarterly Financial Data (Unaudited)

Selected summarized quarterly financial information for each of the last three fiscal years is as follows (in thousands):

	Year Ended December 31, 2020			
	First	Second	Third	Fourth
Revenue	$ 2,902	$ 523	$ 265	$ 356
Operating expenses	$ 3,596	$ 9,049	$ 7,854	$ 13,717
Net loss	$ (1,297)	$ (8,977)	$ (8,085)	$ (13,861)
Net loss per share – basic and diluted	$ (0.02)	$ (0.12)	$ (0.08)	$ (0.13)

	Year Ended December 31, 2019			
	First	Second	Third	Fourth
Revenue	$ 5,407	$ 85	$ 454	$ 3,916
Operating expenses	$ 5,855	$ 5,082	$ 5,168	$ 9,542
Net loss	$ (1,339)	$ (5,637)	$ (5,260)	$ (6,409)
Net loss per share – basic and diluted	$ (0.18)	$ (0.39)	$ (0.32)	$ (0.13)

	Year Ended December 31, 2018			
	First	Second	Third	Fourth
Revenue	$ 1,503	$ 608	$ 281	$ 1,767
Operating expenses	$ 5,418	$ 8,383	$ 6,161	$ 5,953
Net income (loss)	$ 2,314	$ (8,871)	$ (6,548)	$ (4,902)
Net income (loss) attributable to common stockholders	$ 1,975	$ (8,871)	$ (6,548)	$ (4,902)
Net income (loss) per share – basic	$ 0.54	$ (1.24)	$ (0.92)	$ (0.69)
Net income (loss) per share – diluted	$ 0.49	$ (1.24)	$ (0.92)	$ (0.69)

NOTE 20. Subsequent Events

Since December 31, 2020, the Company has issued 6,654,367 shares of common stock under the Sales Agreement (see Note 1) for net proceeds totaling $65.8 million and has issued 830,722 shares of common stock upon the exercise of warrants for cash proceeds totaling $1.6 million.

Changes in the status of litigation since December 31, 2020, are included in “Note 11. Commitments and Contingencies—(c) Litigation”.

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 President and Chief Executive 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, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020, has been audited by an independent registered public accounting firm, as stated in their report which appears below.

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, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial statements.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
Vaxart, Inc.
South San Francisco, California

Opinion on Internal Control over Financial Reporting

We have audited Vaxart, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2020, and the related notes and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ OUM & Co. LLP

San Francisco, California

February 25, 2021

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company's fiscal year end and is incorporated herein by reference.

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

The information required by this Item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company's fiscal year end and is incorporated herein by reference.

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

The information required by this Item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company's fiscal year end and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

Exhibits

The following documents are being filed with this Annual Report on Form 10-K.

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

(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).

(3) Exhibits.

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	Restated By-laws of Aviragen Therapeutics, Inc.	10-K	001-35285	3.2	September 13, 2016
4.1	Reference is made to Exhibits 3.1 to 3.6				
4.2	Specimen Common Stock Certificate	S-3	333-228910	4.2	December 20, 2018
4.3	Form of Pre-Funded Warrant (April 2019)	S-1	333-229536	10.25	February 6, 2019
4.4	Form of Common Stock Warrant (April 2019)	S-1/A	333-229536	4.4	April 8, 2019
4.5	Form of Representative Warrant (April 2019)	S-1/A	333-229536	4.5	April 8, 2019
4.6	Form of Pre-Funded Warrant (September 2019)	S-1	333-233717	4.3	September 11, 2019
4.7	Form of Common Stock Warrant (September 2019)	S-1	333-233717	4.4	September 11, 2019
4.8	Form of Representative Warrant (September 2019)	S-1/A	333-233717	4.5	September 24, 2019
4.9	Form of Common Stock Warrant (March 2020)	8-K	001-35285	4.1	March 2, 2020
4.10	Form of Placement Agent Warrant (March 2020)	8-K	001-35285	4.2	March 2, 2020
4.11 *	Description of Securities of the Registrant				
10.1 +	Collaboration and License Agreement dated September 29, 2003, between Biota Holdings Limited and Sankyo Co., Ltd.	10-Q	001-35285	10.5	May 10, 2013
10.2 +	Amendment #1 to Collaboration and License Agreement dated June 30, 2005, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Sankyo Company, Ltd.	10-Q	001-35285	10.6	May 10, 2013
10.3	Amendment #2 to Collaboration and License Agreement, dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Daiichi Sankyo Company, Limited	10-Q	001-35285	10.7	May 10, 2013
10.4 +	Commercialization Agreement dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd and Daiichi Sankyo Company, Ltd.	10-Q	001-35285	10.8	May 10, 2013
10.5 +	Contract dated March 31, 2011, between Biota Scientific Management Pty. Ltd. and Office of Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for preparedness and Response at the U.S. Department of Health and Human Services	10-Q	001-35285	10.9	May 10, 2013
10.6 +	Research and License Agreement dated February 21, 1990, by and among Biota Scientific Management Pty. Ltd., Biota Holdings Limited, Glaxo Australia Pty. Ltd. and Glaxo Group Limited	10-K	001-35285	10.6	September 27, 2013
10.7 #	2007 Omnibus Equity and Incentive Plan (included as Appendix A to the proxy statement)	DEF 14A	000-04829	-	April 12, 2007
10.8 #	Form of Employee Stock Option Agreement under the 2007 Omnibus Equity and Incentive Plan	8-K	001-35285	10.1	December 10, 2013

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
10.9 +	Royalty Interest Acquisition Agreement by and between Aviragen Therapeutics, Inc., Biota Holdings Pty Ltd, Biota Scientific Management Pty. Ltd. and HealthCare Royalty Partners III, L.P. dated April 22, 2016	8-K	001-35285	10.1	April 26, 2016
10.10	Protective Rights Agreement between Aviragen Therapeutics, Inc. and HealthCare Royalty Partners III, L.P. dated April 22, 2016	8-K	001-35285	10.2	April 26, 2016
10.11 #	Form of Employee Stock Option Agreement under the 2016 Equity Incentive Plan	10-Q	001-35285	10.1	May 8, 2017
10.12 #	2016 Equity Incentive Plan (included as Appendix A to the proxy statement)	DEF 14A	001-35285	-	September 27, 2016
10.13 #	Director Stock Option Agreement	S-4	333-222009	10.22	December 12, 2017
10.14	Form of Indemnification Agreement by and between Vaxart, Inc. and its Directors and Executive Officers	8-K	001-35285	10.3	February 20, 2018
10.15 #	Vaxart, Inc. Amended and Restated 2007 Equity Incentive Plan, Stock Option Agreement, form of Notice of Stock Option Grant, form of Additional Terms and Conditions to Option and Stock Option Exercise Agreement	S-4/A	333-222009	10.24	December 29, 2017
10.16 #	Offer Letter, dated May 25, 2011, and Amendment to Offer Letter and Option Grant Agreement, dated October 1, 2011, by and between Vaxart, Inc. and Wouter W. Latour, M.D.	S-4/A	333-222009	10.25	December 29, 2017
10.17	Industrial Lease dated October 28, 2013, by and between Vaxart, Inc. and Oyster Point LLC	S-4/A	333-222009	10.26	December 29, 2017
10.18	Lease Agreement dated April 17, 2015, by and between Vaxart, Inc. and CRP Edgewater, LLC	S-4/A	333-222009	10.27	December 29, 2017
10.19 #	Severance Benefit Plan and Form of Severance Benefit Plan Participation Notice	8-K	001-35285	10.1	June 6, 2018
10.20	Form of Sales Agreement dated December 19, 2018 by and between Vaxart, Inc. and B. Riley FBR, Inc.	S-3	333-228910	1.2	December 02, 2018
10.21	Amended and Restated Warrant issued to Oxford Finance LLC, dated February 13, 2018	8-K	001-35285	10.2	February 20, 2018
10.22	Engagement Letter, dated as of January 25, 2019, by and between Vaxart, Inc. and H.C. Wainwright & Co., LLC, as amended	8-K	001-35285	10.2	March 20, 2019
10.23	Form of Placement Agent Warrant (March 2019)	8-K	001-35285	10.3	March 20, 2019

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
10.24 #	2019 Equity Incentive Plan, as amended	S-8	333-239727	10.1	July 7, 2020
10.25 #	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the 2019 Equity Incentive Plan	S-8	333-239727	10.2	July 7, 2020
10.26 #	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2019 Equity Incentive Plan	8-K	001-35285	10.3	April 24, 2019
10.27 +	Manufacturing Services Agreement dated July 17, 2019, by and between Vaxart, Inc. and Lonza Houston, Inc.	S-1/A	333-233717	10.30	September 24, 2019
10.28	First Amendment to Lease Agreement dated September 17, 2019, by and between Vaxart, Inc. and HCP Inc.	8-K	001-35285	10.1	September 19, 2019
10.29	Form of Securities Purchase Agreement, dated February 27, 2020, by and among Vaxart, Inc. and the Purchasers named therein	8-K	001-35285	10.1	March 2, 2020
10.30 #	Offer Letter, dated May 1, 2006, by and between the Company and Dr. Sean Tucker	10-Q	001-35285	10.2	May 12, 2020
10.31 #	Offer Letter, dated March 26, 2018, by and between the Company and Margaret Echerd	10-Q	001-35285	10.3	May 12, 2020
10.32 #	Letter dated December 27, 2018, from the Company to Margaret Echerd	10-Q	001-35285	10.4	May 12, 2020
10.33 #	Separation Agreement, dated June 14, 2020, between Vaxart, Inc. and Wouter W. Latour, M.D.	8-K	001-35285	10.1	June 15, 2020
10.34 #	Letter Agreement, dated June 14, 2020, between Vaxart, Inc. and Andrei Floroiu	8-K	001-35285	10.2	June 15, 2020
10.35	Sales Agreement, dated July 8, 2020, by and between SVB Leerink LLC, B. Riley FBR, Inc. and Vaxart, Inc.	S-3ASR	333-239751	1.2	July 8, 2020
10.36 +	Master Services Agreement, dated April 17, 2020, by and between Vaxart, Inc. and Kindred Biosciences, Inc.	10-Q	001-35285	10.4	November 12, 2020
10.37 +	Statement of Work 003, dated September 11, 2020, under the Master Services Agreement, dated April 17, 2020, by and between Vaxart, Inc. and Kindred Biosciences, Inc.	10-Q	001-35285	10.5	November 12, 2020
10.38 +	Statement of Work 004, dated September 11, 2020, under the Master Services Agreement, dated April 17, 2020, by and between Vaxart, Inc. and Kindred Biosciences, Inc.	10-Q	001-35285	10.6	November 12, 2020
10.39	Open Market Sale Agreement, dated October 13, 2020, by and between Vaxart, Inc., Jefferies LLC, and Piper Sandler & Co.	8-K	001-35285	1.1	October 14, 2020
10.40 *	Sublease Agreement dated November 16, 2020, by and between Vaxart, Inc. and Vera Therapeutics, Inc.				
21.1 *	Subsidiaries of the Registrant				
23.1 *	Consent of OUM & Co. LLP, Independent Registered Public Accounting Firm				
23.2 *	Consent of KPMG LLP, Independent Registered Public Accounting Firm				
24.1 *	Power of Attorney. Reference is made to the signature page hereto				
31.1 *	Certification of Principal Executive and 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				

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
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				
101 *	The following financial information from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of December 31, 2020 and 2019, (ii) the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020, 2019 and 2018, (iii) the Consolidated Statements of Stockholders' Equity (Deficit) for the three years ended December 31, 2020, (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018, and (v) Notes to the Consolidated Financial Statements				

***** Filed herewith

\# Management contract or compensation plan or arrangement

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

§ In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certification furnished in Exhibit 32.1 hereto is deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VAXART, INC.

By: /s/ ANDREI FLOROIU
Andrei Floroiu
President and Chief Executive Officer

Date: February 25, 2021

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrei Floroiu and Margaret A. Echerd, 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/ ANDREI FLOROIU Andrei Floroiu	President and Chief Executive Officer *(Principal Executive Officer and Principal Financial Officer)*	February 25, 2021
/s/ MARGARET A. ECHERD Margaret A. Echerd	Vice President, Corporate Controller *(Principal Accounting Officer)*	February 25, 2021
/s/ WOUTER W. LATOUR, M.D. Wouter W. Latour, M.D.	Chairman of the Board	February 25, 2021
/s/ TODD C. DAVIS Todd C. Davis	Director	February 25, 2021
/s/ MICHAEL J. FINNEY Michael J. Finney, Ph.D.	Director	February 25, 2021
/s/ KAREN L. WILSON Karen L. Wilson	Director	February 25, 2021
/s/ ROBERT A. YEDID Robert A. Yedid	Director	February 25, 2021

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, bylaws and the Delaware General Corporation Law.

General

Our authorized capital stock consists of (i) 100,000,000 shares of common stock, par value $0.10 per share and (ii) 5,000,000 shares of preferred stock, par value $0.10 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).

Nasdaq Capital Market Listing

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

Transfer Agent and Registrar

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

SUBLEASE AGREEMENT

This Sublease Agreement ("***Sublease***") is dated as of November 16, 2020 for reference purposes only, by and between VERA THERAPEUTICS, INC., a Delaware corporation ("***Sublandlord***"), having an address of 170 Harbor Way, Third Floor, South San Francisco, California 94080, and VAXART, INC., a Delaware corporation ("***Subtenant***"), having an address of 385 Oyster Point Boulevard, Suite 9A, South San Francisco, CA 94080. This Sublease shall be effective as of the Effective Date (as defined in Section 2, below).

RECITALS

A. Sublandlord (formerly known as Trucode Gene Repair, Inc.), currently leases certain premises from Britannia Pointe Grand Limited Partnership, a Delaware limited partnership ("***Master Landlord***"), pursuant to the terms and conditions of that certain Lease dated April 10, 2018 (the "***Master Lease***"). Pursuant to the Master Lease, Sublandlord currently leases from Master Landlord those certain premises consisting of approximately 24,606 rentable square feet (as more particularly described in the Master Lease, the "***Master Premises***"), located on the third (3rd) floor of that certain building located at 170 Harbor Way, South San Francisco, California (the "***Building***"), within the project commonly known as Britannia Pointe Grand Business Park (the "***Property***"), as more particularly described in the Master Lease. All terms capitalized but undefined herein shall have the meanings ascribed to them in the Master Lease, a copy of which Master Lease has been made available to Subtenant.

C. Sublandlord desires to sublease the entirety of the Master Premises, as depicted on the attached Exhibit A (the "***Sublease Premises***") to Subtenant and Subtenant desires to sublease the Sublease Premises from Sublandlord pursuant to the terms and conditions of this Sublease.

AGREEMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, Sublandlord and Subtenant hereby agree as follows:

1. Sublease Premises. Sublandlord hereby subleases to Subtenant the Sublease Premises, and Subtenant hereby subleases the Sublease Premises from Sublandlord, pursuant to the terms and conditions of this Sublease. Subtenant shall accept exclusive possession of the Sublease Premises "broom clean" and in the condition and state of repair obtaining on the date of this Sublease, subject to reasonable wear and tear between the date of this Sublease and the Commencement Date (as defined in Section 3 below) in its "AS IS" and "WHERE IS" condition, and Sublandlord makes no representation or warranty regarding the Sublease Premises, except as provided to the contrary herein. Notwithstanding the foregoing sentence, Sublandlord will deliver the Sublease Premises to Subtenant with the portions of the Building structure, roof, interior improvements, HVAC, plumbing and all other Building components and systems comprising or serving the Sublease Premises (collectively, the "***Sublease Premises Systems***") in good working order and operating condition, provided that if any of the Sublease Premises Systems are not in operating condition as of the Commencement Date, Sublandlord will request that Master Landlord repair the same. Subtenant expressly acknowledges and agrees Sublandlord shall not have any obligation to (a) perform any work to prepare the Sublease Premises for Subtenant's use and occupancy or (b) make any repairs to the Sublease Premises or Sublease Premises Systems. By taking possession of the Sublease Premises, Subtenant is deemed to have accepted the Sublease Premises and agreed that, to Subtenant's knowledge, the Sublease Premises and the Sublease Premises Systems are in good working order and satisfactory condition, with no representation or warranty by Sublandlord as to the condition of the foregoing, except as provided in the third (3rd) grammatical sentence of this Section 1, or the suitability thereof for Subtenant's use. Subject to Master Landlord's consent, Subtenant shall have the right to inspect the Sublease Premises from time to time prior to the Commencement Date upon reasonable advance prior notice to Sublandlord. Pursuant to California Civil Code Section 1938, Sublandlord is required to state as follows regarding the Sublease Premises:

A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

2. Effective Date; Master Landlord's Consent Required. This Sublease shall not become effective or binding upon either party until the date on which Master Landlord's written consent to this Sublease (the "***Consent***") is fully-executed and delivered to Sublandlord and Subtenant (the "***Effective Date***"). Sublandlord hereby disclaims any representation or warranty, whether express or implied, to Subtenant that Sublandlord will obtain the consent of Master Landlord to this Sublease or that such Consent will contain any particular provisions requested by Subtenant, but Sublandlord shall use good faith efforts to obtain the same in accordance with the provisions of the Master Lease and Subtenant shall cooperate with Sublandlord in its efforts to obtain the same, at no out-of-pocket cost to Subtenant. Sublandlord shall request such consent and Subtenant shall pay any fees or charges expressly provided for in the Master Lease with respect to the obtaining of such consent. Subtenant agrees promptly to provide any reasonable financial or other information requested by Master Landlord; provided that in connection with such financial or other information, Sublandlord shall request the execution by Master Landlord of a commercially reasonable confidentiality and non-disclosure agreement reasonably acceptable in form and substance to Subtenant. Sublandlord agrees to request, on behalf of Subtenant, that Master Landlord include a provision in the Consent that, in the event the Master Lease is terminated due to a default by Sublandlord, Master Landlord agrees to enter into a direct lease with Subtenant for the balance of the Term of this Sublease on the applicable terms and conditions of the Master Lease. Each party agrees promptly to execute and deliver a consent agreement in a form reasonably acceptable to Master Landlord, Sublandlord and Subtenant. If Master Landlord's consent is not received within thirty (30) days of the full execution and delivery hereof, either party by notice to the other given prior to the receipt of Master Landlord's consent, may terminate this Sublease, in which case this Sublease shall be deemed void *ab initio* and Sublandlord shall promptly return to Subtenant all sums theretofore paid by Subtenant hereunder. Subtenant waives any claim against Master Landlord and Sublandlord arising out of any failure or refusal by Master Landlord to grant consent. Simultaneously with the delivery to Sublandlord of an executed counterpart of this Sublease, and as a precondition to Sublandlord's obligation to deliver possession of the Sublease Premises to Subtenant, Subtenant shall deliver to Sublandlord (i) the Security Deposit (as defined in Section 6 of this Sublease) and (ii) the first installment of monthly Base Rent (as defined below).

3. Sublease Term. The term of this Sublease (the "***Sublease Term***") shall commence on the date that is fourteen (14) days after Master Landlord executes and delivers the Consent (the "***Commencement Date***") and shall expire on the Lease Expiration Date of the Master Lease (the "***Expiration Date***"). Notwithstanding the foregoing sentence, Subtenant shall not access the Sublease Premises until Subtenant delivers to Sublandlord certificates evidencing that the insurance coverages that Subtenant is obligated to carry pursuant to the Master Lease and this Sublease have been procured and are in full force and effect (the "***Insurance Requirement***").

4. Early Access. Notwithstanding anything herein to the contrary, Subtenant shall have the right to access the Sublease Premises fourteen (14) days prior to the Commencement Date ("***Subtenant's Early Access***"); provided that each of the following have occurred: (a) Subtenant shall have satisfied the Insurance Requirement, and (b) the Master Landlord shall have consented to this Sublease and Subtenant's Early Access. Subtenant's Early Access shall be on all of the terms set forth in this Sublease, except for the obligation to pay Sublease Rent, which shall commence on the Commencement Date, subject to the other and further provisions of this Sublease. Subtenant's Early Access shall be for the sole purpose of installing Lines (in accordance with Section 8.1(r) below) and Subtenant's furniture, fixtures and equipment, and if Subtenant shall commence the regular conduct of business operations in the Sublease Premises then the Commencement Date shall be deemed to have automatically occurred notwithstanding any other provision of this Sublease. Subtenant's Early Access shall be subject to Sublandlord's access and safety controls and shall not interfere with any decommissioning activities in the Sublease Premises.

5. Rent. Provided that Subtenant timely satisfies its rental and other obligations under this Sublease within the cure periods set forth herein, Sublandlord shall be responsible for the timely payment of Base Rent and Additional Rent under the Master Lease during the Sublease Term, and Subtenant shall pay to Sublandlord the following as sublease rent hereunder ("***Sublease Rent***"):

5.1 Sublease Base Rent. Beginning on the Commencement Date, and continuing during the Sublease Term, Subtenant shall pay to Sublandlord, as sublease rent ("***Base Rent***"), in lawful money of the United States of America, without any deduction, offset, prior notice or demand (except as expressly provided to the contrary in this Sublease), in advance on the first date of each month of the Sublease Term from the Commencement Date through the expiration or earlier termination of this Sublease, the amount of $95,963.40 per month, which amount shall increase by three and one-half percent (3.5%) annually on the first day of the month in which the anniversary of the Commencement Date occurs, if this Sublease has not yet expired or terminated. Any Sublease Rent obligations for any partial month during the Sublease Term shall be prorated.

5.2 Additional Rent.

(a) Subtenant shall pay Sublandlord, within ten (10) days of receipt of written demand for same, for any Additional Rent (as defined in the Master Lease), expressly including payments of Direct Expenses and Estimated Direct Expenses, payable by Sublandlord to Master Landlord in respect of the Sublease Premises for the term of this Sublease. Subtenant shall have the same audit rights with respect to Statements, Estimates or other statements regarding Direct Expenses or Estimated Direct Expenses provided by Master Landlord to Sublandlord as Sublandlord has under Section 4.6 of the Master Lease which rights shall be exercised by Sublandlord on Subtenant's and its own behalf; and any such estimates or statements shall be binding as between Sublandlord and Subtenant to the same extent that such estimates or statements are binding as between Master Landlord and Sublandlord; provided that Subtenant shall reimburse Sublandlord for any and all costs and expenses actually incurred by Sublandlord in connection with such audit, and such costs shall be deemed Sublease Rent hereunder. The intent of the parties is that all payments of Additional Rent, including all Direct Expenses, payable under the Master Lease will be passed through to Subtenant during the Sublease Term. Notwithstanding the foregoing, any Additional Rent payable for any partial month during the Sublease Term shall be prorated on a daily basis based on the actual number of days in such month. The terms of this Section 5.2 shall survive and remain in full force and effect notwithstanding the expiration or earlier termination of the Sublease Term. Subtenant shall pay all taxes applicable to Subtenant's personal property or any other taxes that are otherwise Sublandlord's responsibility, as tenant, under the Master Lease.

(b) Sublandlord represents that the current recurring charges on account of Additional Rent are approximately as follows: (i) common area charges, which include utilities are approximately $1.39/sf per month, (ii) insurance and affiliated charges are approximately $0.16/sf per month, and (iii) real property taxes are approximately $0.48/sf per month. Additionally, janitorial services are provided separately from the property manager and are invoiced directly to Sublandlord on a monthly basis.

(c) Promptly following receipt from Master Landlord, Sublandlord shall send a copy of any bill or statement for Direct Expenses or Estimated Direct Expenses to Subtenant, along with copies of any other supporting documentation received from Master Landlord, which statement shall set forth the amount of the Direct Expenses and Estimated Direct Expenses payable by Subtenant and the manner in which it was derived. If and to the extent Sublandlord receives a refund from Master Landlord of any Direct Expenses and Estimated Direct Expenses or any other charge paid by Subtenant under this Sublease, Sublandlord shall credit such refund against the Sublease Rent. This provision shall survive the expiration or any earlier termination of this Sublease.

5.3 Services and Utilities. Subtenant shall be solely responsible, at its sole cost and expense, for payment for all services of any nature furnished with respect to the Sublease Premises in accordance with the Master Lease or this Sublease, including such services referenced in Section 6.1 of the Master Lease (and paid as Additional Rent pursuant to Section 5.2 above). Subtenant shall be responsible for and shall either reimburse Sublandlord for the cost of all utilities provided to the Sublease Premises as Additional Rent or pay the provider directly, as directed from time to time by Sublandlord. Subtenant shall make payment for such expense for utilities within ten (10) days of receipt of any and all invoices and statements received from Master Landlord or Sublandlord with respect to the same. If Subtenant desires to use heat, ventilation or air conditioning during hours other than those for which Master Landlord is obligated to supply such utilities pursuant to the Master Lease, Sublandlord shall pass on Subtenant's request to Master Landlord. Subject to Master Landlord's consent, Sublandlord hereby agrees that Subtenant may communicate directly with Master Landlord with respect to all requests for overtime services, provided a copy of all such requests shall be delivered to Sublandlord. The terms of this Section 5.3 shall survive the expiration or earlier termination of the Sublease Term.

5.4 Late Payment Charges. If any payment of Sublease Rent due from Subtenant is not received within five (5) business days of the date when due hereunder, Subtenant shall pay to Sublandlord, in addition to any late charges incurred by Sublandlord under the Master Lease, a late charge equal to five percent (5.0%) of the overdue amount. In addition, Sublease Rent not paid when due shall bear interest at the Default Rate (as defined below) from the 5th day after the date due until paid.

6. Security Deposit. Subtenant shall deliver to Sublandlord a security deposit for two (2) months' Base Rent and related Direct Expenses in the total amount of $286,413.84(the "***Security Deposit***") to secure the faithful observance and performance by Subtenant of the terms and conditions of this Sublease. If there is an Event of Default (as defined in Article 19 of the Master Lease) by Subtenant in the observance or performance of any of such terms and conditions beyond the date of any notice and cure period for such Event of Default, Sublandlord may use or apply all or any part of the Security Deposit for the payment of any Sublease Rent not paid when due or for the payment of any other amounts due Sublandlord by reason of such Event of Default, including any costs of Sublandlord's observing or performing such terms or conditions on Subtenant's behalf and any deficiencies in reletting or damages incurred by Sublandlord. If Sublandlord shall use or apply all or any part of the Security Deposit, Subtenant shall, within five (5) business days following notice from Sublandlord, deliver to Sublandlord additional funds so as to restore the Security Deposit to the to the amount before such application of funds by Sublandlord. The Security Deposit, or so much thereof as shall not have been used or applied in accordance with this Section 6, shall be returned to Subtenant no later than thirty (30) days following the later of: (i) the expiration or sooner termination of this Sublease, and (ii) the surrender of the Sublease Premises to Sublandlord vacant and in accordance with this Sublease. Subtenant hereby waives the provisions of Section 1950.7 of the California Civil Code. If Sublandlord shall transfer the Security Deposit to an assignee of Sublandlord's interest under the Master Lease, the Sublandlord making such transfer and assignment shall be deemed released from all liability to Subtenant with respect to the Security Deposit or the return thereof, and Subtenant agrees to look solely to the transferee and assignee with respect thereto. Subtenant shall not assign (other than to an assignee of this Sublease) or encumber its interest in the Security Deposit and no such assignment or encumbrance shall be valid or binding upon Sublandlord.

7. Furniture, Fixtures, and Equipment. As of the Commencement Date, Subtenant shall purchase those items of Sublandlord's furniture, fixtures, and equipment existing within the Sublease Premises as of the Commencement Date and listed on Exhibit B attached hereto, excluding the leased property (the "***Leased FF&E***") listed under the "Other Leased Furnishings & Equipment" subheader (the remainder, the "***FF&E***") for the sum of One Dollar ($1.00) pursuant to a bill of sale substantially in the form attached hereto as Exhibit C, and Subtenant shall thereafter be solely responsible for removal of the FF&E from the Sublease Premises and the Building, to the extent required by the Master Lease and Section 8.1(m) below, and for repair and/or restoration of any damage to the Building caused by or resulting from such removal. Sublandlord is the sole owner of the FF&E and the FF&E is unencumbered. Except as aforesaid, Sublandlord has not made, does not make, and will not make, any representations or warranties of any kind, express or implied, to Subtenant with respect to the FF&E including, without limitation, any representations or warranties as to the condition or functionality of the FF&E, or the suitability of the FF&E for Subtenant's purposes. Subtenant agrees to accept the FF&E for purchase in its "*as is, where is, with all faults*" condition as of the date of this Sublease, subject to reasonable wear and tear between the date of this Sublease and the Commencement Date. From and after the Commencement Date, Subtenant shall be solely responsible, at Subtenant's sole cost and expense, for maintenance, repair, operation, and replacement, from time to time, of the FF&E. If Subtenant provides written notice to Sublandlord within fourteen (14) days after the Commencement Date, such notice specifying some or all of the Leased FF&E that Subtenant rejects in connection with this Sublease, then Sublandlord shall remove such specified Leased FF&E from the Sublease Premises within a reasonable time following receipt of such notice. Subtenant shall permit Sublandlord access to perform such removal during normal business hours upon at least twenty-four (24) hours prior written notice to Subtenant. Sublandlord shall use commercially reasonable efforts to conduct such removal with minimal interference to Subtenant's business operations.

8. Master Lease.

8.1 Sublease Subordinate to Master Lease; Subtenant's Covenants. This Sublease is in all respects subject and subordinate to all of the terms, provisions, covenants, stipulations, conditions and agreements of the Master Lease. Subtenant agrees as follows (to the extent certain provisions of the Master Lease are incorporated below, all references in such incorporated provision to the term "Tenant" shall be deemed to refer to Subtenant, all references to the term "Premises" shall be deemed to refer to the Sublease Premises, all references to the term "Lease" shall be deemed to refer to this Sublease, all references to the term "Lease Term" shall be deemed to refer to the Sublease Term, all references to the term "Landlord" shall be deemed to refer to Sublandlord, and all references to the term "Landlord Parties" shall be deemed to refer to the Sublandlord Indemnified Parties (as defined below), each unless expressly stated, or the context would imply, otherwise):

(a) Summary of Basic Lease Information. Sections 2.1, 2.3, 6, 7, 9 and 11 of the Summary of Basic Lease Information in the Master Lease are incorporated herein by reference.

(b) Rent. Articles 3 and 4 of the Master Lease are incorporated herein by reference, except for Section 4.6 thereof.

(c) Permitted Use. Article 5 of the Master Lease is incorporated herein by reference, except that references to the term "Landlord" therein shall be deemed to refer to Master Landlord and Sublandlord, except where the context requires Master Landlord only. Subtenant and its officers, directors, shareholders, agents, representatives and employees shall not produce, use, store or generate any Hazardous Materials in or about the Property or Sublease Premises, except in strict accordance with Section 5.3 of the Master Lease. Subtenant shall indemnify and hold harmless Master Landlord and Sublandlord for any breach by Subtenant of Section 5.3 of the Master Lease during the Term of this Sublease. Subtenant hereby acknowledges and affirms its indemnification obligations to Master Landlord, Sublandlord and the Sublandlord Indemnified Parties (as defined below) under Section 5.3.1.4.1 of the Master Lease to the extent such obligations first arose subsequent to the Effective Date of this Sublease. Sublandlord hereby acknowledges and affirms its indemnification obligations to Master Landlord under Section 5.3.1.4.1 of the Master Lease to the extent such obligations first arose prior to the Term of this Sublease and are attributable to Sublandlord's breach of the Master Lease ("***Sublandlord's Environmental Obligations***"), and Sublandlord agrees to indemnify and hold harmless, Subtenant and the Subtenant Indemnified Parties (as defined below) for Sublandlord's Environmental Obligations to the same extent as to the Master Landlord.

(d) Services and Utilities. Sections 6.1, 6.3 and 6.4 of the Master Lease are incorporated herein by reference, except that references to "Landlord" therein shall mean the Master Landlord only (except that references to "Landlord" in Section 6.3 (except for the reference to Section 19.5 included therein) shall be deemed to refer also to Sublandlord under this Sublease). Subtenant shall be entitled to receive all of the same services, utilities and facilities as Sublandlord is entitled to receive under the Master Lease. Any overstandard use by Subtenant shall require that Subtenant shall pay all of Master Landlord's charges and fees for such overstandard request and use.

(e) Repairs and Maintenance. Sections 7.1, 7.3, and 7.4 of the Master Lease are incorporated herein by reference, except that references to "Landlord" therein shall be deemed to refer to Master Landlord only. With respect to maintenance, Subtenant shall perform all repair, maintenance and replacement obligations of Sublandlord (as described therein), as "Tenant" under the Master Lease, to the extent that such obligations relate to the Sublease Premises during the Sublease Term.

(f) Additions and Alterations. Article 8 of the Master Lease is incorporated herein by reference, except for the third and fourth grammatical sentences of Section 8.1. Subtenant shall not make any alterations, additions or improvements to the Sublease Premises without the prior written consent of (i) Master Landlord, which consent may be granted or withheld as set forth in Article 8 of the Master Lease, and (ii) Sublandlord, which consent shall not be unreasonably withheld, delayed or conditioned and which shall be granted with respect to any alterations, additions or improvements to the Sublease Premises that do not require the consent of the Master Landlord under the Master Lease.

(g) Covenant Against Liens. Article 9 of the Master Lease is incorporated herein by reference.

(h) Indemnification and Insurance. Subtenant shall obtain the insurance coverages required by Section 10.3 of the Master Lease, as incorporated herein by reference. Each policy of insurance shall name Sublandlord as an additional insured. Sections 10.1, 10.4, 10.5 and 10.6 of the Master Lease are incorporated herein by reference, and the indemnification and exculpation in Section 10.1 shall run in favor of both Master Landlord and Sublandlord. The waiver of subrogation requirements in Section 10.5 of the Master Lease shall operate between Sublandlord and Subtenant, in the same manner as between Master Landlord and Sublandlord. Subtenant shall be entitled to a waiver of subrogation on the same terms as are applicable to Sublandlord under the Master Lease in the same manner as between Master Landlord and Sublandlord. Subtenant and Sublandlord each hereby waives any claims for consequential, special, or punitive damages against the other arising out of this Sublease or Subtenant's use of the Sublease Premises (except that this sentence shall not be construed to limit consequential damages recoverable from Subtenant in the event of (1) a holdover by Subtenant, or (2) a release of Hazardous Materials by Subtenant or its officers, directors, shareholders, agents, representatives or employees, or any other party acting by or through Subtenant.

(i) Casualty Damage. In the event of a casualty as described in Article 11 of the Master Lease, Subtenant shall only be entitled to an abatement of Sublease Rent to the same extent that Sublandlord is entitled to rental abatement under the Master Lease with respect to the Sublease Premises. Subtenant shall have the right to terminate this Sublease under the same circumstances that "Tenant" is entitled to terminate under Article 11 of the Master Lease, and may exercise such right at the same times and in the same manner as "Tenant" may do so under such paragraph, but only in the event that the damage or casualty occurs in the Sublease Premises.

(j) Nonwaiver. Article 12 of the Master Lease is incorporated herein by reference.

(k) Condemnation. Article 13 of the Master Lease is incorporated herein by reference but shall only apply to a condemnation of the Sublease Premises, and Subtenant shall have no rights with respect to any other premises or portion of the Property and references to "Landlord" therein shall mean Master Landlord.

(l) Assignment and Subletting. Article 14 of the Master Lease is incorporated herein by reference, provided that, Subtenant shall not assign or sublet the Sublease Premises without the prior written consent of (i) Master Landlord, which may be granted or withheld as set forth in Article 14 of the Master Lease, and (ii) Sublandlord, which consent shall not be unreasonably withheld, conditioned or delayed, provided that Master Landlord has consented to such Transfer. Notwithstanding the foregoing, Sublandlord's consent shall not be required for any Permitted Transfer, provided that Subtenant complies with all conditions and obligations under Section 14.8 of the Master Lease.

(m) Surrender. Article 15 of the Master Lease is incorporated herein by reference, and Subtenant shall be solely obligated to remove or restore the Sublease Premises as required by the Master Lease, as incorporated herein, and this Sublease. Subtenant shall have no obligation to remove any alterations or improvements made by or for Sublandlord, nor shall Subtenant be required to restore any alterations, additions or improvements to the Sublease Premises which are in existence as of the Commencement Date or which are not required to be restored under the terms of the Master Lease.

(n) Holding Over. Article 16 of the Master Lease is incorporated herein by reference.

(o) Subordination; Estoppel Certificate. Articles 17 and 18 of the Master Lease are incorporated herein by reference, and Sublandlord or Subtenant may request an estoppel certificate or other documents from the other pursuant to the requirements therein.

(p) Events of Default; Remedies. Article 19 of the Master Lease is incorporated herein by reference (except for Section 19.5 of the Master Lease, which is not incorporated herein).

(q) Covenant of Quiet Enjoyment. Article 20 of the Master Lease is incorporated herein by reference.

(r) Lines. Article 22 of the Master Lease is incorporated herein by reference.

(s) Signs. Subject to Master Landlord's approval in the Consent, Article 23 of the Master Lease is incorporated herein by reference, except that all signage shall be installed at Subtenant's sole cost, and Subtenant shall be responsible to remove all signage at Subtenant's sole cost at the expiration or earlier termination of the Sublease Term.

(t) Compliance with Laws. Article 24 of the Master Lease is incorporated herein by reference, except that references to "Landlord" therein shall mean the "Master Landlord" only. To Sublandlord's knowledge as of the date hereof, the Sublease Premises are in compliance with all applicable laws and regulations.

(u) Late Charges. Article 25 of the Master Lease is incorporated herein by reference and shall apply to the Sublease Rent obligations hereunder. The rate calculated pursuant to the third (3rd) sentence of Article 25 shall be referred to herein as the "***Default Rate***."

(v) Right to Cure Default; Payments by Subtenant. Article 26 of the Master Lease is incorporated herein by reference, and references to "Landlord" therein shall mean both Master Landlord and Sublandlord.

(w) Entry by Landlord. Article 27 of the Master Lease is incorporated herein by reference, and references to "Landlord" therein shall mean both Master Landlord and Sublandlord.

(x) Parking. Article 28 of the Master Lease is incorporated herein by reference, and Subtenant shall be entitled to the parking spaces provided thereunder on the same terms and conditions as Sublandlord, provided that Subtenant shall comply with Sublandlord's reasonable rules and regulations regarding use of parking.

(y) Miscellaneous. Except for Sections 29.18, 29.24, 29.26, 29.29 and 29.31, the entirety of Article 29 of the Master Lease is incorporated herein by reference.

(z) Consents. If any consent is required of Master Landlord for any action of "Tenant" under the Master Lease, then such consent shall be required from both Master Landlord and Sublandlord under this Sublease, except as in this Sublease expressly provided to the contrary. Any consent or approval requested from Sublandlord in accordance with this Sublease shall be deemed reasonably withheld if Master Landlord withholds its consent or approval in accordance with the Master Lease.

Except as set forth above, the provisions of the Master Lease are not incorporated into this Sublease except as necessary to effectuate the terms and conditions of this Sublease. Neither party shall take any action or do or permit to be done anything which: (i) is or may be prohibited under the Master Lease; (ii) might result in a violation of or default under any of the terms, covenants, conditions or provisions of the Master Lease or any other instrument to which this Sublease is subordinate; or (iii) would result in any additional cost or other liability to Sublandlord or Subtenant respectively.

8.2 Sublandlord Not Responsible for Representations and Covenants of Master Landlord under Master Lease. Sublandlord shall not be deemed to have made any representation made by Master Landlord in any of the provisions of the Master Lease. Moreover, during the Sublease Term, Subtenant acknowledges and agrees that Sublandlord shall not be responsible for Master Landlord's covenants and obligations under the Master Lease, although Subtenant shall be entitled to receive, subject to the terms and conditions of the Master Lease and this Sublease, all services and facilities to which Sublandlord shall be entitled under the Master Lease. Without limiting the generality of the foregoing, Sublandlord shall not be obligated (i) to provide any of the services or utilities that Master Landlord has agreed in the Master Lease to provide, (ii) to make any of the repairs or restorations that Master Landlord has agreed in the Master Lease to make, (iii) to complete any work or maintenance in the Sublease Premises, the Building or the Property required to be completed by Master Landlord under the Master Lease (and no such failure will in any way excuse Subtenant's performance under this Sublease or entitle Subtenant to any abatement of Sublease Rent), (iv) to comply with any laws or requirements of public authorities with which Master Landlord has agreed in the Master Lease to comply, or (v) to take any action with respect to the operation, administration or control of the Property or any of the Common Areas that the Master Landlord has agreed in the Master Lease to take, and Sublandlord shall have no liability to Subtenant on account of any failure of Master Landlord to do so, or on account of any failure by Master Landlord to observe or perform any of the terms, covenants or conditions of the Master Lease required to be observed or performed by Master Landlord, provided that Sublandlord shall use reasonable efforts to enforce its rights against Master Landlord under the Master Lease for the benefit of Subtenant following Subtenant's written request therefor (and to forward to Landlord any notices or requests for consent as Subtenant may reasonably request). In the event that Subtenant determines in good faith that Master Landlord has not performed its obligations under the Master Lease, then upon receipt of written notice from Subtenant, Sublandlord shall use commercially reasonable efforts to cause such breaches, defaults or failures of Master Landlord under the Master Lease to be resolved or otherwise settled; provided, further however: (A) Sublandlord shall not have any obligation to incur out-of-pocket expenses in connection with its covenants under this Section 8.2 and (B) Sublandlord shall not have any obligation to commence litigation or other dispute resolution proceedings to cause Master Landlord to comply with the Master Lease; provided, however, such clause (B) is subject to the next following provisions. If Sublandlord shall elect not to institute litigation or other dispute resolution to enforce Subtenant's rights for any material default by Master Landlord under the Master Lease beyond all applicable notice and cure periods, then, at the written request of Subtenant, Sublandlord shall permit Subtenant to institute an action or proceeding against Master Landlord in the name of Sublandlord to enforce Sublandlord's rights under the Master Lease which are applicable to Subtenant (and shall reasonably cooperate with such reasonable requests of Subtenant as are necessary to enable Subtenant to proceed in Sublandlord's name at no cost to Sublandlord), provided that: (i) Subtenant shall not then be in default under any of the terms, covenants or conditions of this Sublease beyond any applicable notice and cure periods; (ii) Subtenant shall pay all costs and expenses arising out of such action, and Subtenant shall agree to indemnify and hold Sublandlord harmless from and against any loss, claims, liabilities, damages, costs and expenses (including without limitation, reasonable attorneys, fees and disbursements) incurred or suffered by Sublandlord in connection with such action or proceeding; (iii) such suit or action is not arbitrary or capricious or primarily of nuisance value, as determined by Sublandlord in its sole and reasonable discretion; (iv) Sublandlord and the Sublandlord Indemnified Parties (as defined below) shall not appear in any pre-trial (including any depositions or other events related to discovery), trial or other in-person (whether physically, telephonically or virtually) proceeding; and (v) Sublandlord shall have first given Master Landlord a demand and notice of default (it being agreed that Sublandlord shall give Master Landlord such demand and notice of default within a reasonable time after Subtenant shall request that such notice be given) and Master Landlord shall have failed to cure such default within the period, if any, set forth in the Master Lease for the curing of such default, or if no such period is provided for, within a reasonable period thereafter (giving due consideration to the nature of the default).

9. Indemnity by Subtenant and Sublandlord. Subtenant shall indemnify Sublandlord, its officers, directors, shareholders, agents, representatives and employees (collectively "***Sublandlord Indemnified Parties***") against, and hold Sublandlord, and the Sublandlord Indemnified Parties harmless from, any and all demands, claims, causes of action, fines, penalties, damages, losses, liabilities, judgments, and expenses (including, without limitation, reasonable attorneys' fees and court costs) incurred in connection with, or arising from: (a) the use or occupancy of the Sublease Premises or the Property by Subtenant or any persons claiming under Subtenant; (b) any activity, work, or thing done, permitted or suffered by Subtenant in or about the Sublease Premises; (c) any acts, omissions, or negligence of Subtenant or any person claiming under Subtenant, or the contractors, agents, employees, invitees, or visitors of Subtenant or any such person; (d) any breach, violation, or nonperformance by Subtenant or any person claiming under Subtenant or the employees, agents, contractors, invitees, or visitors of Subtenant or any such person of any term, covenant, or provision of this Sublease or any law, ordinance, or governmental requirement of any kind; (e) any injury or damage to the person, or property of Sublandlord, or any Sublandlord Indemnified Parties, or any other person entering upon the Sublease Premises to the extent caused by Subtenant; and (f) Subtenant's failure to comply with the surrender provisions of this Sublease at the expiration or earlier termination of the Sublease Term, except to the extent any of the foregoing results from the gross negligence or willful misconduct of Sublandlord or its officers, directors, shareholders, agents, contractors, employees, invitees or visitors. If any action or proceeding is brought against Sublandlord, or any Sublandlord Indemnified Parties by reason of any such claim, Subtenant, upon notice from Sublandlord, shall defend the claim at Subtenant's expense with counsel reasonably satisfactory to Sublandlord. Sublandlord shall indemnify Subtenant, its officers, directors, shareholders, agents, representatives and employees (collectively "***Subtenant Indemnified Parties***") against, and hold Subtenant, and the Subtenant Indemnified Parties harmless from, any and all demands, claims, causes of action, fines, penalties, damages, losses, liabilities, judgments, and expenses (including, without limitation, reasonable attorneys' fees and court costs) incurred in connection with, or arising from: (a) any acts, omissions, or negligence of Sublandlord or any person claiming under Sublandlord, or the contractors, agents, employees, invitees, or visitors of Sublandlord or any such person; (b) any breach, violation, or nonperformance by Sublandlord or any person claiming under Sublandlord or the employees, agents, contractors, invitees, or visitors of Sublandlord or any such person of any term, covenant, or provision of this Sublease or any law, ordinance, or governmental requirement of any kind; or (c) any injury or damage to the person, or property of Subtenant, or any Subtenant Indemnified Parties, or any other person entering upon the Sublease Premises to the extent caused by Sublandlord, except to the extent any of the foregoing results from the gross negligence or willful misconduct of Subtenant or its officers, directors, shareholders, agents, contractors, employees, invitees or visitors. If any action or proceeding is brought against Subtenant, or any Subtenant Indemnified Parties by reason of any such claim, Sublandlord, upon notice from Subtenant, shall defend the claim at Sublandlord's expense with counsel reasonably satisfactory to Subtenant.

10. RESERVED.

11. Master Landlord Notices. Sublandlord and Subtenant shall, promptly following receipt thereof, deliver to the other party a copy of any and all notices received from Master Landlord which would have any material effect upon the Sublease Premises or this Sublease.

12. Reciprocal Right to Cure Defaults. Upon an Event of Default (as defined in Article 19 of the Master Lease) by Subtenant under this Sublease (after lapse of any applicable notice and cure periods), Sublandlord may, without waiving or releasing any obligation of Subtenant hereunder and without waiving any rights or remedies at law or otherwise, make such payment or perform such act. All sums so paid or incurred by Sublandlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to 10% per annum or the highest rate permitted by law, whichever is less, shall be payable to Sublandlord on demand as additional Sublease Rent. Upon an Event of Default by Sublandlord under this Sublease (after lapse of all applicable notice and cure periods), Subtenant may, without waiving or releasing any obligation of Sublandlord hereunder and without waiving any rights or remedies at law or otherwise, make such payment or perform such act; provided that Subtenant shall have first given Sublandlord a written demand and notice of default and Sublandlord shall have failed to cure such default within the period, if any, set forth in this Sublease for the curing of such default, or if no such period is provided for, within a reasonable period thereafter (giving due consideration to the nature of the default). All out-of-pocket costs so paid or incurred by Subtenant, together with interest thereon, from the date such sums were paid, at the annual rate equal to 5% per annum or the highest rate permitted by law, whichever is less, shall be payable by Sublandlord and credited against Sublease Rent hereunder. Without limiting the foregoing, in the event that Subtenant receives written notice from the Master Landlord that Sublandlord is in default beyond all applicable notice and cure periods with respect to any monetary obligation of Sublandlord under the Master Lease, Sublandlord hereby agrees that, should the Master Landlord agree to accept Base Rent and Additional Rent (as each such term is defined in the Master Lease) from Subtenant in satisfaction of such Sublandlord default then, upon written notice to Sublandlord, Subtenant may pay such Base Rent and/or Additional Rent directly to Master Landlord in satisfaction of Sublandlord's obligations under the Master Lease; and, if Master Landlord shall accept such cure by Subtenant, Subtenant may thereupon offset such amounts so paid by Subtenant to the Master Landlord on Sublandlord's behalf against the Sublease Rent payable under this Sublease.

13. Notices. Any notice, request, demand, consent, approval, or other communication required or permitted under this Sublease shall be in writing. All notices shall be addressed to the addresses set forth in the introductory paragraph, or such other address as the parties may notify each other from time to time, and shall be: (a) personally delivered; (b) sent by certified or registered mail, postage prepaid, return receipt requested; or (c) sent by a nationally recognized overnight courier service, with charges prepaid and a receipt provided therefor. All notices shall be deemed to have been given on the earlier of: (i) the date of actual receipt; or (ii) one (1) business day after being properly deposited with a nationally recognized overnight courier service.

14. Time Is of the Essence. Time is of the essence with respect to the performance of every provision of this Sublease in which time of performance is a factor.

15. Attorneys' Fees. If any action or proceeding is instituted by Sublandlord or Subtenant to construe, interpret or enforce the provisions of this Sublease, the prevailing party shall be entitled to the reimbursement of its reasonable attorneys' fees and costs incurred in connection with such proceeding by the non-prevailing party, through all appeals.

16. Brokers. Each party represents and warrants that it has not been represented by any real estate broker or agent in connection this Sublease, except for Kidder Mathews (the "***Broker***"), and each party hereby indemnifies, protects, defends (with legal counsel acceptable to the other party) and holds the other party free and harmless from and against any and all costs and liabilities, including, without limitation, reasonable attorneys' fees, for causes of action or proceedings that may be instituted by any broker, agent or finder, licensed or otherwise, other than the Broker, claiming through, under or by reason of the conduct of such party in connection with this Sublease. Any commission, fee or other charge payable to the Broker shall be paid by Sublandlord pursuant to a separate agreement.

17. Counterparts. This Sublease may be executed in duplicate counterparts, each of which shall be deemed an original hereof. Electronically transmitted signatures shall be deemed originals.

18. Entire Agreement/Modification. This Sublease, including the Exhibits, contains all of the agreements of the parties hereto with respect to any matter covered or mentioned in this Sublease, and no prior agreements or understanding or letter or proposal pertaining to any such matters shall be effective for any purpose. This Sublease may only be modified by a writing signed by Sublandlord and Subtenant. No provisions of this Sublease may be amended or added to, whether by conduct, oral or written communication, or otherwise, except by an agreement in writing signed by the parties hereto or their respective successors-in-interest.

19. Interpretation. The title and paragraph headings are not a part of this Sublease and shall have no effect upon the construction or interpretation of any part of this Sublease. Unless stated otherwise, references to paragraphs and subparagraphs are to those in this Sublease. This Sublease shall be strictly construed neither against Sublandlord nor Subtenant.

20. Authority. Subtenant hereby represents and warrants that Subtenant is a duly formed and existing entity qualified to do business in the State of California and that Subtenant has full right and authority to execute and deliver this Sublease and that each person executing this Sublease on behalf of Subtenant is authorized to do so. Sublandlord hereby represents and warrants that Sublandlord has full right and authority to execute and deliver this Sublease and that each person executing this Sublease on behalf of Sublandlord is authorized to do so.

21. OFAC Compliance. Subtenant and all beneficial owners of Subtenant are currently (a) in compliance with and shall at all times during the Sublease Term remain in compliance with the regulations of the Office of Foreign Assets Control ("***OFAC***") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "***OFAC Rules***"), (b) not listed on, and shall not during the Sublease Term be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

22. Sublandlord covenants not to (a) voluntarily surrender or terminate the Master Lease prior to the expiration of the Sublease Term, or (b) enter into, without the consent of Subtenant, any amendment to the Master Lease which would adversely affect Subtenant's rights or increase Subtenant's monetary obligations under this Sublease. Sublandlord will pay all Base Rent and Additional Rent due under the Master Lease to Master Landlord pursuant to the terms of the Master Lease, provided Subtenant pays the Sublease Rent hereunder, and Sublandlord will comply with all other terms and conditions of the "Tenant" under the Master Lease where the Sublandlord's obligations does not relate to possession of the Sublease Premises and which are not otherwise performed by Subtenant hereunder. Notwithstanding anything contained in this Sublease to the contrary, Subtenant shall not be responsible for (i) any default of Sublandlord, its agents, employees or contractors under the Master Lease unless attributable to a default under this Sublease or the Master Lease by Subtenant, its agents, employees, contractors, invitees or anyone claiming by, through or under Subtenant, (ii) conditions at the Sublease Premises, for which the obligation to maintain and repair resides with Master Landlord under the Master Lease and/or which existed as of the Commencement Date, (iii) any violations of law resulting from such conditions described by (ii) above, and (iv) making payment of any sums either to Master Landlord or Sublandlord in satisfaction of any charges accruing under the Master Lease (whether denominated as rent, rental, additional rent or otherwise) for any period prior or subsequent to the Term of this Sublease.

23. Sublandlord hereby represents and warrants to Subtenant (which shall be true as of the date hereof and as of the Commencement Date) that:

23.1 The Master Lease is in full force and effect and has not been terminated;

23.2 The Expiration Date of the Master Lease is September 30, 2025;

23.3 The copy of the Master Lease annexed hereto and made a part hereof is a true and complete copy of the Master Lease, as amended to date, except as to certain intentionally redacted provisions, which provisions are expressly made inapplicable to Subtenant and the Sublease Premises, and none of which provisions limit the use and occupancy of the Sublease Premises;

23.4 The Master Lease has not been amended or modified, except as otherwise stated in this Sublease;

23.5 Sublandlord is the holder of the entire tenant's interest in the Master Lease free and clear of any liens, claims, mortgages, charges or encumbrances, subleases and occupancies (other than this Sublease);

23.6 Sublandlord has not assigned its interest in the Master Lease, and as of the date hereof, the Sublease Premises or any portion thereof are not subject to any subletting other than pursuant to this Sublease;

23.7 Sublandlord presently is, and on the Commencement Date will be, the owner of all the FF&E free and clear of any liens, claims, encumbrances and security interests;

23.8 Sublandlord is not currently in default under the Master Lease, nor has any act or event occurred which with the delivery of a notice or passage of time or both would constitute a default under the Master Lease (but no such notice has been received or time passed), nor does Sublandlord have any knowledge of any default by Landlord under the Master Lease;

23.9 To the best of Sublandlord's knowledge, Master Landlord has complied with all of its obligations under the Master Lease; and

23.10 Sublandlord has not received any written notice of violations of law against the Sublease Premises nor has Sublandlord made or received within the prior six (6) months any written material complaints regarding the building systems in and/or serving the Sublease Premises, including the HVAC, electrical and plumbing systems.

[signature page follows]

IN WITNESS WHEREOF, Sublandlord and Subtenant have executed this Sublease as of the date first above written.

SUBLANDLORD:

VERA THERAPEUTICS, INC.

By: /s/ Marshall Fordyce
Name: Marshall Fordyce
Title: CEO

SUBTENANT:

VAXART, INC.

By: /s/ Andrei Floroiu
Name: Andrei Floroiu
Title: CEO and President

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 consent to the incorporation by reference in the registration statements on Form S-3 (No. 333-239751, 333-228910) and Form S-8 (No. 333-239727, 333-231013, 333-225475, 333-215141, 333-143238) of Vaxart, Inc. of our reports dated February 25, 2021 relating to the consolidated financial statements and the effectiveness of Vaxart, Inc.'s internal control over financial reporting, which reports appear in this Annual Report on Form 10-K.

/s/ OUM & Co. LLP

San Francisco, California
February 25, 2021

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Vaxart, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-239751, 333-228910) on Form S-3 and (No. 333-239727, 333-231013, 333-225475, 333-215141, 333-143238) on Form S-8 of Vaxart, Inc. of our report dated February 6, 2019, with respect to the consolidated balance sheet of Vaxart, Inc. as of December 31, 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year ended December 31, 2018, and the related notes (collectively, the consolidated financial statements), which report appears in the December 31, 2020 annual report on Form 10-K of Vaxart, Inc.

Our report dated February 6, 2019 contains an explanatory paragraph that states that the Company has experienced losses and negative cash flows from operations since its inception, has an accumulated deficit, and has debt obligations, which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

San Francisco, California
February 25, 2021

Exhibit 31.1

CERTIFICATION

I, Andrei Floroiu, 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: February 25, 2021

By: /s/ ANDREI FLOROIU

Andrei Floroiu
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial 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), Andrei Floroiu, President and Chief Executive Officer of Vaxart, Inc. (the "Company"), hereby certifies that, to his knowledge:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2020, 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: February 25, 2021

By: /s/ ANDREI FLOROIU
Andrei Floroiu
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial 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.