

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: 001-32587



**ALTIMMUNE, INC.**  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
910 Clopper Road, Suite 201S, Gaithersburg, MD  
(Address of principal executive offices)

20-2726770  
(I.R.S. Employer  
Identification No.)

20878  
(Zip Code)

Registrant's telephone number, including area code

(240) 654-1450

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

<i>Title of each class</i>	<i>Trading Symbol(s)</i>	<i>Name of each exchange on which registered</i>
Common stock, par value \$0.0001 per share	ALT	The NASDAQ Global 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 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, 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  Accelerated filer   
Non-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. Yes  No

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

The aggregate market value of voting and non-voting common equity held by non-affiliates, based upon the closing price of the registrant's common stock on the NASDAQ Global Market on June 30, 2020, was approximately \$280.6 million.

As of February 23, 2021, there were 37,150,376 shares of the registrant's common stock, \$0.0001 par value per share, outstanding.

ALTIMMUNE, INC.  
ANNUAL REPORT ON FORM 10-K  
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## Forward-looking statements

This Annual Report on Form 10-K for the year ended December 31, 2020 (this “Annual Report”) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Private Securities Litigation Reform Act of 1995. Written or oral statements that constitute forward-looking statements may be made by us or on our behalf. Words such as “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate,” “may,” “will,” “should,” “could,” “target,” “strategy,” “intend,” “project,” “guidance,” “likely,” “usually,” “potential,” or the negative of these words or variations of such words, similar expressions, or comparable terminology are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about the industry and markets in which we operate, and management’s beliefs and assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties, and assumptions that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with the following:

- our ability to develop and commercialize our current and future product candidates;
- our ability to expand our pipeline of product candidates and the success of future product candidate advancements, including the success of future preclinical and clinical trials, and our ability to commercialize our products;
- the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of our product candidates;
- funding delays, reductions in or elimination of U.S. government funding and/or non-renewal of expiring funding under our agreement with the Biomedical Advanced Research and Development Authority (“BARDA”);
- our ability to satisfy certain technical milestones under our contracts with BARDA that would entitle us to receive additional funding over the period of the agreement;
- delays caused by third parties challenging government contracts awarded to us;
- the receipt of future potential payments under government contracts or grants;
- our ability to identify potential future government contracts or grant awards;
- our ability to obtain potential regulatory approvals on the timelines anticipated, or at all;
- our ability to obtain additional patents or extend existing patents on the timelines anticipated, or at all;
- our ability to identify and consummate potential future strategic partnerships or business combinations;
- our anticipated financial or operational results;
- our ability to obtain additional capital resources;
- breaches of data privacy, or disruptions in our information technology systems;
- our ability to continue to satisfy the listing requirements of the NASDAQ Global Market; and
- risks detailed under the caption “Risk Factors” in this Annual Report and in our other reports filed with the U.S. Securities and Exchange Commission (“SEC”), from time to time hereafter.

We have based the forward-looking statements included in this Annual Report on information available to us on the date of this annual report. Except as required by law we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised to consult any additional disclosures that we may make in reports that we, in the future, may file with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K.

All forward-looking statements included herein are expressly qualified in their entirety by the foregoing cautionary statements. Unless otherwise indicated, the information in this Annual Report is as of December 31, 2020.

**Note regarding trademarks**

“Altimune,” our logo and other trademarks, trade names or service marks of the Company appearing in this Annual Report, including, AdCOVID, NasoShield, NasoVAX, T-COVID, HepTcell, Densigen, and RespirVec., are the property of the Company. The other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies’ trademarks, trade names or service marks to imply an endorsement or sponsorship of us by such companies, or any relationship with such companies. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the ® or TM symbol.

## Summary of Risk Factors

*The risk factors detailed in Item 1A entitled "Risk Factors" in this Annual Report on Form 10-K are the risks that we believe are material to our investors and a reader should carefully consider them. Those risks are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. The following is a summary of the risk factors detailed in Item 1A:*

### Risks Related to Our Business, Financing Requirements, Product Development and Clinical Trials

- our ability to raise capital
- our history of operating losses since our founding and the anticipation that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability
- our ability to develop and commercialize our current and future product candidates
- our ability to predict the time and cost of product development for our product candidates
- our reliance on third parties to conduct preclinical studies and clinical trials for our product candidates
- delays in our clinical trials or the failure of our trials to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities
- our ability to enroll patients in our clinical trials

### Risks Related to the Development of Our COVID-19 Vaccine and Therapeutic

- our ability to receive emergency use authorization or approval for any of our COVID-19 product candidates a timely manner, if at all, and the potential that our COVID-19 product candidates may never be authorized for emergency use or approved
- unforeseen or unexpected challenges in the regulatory pathway for T-COVID and AdCOVID

### Risks Related to the Regulatory Approval Process

- our ability to obtain required regulatory approvals, including in non-U.S. jurisdictions
- the potential that our product candidates have undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential
- the expense and restrictions of the marketing approval process and ongoing regulatory review if our product candidates ever received regulatory approval

### Risks Related to Our Intellectual Property

- the cost and difficulty of protecting our proprietary rights and the potential that our intellectual property rights do not adequately protect our product candidates
- our ability to protect our intellectual property rights throughout the world
- the adequacy of our patent terms to protect our competitive position on our products for an adequate amount of time
- third-party claims of intellectual property infringement or misappropriation, including circumstances involving our employees, independent contractors or consultants

### Risks Related to Commercialization of the Company's Product Candidates

- our ability to attain significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payers and others in the medical community
- our reliance on third parties to manufacture our product candidates and related materials for our clinical trials and preclinical studies
- our ability to manufacture our products in sufficient quantities, or at sufficient yields, or obtain regulatory approvals for a manufacturing facility for our products

**Risks Related to our BARDA Contract and Other Government Programs**

- our ability to move forward with the NasoShield program without the BARDA anthrax contract award
- the activities for which we received reimbursement under our BARDA contracts, which are cost-plus-fixed-fee contracts
- our reliance for further revenues from grants, contracts and loans from the U.S. and other governments, non-profit entities and academic institutions

**Risks Related to Reimbursement and Government Regulation**

- our ability to obtain coverage and reimbursement in certain market segments for our product candidates, if they are approved
- the imposition of price controls
- our ability to comply with multiple substantial federal and state health care and other laws, and the complexity of our regulatory compliance obligations
- the unknown impact of recent health care reform legislation and other changes in the health care industry and in health care spending

**Risks Related to our Securities**

- the volatility of the trading price of our common stock and substantial price fluctuations on heavy volume

**Item 1. Business****Overview**

Altimmune, Inc. is a clinical stage biopharmaceutical company focused on developing intranasal vaccines, immune modulating therapies and treatments for liver disease. Our diverse pipeline includes proprietary intranasal vaccines for COVID-19 (AdCOVID), anthrax (NasoShield) and influenza (NasoVAX); an intranasal immune modulating therapeutic for COVID-19 (T-COVID); and next generation peptide therapeutics for non-alcoholic steatohepatitis (“NASH”) (ALT-801) and chronic hepatitis B (HepTcell).

Our business is the result of a merger between PharmAthene, Inc. (“PharmAthene”) and the business previously known as Altimmune, Inc. (“Private Altimmune”). On May 4, 2017, Private Altimmune merged with PharmAthene in a series of mergers and reorganizations (collectively, the “Mergers”) pursuant to an Agreement and Plan of Merger and Reorganization (the “PharmAthene Merger Agreement”) dated January 18, 2017, among Private Altimmune, PharmAthene, its wholly owned acquisition subsidiaries Mustang Merger Sub Corp I Inc. and Mustang Merger Sub II LLC. Upon closing of the Mergers, all equity instruments of Private Altimmune were exchanged for corresponding equity instruments of PharmAthene. Prior to the Mergers, PharmAthene was a publicly traded biodefense company engaged in Phase 2 clinical trials. Except where the context indicates otherwise, references to “we,” “us,” “our,” “Altimmune” or the “Company” refer, for periods prior to the completion of the Mergers, to Private Altimmune and its subsidiaries, and for periods following the completion of the Mergers to the combined company and its subsidiaries.

**AdCOVID**

AdCOVID is an intranasal COVID-19 vaccine candidate designed to guard the respiratory tract from viral invasion and to provide downstream protection against viral spread through stimulation of both mucosal and systemic antibodies (IgA and IgG) as well as cell-mediated immunity. By stimulating mucosal immunity in the nasal cavity, a key point of entry and replication for the SARS-CoV-2 virus, AdCOVID has the potential to defend against both the infection and spread of the virus to others. AdCOVID’s intranasal delivery method provides an easier route of administration than an injection and may eliminate the need for administration by trained medical personnel. We believe nasal mucosal immunity has the potential to provide an effective protection at the site of viral entry and early replication, and may block transmission by shed virus. We believe AdCOVID has the potential to meet most of the World Health Organization’s published preferred attributes for a COVID-19 vaccine, including single dose, rapid onset of protection, immunity lasting one year, non-injected and temperature stability. In particular, data from our NasoVAX clinical trials demonstrated a strong serological response at two weeks that remained unchanged at 400 days, after a single dose. In addition, since it is expected to have extended stability at room temperature, AdCOVID may avoid the need for costly cold chain logistics. During 2020, we completed initial preclinical mouse studies in collaboration with the University of Alabama at Birmingham (“UAB”), and began manufacturing AdCOVID during the third quarter of 2020. We submitted an Investigation New Drug application (“IND”) with the U.S. Food and Drug Administration (“FDA”) in the fourth quarter of 2020 and received clearance from the FDA in February 2021 to initiate a Phase 1 clinical trial of AdCOVID. The Phase 1 clinical trial is currently enrolling and will evaluate the safety and immunogenicity of AdCOVID in up to 180 healthy adult volunteers between the ages of 18 and 55, with data expected in the second quarter of 2021.

**T-COVID**

T-COVID is an intranasal immune modulating therapeutic candidate based on the same replication-deficient adenovirus 5 (“RD-Ad5”) vector technology behind our other intranasal vaccine candidates, but it acts through a different mechanism. In preclinical studies sponsored by the National Institute of Allergy and Infectious Diseases, intranasal administration of RD-Ad5 vectors modulated the innate immune response to lethal challenge with a respiratory virus in mice and protected them from death. The immunomodulatory effects resulted in significantly decreased cellular inflammation and lower concentrations of IL-6 and other inflammatory cytokines in the lungs of treated animals compared to controls. Excessive production of inflammatory cytokines like IL-6 has been associated with the lung pathology and death in COVID-19. The protective effects were independent of any specific immunity or vaccine effects against the challenge virus. These protective effects were only observed with intranasal administration of RD-Ad5, and intramuscular administration provided no survival benefit.

With the support of the U.S. Army Medical Research & Development Command in collaboration with the Medical Technology Enterprise Consortium, we initiated a placebo-controlled Phase 1/2 double-blind clinical trial to evaluate the potential of T-COVID to prevent clinical worsening in patients with early COVID-19 during 2020. The trial is expected to enroll 96 community-based patients who are 18 years and older that present with fever, cough, or shortness of breath, with onset of symptoms within 48 hours, and a diagnosis of COVID-19 within 24 hours. The trial consists of three cohorts of increasing age and risk for complications of COVID-19, and patients are randomized 1:1 to NasoVAX or placebo administered as a single 0.5ml nasal spray within 24 hours of diagnosis. The primary endpoint of the trial is the proportion of patients with clinical worsening, defined as a 4% decrease in pulse oxygen saturation, or the need for hospitalization. Secondary endpoints will measure the average decrease in resting pulse oxygen saturation, average

increase in resting pulse rate and proportion of patients requiring oxygen supplementation and mechanical ventilation. In order to expedite the study, we have been permitted by the FDA to use existing lots of NasoVAX, which is an identical vector to T-COVID, in lieu of newly manufactured T-COVID. The protocol was recently amended such that 40% of patients in the final cohort, in which efficacy will primarily be assessed, to be either 65 years and older or have risk for complications of COVID-19. Based on these protocol changes, we expect to receive results from the Phase 1/2 trial in the second quarter of 2021.

#### *NasoShield*

NasoShield is an anthrax vaccine product candidate designed to provide rapid and stable protection after a single intranasal administration. It is being developed with the support of the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) for post-exposure prophylaxis against anthrax following exposure to aerosolized *B. anthracis* spores. After an individual has been exposed to the spores that cause anthrax, *B. anthracis* bacteria multiply and release toxins within the host. Although antibiotic therapy is effective at eliminating the actively growing bacteria, vaccination is necessary to protect against the germination of dormant spores after the cessation of antibiotic therapy. Because NasoShield is intended to protect against anthrax after a single intranasal dose, we believe it may be a convenient and simple alternative to the only approved vaccine, which must be given as a series of three injections over 1 month. We believe the simplified immunization route and schedule, together with the reliable stability at ambient temperature may allow NasoShield to be deployed in an anthrax event more easily and faster than the currently approved vaccine. We commenced a Phase 1b trial of NasoShield in adults in 2020 which builds on the Phase 1a trial completed in 2018 and evaluates the effect of modified methods of intranasal dosing on NasoShield safety and immunogenicity. Results are expected in the first quarter of 2021.

#### *NasoVAX*

NasoVAX is a recombinant intranasal vaccine product candidate that is being developed for both seasonal and pandemic use. NasoVAX is believed to simultaneously activate the humoral, mucosal and cellular immune arms which may enable a more comprehensive immune response. The data from our Phase 2a trial with a monovalent NasoVAX vaccine indicated that NasoVAX was generally well-tolerated and achieved 100% seroprotection with serum antibody responses, which was comparable to published results of a licensed injected influenza vaccine. Statistically significant increases in mucosal antibody were noted as well as a robust T cell response directed against influenza. Approximately half of the subjects from the highest dose were evaluated between 12 and 14 months after initial dosing for additional immunogenicity assessment. The durability data show that the immune response elicited by NasoVAX was stable with no overall change in the antibody titer or level of seroprotection over an average of 13 months. The combination of serum antibody, mucosal antibody and T-cell response in combination with the durability data provides the potential for improved protection against influenza and suggests that NasoVAX could have a great impact on flu symptoms and shedding of the influenza virus. We are currently evaluating the development path of NasoVAX.

#### *ALT-801*

We completed an acquisition in July 2019 of all of the equity interests of Spitfire Pharma, Inc. (“Spitfire”). Spitfire was a privately held, preclinical pharmaceutical company with the primary asset being a novel peptide-based dual GLP-1/glucagon receptor agonist for the treatment of NASH. We refer to this product candidate as ALT-801, and it is designed to treat the obesity and metabolic dysfunction that causes NASH. NASH, the most severe form of non-alcoholic fatty liver disease (“NAFLD”), involves multiple metabolic pathways leading to the abnormal accumulation of liver fat, toxic lipid metabolites, and inflammation, leading to fibrosis or eventually liver cancer. NAFLD is present in up to 90% of obese patients, and approximately 20% of NAFLD patients progress to NASH. In addition, up to 40% of NASH patients develop NAFLD recurrence one year after liver transplant, which we believe indicates that the underlying metabolic disease is still present after transplant. We believe the treatment of obesity is the cornerstone of treating NASH and the principal morbidities of NASH.

ALT-801’s dual agonist mechanism of action is designed to combine the activity of GLP-1 for the reduction of appetite and inflammation, with the direct activity of glucagon on the liver, including increased energy expenditure, adipose browning, lipolysis and mobilization of the liver fat. ALT-801 incorporates the EuPort domain, which is designed to enhance pharmacokinetics for tolerability in the gastrointestinal tract and permit weekly dosing. As observed in a well-established preclinical model of the disease, ALT-801 is capable of inducing significant weight loss with concomitant decreases in liver fat, inflammation and fibrosis, with superior results compared to elafibranor and semaglutide. In addition, ALT-801 demonstrated improved metabolic function and exhibited pleiotropic effects in our preclinical testing across multiple metabolic pathways that are involved in NASH. We also observed in preclinical studies that ALT-801 resulted in more profound suppression of genes associated with steatosis, inflammation and stellate cell fibrosis by RNA sequencing compared to elafibranor and semaglutide. We commenced a Phase 1 clinical trial in Australia in overweight and obese adult volunteers in the fourth quarter of 2020. The trial is expected to have both single-ascending and multiple-ascending dose arms over a 6-week treatment duration, with data readouts planned for each arm in the second quarter of 2021. The endpoints of the Phase 1a trial are expected to be safety, tolerability and pharmacokinetics, with a preliminary readout on weight loss, resting energy expenditure, liver fat by MRI-PDFF and glucose homeostasis. Pending interim results of the single-



ascending dose arms, we intend to extend the multiple-ascending dose arms by 6 weeks for a twelve-week, parallel-dosing Phase 1b clinical trial. The endpoints of the Phase 1b trial are expected to be safety, tolerability, pharmacokinetics, weight loss, decrease in liver fat (as measured by the MRI-PDFF standard) and lean body mass, as well as other metabolic biomarkers. If successful, we expect data from the Phase 1b study Q3 2021.

### *HepTcell*

HepTcell is an immunotherapeutic product candidate for patients chronically infected with the hepatitis B virus (“HBV”). Approximately 300 million people worldwide live with chronic HBV infection, including approximately 2.2 million in the United States. Chronic HBV infection can lead to serious complications, including cirrhosis and liver cancer. Approximately 780,000 people die per year worldwide due to cirrhosis and liver cancer. HepTcell is designed to drive CD4+ and CD8+ T-cell responses against all HBV genotypes in patients of all ethnic backgrounds. Stimulating T-cell responses in chronically infected HBV patients has been challenging because chronic infection with HBV and elevated hepatitis B surface antigen (HBsAg) levels strongly diminishes T-cell immunity directed against the virus. HepTcell focuses the immune system on discrete highly conserved regions of the HBV proteome. We believe our approach allows HepTcell to break immune tolerance by activating T-cells against critical viral sequences with decreased probability of immune escape due to viral mutation. HepTcell is based on our synthetic peptide technology platform and is given by intramuscular injection. In 2018, we completed a Phase 1 trial in the United Kingdom and South Korea in adult patients with chronic HBV. The HepTcell Phase 1 trial was a double-blinded, placebo-controlled, randomized, dose-escalation study that enrolled 61 subjects with chronic HBV who were HBeAg-negative and well-controlled on licensed antivirals. A total of 41 patients received one of two dose levels of HepTcell, with and without IC31™, a depot-forming TLR9 adjuvant developed by Valneva SE, while 20 control patients received either placebo or IC31 alone. Patients received three injections each 28 days apart and were followed for six months after the final dose. All dose combinations showed excellent tolerability and met the primary endpoint of safety. In the two adjuvanted HepTcell arms, T-cell responses against HBV markedly increased over baseline compared to placebo.

We initiated a Phase 2 study during Q4 2020 in the United States, Canada and Europe that is a double-blind, randomized, placebo-controlled study of 80 adult patients with HBeAg-negative inactive CHB and HBsAg  $\leq 100$  IU/mL. HepTcell will be administered in 6 doses at 4-week intervals for 24 weeks, and patients will be followed for one year to evaluate safety and durability of response. The primary efficacy endpoint is virological response, defined as a 1-log reduction in HBsAg levels from baseline at 24 weeks. Secondary efficacy endpoints include reactivation of anti-HBV T cell responses, HBsAg clearance, and other assessments of virologic response. We expect data from this study in the first quarter of 2022.

### **Our Strategy**

Key elements of our strategy include the following:

- Apply our RespirVec platform technologies to design and develop vaccines and therapeutics tailored to address a wide range of infectious diseases, including COVID-19, anthrax, and influenza;
- Apply our EuPort platform technologies to design and develop treatments for NASH, obesity, and other metabolic diseases;
- Apply our Densigen platform technologies to design and develop immunotherapeutic products tailored to address acute and chronic infections;
- Strategically partner or out-license certain product candidates at later stages of development to focus our efforts on early to mid-stage product development; and
- In-license or acquire complementary immunotherapeutic technologies and product candidates that are either synergistic or complementary to our capabilities to expand our pipeline.

### **Our Technology Platforms**

Certain product candidates are based on our proprietary platform technologies as described below.

#### ***Intranasal Vaccines - RespirVec***

NasoShield, NasoVAX, AdCOVID and T-COVID, our respiratory anti-infective product candidates, are derived from our RespirVec platform, which is designed to elicit rapid and long-term immune protection by intranasal delivery of adenovectored pathogen sequences. We believe that our RespirVec technology may be particularly well-suited for pandemic response to respiratory pathogens as a result of its ability to stimulate mucosal immunity in the nasal cavity, a site of viral attack. RespirVec is designed to stimulate serum neutralizing antibody and cellular immune response for a broad immune response and is stable at room temperature

for several months. We believe that the favorable stability profile of RespirVec vaccines, when combined with the simple intranasal route of administration, has the potential for efficient and inexpensive distribution of the vaccine in a pandemic.

RespirVec technology is comprised of intranasal delivery of replication-deficient adenoviruses and is protected by patents that we own or license.

Key aspects of our RespirVec technology, supported by findings in our preclinical studies and clinical trials, include its potential to:

- enable intracellular expression of the vaccine antigen for authentic immune presentation;
- mobilize the innate, cellular and mucosal immune systems, not just the antibody-based response triggered by conventional injectable vaccines;
- elicit a more durable antibody response than typical licensed injectable vaccines;
- provide a self-adjuvanting adenovector delivery system with the potential to improve immunogenicity; and
- allow a rapid production cycle at anticipated lower costs.

#### ***Incretin-based Peptide Technology – EuPort***

EuPort is a platform technology exclusively licensed by us and comprises a hydrophobic domain (e.g., substituted or unsubstituted alkyl chain) and a hydrophilic group (e.g., saccharide) conjugated to a non-terminal amino acid of the peptide. Pursuant to a license agreement between the Company and Mederis Diabetes, LLC (“Mederis”) (the “Mederis IP License Agreement”), we are the exclusive licensee of patent rights owned by Mederis to develop and commercialize surfactant functionalized (“EuPort domain”) incretin-based peptide therapeutics, including GLP-1, Glucagon, Oxyntomodulin, and variants thereof, for any indication, and Mederis has certain patent rights granted back to it for the use of the EuPort technology outside of the Company’s exclusive field of incretin-based peptide therapeutics.

ALT-801, our GLP-1/ Glucagon dual agonist, was developed using the EuPort technology and is based on peptides at least four amino acids in length that bind receptors for Glucagon and/or GLP-1, conjugated to an alkyl saccharide surfactant, including an alkyl glycoside surfactant.

Key aspects of our EuPort technology, supported by findings in our preclinical studies, include its potential to:

- Induce significant weight loss;
- Enhance pharmacokinetics for gastrointestinal tract tolerability; and
- Improve metabolic function and exhibit pleiotropic effects, including suppression of genes associated with steatosis, inflammation and stellate cell fibrosis by RNA sequencing.

#### ***Synthetic Peptide Technology - Densigen***

Densigen is our synthetic fluorocarbon peptide technology platform. HepTcell, an immunotherapeutic developed using our Densigen platform, is designed to activate T-cells to generate a cytotoxic immune response against intracellular pathogens. This synthetic peptide technology is based on peptides of 30 – 40 amino acids that comprise a high density of CD4 and CD8 T-cell epitopes selected to focus the T-cell response on highly conserved targets and allow diverse populations to respond to the product candidate. Densigen technology is protected by patents owned by us.

Key aspects of our Densigen technology, supported by findings in our preclinical studies and clinical trials, include its potential to:

- elicit responses across multiple targets for the disease;
- direct an immune response precisely to specific antigen sites, thereby avoiding more reactive but less effective sites present in the full-length protein; and
- prompt a stronger immune response than naked peptides due to depot effect caused by attaching a biologically inert fluorocarbon chain to each peptide.

## Competition

The biopharmaceutical industry and the vaccine market are intensely competitive and are characterized by rapid technological progress. In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also depends upon our ability to show differentiation with a product that is more efficacious, particularly in the relevant target populations, and/or be less expensive and quicker to manufacture. 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 often substantial period between technological conception and commercial sale.

Large and established companies such as Roche, Novartis, Pfizer and Sanofi Pasteur, among others, compete in the same market as our product candidates. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete. We also 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 face competition from multiple biotechnology and bio-pharmaceutical companies, such as Pfizer, Moderna, AstraZeneca, Regeneron and Johnson & Johnson, that are in the process of developing vaccines and therapeutics against COVID-19. Certain of these vaccine and therapeutic technologies are being developed at a faster rate than AdCOVID and T-COVID or have superior immunogenicity or manufacturability attributes. We face competition for NasoShield, our single dose intranasal anthrax vaccine product candidate, from Emergent Biosolutions which manufactures the existing anthrax vaccine. Additionally, we generally face substantial competition for government funding from companies that develop products with government contracts and grants. We face competition for NasoVAX, our intranasal influenza candidate from Novavax, which is developing an influenza vaccine; and a number of companies of varying sizes are also pursuing the development of a "universal" flu vaccine. We face competition for ALT-801, our dual GLP-1/glucagon dual agonist for the treatment of NASH, from companies such as Intercept Pharmaceuticals, which is developing a farnesoid X receptor agonist; Madrigal Pharmaceuticals, which is developing an orally administered, small-molecule, liver-directed, thyroid hormone receptor (THR)  $\beta$ -selective agonist; and, Akero Therapeutics, which is developing a fibroblast growth factor 21 analog. Finally, we face competition for HepTcell, our immunotherapeutic HBV product candidate, from companies such as Transgene which is developing an adenovirus-based vaccine; Arrowhead Pharmaceuticals, which is developing an HBV therapeutic vaccine; and Inovio, which is developing a DNA vaccine delivered by in vivo electroporation. Any of these companies may develop competing products more rapidly than we do.

## Intellectual Property

We generally seek patent protection for our technology and product candidates in the United States and abroad. The patent coverage available to biotechnology companies is generally uncertain because it involves complex legal and factual considerations. Our success will depend, in part, on whether we can:

- obtain patents to protect our own technologies and product candidates;
- obtain licenses to use the technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

We have relied upon certain proprietary trade secrets, know-how and continuing technological advances to develop a competitive position. In efforts to maintain confidentiality and ownership of trade secrets, proprietary information and developments, all of our employees are required to execute agreements regarding confidentiality and assign to us all rights to any inventions and processes they develop while they are employed by us. We may in the future use license agreements to access external products and technologies as well as to convey our own intellectual property to others. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

## Patent Rights Related to our RespirVec Platform Technology

### *Immunotherapy for Respiratory Pathogens — Intranasal Application of Adenoviral Vector Vaccines*

We are developing a rapid and prolonged immunologic-therapeutic technology, for which we have a patent issued or allowed in the United States, Europe, South Korea and Japan for respiratory pathogens including influenza, coronavirus and anthrax; and pending applications in the United States, Europe, Japan, and other commercially relevant jurisdictions. The claims are directed to methods for inducing an immune response against respiratory pathogens including influenza, coronavirus and Bacillus anthracis, the causative agent of anthrax, comprising intranasal administration of an effective amount of E1 and/or E3 deleted adenovirus. The patent and, if issued, the patent(s) resulting from the pending applications have an expiration date no earlier than March 2032, not giving effect to any potential extensions and assuming payment of all associated fees.

We are also developing methods of administering and dosing the intranasal adenoviral vector vaccine compositions, for which we have an international (PCT) patent application filed, with expectation that in due course in jurisdictions of commercial consideration (e.g., United States, Europe, Japan) there will be national or regional patent applications based on the PCT. The claims are directed to transmucosal administration of our respiratory anti-infective product candidates based on our RespirVec platform technology. The patent(s), if issued, resulting from the pending application have an expiration date of no earlier than August 2040, not giving effect to any potential extensions and assuming payment of all associated fees.

### *PER.C6 Cell Line — In-Licensed from Janssen Vaccines & Prevention B.V. (Formerly Crucell Holland, B.V.)*

We are the non-exclusive licensee of patent rights held by Janssen Vaccines & Prevention B.V. (Formerly Crucell Holland, B.V.) (“Janssen”), covering a method of producing an adenoviral vector stock using cell lines including the PER.C6 cell line, which may be used for the development and manufacture of vaccine products.

We entered into an amended license agreement with Janssen, effective as of October 4, 2005, which amended and restated our prior license agreements with Janssen. Under the amended license agreement, we obtained a non-exclusive, worldwide license (with the right to sublicense) under certain patent rights and know-how to use Janssen’s proprietary cell line to develop, manufacture and commercialize vaccines to prevent and/or treat influenza virus and anthrax infection in humans.

In consideration for the license, we paid an up-front license fee, issued equity shares, and agreed to pay certain development-based milestone payments through approval of licensed products by the Food and Drug Administration (“FDA”), up to an aggregate amount of approximately \$2.5 million. We also agreed to pay royalty payments as a percentage of net sales of products in any country where the manufacture of such product is covered by a valid claim of any licensed patent or uses licensed know-how, subject to a royalty stacking reduction and minimum annual royalty payments, until the expiration of the term of the amended agreement.

We further amended our license agreement with Janssen, effective September 25, 2015, primarily to streamline our manufacturing license arrangements. Prior to the 2015 amendment, we entered into three-party manufacturing license agreements with each manufacturer and Janssen. The 2015 amendment enables us to directly grant sublicenses of certain of our rights under Janssen’s patent rights and know-how to manufacturers, subject to Janssen’s consent which may not be withheld if the manufacturer meets certain criteria.

We may terminate the amended license agreement without cause, and the agreement contains customary provisions for either party to terminate prior to the expiration of the agreement. The amended license agreement expires on a product-by-product and country-by-country basis on the later of the date upon which the last of the licensed patents applicable to the relevant product expires or 15 years from the date of first commercial sale of the relevant product. The Janssen patent rights include patents issued in the United States with an expected expiration date no earlier than April 2020, in each case not giving effect to any potential extensions and assuming payment of all associated fees. Upon expiration of the amended license agreement, or if we terminate the amended license agreement for Janssen’s material breach, we retain the right to exploit the rights granted.

On April 2, 2020, we entered into Amendment No. 3 to the Second Restated License Agreement and additionally entered into Amendment No. 4, 5 and 6 throughout 2020 (collectively, the “Amendments”), by and between us and Janssen (as amended by Amendment No. 1 to Second Restated License Agreement and Amendment No. 2 to Second Restated License Agreement, together with the Amendments, the “License Agreement”). Pursuant to the Amendment, the field of licenses granted to us for the use of the PER.C6 cell line under the License Agreement is expanded to cover COVID-19 caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), in addition to the existing licenses related to Bacillus anthracis and influenza virus. Pursuant to the Amendment, we agreed to pay certain additional development-based milestone payments through approval of licensed products by the FDA for the treatment or prevention of COVID-19, up to an aggregate amount of \$1.2 million. We also agreed to pay royalty payments as a percentage of net sales of products to a royalty stacking reduction and minimum annual royalty payments, until the expiration of the term of the License Agreement, as amended. We additionally entered into Amendment No. 4, 5 and 6 throughout

2020 to add additional manufacturing partners related to manufacturing AdCOVID. As of December 31, 2020, we have paid Janssen \$2.7 million in cash and equity under the amended agreement.

## **Patent Rights Related to our EuPort Platform Technology**

### ***EuPort Technology — In-Licensed from Mederis Diabetes, LLC***

Pursuant to a license agreement between the Company and Mederis Diabetes, LLC (“Mederis”) (the “Mederis IP License Agreement”), we are the exclusive licensee of patent rights owned by Mederis to develop and commercialize surfactant functionalized (“EuPort domain”) incretin-based peptide therapeutics, including GLP-1, Glucagon, Oxyntomodulin, and variants thereof, for any indication, and Mederis has certain patent rights granted back to it for the use of the EuPort technology outside of the Company’s exclusive field of incretin-based peptide therapeutics. The EuPort domain comprises a hydrophobic domain (e.g., substituted or unsubstituted alkyl chain) and a hydrophilic group (e.g., saccharide) conjugated to a non-terminal amino acid of the peptide. Patents under Mederis IP License Agreement have been granted in the United States and Korea, and applications pending in the United States, Japan as well as other commercially relevant jurisdictions. The claims are directed to peptides (at least four amino acids in length), including peptides that bind receptors for Glucagon and/or GLP-1, conjugated to an alkyl saccharide surfactant, including an alkyl glycoside surfactant. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2032, not giving effect to any potential extensions and assuming payment of all associated fees. Patents subject to the Mederis IP License Agreement have also been granted in the United States, and Japan, and applications pending in the United States, Europe, Japan, China and other commercially relevant jurisdictions, wherein the claims are directed to specific GLP-1 and/or Glucagon peptides conjugated to the EuPort domain. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2035.

## **Patent Rights Related to Our Densigen Platform Technology**

### ***Fluorocarbon Antigen Delivery Vectors***

We are developing a fluorocarbon antigen construct platform technology. Our patents covering this technology are issued in the United States, China, Japan and certain European countries, including the United Kingdom, Germany and France. Additional patents are issued in other commercially relevant jurisdictions and an application is pending in the United States. The claims are directed to the fluorocarbon linked antigen construct, compositions comprising the construct and methods of using the construct to stimulate an immune response. The patents and, if issued, the patent(s) resulting from the pending patent applications are expected to have an expiration date no earlier than April 2025, not giving effect to any potential extensions and assuming payment of all associated fees.

### ***Formulation of Antigen Delivery Vectors — Manufacturing Process for the Final Formulation of the Antigen Delivery Vectors***

We are developing a manufacturing process for solubilizing certain fluorocarbon peptides and final lyophilized compositions thereof that are soluble in an aqueous solution, for which we have a patent issued in the United States, Europe and Japan and patent applications pending in the United States and Japan, as well as other commercially relevant jurisdictions. The claims are directed to methods of solubilizing certain fluorocarbon antigen peptides using acetic acid formulations and manufactured lyophilized compositions thereof that are soluble in an aqueous solution. The patent and, if issued, the patent(s) resulting from the pending patent applications are expected to have an expiration date no earlier than December 2031, not giving effect to any potential extensions and assuming payment of all associated fees.

## **Patent Rights Related to Our Product Candidates**

### ***AdCOVID, COVID-19 Vaccines***

We are developing an intranasal COVID-19 vaccine candidate based on our replication-deficient adenoviral vectored RespirVec platform technology, for which we have a patent application filed in the United States, Taiwan, Argentina and an international (PCT) patent application filed, with expectation that in due course in jurisdictions of commercial consideration (e.g., Europe, Japan) there will be national or regional patent applications based on the PCT. The claims are directed to the AdCOVID vaccine composition and its method of use. If issued, patent(s) resulting from the pending application(s) have an expiration date of no earlier than February 2041, not giving effect to any potential extensions and assuming payment of all associated fees.

AdCOVID is further covered by our patent rights related to our RespirVec platform technology, for which we have patent applications pending in the US, Europe and Japan. The claims are directed to a method of inducing an innate immune response against coronavirus following intranasal administration of an effective amount of E1 and/or E3 deleted adenovirus expressing a coronavirus antigen. The patent application(s), if issued, would have an expiration date no earlier than March 2032, not giving effect to any potential extensions and assuming payment of all associated fees. Use and dosing of AdCOVID is further covered by an international (PCT) patent application, from which we expect to file national and regional applications in the U.S., Europe and other commercially

relevant jurisdictions. The claims are directed to transmucosal administration of our respiratory anti-infective product candidates, including AdCOVID. If issued, the patents resulting from the pending applications have an expiration date of no earlier than August 2040, not giving effect to any potential extensions and assuming payment of all associated fees.

#### ***T-COVID, COVID-19 Therapeutic***

We are developing an intranasal COVID-19 therapeutic candidate based on our replication-deficient adenoviral vectored RespirVec platform technology, for which we have a patent application filed in the United States, Taiwan, Argentina and an international (PCT) patent application filed, with expectation that in due course in jurisdictions of commercial consideration (e.g., Europe, Japan) there will be national or regional patent applications based on the PCT. The claims are directed to the T-COVID therapeutic composition and its method of use. If issued, patent(s) resulting from the pending application(s) have an expiration date of no earlier than February 2041, not giving effect to any potential extensions and assuming payment of all associated fees.

T-COVID is further covered by our patent rights related to our RespirVec platform technology, for which we have a granted patent in Europe and have recently received a Notice of Allowance from the United States Patent and Trademark Office (“USPTO”) for claims directed to a method of inducing an innate immune response against coronavirus. That patent, once issued, will have an expiration date of no earlier than March 2032. Use and dosing of T-COVID is further covered by an international (PCT) patent application, from which we expect to file national and regional applications in the U.S., Europe and other commercially relevant jurisdictions. The claims are directed to transmucosal administration of our respiratory anti-infective product candidates, including T-COVID. If issued, patent(s) resulting from the pending application(s) have an expiration date of no earlier than August 2040, not giving effect to any potential extensions and assuming payment of all associated fees.

#### ***NasoShield, Anthrax Vaccine***

We are developing a rapid and prolonged immunologic-therapeutic technology for anthrax (NasoShield), for which we have a patent granted in the United States, Canada, Europe and Japan. Additional patent applications are pending in the United States, Europe, Japan and other commercially relevant jurisdictions. The issued and pending claims are directed to methods for inducing a rapid protective response against anthrax, comprising intranasal administration of an effective amount of E1 and/or E3-deleted adenovirus expressing a Bacillus anthracis antigen. The patent, if issued, resulting from the pending applications are expected to have an expiration date no earlier than March 2032, not giving effect to any potential extensions and assuming payment of all associated fees.

NasoShield is further covered by an issued and pending U.S. patent. The issued claims are directed to methods of inducing a protective immune response against inhalation anthrax, comprising intranasal administration of an adenoviral vector expressing anthrax protective antigen. The patent has an expiration date no earlier than July 2024, not giving effect to any potential extensions and assuming payment of all associated fees.

Use and dosing of NasoShield is further covered by an international (PCT) patent application, from which we expect to file national and regional applications in the US, Europe and other commercially relevant jurisdictions. The claims are directed to transmucosal administration of our respiratory anti-infective product candidates, including NasoShield. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than August 2040, not giving effect to any potential extensions and assuming payment of all associated fees.

#### ***NasoVAX, an Influenza Vaccine***

We are developing a rapid and prolonged immunologic-therapeutic technology for influenza, for which we have a patent issued in the United States, Europe and Japan for influenza and patent applications pending in the United States, Canada, Europe and Japan, as well as other commercially relevant jurisdictions. The issued and pending claims are directed to methods for inducing a rapid protective response against influenza, comprising intranasal administration of an effective amount of E1 and/or E3 deleted adenovirus. The patent and, if issued, the patent(s) resulting from the pending applications are expected to have an expiration date no earlier than March 2032, not giving effect to any potential extensions and assuming payment of all associated fees.

Use and dosing of NasoVAX is further covered by an international (PCT) patent application, from which we expect to file national and regional applications in the U.S., Europe and other commercially relevant jurisdictions. The claims are directed to transmucosal administration of our respiratory anti-infective product candidates, including NasoVAX. The patents, if issued, resulting from the pending application have an expiration date of no earlier than August 2040, not giving effect to any potential extensions and assuming payment of all associated fees.

Single dose NasoVAX formulations and their use for inducing a combined mucosal, humoral and T cell immune response against influenza virus is further covered by an international (PCT) patent application, from which we expect to file national and

regional applications in commercially relevant jurisdictions, and a pending U.S. patent application. The claims are directed to a single dose NasoVAX intranasal formulation and its use for inducing a combined immune response in humans providing durable immunity against influenza. If issued, patent(s) resulting from the pending application(s) have an expiration date of no earlier than April 2040, not giving effect to any potential extensions and assuming payment of all associated fees.

#### ***ALT-801, Dual GLP-1/Glucagon Dual Agonist for NASH***

We are the exclusive licensee of patent rights owned by Mederis Diabetes, LLC (“Mederis”) to develop and commercialize surfactant functionalized GLP-1/Glucagon/Oxyntomodulin-based peptide therapeutics, and variants thereof, for any use including the treatment of obesity, metabolic syndrome, insulin resistance, diabetes and cardiovascular disease. Patents under this license agreement (“Mederis IP License Agreement”) have been granted in the United States, Europe, Japan, Australia and Mexico with pending applications in the United States, Europe, Japan, and Korea, as well as other commercially relevant jurisdictions. The claims are directed to GLP-1/glucagon dual agonist peptides conjugated to a surfactant and their use to treat metabolic syndrome, obesity and other related diseases. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2032 and extending to May 2035, not giving effect to any potential extensions and assuming payment of all associated fees. Use of ALT-801 for treating NASH is further covered by, and subject to the Mederis IP License Agreement, pending applications in the U.S., Europe, Japan and other commercially relevant jurisdictions. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than January 2039, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of ALT-801 in methods with improved tolerability, dosing and therapeutic regimens is further covered in two pending U.S. provisional patent applications owned by us and not subject to the Mederis IP License Agreement, and from which we expect to file U.S. and international patent applications. The claims are directed to the use of ALT-801 in a therapeutic dosing regimen with improved tolerability. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than February 2041 and December 2041, respectively, not giving effect to any potential extensions and assuming payment of all associated fees.

#### ***HepTcell, Chronic Hepatitis B Immunotherapy***

We are developing an HBV immunotherapy technology directed to compositions comprising fluorocarbon constructs with specific peptide HBV antigen sequences. We have an issued patent for this technology in the United States, and pending applications in the United States, Europe, Japan, China and Korea, as well as other commercially relevant jurisdictions. The claims are directed to HBV antigen peptide sequences comprising T-cell epitopes linked to fluorocarbon chains and compositions comprising a combination of HBV antigen peptide sequences. If issued, the patent(s) resulting from the pending patent applications are expected to have an expiration date no earlier than December 2033, not giving effect to any potential extensions and assuming payment of all associated fees. HepTcell is also covered by the patents and patent applications relating to our Densigen platform technology.

Use of HepTcell for treating patients with chronic hepatitis B viral (HBV) infection is further covered by a pending U.S. provisional patent application, from which we expect to file U.S. and international patent applications. The claims are directed to treating patients with chronic hepatitis B virus (HBV) infection characterized with low hepatitis B surface antigen (HBsAg). If issued, the patent(s) resulting from the pending patent application(s) are expected to have an expiration date no earlier than December 2041, not giving effect to any potential extensions and assuming payment of all associated fees.

#### **Government Contracts**

Substantially all of our revenues to date have been derived from grants and United States government contracts. There can be no assurances that our remaining U.S. government contract will be continued, renewed beyond the base period, or that we can enter into new contracts or receive new grants to supply the U.S. or other governments with our products. The process of obtaining government contracts is lengthy and uncertain.

U.S. government contracts typically are subject to audit by the government and contain termination provisions for the government allowing it to terminate at its discretion, which subjects us to additional risks. These risks include the ability of the U.S. government unilaterally to:

- preclude us, either temporarily or for a set period of time, from receiving new contracts or extending our remaining contracts based on violations or suspected violations of laws or regulations;
- terminate our remaining contracts either for the convenience of the government (at the government’s sole discretion, for example, if funds become unavailable or the government no longer wants the work) or for default (for failing to perform in accordance with the contract schedule and terms);

- revise the scope and value of our contracts and/or the timing for work to be performed;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products;
- claim rights to intellectual property, including our products, developed under the contract;
- add or remove the terms and conditions in our contracts; and
- cancel or amend planned procurements, including outstanding request for proposal solicitations.

Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed, settlement expenses, and profit on the work completed prior to termination. Termination-for-default provisions do not permit these recoveries and would make us liable for excess costs incurred by the U.S. government in procuring undelivered items from another source.

#### ***MTEC COVID-19 Contract***

We are funding our Phase 1/2 clinical trial of T-COVID with a \$4.7 million grant from the U.S. Army Medical Research & Development Command (“USAMRDC”). The competitive award was granted by USAMRDC in collaboration with the Medical Technology Enterprise Consortium (“MTEC”), a 501(c)(3) biomedical technology consortium working in partnership with the Department of Defense (“DoD”). Under the contract, MTEC pays us a firm fixed fee based on achieving certain milestones for conduct and completion of a Phase 1/2 study. As of December 31, 2020, we have collected an aggregate of approximately \$1.1 million in receivables under the contract.

We own the intellectual property rights to inventions made by us in the performance of work under the MTEC contracts provided that we disclose such inventions to the U.S. government and notifies the U.S. government of our election to retain title. The U.S. government will have a non-exclusive, non-transferable, irrevocable, paid-up license to practice, or have practiced for or on our behalf, such inventions throughout the world, in addition to other rights customarily reserved by the U.S. government for intellectual property generated using government funds.

#### ***BARDA Anthrax Contract***

We are developing our NasoShield anthrax vaccine pursuant to a contract with BARDA that commenced in July 2016. Under this contract, BARDA pays us a fixed fee and reimburses certain of our costs for the research and development of an Ad5-vectored, protective antigen-based intranasal anthrax vaccine through current good manufacturing practice (“cGMP”) manufacture and conduct of a Phase 1 clinical trial dose ranging assessment of safety and immunogenicity. The contract consists of an initial base performance period providing approximately \$27.8 million in funding for the period July 2016 through June 2021. BARDA has seven options to extend the contract to fund certain continued development and manufacturing activities for the anthrax vaccine, including Phase 2 clinical studies for a three-year period. Each option, if exercised by BARDA, would provide additional funding ranging from approximately \$1.1 million to \$34.4 million, providing a total contract potential of \$133.7 million. As of December 31, 2020, we have collected an aggregate of approximately \$24.7 million in receivables under the current BARDA contract.

We have been audited by BARDA through 2016 and have agreed on final indirect rates with the Defense Contract Audit Agency (“DCAA”) through 2016.

We own the intellectual property rights to inventions made by us in the performance of work under the BARDA contracts, provided that we disclose such inventions to the U.S. government and notifies the U.S. government of our election to retain title. The U.S. government will have a non-exclusive, non-transferable, irrevocable, paid-up license to practice, or have practiced for or on our behalf, such inventions throughout the world, in addition to other rights customarily reserved by the U.S. government for intellectual property generated using government funds.

BARDA is a division of the U.S. Department of Health and Human Services (“HHS”) in the Office of the Assistant Secretary for Preparedness and Response that supports the advanced research and development, manufacturing, acquisition and stockpiling of medical countermeasures. Our contracts with BARDA, like those awarded by other U.S. government agencies, contain provisions not typically found in commercial contracts. Most notably, BARDA, or the U.S. government acting through BARDA, may terminate, modify or amend our contract, in whole or in part, for nearly any reason or no reason.

#### ***NIAID Anthrax Contract***

Through the third quarter of 2019, we were developing our SparVax-L anthrax vaccine pursuant to a contract with the National Institute of Allergy and Infectious Diseases (“NIAID”). SparVax-L, a recombinant protein-based anthrax vaccine, was designed to



require fewer doses and have a longer shelf life than the only currently licensed anthrax vaccine. We demonstrated a significant improvement in shelf life (two years at room temperature and six years at refrigerated temperatures) with a lyophilized formulation. Preclinical experiments showed it to be 100% protective with a two-dose regimen (administered on study Days 0 and 14 days) with higher protective (toxin neutralizing) antibodies than the currently licensed vaccine administered under the same schedule. Activities under this contract were completed during the quarter ended September 30, 2019 and no further funding is expected for this program. As a result of the contract completion and the U.S. government's funding prioritization of only single dose anthrax vaccine candidates, we abandoned the project and impaired the \$1.0 million net book value of the SparVax-L IPR&D asset in 2019.

### **United States Government Regulation**

Biological products, such as our product candidates, are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), the Public Health Service ("PHS Act"), the FDA regulations under Title 21 of the Code of Federal Regulations (21 CFR), as well as other federal, state and local statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, research, manufacturing, approval, safety, efficacy, labeling, packaging, storage, record keeping, distribution, import, export, reporting, sale, advertising and other promotional practices involving biological products. An investigational new drug ("IND") application must be in effect before clinical testing of biological products can begin. FDA approval must be obtained before biological products can be marketed. 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, and each process may take several years to complete, although certain expedited programs potentially applicable to our product candidates, such as FDA fast track designation for certain new drugs with the potential to address unmet medical needs for certain serious or life-threatening conditions, may potentially expedite development and/or approval processes. Certain federal incentive programs are also potentially applicable to our product candidates, such as for "orphan drugs" that treat rare conditions, and programs supporting the development of bioterrorism medical countermeasures. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product candidates. In addition, the FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. In addition, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could adversely affect our ability to commercialize our product candidates.

### ***Biological Products Development Process***

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to applicable good laboratory practices ("GLP") applicable requirements for the humane use of laboratory animals, such as the Animal Welfare Act or other applicable regulations;
- submission to the FDA of an application for an IND which must become effective before human clinical trials may begin;
- obtaining approval by an independent Institutional Review Board ("IRB") at each clinical site before a clinical trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices ("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 includes substantial evidence of safety, purity and potency from results of clinical trials, as well as the results of preclinical testing, detailed information about the chemistry, manufacturing and controls, and proposed labeling and packaging for the product candidate;
- review of the product candidate by an FDA advisory committee, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product candidate is produced to assess compliance with cGMP and to confirm that the facilities, methods and controls are adequate to assure the biological product candidate's identity, strength, quality and purity;
- satisfactory completion of potential FDA audits of the preclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA, including agreement on post-marketing commitments, if applicable.

Before testing any biological product candidate in humans, the product candidate enters the preclinical study stage. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of certain preclinical studies must comply with federal regulations and requirements including GLP and the Animal Welfare Act.

The clinical trial sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical trial protocol, to the FDA as part of the IND. Some preclinical studies may continue even after the IND is submitted. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. The FDA may also place the clinical 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. Even after the IND has gone into effect and clinical testing has begun, the FDA may also impose clinical holds on clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies 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 the trials have begun, issues will not arise that suspend or terminate such studies.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators. 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 ("AEs"), should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND, during applicable phases of development. Clinical trials must be conducted and monitored in accordance with the FDA's regulations and GCP requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials, with the goals of assuring that the data and results are credible and accurate and that study participants' rights, safety, and well-being are protected. GCP requirements include the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an 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, not only from the investigational product itself but also from any required procedures or study visits to be conducted during the trial, 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.

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 group of healthy human subjects (e.g., 10 to 20 volunteers) 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 patients.
- *Phase 2.* The biological product is evaluated in a larger but limited patient population (e.g., a few hundred patients) 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.* These clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population (e.g., several hundred to several thousand patients) at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit profile of the product and provide an adequate basis for product labeling.

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 AEs, any findings from other studies, tests in laboratory animals or in vitro testing and other sources 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 may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients 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 patients.

In limited circumstances, FDA also permits the administration of investigational biological products to patients under its expanded access regulatory authorities. Under the FDA's expanded access authority, patients who are not able to participate in a clinical trial may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requesting physician. For medical countermeasure ("MCM") focused products, in particular, FDA has recently indicated that its expanded access authorities may be important in enabling quicker access to investigational products intended for MCM uses in the COVID-19 pandemic.

Concurrent with clinical trials, companies usually complete additional animal studies, develop additional information about the physical characteristics of the biological product candidate and 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 PHS Act emphasizes the importance of manufacturing controls 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 things, 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.

Certain FDA programs are available to facilitate and expedite the development and review of new drugs intended to address unmet needs in the treatment of serious or life-threatening conditions. These expedited programs include fast track designation, breakthrough therapy designation, priority review, and accelerated approval. Each of these programs has its own features and qualifying criteria. A sponsor must submit a request for fast track designation, breakthrough therapy designation, or priority review, which may or may not be granted by the FDA. For accelerated approval, a sponsor generally discusses the possibility of accelerated approval with the FDA during development, and the FDA may or may not agree that accelerated approval is an appropriate pathway for a particular drug. Some of these expedited programs could potentially apply to our product candidates, although this cannot be assured, and we do not currently have any products with expedited program designations.

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. Additionally, a manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

### ***Review and Approval Processes***

After the completion of clinical trials of a biological product candidate, the FDA's approval of a BLA must be obtained before commercial marketing of the biological product may begin. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, as amended, a BLA or supplement to a BLA generally must contain data to assess the safety and effectiveness of the biological 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 depending on the designated pathway for submission. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act (“PDUFA”), as amended, each BLA must be accompanied by a significant user fee. PDUFA also imposes an annual prescription drug product program fee for biologics. 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.

Following submission of the application, the FDA reviews the BLA 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 10 months of the 60-day filing date, or within 12 months of its submission. That deadline can be extended under certain circumstances, including by the FDA’s requests for additional information. The targeted action date can also be shortened to 6 months of the 60-day filing date, or 8 months after submission, for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure the product’s identity, safety, 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 BLA review process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (“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 the 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 BLA 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 study 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. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than how 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 usually 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 may take 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 complete response 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 REMS, 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. Post-approval modifications to a drug product, such as changes in indications, labeling or manufacturing processes or facilities, may require development and submission of additional information or data in a new or supplemental BLA, which would also require prior FDA approval.

### ***Post-Approval Requirements***

After regulatory approval of a product is obtained, products are subject to continuing extensive regulation and post-approval requirements. For example, as a condition of approval of a BLA, the FDA may require post-marketing testing and surveillance to monitor the product’s safety or efficacy. In addition, holders of an approved BLA are required to submit annual reports, keep extensive records, to report certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations and practices, as well as the manufacturing conditions of approval set forth in the BLA. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time,

money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the BLA), additional regulatory review and approval may be required.

Future FDA inspections may identify cGMP compliance issues at manufacturer facilities or at the facilities of third-party suppliers that may disrupt production or distribution or require substantial resources to correct and prevent recurrence of any deficiencies and could result in fines or penalties by regulatory authorities. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action, including warning letters, fines, injunctions, civil penalties, license revocations, seizure, total or partial suspension of production or criminal penalties, any of which could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications.

## **Certain U.S. Regulatory Incentives and Other Programs**

### ***Priority Rule Voucher (PRV)***

The 21st Century Cures Act ("Cures Act"), which was signed into law on December 13, 2016, established a new priority review voucher ("PRV") program for material threat MCMs. Upon approval of a material threat MCM application, the FDA will award a PRV provided certain criteria are met. A PRV voucher can be used to obtain priority review for a subsequent marketing application that would not otherwise have met the criteria for priority review. When a marketing application receives priority review, the FDA's goal is to take action on that application within 6 months of the filing date. To be considered a material threat MCM application, the application must be: (i) intended for use to prevent or treat harm from a chemical, biological, radiological, or nuclear ("CBRN") agent (or intended to mitigate, prevent or treat harm caused by an MCM used against such agent) determined by the Department of Homeland Security to be a material threat; (ii) eligible for priority review; (iii) approved after the date of enactment of the Cures Act; and (iv) for a drug for which an active ingredient has not been previously approved by the FDA.

Although the material threat MCM PRV program is separate and distinct from the FDA's other PRV programs, FDA intends to implement the law consistently with implementation of the other PRV programs.

### ***Animal Rule and Project BioShield Emergency Use Authorization***

In 2002, the FDA amended its requirements applicable to BLAs to permit the approval of certain biologics that are intended to treat or prevent serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic CBRN substances based on evidence of safety from trial in healthy human subjects and animal studies, and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, also known as the "Animal Rule," and published in the Code of Federal Regulations (21 CFR 601 Subpart H), authorize the FDA to rely on evidence from animal studies to provide evidence of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the toxicity of the agent and its prevention or substantial reduction by the biological product, the effect is demonstrated in more than one animal species expected to react with a response predictive for humans, the animal study endpoint is clearly related to the desired benefit in humans, and the data or information on the kinetics and pharmacodynamics of the product or other relevant data or information, in animals and humans, allows selection of an effective dose in humans. Under these requirements, and with FDA's prior agreement, biologics used to reduce or prevent the toxicity of CBRN substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated for effectiveness under this rule are evaluated for safety under preexisting requirements for establishing the safety of new drug and biological products, including Phase 1 through Phase 2 clinical trials. Under certain circumstances a single animal species may be acceptable if that animal model is sufficiently well-characterized for predicting a response in humans. The Animal Rule also requires post-marketing studies, such as field studies, to verify and describe the product's clinical benefit and assess its safety should an exigency exist that leads to the product being used in humans; the nature of these studies will be discussed with the FDA as part of the BLA process. Products approved under the Animal Rule are subject to additional requirements, such as restrictions imposed on distribution or labeling requirements to inform patients that the product's approval was based on efficacy studies conducted in animals alone. The Animal Rule drug development pathway typically involves costs and time for nonclinical studies and animal models in excess of what would be expended in conducting human vaccine clinical trials not requiring compliance with the Animal Rule.

Under the Project BioShield Act of 2004 and subsequent amendments by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 ("Project Bioshield"), the Secretary of HHS may, with the concurrence of the Secretary of the Department of Homeland Security ("DHS"), and upon the approval of the President, contract to purchase unapproved MCMs for the Strategic National Stockpile ("SNS"), in specified circumstances. The U.S. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the SNS is paid on delivery of a substantial portion of the countermeasure. To be eligible for purchase under these provisions, the Secretary of HHS must

determine that there are sufficient and satisfactory clinical results or research data, including data, if available, from preclinical studies and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for FDA approval or licensing within eight years. The legislation also allows unlicensed products to be procured for the SNS so that they are available at the time an emergency is declared.

Project BioShield also allows the Secretary of HHS to authorize the emergency use of unapproved medical products or an unapproved use of an approved medical product under certain emergency circumstances (“Emergency Use Authorization”). To exercise this authority, the FDA must conclude that:

- the CBRN agent for which the countermeasure is designed to treat can cause serious or life-threatening disease;
- based on the totality of scientific evidence available to the FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks; and
- there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition.

Some product candidates may be eligible both for consideration for procurement into the SNS and for Emergency Use Authorization, although there is no guarantee that our product candidates will meet the criteria set forth by HHS or the FDA for procurement and Emergency Use Authorization, respectively.

### ***Marketing Exclusivity for Reference Biological Products***

As part of the ongoing efforts of governmental authorities to lower health care costs by facilitating generic competition to pharmaceutical products, the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “Health Care Reform Law”), created a new abbreviated regulatory approval pathway in the United States for biological products that are found to be “biosimilar” or “interchangeable” with a biological “reference product” previously licensed under a BLA. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively by relying to some extent on the data generated by the reference product’s sponsor, and the FDA’s previous review and approval of the reference product. Under the BPCIA, a biosimilar sponsor’s ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted by the FDA to the holder of the reference product’s BLA, and no biosimilar application may be accepted by the FDA for review until 4 years after the date the reference product was first licensed by the FDA, and no biosimilar application, once accepted, may receive final approval until 12 years after the reference product was first licensed by the FDA.

While we would expect to be granted this 12-year period of exclusivity for our product candidates, if approved, notably, this period of reference product market exclusivity applies only to the biosimilar pathway and will not, for example, provide protection against any biological product for a similar indication that achieves FDA approval under a traditional BLA based on the sponsor’s own research data. There is also risk that the 12-year period of biological reference product exclusivity could be shortened due to congressional action, or that the FDA will not consider our product candidates, if they are approved, to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Once approved, biosimilars likely would compete with, and in some circumstances may be deemed under the law to be “interchangeable with,” the previously approved reference product. The extent to which a biosimilar, once approved, will be substituted for any one of our product candidates, if approved, in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Although there is uncertainty regarding the impact of this program, there is risk that the approval of a biosimilar competitor to one of our products, if approved, could have an adverse impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our product, if approved by the FDA.

### ***Pediatric Exclusivity***

Biologics, such as our product candidates, may be eligible for pediatric exclusivity, an incentive intended to encourage medical product research for children. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods applicable to biological products — namely, the four-year period during which the FDA will not consider an application for a biosimilar product, and the 12-year period during which the FDA will not approve a biosimilar application. This six-month exclusivity, which runs from the end of these exclusivity protection periods, may be granted based on the completion of one or more pediatric trials in response to a Written Request from the FDA. It is possible, but not assured, that certain of our current or future product candidates may be targeted to pediatric populations, such as our influenza vaccine candidate.

### ***Orphan Drug Designation***

The FDA may grant orphan drug designation to drugs intended to treat a “rare disease or condition” that affects fewer than 200,000 individuals in the United States, or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such a disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation can provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user fee exemptions. In addition, if a product that has an orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product may be entitled to orphan drug exclusivity, which means the FDA would not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. It is possible, but not assured, that certain of our current or future product candidates may be targeted to rare diseases or conditions.

### ***U.S. Regulations Affecting Health Care Companies***

Pharmaceutical manufacturers with products that are reimbursed by U.S. federally funded health care programs such as Medicare and Medicaid are subject to so-called fraud and abuse laws including false claims and anti-kickback laws.

The federal Anti-Kickback Law prohibits anyone from, among other things, knowingly and willingly, directly or indirectly, soliciting, receiving, offering, or paying any remuneration with the intent of (or in return for) generating referrals of individuals or purchases, orders, or recommendations for services or items reimbursable by federal health care programs like Medicare and Medicaid. Courts have interpreted this law very broadly, including by holding that a violation has occurred if one purpose of the remuneration is to generate referrals even if there are other lawful purposes. Moreover, liability under the Anti-Kickback Law may be established without proving actual knowledge of the law or specific intent to violate. There are statutory exceptions and regulatory safe harbors that protect certain arrangements from prosecution or administrative sanctions, but the exceptions and safe harbors are drawn narrowly. The fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Law, but the arrangement may be subject to scrutiny based on the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Violations of the Anti-Kickback Law may be punished by civil and criminal penalties, damages, fines, or exclusion from participation in federal health care programs like Medicare and Medicaid. Many states have enacted similar laws, some of which apply regardless of payer.

The Federal civil False Claims Act (“FCA”) prohibits any person from, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or making, or causing to be made, a false statement material to a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, or decreasing an obligation to pay or transmit money or property to the government. The FCA is commonly used to sue those who submit allegedly false Medicare or Medicaid claims, as well as those who induce or assist others to submit a false claim. “False claims” can result not only from non-compliance with the express requirements of applicable governmental reimbursement programs, such as Medicaid or Medicare, but also from non-compliance with other laws, such as the Anti-Kickback Law or laws that require quality care in service delivery. Actions under the FCA may be brought by the government or by whistleblowers referred to as “relators,” who may initiate an action in the name of the government and the individual and may share in any monetary recovery. Violations of the FCA can result in treble damages, mandatory per claim penalties, and exclusion from participation in federal health care programs. Most states have adopted similar state false claims laws, some of which are broader than the FCA, and these state laws have their own penalties which may be in addition to FCA penalties.

The Health Care Reform Law significantly strengthened the FCA and federal Anti-Kickback Law provisions, which could lead to the possibility of increased whistleblower or relator suits, and among other things, made clear that a federal Anti-Kickback Law violation can be a basis for federal FCA liability. The bringing of any FCA or other enforcement investigation or action, even if unsuccessful, could require us to devote resources to investigate and defend the action, as well as result in reputational harm. Failure to comply with fraud and abuse laws could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. In addition, many of these laws are vague, subject to modification, and are subject to evolving interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance. We cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws, could have a material adverse effect on our business.

In addition to the above, several other laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements

generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

For example, the federal Health Insurance Portability and Accountability Act of 1996, and its implementing regulations (collectively, “HIPAA”), created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti-Kickback Law, a person or entity can be found guilty of violating the HIPAA fraud statute without actual knowledge of the statute or specific intent to violate it.

### ***Privacy Laws***

In the U.S., we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state data breach notification laws, state health information and/or genetic privacy laws and federal and state consumer protection laws (e.g., Section 5 of the FTC Act and the California Consumer Privacy Act (“CCPA”)), govern the collection, use, disclosure, and protection of health-related and other personal information. Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Federal regulators, state attorneys general, and plaintiffs’ attorneys, including class action attorneys, have been and will likely continue to be active in this space.

HIPAA imposes requirements relating to the privacy, security and transmission of individually identifiable health information. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the CCPA became effective on January 1, 2020 and establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. The CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners.

If we, our agents, or our third-party partners fail to comply or are alleged to have failed to comply with these or other applicable data protection and privacy laws and regulations, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

Outside the U.S., the legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation, which entered into effect on May 25, 2018 and imposes penalties up to 4% of annual global turnover. In addition, laws and regulations enacted in the United States, Europe, Asia, and Latin America increases potential enforcement and litigation activity.

### ***U.S. Health Care Reform Law***

Our financial prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to, among other things, health care availability, or the method of delivery of or payment for health care products and services could negatively impact our business, operations and financial condition.



For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Health Care Reform Law. The Health Care Reform Law substantially changed the way health care is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. The Health Care Reform Law contains provisions that may reduce the profitability of drug products, including, for example, by increasing the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care plans, addressing a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and imposing certain annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Health Care Reform Law established and provided significant funding for a new Patient-Centered Outcomes Research Institute to coordinate and fund comparative effectiveness research. While the stated intent of comparative effectiveness research is to develop information to guide providers to the most efficacious therapies, outcomes of comparative effectiveness research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results.

Certain provisions of the Health Care Reform Law have been subject to judicial challenges, as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the tax-based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare prescription drug plans, commonly known as the "donut hole," by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%. Additional legislative changes, regulatory changes and judicial challenges related to the Health Care Reform Law remain possible. It is unclear how the Health Care Reform Law and its implementation, as well as efforts to repeal, replace or otherwise modify, or invalidate, the Health Care Reform Law, or portions thereof, will affect our business. Another provision of the Health Care Reform Law, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made (starting in 2021) to certain non-physician providers such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. CMS publishes information from these reports on a publicly available website. Our compliance with these rules may also impose additional costs and may impact our relationships with physicians, teaching hospitals, and the other non-physician health care providers.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, among other things led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2% per fiscal year beginning April 1, 2013, and, due to subsequent legislation, will continue until 2030 (with the exception of a temporary suspension from May 1, 2020, through March 31, 2021) unless Congress takes additional action.

Additional legislative changes, regulatory changes or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates.

Further, there has been increasing legislative, regulatory and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. And, on November 20, 2020, CMS issued an interim final rule to implement a "Most Favored Nation" demonstration project to test Medicare Part B reimbursement of certain separately payable drugs and biologics based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. If the rule survives judicial scrutiny, the Most Favored Nation model will subject certain drugs or biologics identified by CMS as having the highest annual Medicare Part B spending to an alternative payment methodology based on international reference prices, with the list of products to be updated annually to add more products and products not to be removed absent limited circumstances. There has also been legislation that would establish an international reference price-based Medicare Part B drug and biological payment methodology.

It is possible that the Health Care Reform Law, as currently enacted or may be amended or otherwise modified in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare payment and other health care financing, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. These continuing health care reform initiatives may adversely affect:

- the demand for any product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

### ***Coverage and Reimbursement***

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, 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 coverage and adequate reimbursement is not available, or is available only to limited levels, 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 pricing sufficient to realize a sufficient return on our investment.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

### ***Environmental Regulations***

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involve the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Act regulations.

### ***Pricing Regulations***

There have been a number of federal and state legislative changes made over the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the health care system of the United States. Concerns about drug pricing have been expressed by members of Congress and prior presidential administrations. It is uncertain how such legislative changes will be adopted or what actions federal, state or private payers for medical goods and services may take in response to such legislation. We cannot predict the effect such health care changes will have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

## **Non-U.S. Government Regulations**

### ***European Drug Development***

Our products will also be subject to extensive regulatory requirements in the European Union. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained. See “European Marketing Authorization” below.

As in the United States, the various phases of preclinical and clinical research in European Union are subject to significant regulatory controls. The EU Clinical Trials Directive (2001/20/EC) (Clinical Trials Directive) provides the clinical trials regulatory framework in the European Union, but the European Union member states have transposed and applied the provisions of the Directive differently. This has led to significant variations in the regimes of the different member states. Under the current regime, before a clinical trial can be initiated it must be approved in each of the European Union countries where the trial is to be conducted by the relevant National Competent Authority (“NCA”), and one or more Ethics Committees (“ECs”), and a Clinical Trial Authorization must be obtained.

Similar to the FDA, Europe’s Committee for Medicinal Products for Human use (“CHMP”) has adopted ICH S6 as a guideline governing preclinical testing of biologics. Sponsors usually must conduct pharmacodynamic (“PD”) studies, such as *in vitro* binding assays and *in vivo* studies that assess the product’s pharmacologic activity and define its mechanism of action. Biologics typically undergo single- and repeat-dose toxicity studies using relevant species. Safety pharmacology studies, which evaluate the product’s functional effects on major body systems and specific organs, and local tolerance testing can be done separately or subsumed in toxicity testing. Sponsors also usually conduct single- and multiple-dose pharmacokinetic (“PK”) and/or toxicokinetic studies to assess absorption, disposition, exposure and clearance (in particular, antibody-mediated clearance), and explore dose-response relationships. This information is used to predict margins of safety for human studies. Immunogenicity testing might include screening and mechanistic studies.

### ***Clinical Trial Authorization in the European Union***

The Clinical Trials Directive and European Commission guidance describe the steps that a sponsor must take before commencing a clinical trial in the European Union. According to these documents, a clinical trial may commence only if: (i) the anticipated therapeutic and public health benefits outweigh any foreseeable risks and inconveniences to the subjects; (ii) the trial subjects understand the objectives and risks of the trial and give informed, written consent to participate; (iii) the trial safeguards the physical and mental integrity of the subjects; and (iv) insurance covers the liability of the sponsor and investigator. To comply with these requirements, the trial sponsor must take certain steps. In general, the sponsor must take responsibility for trial conduct, appointment of an appropriate investigator, selection of the institution that will conduct the trial, quality control, data collection standards, protocol drafting, and creation of the investigator’s brochure. The sponsor then must apply for approval from both the ethics committee and the relevant NCA in the member state. Written authorization may be required for all biologics trials and is required for trials involving medicines containing genetically modified organisms, medicines for gene therapy, and medicines for somatic cell therapy (including xenogeneic cell therapy). The opinion of the ethics committee should be issued within 60 days. A review period of 30 days can be added for medicines requiring written authorization noted earlier, and for xenogeneic cell therapy, there are no time limits for authorization. This timeframe can be extended by an additional 90 days (in addition to the original 90 days) if the ethics committee consults a national group or committee. The trial may begin only if (i) the ethics committee has issued a favorable opinion and (ii) no competent authority has informed the applicant of grounds for non-acceptance.

### ***Good Clinical Practices and Other Considerations for Clinical Trials***

Clinical trials of biologics must comply with GCP, as described in Directive 2005/28/EC on Good Clinical Practice and the ICH E6 guideline, which the CHMP has adopted. The directive and guideline describe general governing principles for clinical trials. The rights, safety and well-being of trial subjects must prevail over the interests of science and society. Investigators must obtain freely given informed consent from every trial subject before each subject is enrolled. Clinical trial information must be handled, recorded and stored with respect for relevant confidentiality and privacy rules. Trials must comply with the ethical principles of the World Medical Association’s Declaration of Helsinki. Specific GCP guidelines apply to trials of advanced therapy medicinal products. These guidelines regulate issues such as the donation, procurement and testing of human tissues and cells; the implementation of a traceability system; and specific rules on safety reporting and long-term follow-up. Under the Clinical Trials Directive, special requirements apply to clinical trials conducted on minors and other persons not able to give informed legal consent. These requirements are intended to preserve the dignity of the trial subjects, confirm that the benefits of the trial outweigh the risks and ensure that subjects’ representatives give consent with as much involvement of the subject as possible. Competent authorities must record information regarding trials in the European database of clinical trials which is accessible only to other competent authorities, the European Medicines Agency (“EMA”), and the European Commission. CHMP has issued a guideline on quality requirements during the clinical trial period for investigational medicinal products containing biological or biotechnology-derived substances. The guideline describes quality documentation that should be submitted to the competent authority as part of the sponsor’s investigational

medicinal product dossier (“IMPD”). The IMPD should include, among other things, (i) an adequate description of the process and process controls, including a flow chart of all successive steps and details of in-process testing and (ii) a description and justification of “any reprocessing during manufacture of the drug substance.” The guideline also recognizes that sponsors will improve and optimize their manufacturing processes during clinical development and describes the steps sponsors should take following these changes. Specifically, the sponsor must compare the quality attributes of the pre- and post-change biological active substances and relevant intermediates and conduct a comparability exercise where necessary. For first-in-human clinical trials, sponsors should use product representative of the material used during the non-clinical testing phase. Finally, with regard to characterization, the guideline requires details on the biological activity to be provided, recognizing that the extent of characterization data will further increase in later phases.

### ***Study Design Considerations***

General regulatory guidance on study design applies to biologics as well as small molecule medicines. According to the guidance, there is a “close, but variable correlation” between phase of development and type of study, but one type of trial can occur in several different phases. The guidance therefore identifies the most typical kind of study for each phase.

Phase 1 usually involves the initial introduction of the investigational product into human subjects, and studies in this phase usually have non-therapeutic objectives. Specifically, Phase 1 studies typically investigate initial safety and tolerability, PK, PD and/or drug activity, to preliminarily determine the potential therapeutic benefit of a medicine. Phase 1 studies may be conducted in healthy volunteers or certain types of patients. If the medicine has significant potential toxicity (e.g., cytotoxic products), the trial will usually be conducted in patients.

The most typical Phase 2 study is a therapeutic exploratory study that explores efficacy in narrowly defined, relatively homogenous groups of patients. Initially, studies may use a variety of designs (e.g., concurrent controls and comparisons with baseline status). Subsequent Phase 2 trials usually are randomized and concurrently controlled, allowing for evaluation of the medicine’s safety and efficacy for a particular indication. A major goal of this phase is to determine the dose(s) for Phase 3 trials.

Phase 3 typically involves therapeutic confirmatory studies that are designed to verify the preliminary evidence obtained in Phase 2 and to provide a sufficient basis for marketing authorization. Phase 3 studies may also further explore the dose response relationship, or explore the drug’s use in wider populations, in different stages of disease, or in combination with another drug. With regard to medicines administered for long periods, extended exposure trials ordinarily occur during Phase 3, although the sponsor may start them in Phase 2.

To ensure that clinical trials in all three phases of development will be adequate to support a Marketing Authorization Application (“MAA”), sponsors should design these trials with the MAA requirements in mind. Biologics in general need to comply with the requirements set out in Part III of the Annex I to Directive 2003/63/EC (which amends the core EU medicines legislation, Directive 2001/83/EC), and advanced therapy medicinal products need to comply with the requirements described in Part IV.

### ***Consultation with the European Medicines Agency***

A sponsor may obtain, from the EMA, scientific advice regarding clinical trial protocols. Although this advice does not bind the ethics committees or NCAs and is not binding for purposes of a future MAA, it can be useful to guide revisions to the protocol. EMA’s remarks will only address scientific issues and will generally focus on matters such as the selection of endpoints and comparator, the duration of treatment or follow-up and the design of pivotal studies. Advice also might address a sponsor’s proposal to deviate from a CHMP guideline. If the applicant decides not to follow the EMA’s advice, it should justify this decision in its MAA. EMA guidance details the procedures for requesting scientific advice. The fact that an applicant requests advice from EMA does not preclude it from also seeking advice from national competent authorities or from foreign regulators, such as the FDA. The process of obtaining advice from the national competent authorities is often less formal than requesting advice from the EMA, and such advice can prove helpful. Consequently, seeking such advice is a common choice among applicants. Generally, the parallel scientific procedure is available for “important breakthrough drugs,” that is, products that the EMA and FDA have identified as falling within therapeutic areas of overlapping interest (e.g., oncology products, vaccines and blood products). The goal of these meetings is to provide clarity regarding the regulatory requirements of each region and the reasons for any differences between them. A sponsor requesting parallel scientific advice should authorize the agencies to exchange all information about the product, including trade secrets. After the parallel scientific advice procedure, each agency will provide its own independent advice on the questions at issue. There is no guarantee of harmonized advice or identical regulatory decisions on the approvability of the product.

### ***European Marketing Authorization***

In the European Economic Area (“EEA”), which includes the 27-member states of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be placed on the market after approval of a Marketing Authorization Application, or

MA. The MA is based on the results of pharmaceutical tests, preclinical tests and clinical trials conducted on the medicinal product in question. There are two types of MAs:

- The Centralized MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the CHMP and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of drugs, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing new active substances indicated for certain diseases. The Centralized Procedure is optional for other drugs provided eligibility criteria are met. In all cases, to find out whether a product can be evaluated via the Centralized Procedure, applicants must always submit an eligibility request.
- National MAs, which are issued by the competent authorities of the member states of the EEA and only cover their respective territory, are available for drugs not falling within the mandatory scope of the Centralized Procedure. Where a drug has already been authorized for marketing in a member state of the EEA, this National MA can be recognized in other member states through the Mutual Recognition Procedure. If the drug has not received a National MA in any member state at the time of application, it can be approved by multiple member states in parallel through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the drug on the basis of scientific criteria concerning its quality, safety and efficacy.

#### ***The Marketing Authorization Application: Contents and Approval Standard***

Many biologics fall under the scope of the Centralized Procedure, which, as mentioned above, is mandatory for medicines developed through biotechnological methods, such as recombinant DNA technology; controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells; and hybridoma and mAb methods. For example, cell therapy, gene therapy, vaccines from strains developed through recombinant DNA technology (including gene deletion), and “any medicinal product for which a monoclonal antibody is used at any stage in the manufacturing process” are all subject to the Centralized Procedure. Nonetheless, some biologics are still approved at the member state level. For example, many vaccines do not fall within the scope of the Centralized Procedure. The EMA has published a guideline intended to harmonize the summaries of product characteristics and patient information leaflets for human vaccines.

With respect to the Centralized Procedure, the approval standards for biotechnology products are the same as for chemically synthesized medicines. Both types of products must be safe and effective and have appropriate quality. Because of their special characteristics, however, biotechnology products must comply with several additional dossier requirements. The MAA for a biotechnology product must meet the standard dossier submission requirements, as described in Article 8 of the Medicines Directive (2001/83/EC). Consequently, the MAA must generally comply with the Common Technical Document format, including with respect to Module 1 (administrative information, including labeling and mock-ups), Module 2 (various summaries), Module 3 (chemical, pharmaceutical and biological information), Module 4 (non-clinical reports) and Module 5 (clinical study reports). MAAs for biologics also must meet special requirements. The applicant must thoroughly describe the manufacturing process and must: (i) provide information on the origin and history of the starting materials; (ii) demonstrate that the active substance complies with specific measures for preventing the transmission of animal spongiform encephalopathies; (iii) if cell banks are used, demonstrate that cell characteristics remain unchanged at the passage level for production (and beyond); (iv) provide information as to whether there are adventitious agents in seed materials, cell banks, pools of serum or plasma, and all other materials of biological origin, and, if it is not possible to avoid the presence of potentially pathogenic adventitious agents, show that further processing ensures elimination or inactivation of the agents; (v) if possible, base vaccine production on a seed lot system and established cell banks; (vi) in case of medicines derived from human blood or plasma, describe the origin, criteria and procedures for the collection, transportation and storage of the starting material; and (vii) describe the manufacturing facilities and equipment. Other special rules apply certain types of biological medicines. For example, for plasma-derived medicinal products, the applicant must provide an information dossier, the Plasma Master File. MAAs for vaccines other than for influenza need to contain a Vaccine Antigen Master File. Special rules also apply to advanced therapy medicinal products, including gene therapies, somatic cell therapies and tissue-engineered products.

#### ***Data and Market Exclusivity in the European Union***

In the European Union, new medicinal products qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity prevents regulatory authorities in the European Union from referencing the innovator’s data to assess a generic or biosimilar application for eight years, after which generic or biosimilar marketing authorization can be submitted, and the innovator’s data may be referenced, but not approved for two years. The overall ten-year period may be extended to a maximum of 11 years if, during the period of data exclusivity, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

### ***Orphan Designation in the European Union***

The European Commission is also able to grant orphan designation in respect of medicinal products. To qualify the medicinal product must be intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the European Union where without incentives it is unlikely that the marketing of the medicinal product in the European Union would generate sufficient return to justify the necessary investment. Further, no satisfactory method of diagnosis, prevention or treatment of the condition in question must exist in the European Union or, if such method exists, the medicinal product must be of significant benefit to those affected by that condition.

Orphan medicinal products still remain subject to the same regulatory approval process, albeit that they are always assessed through the Centralized Procedure. Effective September 19, 2018, sponsors applying for Orphan Designation must use EMA's secure online IRIS platform. However, sponsors of orphan medicinal products are eligible to benefit from a number of incentives offered, including certain assistance with development of the medicinal product, reduced fees for MA applications and protection from market competition once the medicinal product is authorized, as below.

Where an MA in respect of an orphan medicinal product is granted, the European Commission, EMA and the competent authorities of the member states shall not, for a period of ten years, accept another application for an MA, or grant an MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar medicinal product, unless: (i) the holder of the MA for the original orphan medicinal product has given its consent to the second applicant; (ii) the holder of the MA for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product; or (iii) the second applicant can establish the second medicinal is safer, more effective or otherwise clinically superior.

### ***Other government regulation in the European Union***

The European Union and the European Union member states have extensive laws and regulations relating to a variety of other topics that would be of relevance for us if we are active in the European Union, including but not limited to laws and regulations regarding data privacy, drug pricing and reimbursement, advertising and interactions with healthcare professionals.

### **Other Jurisdictions**

In addition to regulations in the United States and the European Union, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product. As the United Kingdom is no longer a member state of the European Union, this may also apply to the United Kingdom. Whether or not we obtain FDA approval for a product, we must obtain approval from comparable regulatory authorities in foreign countries before we can commence clinical trials in such countries and the approval of the regulators of foreign countries before we may market products in such countries. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

### **Acceptance of Foreign Clinical Trials in the United States and Europe**

The FDA has issued regulations governing its acceptance of foreign clinical data not conducted under an IND to support IND applications or marketing authorizations, such as BLAs. FDA may accept a well-designed, well-conducted, non-IND foreign study as support for an IND or marketing application if the study was conducted in accordance with GCP and if FDA is able to validate the data from the study through an onsite inspection, if necessary. Where a marketing application is based solely on foreign data, additional requirements apply, including a demonstration that the foreign data are applicable to the U.S. population and U.S. medical practice.

EU Directive 2001/83/EC allows for clinical trials conducted outside the European Union to be taken into consideration during the review of an MAA in the European Union if such trials have been designed, implemented and reported based on principles equivalent to those of the Clinical Trials Directive with regard to good clinical practice and ethical principles. Moreover, they should comply with the ethical principles outlined in the Declaration of Helsinki. The applicant must submit a statement declaring such compliance as part of the MAA. In December 2008 and April 2012, the EMA published a strategy paper on the acceptance of data from foreign clinical trials conducted in "third countries," particularly those outside the "'traditional' Western European and North American research areas." According to the 2008 strategy paper, there is a "growing concern both among regulators and in public debate about how well these trials are conducted from an ethical and scientific/organizational standpoint." The EMA has called for increased cooperation between international regulatory authorities involved in the supervision of clinical trials and has put forth other proposals to address these issues.

## **Manufacturing and Source of Supply**

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical studies and clinical trials, as well as for commercial manufacture if our product candidates receive marketing approval. To date, we have obtained materials for clinical trials and non-clinical studies from third-party manufacturers who are suppliers to us. For our product candidates, we intend to identify and qualify additional contract manufacturers to provide commercial scale manufacturing prior to submission of a BLA to the FDA.

## **Employees and Human Capital Management**

As of December 31, 2020, we had 43 full-time employees, 11 of whom hold M.D. or Ph.D. degrees and 5 of whom hold other advanced degrees. In light of the COVID-19 pandemic, our headcount has grown by 72% in the past year in order to support our pipeline of research programs and product candidates. Of our total workforce, 27 are engaged primarily in research and development activities and 16 are engaged primarily in executive, finance and accounting, and administrative functions. As of December 31, 2020, 42 employees are in the United States and one employee in the United Kingdom. None are represented by labor unions or covered by collective bargaining agreements. We consider our relations with our employees to be good.

### *Compensation and Benefits Program*

Our compensation program is designed to attract and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create long-term value for our stockholders. We provide employees with what we consider to be a very competitive mix of compensation and insurance benefits for all our employees, as well as participation in our equity programs.

### *Diversity and Inclusion*

We believe that an equitable and inclusive environment with diverse teams produces more creative solutions, results in better, more innovative products and services and is crucial to our efforts to attract and retain key talent.

### *Hybrid Culture and COVID-19*

Like other companies, we have learned to adapt during the COVID-19 pandemic. We have prioritized employee safety and transparency during the pandemic and continue to do so, ensuring all employees are set up to work remotely and providing clarity on office closures and evolving guidelines, where possible. In the second quarter of 2020, we made the decision to move to a hybrid workplace model, which means that certain of our employees will have the option to be 100% remote, work full-time in our office, or have the flexibility to work between office and remotely until the pandemic is resolved. This move provides our employees with continued flexibility, through the resolution of the pandemic, to work in person, remotely, or in a hybrid model. This will enable us to grow better as we develop our programs.

## **Available Information**

Our stock is traded on the Nasdaq Global Market (“NASDAQ”) under the symbol “ALT”. Our principal executive offices located at 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878. Our telephone number is (240) 654-1450, and our Internet website is [www.altimmune.com](http://www.altimmune.com) and our investor relations website is located under the “Investors” tab. The information on, or that can be accessed through, our website is not part of this Annual Report and is not incorporated by reference herein.

We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, and amendments to these reports, free of charge through our website ([www.altimmune.com](http://www.altimmune.com)) as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We also make available on our website reports filed by our executive officers and Directors on Forms 3, 4, and 5 regarding their ownership of our securities. Our Code of Business Conduct and Ethics, and any amendments to our Code of Business Conduct and Ethics, are also available on our website under the “Investors” tab.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov).

## **Item 1A. Risk Factors**

*In addition to the other information included in this Annual Report, the following risk factors should be carefully considered when evaluating an investment in us. These risk factors and other uncertainties may cause our actual future results or performance to differ materially from any future results or performance expressed or implied in the forward-looking statements contained in this report and in other public statements we make. In addition, because of these risks and uncertainties, as well as other variables*

*affecting our operating results, our past financial performance is not necessarily indicative of future performance. See “Forward-Looking statements” in Item 1 of this Annual Report.*

## **Risks Related to Our Business, Financing Requirements, Product Development and Clinical Trials**

### ***Our ability to raise capital may be limited by applicable laws and regulations.***

Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, SEC rules and regulations. Under SEC rules and regulations, if our public float (the market value of our common stock held by non-affiliates) is less than \$75.0 million, then the aggregate market value of securities sold by us or on our behalf under our Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. While our public float is currently more than \$75.0 million, we have been subject to this limitation in the past and we may be subject to it again in the future. If our ability to utilize a Form S-3 registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

In addition, under current SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least \$75.0 million as of a date within 60 days prior to the date of filing the Form S-3 or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). While currently our common stock is listed on the NASDAQ Global Market, there can be no assurance that we will be able to maintain such listing.

Our ability to timely raise sufficient additional capital also may be limited by NASDAQ’s stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, NASDAQ requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our then outstanding common stock, unless the transaction is considered a “public offering” by NASDAQ. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering without stockholder approval. NASDAQ also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by NASDAQ to result in a change of control of our company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital or alter the terms of the transaction, which may materially and adversely affect our ability to execute our business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

### ***We have incurred significant losses since our founding and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.***

We are a clinical-stage biotechnology company and have not yet generated revenues from product sales. To date, substantially all of our revenues have been derived from grants and contracts with governmental agencies, consisting primarily our BARDA contract for our anthrax vaccine product candidate. We have incurred net losses in most periods since our inception, including a net loss of \$49.0 million and \$20.5 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we have an accumulated deficit of \$186.4 million. To date, we have not received regulatory approvals for any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable.

We have devoted most of our financial resources to research and development, including preclinical and clinical development of our product candidates. We have not completed pivotal clinical trials for any product candidate. Our leading product candidates remain in early stage clinical development, and it may be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payers and other factors.



The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

***Our profitability depends on our ability to develop and commercialize our current and future product candidates.***

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, forming strategic partnerships and alliances with third parties and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability. If some or all of our product candidates do not prove to be safe, pure and efficacious, then we may have to abandon those product candidates altogether and we will be unable to generate revenues from sales of such products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue our clinical trials for our product candidates;
- initiate additional preclinical studies, clinical trials or other studies or trials for our other product candidates;
- manufacture material for clinical trials and, if any product candidate is approved for marketing, for commercial sale;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make royalty, milestone or other payments under any in-license agreements;
- form strategic partnerships and/or makes additional acquisitions;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

***Future conditions might require us to make substantial write-downs in our assets, which would adversely affect our balance sheet and results of operations.***

We review our long-lived tangible and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. We also test our indefinite-lived intangible assets for impairment at least annually in the fourth quarter, or when events or changes in the business environment indicate that the carrying value of the reporting unit may exceed its fair value. During 2019, the development activities under our SparVax-L governmental contract were completed with no future funding identified. As a result of the contract completion and the US government's funding prioritization of only single dose anthrax vaccine candidates, we impaired \$1.0 million for the remaining net book value of the SparVax-L IPR&D asset during 2019. At December 31, 2020, we continued to carry \$12.4 million of indefinite lived intangible assets. Any such significant write-downs of our long-lived assets in the future could adversely affect our balance sheet and results of operations.

***We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts.***

We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in an amount sufficient to fully fund our operations for the foreseeable future, if ever. Therefore, we will use our existing cash resources, together with funding received from BARDA and MTEC, and will require additional funds to maintain our operations, continue our research and development programs, commence future preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our products. As of December 31, 2020, our cash and short-term investment balance was \$216.0 million. Based on our current operating plan, we believe that our existing cash will be sufficient to fund our projected operating expenses and capital expenditure requirements for at least a twelve-month period from the issuance date of our December 31, 2020 financial statements. However, we do not expect that these funds will be sufficient to enable us to complete the clinical trials needed to seek marketing approval or commercialize any of our product candidates. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We believe that we will continue to expend substantial resources for the foreseeable future developing our product candidates. These expenditures will include costs associated with research and development, maintaining our intellectual property estate, potentially acquiring new technologies, obtaining regulatory approvals and manufacturing products, forming partnerships and strategic alliances, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the progress, results and costs of our clinical trials for our leading product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the amount of funding that we receive from BARDA, MTEC, other government agencies and other non-dilutive funding sources;
- the number and development requirements of other product candidates that we pursue;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful and the outcome of regulatory review of our product candidates;
- our ability to contract with third-party manufacturing facilities for adequate supply and to establish processes that meet regulatory requirements for commercialization;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing and prosecuting patent applications, and maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation.

We may also seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

***Raising additional capital may cause dilution to stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates on unfavorable terms.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, BARDA funding, MTEC funding and license and development agreements through strategic partnerships with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that

adversely affect your rights as a stockholder. Debt or preferred stock financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, issuing additional equity, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates, or otherwise grant licenses on terms that are not favorable. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our leading product candidates or our preclinical product candidates, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.***

Our preclinical and clinical results are not necessarily predictive of the final results of our ongoing or future clinical trials. We have completed a Phase 2 clinical trial of NasoVAX; have initiated a Phase 2 clinical trial of HepTcell; are conducting a Phase 1/2 clinical trial of T-COVID; and, are currently in Phase 1 clinical development with NasoShield, ALT-801, and AdCOVID. Success in preclinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials of a product candidate may not be replicated in later and larger clinical trials. Interim results from clinical trials may not be predictive of final results from clinical trials. Additionally, we have utilized an “open-label” trial design in the past, and may do so again in the future. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Clinical trials are expensive, time consuming and uncertain as to outcome, and we cannot guarantee that any of these activities will be successful. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet our clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates, or we may determine to suspend development of or abandon specific product candidates. For example, we suspended the development of a Densigen platform-based product candidate, Flunisyn, which was being developed as a T-cell vaccine for the treatment of influenza, in favor of NasoVAX. Clinical trials with this product candidate showed that it was generally well-tolerated and able to induce robust T-cell responses against the viral sequences represented, but a comparison of the entire study population in later-stage clinical trials showed no statistical differences between the vaccinated and placebo groups for several measures of protection.

In addition, we can offer no assurances that we have correctly estimated the resources or personnel necessary to seek partners, co-developers or acquirers for our programs. If a larger workforce or one with a different skillset is ultimately required to maintain these operations, we may be unable to maximize our existing programs.

***The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to acquisition of materials, process development or scaling-up of our manufacturing capabilities.***

The manufacture of our product candidates is complex, highly-regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with our clinical development plans and add additional costs. It is possible that we will make changes to our manufacturing process at various points during product development or commercialization for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes can be costly and carry the risk that they will not achieve their intended objectives, or these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of a commercialized product. In some circumstances, changes in the manufacturing process may require us to perform analytical or clinical comparability studies and to collect additional data prior to undertaking more advanced clinical trials, and such studies may introduce additional costs or delays to the program. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process

and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate.

In 2020, we initiated the manufacture of clinical lots of AdCOVID and in parallel began technology transfer to multiple commercial scale CMOs in preparation for process scale-up. Although we have added, and are continuing to add, employees with experience in manufacturing products similar to our product candidates, we have limited experience as a company manufacturing product candidates for use in clinical trials and no experience as a company manufacturing product candidates for commercial supply. We may never be successful in manufacturing product candidates in sufficient quantities or with sufficient quality for some or all of our clinical or commercial uses. Even if we are successful in developing our manufacturing capabilities sufficient for our clinical and commercial uses, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, operator error, natural disasters, availability of qualified personnel, difficulties with logistics and shipping, problems regarding yields or stability of product, product contamination or other quality control issues, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

Compliance with cGMP requirements and other quality or regulatory issues may arise during our internal efforts to manufacturing our product candidates, and with our current or any future CMOs. Furthermore, ongoing stability studies subsequent to manufacture must be periodically conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over its shelf life. If issues affecting the quality of our product candidates, our manufacturing facilities, or those of our CMOs are discovered, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the issue. To the extent any adversely affected material is being used in an ongoing clinical trial, the FDA could impose a clinical hold on our study to investigate and remedy the quality issue. We cannot assure that any manufactured product or product candidate will not suffer a loss in stability or that other issues relating to the manufacture of our product candidates will not occur in the future.

Additionally, we and our CMOs may experience manufacturing difficulties due to resource constraints, material constraints, or as a result of labor disputes or unstable political environments. If we or our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

***We may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays or failure in reaching a consensus with regulatory agencies on trial design;
- delays or failure in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- delays or failure in obtaining required approvals from the Institutional Review Board (“IRB”) or other similar committees or bodies at each clinical trial site;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability or after an inspection of clinical operations or trial sites;
- failure to perform clinical trials in accordance with the FDA’s Good Clinical Practices (“GCP”) or applicable regulatory guidelines in other countries, including the United Kingdom;
- delays or failure in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- any shelter-in-place orders from local, state or federal governments or clinical trial site policies resulting from the COVID-19 pandemic that determine essential and non-essential functions and staff, which may impact the ability of site staff to conduct assessments, or result in delays to the conduct of the assessments, as part of our clinical trial protocols, or the ability to enter assessment results into clinical trial databases in a timeline manner;

- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may, including as a result of the COVID-19 pandemic, withdraw from our clinical trials, fail to complete dosing or fail to return for post-treatment follow-up at higher rates than we anticipate, any of which could result in significant delay;
- withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- occurrence of serious adverse events in clinical trials that are associated with the product candidate that are viewed to outweigh its potential benefits;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators or funders may require us, to conduct additional preclinical testing or clinical trials or to abandon projects that we expected to be promising;
- our third-party contractors (such as CROs, product manufacturers, or investigators) may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review or one or more of our marketing applications by regulatory agencies;
- the cost of our clinical trials may be greater than we anticipate;
- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge by jurisdiction;
- evolution in the standard of care that require amendments to ongoing clinical trials and/or the conduct of additional preclinical studies or clinical trials; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial. For example, we have had delays in previous clinical trials, including those conducted for NasoVAX, as a result of clinical holds imposed by the FDA or other regulatory authorities and requests for additional or new information on vaccine product testing in connection with an Investigational New Drug (“IND”) submitted to the FDA. We have previously experienced multiple failures during the manufacturing of clinical materials for use in a future NasoVAX Phase 2 clinical trial.

We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by manufacturing failures or other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

Even if our clinical trials are successfully completed as planned, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would significantly adversely affect our business prospects.

***We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.***

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. If patients are unwilling to participate in our trials because of the COVID-19 pandemic and restrictions on travel or healthcare institution policies, negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies and

obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by several factors, including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate being tested;
- willingness or availability of patients to participate in our clinical trials (including due to the COVID-19 pandemic);
- proximity and availability of clinical trial sites for prospective patients;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- our ability to obtain and maintain patient consents;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies.

Even if we enroll a sufficient number of eligible patients to initiate our clinical trials, we may be unable to maintain participation of these patients throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those patients. For example, we may face difficulties in identifying patient populations with active disease to enroll in our HBV product clinical trial for HepTcell. Other clinical trials involving patients with active HBV have sometimes faced difficulties in working with these patient populations, which may include significant numbers of individuals with difficulties with treatment compliance, such as active drug users. While we are developing strategies to address this issue, there is no guarantee that these strategies will prove successful.

If we have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

***It may be difficult to predict the time and cost of product development. Unforeseen problems may prevent further development or approval of our product candidates.***

Our product candidates, including vaccines and immunotherapies, involve novel approaches to activate the immune system. Consequently, it may be difficult to predict the time and cost of product development. For example, the RespirVec platform involves intranasally administered adenovectored vaccines, the Densigen platform involves synthetic peptide T-cell vaccines and, the EuPort platform involves a novel peptide-based dual GLP-1/glucagon receptor agonist. Unforeseen problems with our approaches to vaccines and therapies may prevent further development or approval of our product candidates. Because of the novelty of our approaches, there may be unknown safety risks associated with the vaccines that we develop or the clinical endpoints that we establish in trials may not be generally accepted by regulatory agencies, which may therefore require us to perform large field studies to demonstrate efficacy. There can be no assurance that any development problems we may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved.

In addition, novel vaccine adjuvants, which are included in HepTcell, our product candidate based on the Densigen technology, 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. 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 in people with disease. As a result, although it is anticipated that HepTcell is intended for the treatment of patients suffering from a disease, regulatory agencies such as the FDA may nevertheless require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe adverse events caused by our product candidates that include novel vaccine adjuvants.

If approved, the novel mechanism of action of the vaccines may adversely affect physician and patient perception and acceptance of our products. Public perception of vaccine safety issues, including adoption of novel vaccine mechanisms of action, may adversely influence willingness of subjects to participate in clinical trials, or if approved, to prescribe and receive novel vaccines. For example, GSK pulled from the market an approved vaccine to prevent Lyme disease (Lymerix) in February 2002 after anecdotal evidence of joint pain resulted in subjects' unwillingness to receive the vaccine. The FDA found no evidence that the vaccine caused a safety risk; however, GSK pulled the vaccine due to low sales resulting from the negative public perception associated with the reports on joint pain. In addition, parental aversion to new vaccines or vaccines in general may adversely influence later stage clinical trials of our COVID-19 product candidates or, if approved, its commercial success.

***We rely, and expect to continue to rely, on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.***

We rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to assist in managing, monitoring and otherwise carrying out our clinical trials. We compete with many other companies for the resources of these third parties. The third parties on whom we rely generally may terminate their engagements at any time and causing us to enter into alternative arrangements would delay development and commercialization of our product candidates.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with applicable law, regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials complies with GCP requirements. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with applicable law, regulations and standards, including our general investigational plan and protocol.

Furthermore, if these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, then the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, then preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our preclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they cannot perform their contractual duties or obligations due to the impacts of the COVID-19 pandemic on their operations or at the sites they are overseeing, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, receive regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third parties terminates, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. Switching or adding additional third party service providers involves

additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party service provider begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

***We face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.***

The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we intend to commercialize, if successfully commercialized, will compete with existing market-leading products.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products.

Large and established companies such as Roche, Novartis, Pfizer and Sanofi Pasteur, among others, compete in the same market as our product candidates. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete. We also 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 face competition from multiple biotechnology and bio-pharmaceutical companies, such as Pfizer, Moderna, AstraZeneca, Regeneron and Johnson & Johnson, that are in the process of developing vaccines and therapeutics against COVID-19. Certain of these vaccine and therapeutic technologies are being developed at a faster rate than AdCOVID and T-COVID or have superior immunogenicity or manufacturability attributes. We face competition for NasoShield, our single dose intranasal anthrax vaccine product candidate, from Emergent Biosolutions which manufactures the existing anthrax vaccine. Additionally, we generally face substantial competition for government funding from companies that develop products with government contracts and grants. We face competition for NasoVAX, our intranasal influenza candidate from Novavax, which is developing an influenza vaccine; and a number of companies of varying sizes are also pursuing the development of a “universal” flu vaccine. We face competition for ALT-801, our dual GLP-1/glucagon dual agonist product candidate for the treatment of NASH, from companies such as Intercept Pharmaceuticals, which is developing a farnesoid X receptor agonist; Madrigal Pharmaceuticals, which is developing an orally administered, small-molecule, liver-directed, thyroid hormone receptor (THR)  $\beta$ -selective agonist; and, Akero Therapeutics, which is developing a fibroblast growth factor 21 analog. Finally, we face competition for HepTcell, our immunotherapeutic HBV product candidate, from companies such as Transgene which is developing an adenovirus-based vaccine; Arrowhead Pharmaceuticals, which is developing an HBV therapeutic vaccine; and Inovio, which is developing a DNA vaccine delivered by in vivo electroporation. Any of these companies may develop competing products more rapidly than we do.

As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before we do. In addition, any new product that we develop that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow, and our financial condition and operations will suffer.

***We are heavily dependent on the success of our leading product candidates, AdCOVID and ALT-801. If we ultimately are unable to develop, obtain regulatory approval for or commercialize AdCOVID, ALT-801, or any other product candidate, our business will be substantially harmed.***

We currently have no products approved for commercial distribution. Our business strategy is to build a pipeline of product candidates using our proprietary platforms, including our leading product candidates AdCOVID and ALT-801, and to progress those product candidates through clinical development for the treatment of different types of diseases. We may not be able to develop products that are safe and effective for all or any of the indications that we target. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing



approval or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our leading product candidates, AdCOVID and ALT-801, would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates.

***Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- 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 strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent and strength of our third party manufacturer and supplier support;
- the extent and strength of marketing and distribution support;
- the limitations or warnings contained in a product's approved labeling;
- distribution and use restrictions imposed by the FDA or other regulatory authorities outside the United States or that are part of a REMS or voluntary risk management plan; and
- the prevalence and severity of any side effects.

For example, even if our products have been approved by the FDA, physicians and patients may not immediately be receptive to them and may be slow to adopt them. If our products do not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate meaningful revenues and we may not become profitable.

***We may not be able to comply with the requirements of foreign jurisdictions in conducting trials within the United Kingdom, European Union, Australia or any other foreign country.***

We are conducting our Phase 2 clinical trial of HepTcell in the U.S., United Kingdom, Canada, Germany and Spain; conducting our ALT-801 Phase 1 clinical trial in Australia; and future clinical trials may be conducted in other foreign jurisdictions. Our ability to successfully initiate, enroll and complete a clinical trial in any other foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the approval and conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners;

- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of the conduct of clinical trials, pharmaceutical and biotechnology products and treatment; and
- the acceptability of data obtained from studies conducted outside the United States to the FDA in support of U.S. marketing authorizations, such as a BLA.

If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval for our product candidates in the United States or in countries outside of the United States.

***If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.***

We are highly dependent on members of our senior management, including Dr. Vipin Garg, our President and Chief Executive Officer, Will Brown, our Chief Financial Officer, Dr. Scott Harris, our Chief Medical Officer, and Dr. M. Scot Roberts, our Chief Scientific Officer. Although we have entered into employment agreements with each of these members of senior management and key employees, the loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key 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. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than the Company and may have commitments under consulting or advisory contracts with other entities that may limit their availability to the Company. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***A pandemic, epidemic or outbreak of an infectious disease in the United States such as the COVID-19 pandemic may adversely affect our business.***

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and has been declared a pandemic by the World Health Organization. The spread of COVID-19 has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. For example, the COVID-19 outbreak may delay preclinical testing and enrollment in our clinical trials due to prioritization of laboratory and hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Third parties and CROs on which we rely may also reduce staffing which could impact our ability to continue preclinical testing and clinical trials on expected timeframes. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

In response to COVID-19-related government and public health directives and orders, we have implemented work-from-home policies for certain employees. The effects of these orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results, and financial condition.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the coronavirus may impact our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus, the geographic spread of the disease, the duration of the outbreak, and the actions to contain the coronavirus or treat its impact, including travel and other social distancing restrictions in the United States and other countries, among others. A significant outbreak of coronavirus and 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.

***Legal, political and economic uncertainty surrounding the exit of the U.K., from the European Union (“EU”) may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U.K. and pose additional risks to our business, revenue, financial condition, and results of operations.***

On June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted to leave the EU. The U.K.’s withdrawal from the EU is commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on European Union, the U.K. ceased being a Member State of the EU on January 31, 2020. The U.K.’s withdrawal from the EU has created significant uncertainty concerning the future relationship between the U.K. and the EU.

On December 24, 2020, the EU and U.K. reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the U.K. in relation to goods, including medicinal products. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of the Agreement, the EU and the U.K. will recognize Good Manufacturing Practice (GMP) inspections carried out by the other Party and the acceptance of official GMP documents issued by the other Party. The Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures.

Among the areas of absence of mutual recognition are batch testing and batch release. The U.K. has unilaterally agreed to accept EU batch testing and batch release for a period of at least 2 years until 1 January 2023. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the U.K. must be retested and re-released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission.

This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations may negatively impact foreign direct investment in the UK, increase costs, depress economic activity, and restrict access to capital. The uncertainty concerning the UK’s legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit.

These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility. We may also face new regulatory costs and challenges that could have an adverse effect on our operations.

***Our acquisitions may expose us to unknown liabilities.***

Because we have acquired all the outstanding shares of most of our acquired companies, our investment in those companies are or will be subject to all of their liabilities other than their respective debts which we paid or will pay at the time of the acquisitions. If there are unknown liabilities or other obligations, our business could be materially affected. We may also experience issues relating to internal controls over financial reporting, issues that could affect our ability to comply with the Sarbanes-Oxley Act tax examinations by the IRS or state tax authorities, or issues that could affect our ability to comply with other applicable laws.

***Tax laws could change.***

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws resulting from legislative, administrative or judicial decisions may have adverse tax consequences on our business, cash flow, financial condition or results of operations or to a holder of our common stock. Shareholders should consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

***We may not be able to utilize a significant portion of our net operating loss carryforwards, which could harm our results of operations.***

We had U.S. federal and state net operating loss carryforwards of approximately \$45.7 million as of December 31, 2020. Of this amount, \$6.6 million has a 20-year carry forward period that will expire at various dates beginning in 2021. Under current law, the remaining amount of \$39.1 million has an unlimited life and generally may not be carried back to prior taxable years except that net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. For net operating losses arising in taxable years beginning after December 31, 2017, we are permitted a net operating loss deduction that is limited to 80% of our taxable income in such year. The net operating loss carryforwards are reflective of a 382-limitation related to ownership changes. Under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs are subject to limitations arising from previous ownership changes that impact the timing and amount. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change. Accordingly, we may not be able to utilize a material portion of our NOLs and this could harm our future operating results by effectively increasing our future tax obligations.

As of December 31, 2020, we have recorded a valuation allowance of \$18.7 million against our net deferred tax asset.

### **Risks Related to the Development of COVID-19 Therapeutics**

***Our pursuit of potential therapeutic and prophylactic treatments for COVID-19 is at an early stage and subject to many risks. We may be unable to receive emergency use authorization or approval for any of our COVID-19 product candidates in a timely manner, if at all, and our COVID-19 product candidates may never be authorized for emergency use or approved.***

The FDA cleared our IND application in 2020 to proceed with a Phase 1/2 clinical trial of T-COVID, our investigational agent for the treatment of early COVID-19. The FDA recently cleared our IND for AdCOVID, our intranasal vaccine candidate for COVID-19. We have initiated the Phase 1 clinical trial for AdCOVID and are enrolling in the T-COVID trial. We may experience difficulties or delays in enrolling patients in clinical trials due to the impact of the global COVID-19 pandemic or other reasons. Many of the risks related to the development of these product candidates are beyond our control, including risks related to clinical development, the regulatory submission process, potential threats to our intellectual property rights and manufacturing delays or difficulties. We may be unable to produce an efficacious and/or approved product for the treatment of patients with early COVID-19 in a timely manner, if at all.

The results of preclinical studies from our COVID-19 product candidates may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. There can be no assurance that any of our clinical trials for our COVID-19 product candidates, or any other of our product candidates, will ultimately be successful or support further clinical development. In addition, the interpretation of the data from our clinical trials of T-COVID or AdCOVID by FDA and other regulatory agencies may differ from our interpretation of such data and the FDA or other regulatory agencies may require that we conduct additional studies or analyses. Any of these factors could delay or prevent us from receiving regulatory approval of T-COVID or AdCOVID and there can be no assurance that either product candidate will be approved in a timely manner, if at all.

If the COVID-19 outbreak is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture our product candidate, the commercial viability of such product candidate may be diminished or eliminated. We are also committing financial resources and personnel to the development of this product candidate which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our treatment, if successfully developed, may not be effective. Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to

be authorized in the coming months. In addition, other parties are currently developing therapeutic and vaccine candidates for COVID-19, which may be more efficacious than or may be approved prior to T-COVID or AdCOVID.

***The regulatory pathway for T-COVID and AdCOVID is continually evolving, and may result in unexpected or unforeseen challenges.***

The speed at which parties are acting to create and test many therapeutics and vaccines for COVID-19 is unusual, and evolving or changing plans or priorities within the FDA, including those based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for our product candidates. Results from ongoing clinical trials and discussions with regulatory authorities 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. Any such developments could delay the development timeline for our product candidates and materially increase the cost of the development for such candidates.

**Risks Related to the Regulatory Approval Process**

***We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and foreign jurisdictions. Failure to obtain marketing approval for our product candidates will prevent us from commercializing them in those markets.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our current product candidates nor any product candidates that we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

We expect to rely on third-party CROs and consultants to assist in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication of each of our product candidates to establish the product candidates' safety and efficacy for such indications. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, regulatory authorities.

The pathway to regulatory approvals is time consuming and unpredictable, involves substantial costs and consumes management time and attention. It is not possible to predict the timing or success of obtaining regulatory approvals with any degree of certainty, and as a result, it is difficult to forecast our future financial results or prospects. Any unexpected development in the regulatory approval process, including delays or denials of regulatory approvals or significant modifications to our product candidates required by our regulators, could materially and adversely affect our business, results of operations and financial condition, and could substantially harm our stock price.

To obtain marketing approval, United States laws require:

- controlled research and human clinical testing;
- establishment of the safety and efficacy of the product for each use sought;
- government review and approval of a submission containing, among other things, manufacturing, pre-clinical and clinical data; and
- compliance with cGMP regulations.

The process of reviewing and approving a drug is time-consuming, unpredictable, and dependent on a variety of factors outside of our control. The FDA and corresponding regulatory authorities in other jurisdictions have a significant amount of discretion in deciding whether or not to approve a marketing application. Our product candidates could fail to receive regulatory approval from the FDA or comparable regulatory authorities outside the United States for several reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that our candidate is safe and effective for the proposed indication;

- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that the product candidate's benefits outweigh its risks;
- disagreement with our interpretation of pre-clinical or clinical data; and
- inadequacies in the manufacturing facilities or processes of third-party manufacturers.

The FDA or a comparable regulatory authority outside the United States may require us to conduct additional pre-clinical and clinical testing, which may delay or prevent approval and our commercialization plans or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post-marketing clinical trials. Any of these scenarios could materially harm the commercial prospects of a product candidate, and our operations will be adversely effected.

***Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.***

Significant adverse events caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause us, an IRB or ethics committee, and/or regulatory authorities to interrupt, delay or halt clinical trials and could result in clinical trial challenges such as difficulties in patient recruitment, retention, and adherence, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. The most common adverse events in the clinical trials evaluating the safety and tolerability of the product candidates developed using the Respirvec platform have been headaches, runny noses and sore throats. The most common adverse events observed in clinical trials for product candidates developed using the Densigen platform include injection site reactions, headache, malaise and fatigue. We have not yet completed a clinical trial using our EuPort platform.

Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed. In addition, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or revocation of product marketing authorization.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- we may be unable to obtain regulatory approval for our product candidates;
- regulatory authorities may withdraw approvals of our products;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approvals for and market acceptance of our product candidates and could have a material adverse effect on our business and financial results.

***If we fail to obtain regulatory approval in non-U.S. jurisdictions, we will not be able to market our products in those jurisdictions. Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in receiving or maintaining regulatory approval of our product candidates in other jurisdictions.***

We intend to market certain of our product candidates, if approved, in the United Kingdom and other international markets, in addition to the United States. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many

countries outside the United States, such as certain countries of the European Union, a vaccine or therapeutic must be approved for reimbursement, including the price that can be charged, before it can be approved for sale in that country. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product, and additional clinical research may be required to enable comparison of the cost effectiveness of our product candidate to other available alternatives. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

***Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval. We may also be required to conduct post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product potentially over many years. If the FDA or other regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, and compliance with cGMP and GCP for any clinical trials that we conduct post-approval. Any such restrictions may result in significant additional expense or could limit sales of the approved product. If we, or any of the third parties on which we rely, fail to meet those requirements, the FDA or comparable regulatory authorities outside the United States could initiate enforcement action. Other consequences include the issuance of fines, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, and permanent injunctions and consent decrees, including the imposition of civil or criminal penalties, among other consequences, that could significantly impair our ability to successfully commercialize a given product.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines or warning letters, or clinical holds on clinical trials involving related product candidates;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in governmental reimbursement programs, such as Medicare, Medicaid and other federal health care programs and curtailment or restructuring of our operations.

In addition, applicable regulatory policies of governmental authorities, such as the FDA, may change and additional government regulations may be enacted that could affect any regulatory approval that we may receive for our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our existing or future collaboration partners from obtaining approvals for the commercialization of our current product candidates and any other product candidate we develop.***

Any current or future product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, import, export and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we

may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants 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 biologic product candidate's safety, purity, efficacy and potency. 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. Any product candidates we develop 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 our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. 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 are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. 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.

Additionally, product approvals may be delayed as a result of the COVID-19 pandemic. As of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

If we experience delays in obtaining approval or if we fail to obtain approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

***If the FDA or comparable foreign regulatory authorities approve generic or biosimilar versions of any of our products that receive marketing approval, or if any product approvals we obtain do not provide us with the exclusivity periods we hope to achieve, the sales of our products could be adversely affected.***

As part of the ongoing efforts of governmental authorities to lower health care costs by facilitating generic competition to pharmaceutical products, the BPCIA enacted as part of the Health Care Reform Law, created a new abbreviated regulatory approval pathway in the United States for biological products that are found to be "biosimilar" to or "interchangeable" with a biological "reference product" previously licensed under a BLA. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively by relying to some extent on the data generated by the reference product's sponsor and the FDA's previous review and approval of the reference product. Under the BPCIA, a biosimilar sponsor's ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted by the FDA to the holder of the reference product's BLA, and no biosimilar application may be accepted by the FDA for review until four years after the date the reference product was first licensed by the FDA, and no biosimilar application, once accepted, may receive final approval until 12 years after the reference product was first licensed by the FDA.

Once approved, biosimilars likely would compete with, and in some circumstances may be deemed under applicable laws to be "interchangeable with," the previously approved reference product. The extent to which a biosimilar, once approved, will be substituted for any one of our product candidates, if approved, in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Although there is uncertainty regarding the impact of this new program, it seems likely that if any of our product candidates are approved by the FDA, there is risk that the approval of a biosimilar competitor to one of our products could have an adverse impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our product, if approved by the FDA.

We may also be subject to competition from biosimilar products in Europe. To date, many biosimilar products have been authorized by the European Commission, after application at EMA for a centralized marketing authorization. As in the United States the regulatory approval pathway for biosimilar products in Europe is abbreviated. A biosimilar sponsor must however still provide all of the preclinical and clinical data required to demonstrate the similarity of their product with the reference product. The level of data



required is assessed on a case by case basis, but it will be less than that required for an original biological product. The pathway is more complex than the abridged procedure that may be followed to obtain authorization of a generic version of a non-biological product, but it would still allow the biosimilar product to be brought to market more quickly and less expensively than our original product. That said, in the EU, applications for marketing authorizations in relation to biosimilar products are subject to the same data and market exclusivity rules that apply to generic non-biologic products so no biosimilar product can be approved or placed on the market during the period such exclusivity applies to our product. Marketing authorization of a biosimilar product in the EU does not guarantee that the biosimilar product may be substituted for the reference product. Interchangeability of a biosimilar product with the reference product is not assessed by the EMA but this determination is left to each of the member states. We cannot know at this stage the extent to which any biosimilar product would be interchangeable with our reference product, and this may vary between member states.

We may pursue pediatric exclusivity for one or more of our product candidates but may not succeed in obtaining it. There is also a risk that a competitor may achieve pediatric exclusivity that would delay any potential approvals of our product candidates. In the United States, the FDA has the authority to award additional exclusivity for approved products where the sponsor conducts specified testing on pediatric or adolescent populations upon the written request of the FDA. If granted, pediatric exclusivity adds six months to existing exclusivity periods applicable to biological products under the BPCIA — namely, the four-year period during which the FDA will not consider an application for a biosimilar product, and the twelve-year period during which the FDA will not approve a biosimilar application. This six-month exclusivity runs from the end of these exclusivity protection periods. In the EU, as well, pediatric studies are incentivized by the reward of additional exclusivity. Pediatric Investigation Plans (“PIPs”), are determined by the Pediatric Committee of the EMA. Where an application for a marketing authorization is submitted in respect of a medicinal product designated as an orphan medicinal product and that application contains the results of the PIP studies, market exclusivity for that orphan medicinal product is extended by two years. Where an application for a marketing authorization is submitted in respect of a medicinal product that is not designated as an orphan medicinal product and that application contains the results of the PIP studies, it may be possible to obtain a 6-month extension of a supplementary protection certificate extending patent protection for a medicinal product.

Orphan drug designation presents yet another regulatory incentive that may be available to us and our competitors. The FDA may grant orphan drug designation to products intended to treat a “rare disease or condition” that affects fewer than 200,000 individuals in the United States, or affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation can provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user fee exemptions. In addition, if a product that has an orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product may be entitled to orphan drug exclusivity, which means the FDA would not approve any other application to market the same drug for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity.

In the European Union, orphan drug status offers similar but not identical benefits as those in the United States. We may pursue orphan drug designation for one or more of our product candidates but obtaining such designation cannot be assured. Additionally, should a competitor receive orphan drug designation for a product to treat the same disease and same indication as one of our product candidates, there is a risk that the FDA or a comparable European regulatory body could delay approving our product candidate.

***Developing a drug product, such as NasoShield, to address biological warfare involves special considerations, including compliance with the “Animal Rule,” that may increase drug development delays and costs, and result in a longer and more uncertain regulatory approval process.***

Under a special FDA procedure available for studying certain biological warfare products, such as NasoShield, the FDA makes available a research pathway known as the “Animal Rule,” which permits the conduct of clinical trials without exposing human subjects to deadly substances, such as anthrax. These regulations authorize the FDA to rely on evidence from animal studies to provide evidence of a product’s effectiveness under circumstances where there is a reasonably well-understood mechanism for the toxicity of the agent. Under these requirements, and with the FDA’s prior agreement, biologics used to reduce or prevent the toxicity of chemical, biological, radiological or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated for effectiveness under this rule are evaluated for safety under preexisting requirements for establishing the safety of new drug and biological products, including Phase 1 through Phase 2 clinical trials. Under certain circumstances a single animal species may be acceptable if that animal model is sufficiently well-characterized for predicting a response in humans. The animal study endpoint must be clearly related to the desired benefit in humans and the information obtained from animal studies must allow for selection of an effective dose in humans. The Animal Rule also requires post-marketing studies, such as field studies, to verify and describe the product’s clinical benefit and assess its safety should an exigency exist that leads to the product being used in humans; the nature of these studies will be discussed with

FDA as part of the BLA process. Products approved under the Animal Rule are subject to additional requirements, such as restrictions imposed on marketing or distribution or requirements to provide information to patients.

Compliance with the Animal Rule would generally require us to utilize animal model studies for efficacy and provide certain animal and human safety data in order to obtain FDA approval for our anthrax vaccine product candidate. The Animal Rule drug development pathway typically involves costs and delays in excess of what would be expended in conducting human vaccine clinical trials not requiring compliance with the Animal Rule. Although there is an alternative regulatory pathway available for biological warfare drug candidates, called Emergency Use Authorization, which avoids the Animal Rule's reliance on animal models focused on efficacy, there can be no assurance that this alternative model will apply to our anthrax vaccine product candidate.

Developing appropriate animal models in compliance with the Animal Rule is a time-consuming and expensive research effort. Further, we may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these corollaries are difficult to establish and are often unclear. The FDA may decide that our data are insufficient for approval and require additional non-clinical, clinical or other studies, refuse to approve our product candidates, or place restrictions on our ability to commercialize those approved products. As a general matter, complying with the Animal Rule involves a more uncertain pathway to regulatory approval, as relatively few products have been approved in this manner. This means that it may be particularly difficult for us to predict the timing or ultimate success of receiving FDA approval for NasoShield. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process; i.e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the United States and internationally have the capability to perform animal testing with anthrax or otherwise assist us in qualifying the requisite animal models. We compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct testing of our anthrax vaccine product candidate in a predictable timeframe or at all.

***Our NasoShield anthrax vaccine product candidate and our NasoVAX pandemic influenza vaccine product candidate may potentially be eligible for the Strategic National Stockpile ("SNS") under Project BioShield, but there is no guarantee that our product candidates will meet the criteria set forth by HHS or the FDA for procurement and Emergency Use Authorization.***

Under the Project BioShield Act of 2004 ("Project BioShield"), the Secretary of HHS may, with the concurrence of the Secretary of DHS and upon the approval of the President, contract to purchase unapproved medical countermeasures for the SNS, in specified circumstances. The U.S. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the SNS is paid on delivery of a substantial portion of the countermeasure. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there are sufficient and satisfactory clinical results or research data, including data, if available, from preclinical studies and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. The legislation also allows unlicensed products to be procured for the SNS so that they are available at the time an emergency is declared.

Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. To exercise this authority, the Secretary of HHS must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks; and
- there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition.

Although this provision permits the Secretary of HHS to circumvent the FDA approval process, its use would be limited to rare circumstances. Our product candidates will be eligible both for consideration for procurement into the SNS and for use in the event of an emergency, although there is no guarantee that our product candidates will meet the criteria set forth by HHS or the FDA for procurement and Emergency-use Authorization, respectively. Both our NasoShield anthrax vaccine product candidate and our NasoVAX pandemic influenza vaccine product candidate may potentially be eligible for the SNS under Project BioShield.

## Risks Related to Our Intellectual Property

***It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position and other intellectual property rights do not adequately protect our product candidates, others could compete against us (including directly), which could materially harm our business, results of operations and financial condition.***

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, platform technology and know-how. The patent position of biotechnology companies is generally uncertain, because it involves complex legal and factual considerations. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. In addition, some countries do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

The patent prosecution process is expensive and time consuming, and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties, making us reliant on our licensors, licensees or collaborators. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of the Company's business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be lost or impaired. If our licensors, licensees or collaborators are not fully cooperative or disagree with the Company as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

If patent applications we hold or have in-licensed with respect to our 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. We and our licensors have filed several patent applications covering aspects of our product candidates. We cannot offer any assurance about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be successfully challenged by third parties.

Patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued. We cannot be certain that our licensors were the first to satisfy the requirements necessary to secure patent rights relating to any particular invention. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our patent applications.

Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any successful challenge to our patents or patent applications, or to any other patents or patent applications owned by or licensed to us, could deprive us of the rights necessary to prevent competition from third parties, which may impair the commercial success of any product candidate that we may develop. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found, and prior art that we have not identified could be used by a third party to invalidate a patent or prevent a patent from issuing from a pending patent application. Furthermore, even if they are unchallenged, our patents and patent applications, or those of our licensors, may not adequately protect our technology, provide exclusivity for our product candidates, prevent others from designing around our patents with similar products, or prevent others from operating in jurisdictions in which we did not pursue patent protection. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Any loss of, or failure to obtain, patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop

their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in some foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Patents have a limited lifespan. In most countries, including the United States, the natural expiration of a patent is 20 years from the date that the application for the patent is filed. In some cases, the term of a U.S. patent is shortened by a terminal disclaimer that reduces its term to that of an earlier-expiring patent. Various extensions of patent term may be available in particular countries; however, in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. If any of our biologic products qualify as being a “first licensure” under the Biologics Price Competition and Innovation Act (“BPCIA”) provisions of the Affordable Care Act (“ACA”), we also expect to seek regulatory exclusivity for those products from the FDA, which can grant twelve (12) years of exclusivity under the BPCIA provisions of the ACA. However, the applicable authorities, including the USPTO and FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available or whether any of our products qualify as a first licensure, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request, or may not grant regulatory exclusivity. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, and then may be able to launch their product earlier than might otherwise be the case.

***We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets and/or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time consuming, which could divert management resources and harm our business and financial results. Many of our current and potential competitors have the ability to dedicate substantially greater resources to litigate intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

Patent assertion, including initiating litigation, increases the likelihood that the accused third party will seek to narrow or invalidate our asserted patent. The scope and validity of our asserted patent may be challenged in a variety of post-grant proceedings before the USPTO and foreign patent offices. In addition, in an infringement proceeding, a court may decide that our asserted patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding or other legal proceeding could therefore put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. 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.

***Third-party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, and to use our or our licensors’ proprietary technologies without infringing the patents and proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk

increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. We may not have identified all U.S. and foreign patents or published patent applications that affect our business either by blocking our ability to commercialize our product candidates or by covering similar technologies that affect our market.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims, for example, to materials, formulations, methods of manufacture, methods of analysis and/or methods for treatment related to the use or manufacture of our product candidates. For instance, we and certain of our executive officers have been named in a lawsuit brought by a former employee, De-Chu Christopher Tang. The lawsuit asserts a number of claims, including claims that Dr. Tang owns certain portions of our intellectual property and that we wrongfully retained Dr. Tang's lab notebooks after the conclusion of his employment in 2012. We have filed a motion to dismiss and believe the claims are without merit.

In some cases, we may have failed to identify such relevant third-party patents or patent applications. For example, patent applications filed before November 29, 2000 and certain patent applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our platform technology or our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or product candidates and/or the use, analysis and/or manufacture of our product candidates.

If any third-party patents are held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, methods of analysis and/or methods for treatment, the holders of any such patents may be awarded monetary damages, obtain injunctive or other equitable relief, or both. An award of monetary damages may be substantial and may include treble damages and attorneys' fees for willful infringement. An award of injunctive relief could block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we obtain a license. Such licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to redesign an infringing product, prevented from commercializing a product, or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, platform technology or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. In addition, the uncertainties associated with litigation could have an adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

***We may be subject to claims that our employees, independent contractors or consultants have wrongfully used or disclosed alleged trade secrets of their former employers, or our employees may challenge the inventorship of our patents.***

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these individuals, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we use reasonable efforts to ensure that our employees, independent contractors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party.

We may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. In addition, we may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.***

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, RespirVec technology, EuPort technology, and certain of our product candidates including ALT-801. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other of our obligations. If there is any conflict, dispute, disagreement or issue of non-performance between the Company and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

***We may need to license certain intellectual property from third parties, and such licenses may not be available on commercially reasonable terms or at all.***

A third party may hold intellectual property, including patent rights, that is important or necessary to the development or commercialization of our product candidates. If the patented or proprietary technology of third parties is necessary for us to commercialize our product candidates, we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms or at all, which could materially harm our business.

***Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of proprietary information.***

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect trade secrets and proprietary know-how that may not be patentable or that we may elect not to patent, processes for which patents are difficult to enforce and any other elements of our technology and development processes that involve proprietary know-how, information or technology that is not covered by patents. In particular, we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. These agreements require that all confidential information developed by the individual or made known to the individual by the Company during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. We also enter into agreements with our employees that provide that any inventions conceived by the individual in the course of rendering services to the Company shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Although we use reasonable efforts to protect our know-how, our employees, consultants, contractors or outside scientific advisors might intentionally or inadvertently disclose our know-how or other proprietary information to competitors. In addition, competitors may otherwise gain access to our know-how or independently develop substantially equivalent information and techniques.

Enforcing a claim that a third party illegally obtained and is using any of our know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect know-how. Misappropriation or unauthorized disclosure of our know-how could impair our competitive position and may have a material adverse effect on our business.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to those of the Company's, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. For example, we have experienced threatened or actual opposition for two trademarks that we were pursuing. We decided to discontinue

our use of one of those trademarks, and the other matter was resolved on favorable terms. Although these matters have been resolved on terms that did not materially harm the Company, we may become subject to other trademark challenges in the future. If we are unable to establish long-term name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

### **Risks Related to Commercialization of the Company's Product Candidates**

*Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payers and others in the medical community.*

Even if we obtain marketing approval for our product candidates, or any other product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, third-party payers, patients and others in the medical community. Market acceptance of any approved products depends on a number of other factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new vaccines and/or therapies and of physicians to prescribe new vaccines and/or therapies;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of adequate course and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the restrictions on the use of our products together with other medications, if any.

Market acceptance is critical to our ability to generate significant revenue. Any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

*We rely on, and expect to continue to rely on, third parties to manufacture our product candidates and related materials for our clinical trials and preclinical studies, and these third parties may not perform satisfactorily.*

We do not have any manufacturing facilities or personnel, and we rely on, and expect to continue to rely on, third-party manufacturers and suppliers to manufacture and supply vaccines for our preclinical studies and clinical trials, and on related materials, such as anthrax, influenza and HBV products. We rely on a small number of third-party manufacturers and suppliers to manufacture and supply bulk drug substance and fill finished vaccines for our initial clinical trials. This reliance on a small number of third parties increases the risk that we will not have sufficient quantities of our product candidates or other products needed for our preclinical studies and clinical trials, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any of these third parties that we rely upon may terminate their engagement with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. In addition, our reliance on these third parties for manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations regarding manufacturing.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates itself, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance. We do not have control over third party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- delays as a result of manufacturing problems or re-prioritization of projects at a third-party manufacturer;

- our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how or infringement of third-party intellectual property rights by our contract manufacturers; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to preclinical study and clinical trial delays or failure to obtain regulatory approval or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA or other regulatory authority action, including clinical holds, fines, injunctions, civil penalties, license revocations, recall, seizure, total or partial suspension of production, or criminal penalties.

In addition, our product candidates involve technically complex manufacturing processes, and even slight deviations at any point in the production process may lead to production failures and may cause the production of our product candidates to be disrupted, potentially for extended periods of time. For example, one of our third-party manufacturers failed on multiple occasions to successfully manufacture sufficient quantities of our NasoVAX product candidate. This failure required us to delay our planned multi-valent clinical trials. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Furthermore, a contract manufacturer may possess technology related to the manufacture of our product candidate that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product candidates.

Third-party manufacturers may not be able to comply with applicable cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed, including clinical holds, fines, injunctions, civil penalties, delays, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our third-party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events. For example, in December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China. Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

Since March 2020, foreign and domestic inspections by the FDA have largely been on hold with FDA announcing plans in July 2020 to resume prioritized domestic inspections. FDA has stated that foreign inspections not deemed mission-critical remain temporarily postponed, while those that are deemed “mission-critical” will be considered for inspection on a case-by-case basis. Should FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the



FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

The extent to which the novel coronavirus may impact 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.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We have limited arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and it may prove very difficult and time consuming to identify potential alternative manufacturers who could manufacture our product candidates. Accordingly, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

***If we are unable to manufacture our products in sufficient quantities, or at sufficient yields, or are unable to obtain regulatory approvals for a manufacturing facility for our products, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.***

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale, and this manufacturing involves a complicated process with which we have limited experience. Even if clinical trials are successful, we still may be unable to commercialize a product due to difficulties in obtaining regulatory approval for our engineering processes or problems in scaling that process to commercial production. We have no experience manufacturing, or managing third parties in manufacturing, any of our product candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

We expect to rely on third parties for the manufacture of clinical and, if approved for marketing, commercial quantities of our product candidates. These third-party manufacturers must also receive FDA or other applicable governmental authority approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. We may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we may have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time consuming and may result in delays.

No known manufacturer has received FDA clearance to manufacture large scale quantities of commercial products with the modified version of adenovirus used in the production of product candidates based on our proprietary RespirVec technology. We or our contract manufacturers therefore will need to develop a scalable manufacturing process for any product candidates that we may develop and commercialize that use our RespirVec technology. Our contract manufacturing organizations may encounter technical or scientific issues related to development or manufacturing that we may be unable to resolve in a timely manner or with available funds. If we or our manufacturing partners are unable to scale the manufacturing process to produce commercial quantities of our product candidates, or our manufacturing partners do not pass required regulatory pre-approval inspections, our commercialization efforts may be adversely affected.

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, replacement of a manufacturer may be expensive and time consuming and may cause interruptions in the production of our product candidates. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale-up and yields;
- unavailability of raw materials and supplies;
- insufficient quality control and assurance;
- shortages of qualified personnel;

- failure to comply with strictly enforced federal, state and foreign regulations that vary in each country where product might be sold; and
- lack of capital funding.

Any delay or interruption in the manufacture of our products could have a material adverse effect on our business, financial condition, results of operations and cash flows.

***If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, and for which we decide to independently commercialize, we will need to establish a sales and marketing organization.

In the future, we may build a focused sales and marketing infrastructure to market or co-promote some of our product candidates in the United States and in Europe, if and when they are approved. There are risks involved with our establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products 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;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we do not establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, could be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We may encounter difficulties in managing our growth and expanding our operations successfully.***

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for the Company. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our business.

***We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.***

A key part of our strategy is to seek strategic partnerships in the future, including potentially with major biotechnology or pharmaceutical companies for late-stage development and commercialization of our product candidates. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time consuming and complex. In order for the Company 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 products available for licensing from 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 the Company, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product 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 our product candidates and reduce their competitiveness even if they reach the market.

In addition, any future partnerships we may enter into pose a number of risks, including that our partners may breach their agreements with the Company, and we may not be able to adequately protect our rights under these agreements. Furthermore, prospective partners will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we would.

If we fail to establish and maintain strategic partnerships related to our product candidates, we will bear all of the risk 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 which we do not have and for which we have not budgeted. This could negatively affect the development of any unpartnered product candidate.

***We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.***

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations.

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance such a transaction, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to the Company, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates.

We believe our anthrax countermeasures are covered under the general immunity provisions of the U.S. Public Readiness and Emergency Preparedness Act, or Public Readiness Act, but this cannot be assured. Also, there can be no assurance that the Secretary of the HHS will make other declarations in the future that cover any of our other product candidates or that the U.S. Congress will not act in the future to reduce coverage under the Public Readiness Act or to repeal it altogether. Additionally, we are considering applying for liability protection under the U.S. Support Anti-terrorism by Fostering Effective Technologies (SAFETY) Act of 2002 (the "SAFETY Act") which may limit the claims and damages potentially faced by companies who provide certain "qualified" anti-terrorism products. However, we cannot be certain that we will be able to obtain or maintain coverage under the SAFETY Act.

Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigations;
- a diversion of management's time and the Company's resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry liability insurance covering residual liability related to previously completed clinical trials in the amount of \$5.0 million in the U.S., product liability insurance covering our clinical trials in the United Kingdom in the amount of £5.0 million in the aggregate, and clinical trial liability insurance covering our clinical trials in various countries. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

***A breakdown in our information technology systems could result in a significant disruption to our business.***

Our operations and those of our business partners, such as CROs and others that manage sensitive data, are highly dependent on information technology systems, including Internet-based systems, which may be vulnerable to breakdown, wrongful intrusions, data breaches and malicious attack. Information security risks have generally increased in recent years. Our systems, and those of our third-party providers, are potentially vulnerable to data security breaches or cyberattack, whether by employees or others, which may expose sensitive data to unauthorized persons. A data security breach could lead to the loss of trade secrets or other intellectual property, the value of which may be contingent upon maintaining our confidentiality, or could lead to the public exposure of personal information (including sensitive personal medical information) of clinical trial participants, our employees and others, or adversely impact the conduct of scientific research and clinical trials, including the submission of research results to support marketing authorizations. This could require us to expend significant efforts and resources or incur significant expense to eliminate these problems and address related security concerns. In addition, procedures and safeguards must continually evolve to meet new data security challenges, and enhancing protections, and conducting investigations and remediation, may impose additional costs on the Company. If we were to suffer a breakdown in our systems, storage, distribution or tracing, we could experience significant disruptions affecting our business, reputational harm or claims against us by private parties and/or governmental agencies.

In addition, the European Parliament and the Council of the European Union have adopted a new pan-European General Data Protection Regulation ("GDPR"), effective May 25, 2018, which increases privacy rights for individuals in Europe, extends the scope of responsibilities for data controllers and data processors and imposes increased requirements and potential penalties on companies, offering goods or services to individuals who are located in Europe or monitoring the behavior of such individuals (including by companies based outside of Europe). Noncompliance can result in penalties of up to the greater of EUR 20 million, or 4% of global company revenues. While we expect to have substantially compliant programs and controls in place to comply with the GDPR requirements, our compliance with the new regulation is likely to impose additional costs on us and we cannot predict whether the interpretations of the requirements, or changes in our practices in response to new requirements or interpretations of the requirements could have a material adverse effect on our business.

## **Risks Related to our BARDA Contract and Other Government Programs**

***Without the BARDA anthrax contract award, we would only be able to move forward with the NasoShield program at our own risk and without BARDA reimbursement and may therefore suspend or terminate it.***

In recent financial periods, a significant portion of our revenues have been derived from our BARDA contract and other government contracts. For the years ended December 31, 2020 and 2019, BARDA funding for the development of NasoShield accounted for approximately 46% and 92% of our total consolidated revenue and grants and contracts, respectively. There are significant uncertainties and risks associated with our BARDA contract for our NasoShield anthrax vaccine program. Although our current BARDA contract that may fund our NasoShield anthrax vaccine program until 2021, including a \$3.7 million award during the third quarter of 2019, the majority of the funds will be received during the three year period beginning in 2021 and are dependent on achieving positive clinical results during the initial two-year period to demonstrate interim safety and immune response to the vaccine in the Phase 1 clinical study. The results of the Phase 1 study obtained during 2018 met the endpoints for safety, however an appreciable immune response was not observed. We completed an investigation into the results, and the data from this study demonstrated that a simple modification to the method of intranasal dose administration had a dramatic impact on the resulting immunogenicity. These results suggest that the 2018 Phase 1 study of NasoShield in healthy adults might have shown a more robust immunogenic effect had a modified administration method been employed. The \$3.7 million award is to perform a Phase 1b trial employing the modified administration method. BARDA will decide in its sole discretion whether to pursue any of the options under the contract and there can be no assurance that BARDA will elect to pursue any of the designated options. If BARDA does not pursue any of the options, BARDA could terminate the program, and we would not receive any further funds thereunder.

***Our BARDA contracts are cost-plus-fixed-fee contracts that only reimburse certain specified activities.***

Our BARDA contracts are cost-plus-fixed-fee contracts that only reimburse certain specified activities related to our anthrax vaccine program that have been previously authorized by BARDA. There is no guarantee that additional activities will not be needed and, if so, that BARDA will reimburse the Company for these activities. There are also significant requirements associated with operating as a federal government contractor, which include having appropriate accounting, and project tracking systems implemented and operational, and we may not be able to consistently meet these requirements. Performance under the BARDA contracts requires that we comply with appropriate regulations and operational mandates, which require us to engage internal and external expertise for compliance. Our ability to be regularly and fully reimbursed for our activities depends and will depend on our ability to comply and demonstrate compliance with such requirements. In the past, we have experienced delays in reimbursements under a BARDA contract on account of compliance issues, which we have had to dedicate substantial time and resources to remedy, including through modifications to our statement of work related to the program. In addition, under certain circumstances, BARDA may advise us to delay certain activities and invest additional time and resources before proceeding. If we follow such BARDA advice, overall program delays and costs associated with additional resources for which we have not planned may result. The costs associated with following such advice may or may not be reimbursed by BARDA under the contract. We may decide not to follow the advice provided by BARDA and instead pursue activities that we believe are in the best interest of our anthrax vaccine program and our business as a whole, even if BARDA would not reimburse us under our contract.

***Most of our immediately foreseeable future revenues are contingent upon grants, contracts and loans from the U.S. and other governments, non-profit entities and academic institutions, and we may not achieve sufficient revenues from these sources either to maintain operations or eventually attain profitability.***

Substantially all of our revenues to date have been derived from U.S. and European government grants, contracts and loans (such as our current BARDA contract), and from time to time, we may apply for additional contracts, grants or loans from government agencies, non-profit entities and academic institutions. Such contracts, grants or loans can be highly attractive, because they provide additional capital to fund the ongoing development of our technologies and product candidates without diluting our stockholders. However, there is often significant competition for these contracts, grants and loans, and the process of obtaining government and other contracts, grants and loans is lengthy and uncertain. Entities offering contracts, grants or loans may have requirements to apply for or to otherwise be eligible to receive certain contracts, grants or loans that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants or loans, to whom the contracts, grants or loans will be awarded and the size of the contracts, grants or loans to each awardee. Even if we are able to satisfy the award requirements, there is no guarantee that we will be a successful awardee. Therefore, we may not be able to win any contracts, grants or loans in a timely manner, if at all, and there can be no assurance that existing government or other contracts, grants or loans will be renewed or that we can enter into new contracts or receive new grants or loans.

With respect to the BARDA funding we receive for our anthrax vaccine product candidate, if the U.S. government makes significant contract awards to our competitors, rather than to us, our business will be harmed and it is unlikely that we would ultimately be able to supply that particular treatment or product either in the United States or to foreign governments or other third parties. Further, changes in government budgets and agendas, funding strategies, cost overruns in our programs, or advances by our competitors, may result in changes in the timing of funding for, a decreased and deprioritized emphasis on, or termination of, government contracts that support the development and/or procurement of the biodefense product we are developing. For example, the outbreak of Ebola in 2014 changed the near-term focus and priorities of BARDA to help ensure sufficient progress was being made on

a solution for that disease. This resulted in a delay of funding to some non-Ebola programs until Congress appropriated additional funds to BARDA specific for this purpose.

U.S. government funding is also subject to Congressional appropriations generally made on an annual basis even for multi-year contracts. More generally, due to the ongoing economic and political uncertainty, the U.S. government may reduce or delay spending in the biodefense field or eliminate funding of certain programs altogether, which could decrease the likelihood of future government contract awards or that the government would procure products from the Company. Future funding levels for BARDA for the advanced development and procurement of medical countermeasures are uncertain and may be subject to budget cuts and/or government shutdowns as the U.S. Congress and the President look to reduce the U.S. budget deficit. Potential reductions in funding could severely limit our ability to maintain, renew or enter into new contracts and therefore materially and adversely impact our business. A government shutdown could result in a suspension or delayed funding, which may materially and adversely affect our ability to continue our anthrax program.

Further, the 21<sup>st</sup> Century Cures Act (“Cures Act”), was signed into law on December 13, 2016 and, among other things, includes a provision requiring timely and accurate recommended utilization guidelines for MCMs, including for products in the Strategic National Stockpile. The Cures Act requires HHS to report to the appropriate committees of Congress when funding in the Special Reserve Fund (“SRF”), available for the procurement of MCMs falls below \$1.5 billion and how the amount of funding will impact identified MCM priorities. The Cures Act ensures coordinated and efficient processes for executing MCM development and procurement programs by clarifying that the Director of BARDA carry out the programs funded by the SRF, as well as the procurement contracts, grants, and cooperative agreements under BARDA.

***U.S. government agencies have special contracting requirements that give them the ability to unilaterally control contracts such as our BARDA contract.***

U.S. government contracts, such as our BARDA contract, typically contain unilateral termination provisions for the government and are subject to audit and modification by the government at its sole discretion, which will subject the Company to additional risks during the term of such contracts. These risks include the ability of the U.S. government unilaterally to:

- suspend or prevent the Company for a set period of time from receiving new U.S. government contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our existing U.S. government contracts, including for poor performance or if funds become unavailable or are not provided to the applicable governmental agency;
- reduce the scope and value of our U.S. government contracts and/or revise the timing for work to be performed;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products developed under the contract;
- claim rights to products, including intellectual property, developed under the contract;
- change certain terms and conditions in our U.S. government contracts; and
- cancel outstanding Request for Proposal solicitations or Broad Agency Announcements.

The U.S. government will be able to terminate any of its contracts with the Company, including our BARDA contract, either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed, settlement expenses, and profit on the work completed prior to termination. Termination-for-default provisions do not permit these recoveries and would make us liable for excess costs incurred by the U.S. government in procuring undelivered items from another source.

***The U.S. government’s determination to award any contracts may be challenged by an interested party, such as another bidder, at the U.S. Government Accountability Office (the “GAO”) or in federal court. If such a challenge is successful, a contract award may be re-evaluated and terminated.***

The laws and regulations governing the procurement of goods and services by the U.S. government provide procedures by which other bidders and other interested parties may challenge the award of a government contract. Such challenges or protests could be filed with respect to any U.S. government contract awarded to the Company, including our BARDA contract, even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide, and in certain circumstances will be statutorily required, to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of goods and services and payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to

terminate our contract and re-evaluate bids. The government could even be directed to award a potential contract to one of the other bidders.

***Our business is subject to audit by the U.S. government, and may be subject to audit by foreign governments. A negative audit could adversely affect our business.***

Our business is subject to audit by the U.S. government in part because of the funding we receive for our anthrax vaccine program under our BARDA contract. U.S. government agencies such as the Defense Contract Audit Agency (the “DCAA”) routinely audit and investigate government contractors. These agencies review a contractor’s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor’s compliance with, its internal control systems and policies, including the contractor’s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, it may be subject to civil and criminal penalties and administrative sanctions, including termination of contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from conducting business with the U.S. government. In addition, a contractor could suffer serious reputational harm if allegations of impropriety were made against it.

In the future, we may also be subject to audits by foreign governments, as we from time to time receive funding from non-U.S. government sources.

***Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.***

Our business plan includes the continued development of our anthrax vaccine candidate, NasoShield, pursuant to our BARDA contract in addition to applying for additional contracts, grants or loans from government agencies, non-profit entities and academic institutions. We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under these contracts. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulation (“FAR”) and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the FCA and Foreign Corrupt Practices Act (“FCPA”);
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Foreign governments typically also have laws and regulations governing contracts with their respective agencies. These foreign laws and regulations affect how we and our customers conduct business and, in some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially and adversely affect our revenues and results of operations.

#### **Risks Related to Reimbursement and Government Regulation**

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if they are approved, which could make it difficult for us to sell our products profitably.***

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third-party payers and may be affected by existing and future health care reform measures. Third-party payers, such as government health care programs, and private health insurers and health plans, decide which drugs they will provide coverage for and establish reimbursement levels. Coverage and reimbursement decisions by a third-party payer may depend upon a number of factors, including the third-party payer’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. Coverage and reimbursement can vary significantly from payer to payer. As a result, obtaining coverage and reimbursement approval for any approved product from each government and other third-party payer may require us to provide supporting scientific, clinical and cost-effectiveness data for the use of such products to each payer separately, with no assurance that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates, and we cannot be sure that coverage determinations or reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products, even if they are approved by the FDA or other regulatory authorities. In addition, in the United States third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

***Price controls may be imposed, which may adversely affect our future profitability.***

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on coverage, prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce revenues. In some countries, additional clinical research may be required to enable comparison of the cost-effectiveness of our product candidates, if they are approved, to other available vaccines in order to obtain or maintain coverage, reimbursement or pricing approval. Publication of discounts by third-party payers or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. In the United States, concerns about drug pricing have been expressed by members of Congress and prior presidential administrations. There can be no assurance that our product candidates, if approved, will be considered cost-effective by third-party payers, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***We are subject to multiple and substantial federal and state health care and other laws, and the complexity of our regulatory compliance obligations is likely to increase in the event our product candidates are commercialized.***

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal FCA, and their implementing regulations, such as recent rules finalized by OIG which added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others and that (with exceptions) became effective January 19, 2021. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs.

In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. In addition to the Anti-Kickback Statute, FCA and Physician Payments Sunshine Act and their implementing regulations, the laws that may affect our ability to operate include, but are not limited to:

- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.



- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws that require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts, on any of our product candidates that may be approved for marketing (participation in these programs and compliance with the applicable requirements may also subject us to potentially significant discounts on our products and increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);
- the FCPA, which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals), and anti-bribery laws and related laws, and laws pertaining to the accuracy of our internal books and records, which have been the focus of increasing enforcement activity in recent years; and
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws, which may apply to our business practices, including but not limited to, research, distribution, sales-and-marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of the Company's activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws, as well as compliance with the codes of practice of certain associations within such countries (for example, the Association of the British Pharmaceutical Industry (ABPI) in the United Kingdom).

Efforts to help ensure that our business arrangements will comply with applicable health care laws and codes of practice may involve substantial costs. We have adopted policies and practices that are designed to help ensure that the Company, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but it is not always possible to assure compliance with applicable requirements, and the precautions we take to achieve compliance 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. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to the Company, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal and state health care programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws.

***The impact of recent health care reform legislation and other changes in the health care industry and in health care spending on the Company is currently unknown and may adversely affect our business model.***

Our financial prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to, among other things, health care availability, or the method of delivery of or payment for health care products and services could negatively impact our business, operations and financial condition.

For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Health Care Reform Law. The Health Care Reform Law substantially changed the way health care is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. The Health Care Reform Law contains provisions that may reduce the profitability of drug products, including, for example, by increasing the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care plans, addressing a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and imposing certain annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Health Care Reform Law established and provided significant funding for a new Patient-Centered Outcomes Research Institute to coordinate and fund comparative effectiveness research. While the stated intent of comparative effectiveness research is to develop information to guide providers to the most efficacious therapies, outcomes of comparative effectiveness research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results.

Certain provisions of the Health Care Reform Law have been subject to judicial challenges, as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the tax-based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the “individual mandate,” effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare prescription drug plans, commonly known as the “donut hole,” by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%. Additional legislative changes, regulatory changes and judicial challenges related to the Health Care Reform Law remain possible. It is unclear how the Health Care Reform Law and its implementation, as well as efforts to repeal, replace or otherwise modify, or invalidate, the Health Care Reform Law, or portions thereof, will affect our business. We cannot predict what affect further changes to the Health Care Reform Law would have on our business, especially including under the Biden administration.

Another provision of the Health Care Reform Law, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made (starting in 2021) to certain non-physician providers such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. CMS publishes information from these reports on a publicly available website.

Our compliance with these rules may also impose additional costs and may impact our relationships with physicians, teaching hospitals, and other non-physician health care providers.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, among other things led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2% per fiscal year beginning April 1, 2013, and, due to subsequent legislation, will continue until 2030 (with the exception of a temporary suspension from May 1, 2020, through March 31, 2021) unless Congress takes additional action.

Additional legislative changes, regulatory changes or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates.

Further, there has been increasing legislative, regulatory and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. For example, on November 20, 2020, CMS issued an interim final rule to implement a “Most Favored Nation” demonstration project to test Medicare Part B reimbursement of certain separately payable drugs and biologics based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. If the rule survives judicial scrutiny, the Most Favored Nation model will subject certain drugs or biologics identified by CMS as having the highest annual Medicare Part B spending to an alternative payment methodology based on international reference prices, with the list of products to be updated annually to add more products and products not to be removed absent limited circumstances. There has also been legislation that would establish an international reference price-based Medicare Part B drug and biological payment methodology.

It is possible that the Health Care Reform Law, as currently enacted or may be amended or otherwise modified in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare payment and other health care financing, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from commercial payors. We cannot predict the

reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. These continuing health care reform initiatives may adversely affect:

- the demand for any product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

***Certain business practices associated with the commercialization of pharmaceutical products are subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to the Company.***

The laws that would govern our conduct in the United States upon the commercialization of our product candidates are enforceable by criminal, civil and administrative penalties. Violations of laws such as anti-kickback and false claims laws, the FD&C Act, or any regulations promulgated under their authority, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid, the Department of Defense, other regulatory authorities and the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen “relators” under federal or state false claims laws. In the United States, among the laws that may affect our ability to operate and market our products include, but are not limited to:

- The federal Anti-Kickback Law prohibits, among other activities, any person from knowingly and willfully, directly or indirectly soliciting, receiving, offering or paying any remuneration with the intent of (or in return for) generating referrals of individuals or purchases, orders or recommendations for services or items reimbursable by federal health care programs like Medicare and Medicaid. Courts have interpreted this law very broadly, including by holding that a violation has occurred if even one purpose of the remuneration is to generate referrals, even if there are other lawful purposes. Moreover, liability under the Anti-Kickback Law may be established without proving actual knowledge of the law or specific intent to violate. There are statutory exceptions and regulatory safe harbors that protect certain arrangements from prosecution or administrative sanctions, but the exceptions and safe harbors are drawn narrowly. The fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Law, but the arrangement may be subject to scrutiny based on the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Violations of the Anti-Kickback Law may be punished by civil and criminal penalties, damages, fines, or exclusion from participation in federal health care programs like Medicare and Medicaid. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback law constitutes a false or fraudulent claim for purposes of the FCA.
- The FCA prohibits any person from, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or making, or causing to be made, a false statement material to a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, or decreasing, an obligation to pay or transmit money or property to the government. The FCA is commonly used to sue those who submit allegedly false Medicare or Medicaid claims, as well as those who induce or assist others to submit a false claim. “False claims” can result not only from non-compliance with the express requirements of applicable governmental reimbursement programs, such as Medicare or Medicaid, but also from non-compliance with other laws, such as the Anti-Kickback Law, FDA laws on off-label promotion, or laws that require quality care in service delivery. Actions under the FCA may be brought by the government or by whistleblowers referred to as relators, who may initiate an action in the name of the government and may share in any monetary recovery. Violations of the FCA can result in treble damages, mandatory per claim penalties, and exclusion from participation in federal health care programs.
- HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti-Kickback Law, a

person or entity can be found guilty of violating the HIPAA fraud statute without actual knowledge of the statute or specific intent to violate it.

- The Physician Payments Sunshine Act, implemented as the Open Payments program, imposes reporting requirements for pharmaceutical, biologic, and device manufacturers regarding payments or other transfers of value made to physicians, teaching hospitals, and other healthcare providers, including investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Annual reporting of such transfers of value by manufacturers has increased scrutiny of the financial relationships between industry and the physicians, teaching hospitals and other healthcare providers. Failure to submit required annual information may result in civil monetary penalties, which may increase significantly for “knowing failures.”
- Analogous state laws and regulations, including anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid or, in several states, regardless of the payer, including private payers. Some state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Other states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes of conduct.
- The FDCA and comparable foreign laws, in addition to prohibiting the promotion of the safety or effectiveness of product candidates not yet approved for commercialization, an act known as pre-approval promotion, also generally restrict companies from promoting approved products for indications other than those indications for which a product is approved, which is also referred to as off-label use. This means, for example, that we may not make claims about the use of our products, should they be approved for sale, outside of their approved indications, and we may not proactively discuss or provide information regarding any of their off-label uses subject to very specific and limited exceptions. If we or our business partners fail to comply with applicable laws and regulations governing off-label uses of our product candidates, if approved, then we could be subject to administrative or judicially imposed sanctions, including, but not limited to: (i) enforcement proceedings by regulatory agencies; (ii) reduced demand for our products; and (iii) civil or criminal sanctions. Furthermore, actions under the FCA have recently been brought against companies for allegedly promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud.

The bringing of any FCA or other enforcement investigation or action, even if unsuccessful, could require us to devote resources to investigate and defend the action, as well as result in reputational harm. Failure to comply with the fraud and abuse laws could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. In addition, many of these laws are vague, subject to modification, and subject to evolving interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance. We cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws could have a material adverse effect on our business.

If our product candidates are commercialized, then we would also be required to report detailed and complex pricing information, net of included discounts, rebates and other concessions, to CMS for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations, and we would need to develop the expertise, as well as the systems for collecting and reporting this data accurately to CMS and have instituted a compliance program to assure that the information collected is complete in all respects. Companies that fail to accurately report this kind of pricing information to the U.S. government could be subject to fines and other sanctions (including potential FCA liability) that could adversely affect their business.

***We must comply with data privacy and security laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.***

We must operate in compliance with various data privacy and security regulations in the United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, such as the United Kingdom, where we conduct clinical trials.

In the U.S., we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business, including, for example, state data breach notification laws, state health information and/or genetic privacy laws and federal and state consumer protection laws (e.g., Section 5 of the FTC Act and the CCPA), govern the collection, use, disclosure, and protection of health-related and other personal information. Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

HIPAA, for example, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Failure to comply with these laws and regulations can result in substantial penalties and other liabilities. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA became effective on January 1, 2020 and establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and its implementing regulations have already been amended multiple times since their enactment. The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. The obligations to comply with the CCPA and other evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners.

In addition, the European Parliament and the Council of the European Union have adopted a new pan-European General Data Protection Regulation ("GDPR"), effective May 25, 2018, which increases privacy rights for individuals in Europe, extends the scope of responsibilities for data controllers and data processors and imposes increased requirements and potential penalties on companies, offering goods or services to individuals who are located in the EU or monitoring the behavior of such individuals (including by companies based outside of the EU). The GDPR governs the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data. It is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR. Noncompliance can result in penalties of up to the greater of EUR 20 million, or 4% of annual global company revenues. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. While we expect to have substantially compliant programs and controls in place to comply with the GDPR requirements, our compliance with the new regulation is likely to impose additional costs on us and we cannot predict whether the interpretations of the requirements, or changes in our practices in response to new requirements or interpretations of the requirements could have a material adverse effect on our business. There is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. The EU-UK Trade and Cooperation Agreement of 24 December 2020 allows for personal data to be transferred from the EU to the United Kingdom without the need to use a transfer mechanism as set out in Chapter V GDPR until 30 June 2021. This means that personal data may flow freely from the EU to the United Kingdom until 30 June 2021. It is unclear how data transfers to and from the United Kingdom will be regulated after that date. However, the intention of the 6 month grace period is to give the European Commission sufficient time to adopt an adequacy decision in respect of the United Kingdom so that personal data may flow freely from the EU to the United Kingdom after 30 June 2021 as well.

We must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical collaboration partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law,

including the GDPR. Such clients or pharmaceutical collaboration partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***We are subject to extensive government regulatory compliance and ethics oversight, and we will need to develop more extensive compliance and ethics policies in the future.***

Our business is subject to extensive government regulation and ethics oversight, which will become more complex and extensive if we succeed in commercializing products. We have enacted various compliance policies and procedures that govern our business practices as appropriate for a company in our stage of development. These policies and procedures are implemented through education, training and monitoring of our employees, distributors and suppliers. However, our adoption and enforcement of these various policies and procedures does not ensure that we will avoid investigation or the imposition of penalties by applicable government agencies.

In addition, to enhance compliance with applicable health care laws and mitigate potential liability in the event of non-compliance, regulatory authorities, such as OIG, of the HHS have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. Although we believe our existing compliance policies and procedures are adequate for our current operations, these policies and procedures would not be considered a comprehensive health care compliance program consistent with the HHS OIG's recommendations. Depending upon the nature of our future operations, we anticipate developing a more extensive compliance program in the future.

***Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk of fraudulent or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and similar foreign regulatory bodies; fails to comply with manufacturing standards we have established, or with federal, state and foreign health care fraud and abuse laws and regulations; fails to report financial information or data accurately, including to our regulators, such as the FDA and similar foreign regulatory bodies; or fails to disclose unauthorized activities to the Company. In particular, the promotion, sale and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and, structuring and commissions, certain customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. We have adopted a Code of Business Conduct and Ethics Policy and other policies and practices that are designed to help ensure that the Company, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but it is not always possible to identify and deter such 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 the Company, and in some cases regardless of the merits of those actions, those actions could have a significant impact on our business, including the costs of investigation, settlement arrangements, imposition of civil, criminal and administrative penalties (such as additional reporting requirements and oversight if we become subject to Corporate Integrity Agreements and other arrangements, damages, monetary fines, disgorgement, imprisonment, and possible exclusion from participation in Medicare, Medicaid and other federal health care programs), contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***In the United States, legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and it cannot be certain that any such protection will apply to our product candidates or if applied what the scope of any such coverage will be.***

The Public Readiness Act creates general immunity for manufacturers of drug products used to address bioterrorism attacks, when the Secretary of HHS issues a declaration for their manufacture, administration or use. The declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered drug product, generally referred to as a "countermeasure." Manufacturers are excluded from this protection in cases of willful misconduct. Although we believe that our anthrax vaccine product candidate is covered under the general immunity provisions of the Public Readiness Act, there can be no assurance that this coverage will continue, or that the Secretary of HHS will make other declarations in the future that would cover any of our other product candidates, or that the U.S. Congress will not act in the future to reduce coverage under the Public Readiness Act or to repeal it altogether.

In addition, under the Public Readiness Act, upon a declaration by the Secretary of HHS, a compensation fund would be created to provide “timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure.” The “covered injuries” to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer after they have exhausted their remedies under the compensation program. However, there is no assurance that the Secretary of HHS would issue under this act a declaration to establish a compensation fund.

Additionally, we are considering applying for liability protection under the Support Anti-terrorism by the SAFETY Act, which provides certain protections that would limit the damages potentially faced by companies who provide certain “qualified” anti-terrorism products. However, we cannot be certain that we will be able to obtain or maintain coverage under the SAFETY Act. If the U.S. Department of Homeland Security limits the scope of any coverage awarded to the Company, denies it coverage or continued coverage for a particular product or product candidate, or delays in making decisions about whether to grant it coverage, we may become exposed to legal claims.

***We are required to comply with certain export control laws which may limit our ability to sell our products to non-U.S. persons and may subject us to regulatory requirements that may delay or limit our ability to develop and commercialize our products.***

Our product candidates are subject to the Export Administration Regulations (“EAR”), administered by the U.S. Department of Commerce and are, in certain instances subject to the International Traffic in Arms Regulations (“ITAR”), administered by the U.S. Department of State. EAR restricts the export of dual-use products and technical data to certain countries, while ITAR restricts the export of defense products, technical data and defense services. In addition, EAR and ITAR may also regulate the disclosure to certain foreign nationals in the United States, such as research staff, of technical data about controlled commodities. The U.S. government agencies responsible for administering EAR and ITAR have significant discretion in the interpretation and enforcement of these regulations. Failure to comply with these regulations can result in criminal and civil penalties and may harm our ability to enter into contracts with the U.S. government. It is also possible that these regulations could adversely affect our ability to sell our products to non-U.S. customers.

Our product candidates may also be subject to export control laws within the United Kingdom and European Union resulting in the need for authorization from customs authorities before they can leave the United Kingdom or European Union customs territories and restrictions on export from these territories to certain countries. Again, such laws could adversely affect our ability to sell to customers in certain countries and non-compliance can result in civil and criminal penalties. Such restrictions exist across the European Union and within its member states individually and may vary between member states.

***We must comply with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.***

We use hazardous chemicals and biological materials in certain aspects of our business and are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, distribution, storage, handling, treatment and disposal of these materials. We cannot eliminate the risk of accidental injury or contamination from the use, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials. In the event of contamination or injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. In addition, we may be required to pay damages or civil judgments related to third-party claims, for which we are uninsured, including those relating to personal injury (including exposure to hazardous chemicals and biological materials), product quality issues, property damage or contribution to remedial obligations.

***If we use biological and hazardous materials in a manner that causes contamination or injury or violates laws, we may be liable for damages.***

Our research and development activities and clinical trials involve the use of potentially harmful biological materials, including anthrax, as well as hazardous materials and chemicals. We cannot completely eliminate the risk of accidental contamination or injury from the distribution, use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our available financial resources. The Company, our collaborative partners, the third parties that conduct clinical trials on our behalf, and our third-party manufacturers are subject to federal, state, local or foreign laws and regulations governing the use, storage, handling and disposal of these materials and waste products. The cost of compliance with these laws and regulations could be significant. The failure to comply with any of these laws and regulations could result in significant fines and work stoppages.

## Risks Related to our Securities

***The trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders.***

Our stock price has been and, in the future, may be subject to substantial volatility. On September 13, 2018 we amended our Amended and Restated Certificate of Incorporation to effect a reverse stock split at a ratio 1-for-30 (the “Reverse Stock Split”). The Reverse Stock Split was effective on September 13, 2018, and our shares of common stock commenced trading on NASDAQ on a post-Reverse Stock Split basis on September 14, 2018. The volatility of our stock price has increased since we effected the Reverse Stock Split. Since our common stock began trading on a post-Reverse Stock Split basis on September 14, 2018 and through December 31, 2020, our stock has traded in a range with a low of \$1.51 and a high of \$36.25.

Furthermore, the stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors;
- results of clinical trials of our product candidates or those of our competitors;
- announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;
- actual or anticipated variations in our operating results and whether we have achieved key business targets;
- sales of our common stock, including sales by our directors and officers or specific stockholders;
- changes in, or our failure to meet, financial estimates by us or by any securities analysts who might cover our stock;
- changes in securities analysts’ buy and / or sell recommendations;
- general economic, political, or stock market conditions;
- conditions or trends in our industry;
- changes in laws or other regulatory actions affecting us or our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors’ general perception of our company, our business, and our prospects;
- disputes concerning our intellectual property or other proprietary rights; and
- recruitment or departure of key personnel.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies’ stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management’s attention and resources from our business.

***Future sales and issuances of our common stock or rights to purchase common stock could result in substantial dilution to the percentage ownership of our stockholders.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock or other securities convertible into or exchanged for our common stock in one or more transactions, and in a manner we determine from time to time and at prices that may not be the same as the price per share paid by other investors, and dilution to our stockholders could result. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors. New investors could also receive rights, preferences and privileges senior to those of existing holders of our common stock. In addition, in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock, we may be



required to proportionally adjust the conversion price, exercise price or number of shares issuable upon exercise of our outstanding warrants.

***If we do not meet the continued listing standards of The NASDAQ Global Market our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.***

Our common stock is listed on Nasdaq Global Market, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to satisfy the continued listing standards, including with respect to the maintenance of a minimum share price, or if NASDAQ in its discretion, determines that a condition exists that makes further dealings of our Company on the exchange unwarranted, NASDAQ may issue a non-compliance letter or initiate delisting proceedings.

If our securities are delisted from trading on the NASDAQ exchange, our securities could be quoted on the OTCQB or on the Pink Open Market. As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

***Shares that we may issue in the future in connection with certain capital-raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock.***

The issuance or even the expected issuance of a large number of shares of our common stock upon purchase, conversion or exercise of the securities described above could depress the market price of our stock and the issuance of such shares will dilute the stock ownership of our existing stockholders. Shares that we may issue in the future in connection with certain capital-raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock and result in the adjustment of the conversion terms of our existing securities.

***We can give no assurances that we will ever again pay dividends.***

Other than for the PharmAthene board of directors' declaration of a special one-time cash dividend paid in 2017, neither Private Altimmune nor PharmAthene has ever paid any dividends on our common stock. While subject to periodic review, our current policy is to retain all earnings, if any, primarily to finance our future growth or ability to consummate strategic transactions, such as a merger or other business combination. We make no assurances that we will ever pay future dividends, cash or otherwise. Whether we pay any dividends in the future will depend on our financial condition, results of operations, and other factors that we will consider.

#### **Item 1B. Unresolved Staff Comments**

None.

#### **Item 2. Properties**

Our principal executive offices are located in Gaithersburg, Maryland, where we occupy approximately 18,598 square feet of laboratory and office space. For additional information, see Note 6 to our consolidated financial statements.

Management believes that these facilities are suitable and adequate to meet our anticipated needs.

#### **Item 3. Legal Proceedings**

In December 2019, a complaint was filed by Dr. De-Chu Christopher Tang (“Plaintiff”) against us in the United States District Court for the Eastern District of Texas. The Plaintiff amended the complaint in February 2020 to include Vipin K. Garg and David J. Drutz as defendants, in addition to the Company (Dr. Garg, Dr. Drutz, and the Company are collectively referred to as “Defendants”). See Note 17 to the consolidated financial statements appearing in Item 8 of this report for further details.

A prior lawsuit filed by the Plaintiff against us in the United States District Court for the Northern District of Alabama, resulted in the entry of a Final Consent Judgment and Permanent Injunction on August 25, 2016 (the “Alabama Judgment”). In the Alabama Judgment, the court declared, among other things, that we owned the DVD technology that Plaintiff had developed during his employment with us, and enjoined Plaintiff from “using or disclosing any Proprietary Information or Innovations relating to the DVD technology and any associated intellectual property rights” without our written consent.

**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

#### Market Information

Our common stock trades on the NASDAQ Global Market under the symbol "ALT". Prior to the completion of the Mergers, PharmAthene's common stock traded on the NYSE American (formerly the NYSE MKT) under the symbol "PIP."

#### Holders

As of February 23, 2021, we had 172 record holders of our common stock. The number of record holders is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

#### Dividends

Other than the special dividend immediately prior to the Mergers, we have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

#### Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is contained in Part III, Item 12 of this Annual Report under the heading Equity Compensation Plans and is incorporated herein by reference.

#### Recent Sales of Unregistered Securities

Not applicable.

#### Use of Proceeds

Not applicable.

#### Purchases of Equity Securities

Not applicable.

### Item 6. Selected Financial Data

We are a smaller reporting company and not required to provide this information.

## 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 together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis contains forward-looking statements that involve substantial risks and uncertainties. See “Forward-looking statements” in Part I of this Annual Report and the section entitled “Risk Factors” in Part I, Item 1A of this Annual Report for a discussion of certain factors that could cause actual results or events to differ materially from the forward-looking statements that we make.*

### Overview

Altimmune, Inc. is a clinical stage biopharmaceutical company focused on developing intranasal vaccines, immune modulating therapies and treatments for liver disease. Our diverse pipeline includes proprietary intranasal vaccines for COVID-19 (AdCOVID), anthrax (NasoShield) and influenza (NasoVAX); an intranasal immune modulating therapeutic for COVID-19 (T-COVID); and next generation peptide therapeutics for non-alcoholic steatohepatitis (“NASH”) (ALT-801) and chronic hepatitis B (HepTcell).

Our business is the result of a merger between PharmAthene, Inc. (“PharmAthene”) and the business previously known as Altimmune, Inc. (“Private Altimmune”). On May 4, 2017, Private Altimmune merged with PharmAthene in a series of mergers and reorganizations (collectively, the “Mergers”) pursuant to an Agreement and Plan of Merger and Reorganization (the “PharmAthene Merger Agreement”) dated January 18, 2017, among Private Altimmune, PharmAthene, its wholly owned acquisition subsidiaries Mustang Merger Sub Corp I Inc. and Mustang Merger Sub II LLC. Upon closing of the Mergers, all equity instruments of Private Altimmune were exchanged for corresponding equity instruments of PharmAthene. Prior to the Mergers, PharmAthene was a publicly traded biodefense company engaged in Phase 2 clinical trials. Except where the context indicates otherwise, references to “we,” “us,” “our,” “Altimmune” or the “Company” refer, for periods prior to the completion of the Mergers, to Private Altimmune and its subsidiaries, and for periods following the completion of the Mergers to the combined company and its subsidiaries.

### AdCOVID

AdCOVID is an intranasal COVID-19 vaccine candidate designed to guard the respiratory tract from viral invasion and to provide downstream protection against viral spread through stimulation of both mucosal and systemic antibodies (IgA and IgG) as well as cell-mediated immunity. By stimulating mucosal immunity in the nasal cavity, a key point of entry and replication for the SARS-CoV-2 virus, AdCOVID has the potential to defend against both the infection and spread of the virus to others. AdCOVID’s intranasal delivery method provides an easier route of administration than an injection and may eliminate the need for administration by trained medical personnel. We believe nasal mucosal immunity has the potential to provide an effective protection at the site of viral entry and early replication, and may block transmission by shed virus. We believe AdCOVID has the potential to meet most of the World Health Organization’s published preferred attributes for a COVID-19 vaccine, including single dose, rapid onset of protection, immunity lasting one year, non-injected and temperature stability. In particular, data from our NasoVAX clinical trials demonstrated a strong serological response at two weeks that remained unchanged at 400 days, after a single dose. In addition, since it is expected to have extended stability at room temperature, AdCOVID may avoid the need for costly cold chain logistics. During 2020, we completed initial preclinical mouse studies in collaboration with the University of Alabama at Birmingham (“UAB”) and began manufacturing AdCOVID during the third quarter of 2020. We submitted an Investigation New Drug application (“IND”) with the U.S. Food and Drug Administration (“FDA”) in the fourth quarter of 2020 and received clearance from the FDA in February 2021 to initiate a Phase 1 clinical trial of AdCOVID. The Phase 1 clinical trial is currently enrolling and will evaluate the safety and immunogenicity of AdCOVID in up to 180 healthy adult volunteers between the ages of 18 and 55, with data expected in the second quarter of 2021.

### T-COVID

T-COVID is an intranasal immune modulating therapeutic candidate based on the same replication-deficient adenovirus 5 (“RD-Ad5”) vector technology behind our other intranasal vaccine candidates, but it acts through a different mechanism. In preclinical studies sponsored by the National Institute of Allergy and Infectious Diseases, intranasal administration of RD-Ad5 vectors modulated the innate immune response to lethal challenge with a respiratory virus in mice and protected them from death. The immunomodulatory effects resulted in significantly decreased cellular inflammation and lower concentrations of IL-6 and other inflammatory cytokines in the lungs of treated animals compared to controls. Excessive production of inflammatory cytokines like IL-6 has been associated with the lung pathology and death in COVID-19. The protective effects were independent of any specific immunity or vaccine effects against the challenge virus. These protective effects were only observed with intranasal administration of RD-Ad5, and intramuscular administration provided no survival benefit.

With the support of the U.S. Army Medical Research & Development Command in collaboration with the Medical Technology Enterprise Consortium, we initiated a placebo-controlled Phase 1/2 double-blind clinical trial to evaluate the potential of T-COVID to

prevent clinical worsening in patients with early COVID-19 during 2020. The trial is expected to enroll 96 community-based patients who are 18 years and older that present with fever, cough, or shortness of breath, with onset of symptoms within 48 hours, and a diagnosis of COVID-19 within 24 hours. The trial consists of three cohorts of increasing age and risk for complications of COVID-19, and patients are randomized 1:1 to NasoVAX or placebo administered as a single 0.5ml nasal spray within 24 hours of diagnosis. The primary endpoint of the trial is the proportion of patients with clinical worsening, defined as a 4% decrease in pulse oxygen saturation, or the need for hospitalization. Secondary endpoints will measure the average decrease in resting pulse oxygen saturation, average increase in resting pulse rate and proportion of patients requiring oxygen supplementation and mechanical ventilation. In order to expedite the study, we have been permitted by the FDA to use existing lots of NasoVAX, which is an identical vector to T-COVID, in lieu of newly manufactured T-COVID. The protocol was recently amended such that 40% of patients in the final cohort, in which efficacy will primarily be assessed, to be either 65 years and older or have risk for complications of COVID-19. Based on these protocol changes, we expect to receive results from the Phase 1/2 trial in the second quarter of 2021.

### *NasoShield*

NasoShield is an anthrax vaccine product candidate designed to provide rapid and stable protection after a single intranasal administration. It is being developed with the support of the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) for post-exposure prophylaxis against anthrax following exposure to aerosolized *B. anthracis* spores. After an individual has been exposed to the spores that cause anthrax, *B. anthracis* bacteria multiply and release toxins within the host. Although antibiotic therapy is effective at eliminating the actively growing bacteria, vaccination is necessary to protect against the germination of dormant spores after the cessation of antibiotic therapy. Because NasoShield is intended to protect against anthrax after a single intranasal dose, we believe it may be a convenient and simple alternative to the only approved vaccine, which must be given as a series of three injections over 1 month. We believe the simplified immunization route and schedule, together with the reliable stability at ambient temperature may allow NasoShield to be deployed in an anthrax event more easily and faster than the currently approved vaccine. We commenced a Phase 1b trial of NasoShield in adults in 2020 which builds on the Phase 1a trial completed in 2018 and evaluates the effect of modified methods of intranasal dosing on NasoShield safety and immunogenicity. Results are expected in the first quarter of 2021.

### *NasoVAX*

NasoVAX is a recombinant intranasal vaccine product candidate that is being developed for both seasonal and pandemic use. NasoVAX is believed to simultaneously activate the humoral, mucosal and cellular immune arms which may enable a more comprehensive immune response. The data from our Phase 2a trial with a monovalent NasoVAX vaccine indicated that NasoVAX was generally well-tolerated and achieved 100% seroprotection with serum antibody responses, which was comparable to published results of a licensed injected influenza vaccine. Statistically significant increases in mucosal antibody were noted as well as a robust T cell response directed against influenza. Approximately half of the subjects from the highest dose were evaluated between 12 and 14 months after initial dosing for additional immunogenicity assessment. The durability data show that the immune response elicited by NasoVAX was stable with no overall change in the antibody titer or level of seroprotection over an average of 13 months. The combination of serum antibody, mucosal antibody and T-cell response in combination with the durability data provides the potential for improved protection against influenza and suggests that NasoVAX could have a great impact on flu symptoms and shedding of the influenza virus. We are currently evaluating the development path of NasoVAX.

### *ALT-801*

We completed an acquisition in July 2019 of all of the equity interests of Spitfire Pharma, Inc. (“Spitfire”). Spitfire was a privately held, preclinical pharmaceutical company with the primary asset being a novel peptide-based dual GLP-1/glucagon receptor agonist for the treatment of NASH. We refer to this product candidate as ALT-801, and it is designed to treat the obesity and metabolic dysfunction that causes NASH. NASH, the most severe form of non-alcoholic fatty liver disease (“NAFLD”), involves multiple metabolic pathways leading to the abnormal accumulation of liver fat, toxic lipid metabolites, and inflammation, leading to fibrosis or eventually liver cancer. NAFLD is present in up to 90% of obese patients, and approximately 20% of NAFLD patients progress to NASH. In addition, up to 40% of NASH patients develop NAFLD recurrence one year after liver transplant, which we believe indicates that the underlying metabolic disease is still present after transplant. We believe the treatment of obesity is the cornerstone of treating NASH and the principal morbidities of NASH.

ALT-801’s dual agonist mechanism of action is designed to combine the activity of GLP-1 for the reduction of appetite and inflammation, with the direct activity of glucagon on the liver, including increased energy expenditure, adipose browning, lipolysis and mobilization of the liver fat. ALT-801 incorporates the EuPort domain, which is designed to enhance pharmacokinetics for tolerability in the gastrointestinal tract and permit weekly dosing. As observed in a well-established preclinical model of the disease, ALT-801 is capable of inducing significant weight loss with concomitant decreases in liver fat, inflammation and fibrosis, with superior results compared to elafibanor and semaglutide. In addition, ALT-801 demonstrated improved metabolic function and exhibited pleiotropic effects in our preclinical testing across multiple metabolic pathways that are involved in NASH. We also

observed in preclinical studies that ALT-801 resulted in more profound suppression of genes associated with steatosis, inflammation and stellate cell fibrosis by RNA sequencing compared to elafibranor and semaglutide. We commenced a Phase 1 clinical trial in Australia in overweight and obese adult volunteers in the fourth quarter of 2020. The trial is expected to have both single-ascending and multiple-ascending dose arms over a 6 week treatment duration, with data readouts planned for each arm in the second quarter of 2021. The endpoints of the Phase 1a trial are expected to be safety, tolerability and pharmacokinetics, with a preliminary readout on weight loss, resting energy expenditure, liver fat by MRI-PDFF and glucose homeostasis. Pending interim results of the single-ascending dose arms, we intend to extend the multiple-ascending dose arms by 6 weeks for a twelve-week, parallel-dosing Phase 1b clinical trial. The endpoints of the Phase 1b trial are expected to be safety, tolerability, pharmacokinetics, weight loss, decrease in liver fat (as measured by the MRI-PDFF standard) and lean body mass, as well as other metabolic biomarkers. If successful, we expect data from the Phase 1b study Q3 2021.

### *HepTcell*

HepTcell is an immunotherapeutic product candidate for patients chronically infected with the hepatitis B virus (“HBV”). Approximately 300 million people worldwide live with chronic HBV infection, including approximately 2.2 million in the United States. Chronic HBV infection can lead to serious complications, including cirrhosis and liver cancer. Approximately 780,000 people die per year worldwide due to cirrhosis and liver cancer. HepTcell is designed to drive CD4+ and CD8+ T-cell responses against all HBV genotypes in patients of all ethnic backgrounds. Stimulating T-cell responses in chronically infected HBV patients has been challenging because chronic infection with HBV and elevated hepatitis B surface antigen (HBsAg) levels strongly diminishes T-cell immunity directed against the virus. HepTcell focuses the immune system on discrete highly conserved regions of the HBV proteome. We believe our approach allows HepTcell to break immune tolerance by activating T-cells against critical viral sequences with decreased probability of immune escape due to viral mutation. HepTcell is based on our synthetic peptide technology platform and is given by intramuscular injection. In 2018, we completed a Phase 1 trial in the United Kingdom and South Korea in adult patients with chronic HBV. The HepTcell Phase 1 trial was a double-blinded, placebo-controlled, randomized, dose-escalation study that enrolled 61 subjects with chronic HBV who were HBeAg-negative and well-controlled on licensed antivirals. A total of 41 patients received one of two dose levels of HepTcell, with and without IC31TM, a depot-forming TLR9 adjuvant developed by Valneva SE, while 20 control patients received either placebo or IC31 alone. Patients received three injections each 28 days apart and were followed for six months after the final dose. All dose combinations showed excellent tolerability and met the primary endpoint of safety. In the two adjuvanted HepTcell arms, T-cell responses against HBV markedly increased over baseline compared to placebo.

We initiated a Phase 2 study during Q4 2020 in the United States, Canada and Europe that is a double-blind, randomized, placebo-controlled study of 80 adult patients with HBeAg-negative inactive CHB and HBsAg  $\leq$  100 IU/mL. HepTcell will be administered in 6 doses at 4-week intervals for 24 weeks, and patients will be followed for one year to evaluate safety and durability of response. The primary efficacy endpoint is virological response, defined as a 1-log reduction in HBsAg levels from baseline at 24 weeks. Secondary efficacy endpoints include reactivation of anti-HBV T cell responses, HBsAg clearance, and other assessments of virological response. We expect data from this study in the first quarter of 2022.

### **Impact of COVID-19**

We are closely monitoring how the spread of the coronavirus disease (“COVID-19”) is affecting our employees, business, preclinical studies and clinical trials. In response to the COVID-19 pandemic, we have closed our executive offices with certain employees continuing their work outside of our offices and travel for all employees has been restricted. Essential laboratory staff continue to work onsite with enhanced safety measures. We are continuing our regular interactions with the FDA and other regulatory agencies and based on current information, we do not anticipate COVID-19 to materially affect our regulatory timelines for NasoShield, T-COVID, AdCOVID, ALT-801 and HepTcell.

Although operations have not been materially affected by the COVID-19 pandemic at this time, however, there is significant uncertainty relating to the trajectory of the pandemic and the impact of related responses, and disruptions caused by the COVID-19 pandemic may result in difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing trials and the incurrence of unforeseen costs as a result of disruptions in clinical supply or preclinical study or clinical trial delays. The impact of COVID-19 on our future results will largely 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 pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. In addition, a recurrence of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. We continue to monitor developments as we deal with the disruptions and uncertainties relating to the COVID-19 pandemic. See “Risk Factors— Our business, results of operations and financial condition may be adversely affected by the widespread outbreak of an illness or any other communicable disease, or any other public health crisis, including the ongoing COVID-19 pandemic.” in Part I, Item 1A of this Annual Report on Form 10-K.

## U.S. Government Contracts and Grants

In June 2020, we were awarded \$4.7 million from the U.S. Army Medical Research & Development Command (“USAMRDC”) to fund our Phase 1/2 clinical trial of T-COVID. The competitive award was granted by USAMRDC in collaboration with the Medical Technology Enterprise Consortium (“MTEC”), a 501(c)(3) biomedical technology consortium working in partnership with the Department of Defense (“DoD”). Under the contract, MTEC pays us a firm fixed fee based upon the achievement of certain milestones for conduct and completion of a Phase 1/2 study and research and development work on the replication-deficient adenovirus 5 (“RD-Ad5”) vector vaccine platform. For the year ended December 31, 2020, we have recognized approximately \$4.2 million of grant revenue under this contract.

In July 2016, we signed a five-year contract with Biomedical Advanced Research and Development Authority (“BARDA”). The contract, as amended, has a total value of up to \$133.7 million and is used to fund clinical development of NasoShield. Under the contract, BARDA pays us a fixed fee and reimburses certain costs for the research and development of an Ad5-vectored, protective antigen-based intranasal anthrax vaccine through cGMP manufacture and conduct of a Phase 1 clinical trial dose ranging assessment of safety and immunogenicity. The contract consists of an initial base performance period providing approximately \$27.8 million in funding for the period July 2016 through June 2021. BARDA has seven options to extend the contract to fund certain continued development and manufacturing activities for the anthrax vaccine, including Phase 2 clinical trials. Each option, if exercised by BARDA, would provide additional funding ranging from approximately \$1.1 million to \$34.4 million for a three-year period beginning January 2021. For the year ended December 31, 2020, we have recognized approximately \$3.1 million of grant revenue under the current BARDA contract.

## Financing

### *Public Offering*

On July 16, 2020, we offered and sold (i) 3,369,564 shares of our common stock, at a price to the public of \$23.00 per share, and (ii) pre-funded warrants to purchase 1,630,436 shares of our common stock at an exercise price equal to \$0.0001 per share (the “Pre-Funded Warrants”), at a price to the public of \$22.9999 per share of common stock underlying the Pre-Funded Warrants (equal to the public offering price per share of Common Stock, minus the exercise price of each Pre-Funded Warrant). The Pre-Funded Warrants are exercisable at any time, provided that each Pre-Funded Warrant holder will be prohibited from exercising such Pre-Funded Warrants into shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding, which percentage may change at the holders’ election to any other number less than or equal to 19.99% upon 61 days’ notice to us. The gross proceeds of this offering were approximately \$132.2 million, which includes the exercise in full of the underwriters’ option to purchase an additional 750,000 shares of common stock, before deducting underwriting discounts and commissions and offering expenses during the third quarter of 2020. The net proceeds of this offering were approximately \$124.0 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

### *At-the-Market Offering*

On March 27, 2020, we entered into an Equity Distribution Agreement (the “Agreement”) with JMP Securities LLC, serving as placement agent (the “Placement Agent”) with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, par value \$0.0001 per share (the “Common Stock”), having an aggregate offering price of up to \$50.0 million (the “Shares”) through the Placement Agent (the “Offering”). We offered Shares having an aggregate offering price of \$18.9 million pursuant to the prospectus supplement filed with the SEC on March 27, 2020. On June 1, 2020, we filed an amendment to the Agreement which amended the prospectus supplement dated March 27, 2020 to increase the aggregate offering price to \$50.0 million. As of December 31, 2020, we sold 5,594,455 shares of Common Stock under the Agreement resulting in \$48.2 million in net proceeds which completed the At-the-Market Offering.

### *Registered Direct Offering*

On March 12, 2019, we issued a combined total of 4,361,370 common units and pre-funded units to certain institutional investors in a registered direct offering (the “Registered Direct Offering”). Each common unit in the Registered Direct Offering was sold at a price of \$3.21 and consisted of one share of our common stock and 0.70 of a warrant to purchase one share of our common stock at an exercise price of \$3.21. Each warrant sold in the Registered Direct Offering was exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Registered Direct Offering was sold at a public offering price of \$3.20 and consisted of a pre-funded warrant to purchase one share of our common stock at an exercise price of \$0.01 per share and 0.70 of a warrant to purchase one share of our common stock at an exercise price of \$3.21. The pre-funded warrants were immediately exercisable and were able to be exercised at any time. All of the pre-funded warrants were exercised prior to March 31, 2019. The net proceeds of the Registered Direct Offering were approximately \$12.7 million, after deducting the underwriting discount and estimated offering expenses payable by us. The Registered Direct Offering triggered an adjustment to the exercise price of the warrants issued in the 2018 Unit Offering from \$4.1798 to \$2.7568.

## **Current Resources**

We have financed our operations to date principally through our equity offerings and proceeds from issuances of our preferred stock, common stock, and warrants. We secured net proceeds of \$213.2 million through our Public Offering, At-the-Market Offering, and exercise of warrants during the year ended December 31, 2020 and \$12.7 million through equity sales during the year ended December 31, 2019. Accordingly, management believes that we have sufficient capital to fund our plan of operations for at least a twelve-month period from the issuance date of our December 31, 2020 consolidated financial statements. However, in order to address our capital needs in the long-term, including our planned clinical trials, we must continue to actively pursue additional equity or debt financing, government funding, and monetization of our existing programs through partnership arrangements or sales to third parties.

## **Financial Operations Overview**

The consolidated financial information presented below includes the accounts of Altimune, Inc., Altimune UK, Ltd, Spitfire Pharma, LLC., and Altimune AU Pty, Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

### ***Revenue***

To date, we have not generated any product sales. Our revenue consists primarily of government and foundation grants and contracts that support our efforts on specific research projects. These grants and contracts generally provide for reimbursement of approved costs as those costs are incurred by us. Research grants and contracts and the related accounts receivable are recognized as earned when reimbursable expenses are incurred and the performance obligation is complete. Payments received in advance of services being provided are recorded as deferred revenue.

### ***Research and development expenses***

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- costs associated with preclinical and clinical activities and regulatory operations, including the cost of acquiring, developing and manufacturing clinical trial materials; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for insurance and other supplies.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, CROs and clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when or to what extent we will generate sales from the commercialization of any of our product candidates if they receive regulatory approval. The successful development of our product candidates is highly uncertain and may never result in approved products. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- scope, rate of enrollment and expense of our ongoing, as well as any additional, clinical trials, and other research and development activities;
- significant and potentially changing government regulation; and
- the timing and receipt of regulatory approvals, if any.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, we could be required to expend significant additional financial resources and time on the completion of clinical development.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of clinical and preclinical candidates. Our current planned research and development activities include the following:

- complete a Phase 2 clinical trial for HepTcell;



- complete a Phase 1/2 clinical trial for T-COVID;
- complete a Phase 1 clinical trial for ALT-801;
- complete a Phase 1 clinical trial of AdCOVID;
- commence Phase 2 development of NasoShield, contingent on BARDA exercising one or more options under our existing contract;
- additional development of NasoVAX, contingent on non-dilutive funding from BARDA or other entities; and
- manufacture clinical trial materials in support of our clinical trials.

To date, a significant portion of our research and development efforts have been related to the development of AdCOVID, ALT-801, HepTcell, NasoShield, NasoVAX and T-COVID product candidates. We do not allocate personnel-related costs, costs associated with our general research platform improvements, depreciation or other indirect costs to specific programs.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance and human resource functions. Other general and administrative expenses include facility-related costs and professional fees for directors, accounting and legal services, and expenses associated with obtaining and maintaining our intellectual property.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the SEC requirements, director and officer insurance, investor relations costs and other costs associated with being a public company. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in staffing and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

### **Critical Accounting Policies and Significant Judgment and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses, and the disclosure of contingent liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

#### ***Impairment of long-lived assets***

We evaluate our long-lived tangible and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Impairment of long-lived assets other than indefinite lived intangibles is assessed by comparing the undiscounted cash flows expected to be generated by the asset group to its carrying value.

Our IPR&D assets are currently non-amortizing. Until such time as the projects are either completed or abandoned, we test those assets for impairment at least annually at year end, or more frequently at interim periods, by evaluating qualitative factors which could be indicative of impairment. Qualitative factors being considered include, but are not limited to, the current project status, forecasted changes in the timing or amounts required to complete the project, forecasted changes in timing or changes in the future cash flows to be generated by the completed products, a probability of success of the ultimate project and changes to other market-based assumptions, such as discount rates. If impairment indicators are present as a result of our qualitative assessment, we test those assets for impairment by comparing the fair value of the assets to their carrying value. Upon completion or abandonment, the value of the IPR&D assets will be amortized to expense over the anticipated useful life of the developed products, if completed, or charged to expense when abandoned if no alternative future use exists. Key assumptions used in our impairment analysis tests include projected cash flows, a probability of success of the ultimate project, and the discount rate.

For the year ended December 31, 2020, we have one IPR&D asset, HepTcell, that was acquired in 2015. This candidate is a viral pathogen immunotherapy product for the treatment of chronic HBV. We performed a qualitative assessment for the IPR&D impairment testing for 2020 and determined that no impairment indicators were present.

During 2019, we also carried a \$1.0 million IPR&D asset for SparVax-L, a two-dose anthrax vaccine funded by the National Institute of Allergy and Infectious Diseases (“NIAID”). As a result of the completion of the NIAID contract and the U.S. government’s funding prioritization of only single dose anthrax vaccine candidates, we abandoned the project and concluded that the full remaining net book value of the SparVax-L IPR&D asset was impaired, resulting in an impairment charge of \$1.0 million in Q3 2019.

### ***Fair Value Measurements***

We follow the guidance in Financial Accounting Standards Board (“FASB”) Accounting Standard Codification 820, *Fair Value Measurements and Disclosures*, which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities that we can access at the measurement date.

Level 2 — Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term.

Level 3 — Unobservable inputs developed using estimates of assumptions developed by us, which reflect those that a market participant would use.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. We use prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may change for many instruments. This condition could cause an instrument to be reclassified within levels in the fair value hierarchy. There were no transfers within the fair value hierarchy during the years ended December 31, 2020 and 2019.

### ***Contingent Consideration***

We record contingent consideration associated with development and regulatory milestones that meets the definition of a liability under ASC 480 at fair value. The fair value model used to calculate this obligation is based on the Monte Carlo simulation that has been risk adjusted based on the probability of achievement of the milestones. The inputs we use for determining the fair value of the contingent consideration associated with development and regulatory milestones are Level 3 fair value measurements. We re-evaluate the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the probability of achievement of the milestones, stock price, volatility and the risk-free interest rate.

The change in our estimates associated with payments which will become due and payable for development and regulatory milestones will change the fair value of contingent consideration, resulting in a charge or contra expense to research and development expense in the period in which the increase or decrease is determined.

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

Research and development costs are expensed as incurred. Research and development costs consist of payroll and personnel expense, consulting costs, external contract research and development expenses, which includes fees paid to other entities that conduct certain research and development activities on our behalf, such as clinical research organizations (“CROs”) and contract manufacturing organizations (“CMOs”), raw materials, drug product manufacturing costs, laboratory supplies and allocated overhead, including depreciation and amortization, rent and utilities. Material research and development costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Clinical trial costs are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Material advance payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period.

## Results of Operations

### Comparison of years ended December 31, 2020 and December 31, 2019:

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2020	2019	Increase (Decrease)	
Revenue	\$ 8,185	\$ 5,801	\$ 2,384	41 %
Operating expenses:				
Research and development	49,774	17,765	32,009	180 %
General and administrative	13,209	8,501	4,708	55 %
Impairment charge	—	1,000	(1,000)	(100) %
Total operating expenses	62,983	27,266	35,717	131 %
Loss from operations	(54,798)	(21,465)	(33,333)	(155) %
Other income (expense):				
Changes in fair value of warrant liability	—	30	(30)	(100) %
Interest expense	(9)	(2)	(7)	(350) %
Interest income	322	843	(521)	(62) %
Other income, net	24	15	9	60 %
Total other income, net	337	886	(549)	(62) %
Net loss before income tax benefit	(54,461)	(20,579)	(33,882)	(165) %
Income tax benefit	5,417	59	5,358	9,081 %
Net loss	\$ (49,044)	\$ (20,520)	\$ (28,524)	(139) %

### Revenue

Revenue from contracts and grants for the years ended December 31, 2020 and 2019 consisted primarily of research grants in the United States from MTEC for our T-COVID product candidate and BARDA for our NasoShield vaccine candidate. These grants consist of firm fixed fee contracts based on milestones and cost reimbursement contracts, with a fixed fee based on either costs incurred or milestones met.

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2020	2019	Increase (Decrease)	
Revenue	\$ 8,185	\$ 5,801	\$ 2,384	41 %

Revenue increased by \$2.4 million, or 41% for the year ended December 31, 2020 as compared to 2019. The increase was primarily the result of:

- an increase of \$4.2 million in MTEC revenue attributable to a clinical trial and development work on the T-COVID program; and
- a decrease of \$1.6 million in BARDA revenue due to timing of clinical trials and development activities on the NasoShield program.

### **Research and development expenses**

Research and development expenses for the years ended December 31, 2020 and 2019 consisted primarily of expenses related to product candidate development. Research and development expenses for the years ended December 31, 2020 and 2019 are summarized as follows:

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2020	2019	Increase (Decrease)	
Research and development	\$ 49,774	\$ 17,765	\$ 32,009	180 %

Research and development expenses increased by \$32.0 million, or 180%, during the year ended December 31, 2020 as compared to 2019. The increased expense was primarily due to:

- an increase of \$12.9 million due to development activities for the COVID-19 programs, which include AdCOVID and T-COVID;
- an increase of \$8.5 million due to an increase in the fair value of ALT-801 contingent consideration during 2020, that is partially offset by costs incurred in 2019 with respect to the acquisition of ALT-801;
- an increase of \$8.6 million due to development activities for ALT-801 which was acquired in July 2019; and
- a net increase of \$2.0 million due to the timing of clinical trial and development activities related to our other programs, along with costs associated with our pre-clinical projects and non-project specific research and development costs including employee compensation and facility costs.

### **General and administrative expenses**

The following is a summary of general and administrative expenses for the years ended December 31, 2020 and 2019:

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2020	2019	Increase (Decrease)	
General and administrative	\$ 13,209	\$ 8,501	\$ 4,708	55 %

General and administrative expenses increased by \$4.7 million, or 55%, during the year ended December 31, 2020 as compared to 2019. The increased expense is primarily due to an increase of \$1.8 million in labor-related and other costs, \$1.6 million in professional fees, and \$1.3 million in stock compensation expense.

### **Impairment charges**

There were no impairment charges reported during the year ended December 31, 2020. Impairment charges of \$1.0 million reported during the year ended December 31, 2019 resulted from the completion of the SparVax-L NIAID contract with no future funding identified. As a result of the contract completion and the U.S. government's funding prioritization of only single dose anthrax vaccine candidates, we abandoned the project and impaired the remaining net book value of the SparVax-L IPR&D asset.

### **Total other income, net**

Total other income, net decreased by \$0.5 million during the year ended December 31, 2020 as compared to the year ended December 31, 2019. The net decrease was primarily due to changes in interest income related to our short-term investments.

## Income tax benefit

(in thousands except percentages)	Year Ended December 31,		
	2020	2019	Increase (Decrease)
Income tax benefit	\$ 5,417	\$ 59	\$ 5,358 9,081 %

Income tax benefit increased by \$5.4 million during the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase is due to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") signed into law on March 27, 2020 which made temporary changes regarding the utilization and carry back of net operating losses. As of December 31, 2020, we filed a refund claim of \$2.7 million with the U.S. Federal and Maryland tax authorities, reflecting a partial refund of our 2016 tax liability by carrying back a portion of our 2018 and 2019 tax losses. We plan to file additional refund claims during 2021 by carrying back our 2020 tax losses to claim the remaining refund available for the 2016 tax liability.

## Liquidity and Capital Resources

### Overview

Our primary sources of cash for the year ended December 31, 2020 were from equity transactions, maturities of short-term investments and cash receipts of revenue from our BARDA and MTEC contracts. Our cash, cash equivalents, restricted cash, and short-term investments were \$216.0 million at December 31, 2020. We believe, based on the operating cash requirements and capital expenditures expected for 2021 and 2022, our cash on hand and short-term investments at December 31, 2020, together with expected revenue from our government sponsored contracts and tax refunds, are sufficient to fund operations for at least a twelve-month period from issuance date of our December 31, 2020 consolidated financial statements.

We have not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales. Our sources of revenue have consisted of grant revenues under our arrangements with BARDA for the development of NasoShield, MTEC for a clinical trial and development work on T-COVID, and to a lesser degree from other licensing arrangements. We have incurred significant losses since we commenced operations. As of December 31, 2020, we had accumulated losses of \$186.4 million since our inception. In addition, we have not generated positive cash flows from operations. We have had to rely on a variety of financing sources, including the issuance of debt and equity securities. As capital resources are consumed to fund our research and development activities, we may not have sufficient capital to fund our plan of operations. In order to address our capital needs, including our planned clinical trials, we must continue to actively pursue additional equity or debt financing, government funding, and monetization of our existing programs through partnership arrangements or sales to third parties.

In June 2020, we were awarded \$4.7 million from the U.S. Army Medical Research & Development Command ("USAMRDC") to fund our Phase 1/2 clinical trial of T-COVID. The competitive award was granted by USAMRDC in collaboration with the Medical Technology Enterprise Consortium ("MTEC"), a 501(c)(3) biomedical technology consortium working in partnership with the Department of Defense ("DoD"). Under the contract, MTEC pays us a firm fixed fee based upon the achievement of certain milestones for conduct and completion of a Phase 1/2 study and research and development work on the replication-deficient adenovirus 5 ("RD-Ad5") vector vaccine platform. Through December 31, 2020, we have collected approximately \$1.1 million in cash under the contract.

In July 2016, we signed a five-year contract with BARDA. The contract, as amended, has a total value of up to \$133.7 million and is used to fund clinical development of NasoShield. Under the contract, BARDA pays us a fixed fee and reimburses certain costs for the research and development of an Ad5-vectored, protective antigen-based intranasal anthrax vaccine through cGMP manufacture and conduct of a Phase 1 clinical trial dose ranging assessment of safety and immunogenicity. The contract consists of an initial base performance period providing approximately \$27.8 million in funding for the period July 2016 through June 2021. BARDA has seven options to extend the contract to fund certain continued development and manufacturing activities for the anthrax vaccine, including Phase 2 clinical studies. Each option, if exercised by BARDA, would provide additional funding ranging from approximately \$1.1 million to \$34.4 million for a three-year period beginning Q1 2021. Through December 31, 2020, we have collected approximately \$24.7 million in cash under the current BARDA contract.

### Indebtedness

#### Paycheck Protection Program

On April 7, 2020, we applied for a loan from ServisFirst Bank, as lender, pursuant to the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") as administered by the U.S. Small Business Administration (the "SBA"). On April 13, 2020, the Loan was approved and we received the proceeds from a loan in the amount of \$632,000 (the "PPP Loan").

The PPP Loan, which took the form of a promissory note (the “Promissory Note”), was set to mature on April 7, 2022 and bore interest at a rate of 1% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (discussed below), was to commence on November 7, 2020. The Promissory Note provided for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. We could prepay the principal of the PPP Loan at any time without incurring any prepayment charges.

All or a portion of the Loan may be forgiven by the SBA and lender upon application by us upon documentation of expenditures in accordance with the SBA requirements. In July 2020, we voluntarily extinguished the Promissory Note by paying the outstanding principal and accrued interest in cash.

#### BPI France Notes

We had two non-interest-bearing research and development funding arrangements with BPI France that were entered into in December 2013 to provide up to €750,000 in research funding in the first arrangement and up to €250,000 in the second arrangement. We were permitted to draw 50% of the funds upon the signing of the arrangements, an additional 30% contingent upon a financial audit and technical progress report, and the remaining amounts at the completion of the research and development project being funded by the arrangements. In October 2016, we agreed to extend the term on the arrangement by two years. The total amount advanced under the arrangements was €500,000. In April 2019, we were notified that €102,951 exceeded the allowable funding in accordance with the arrangement and made a payment of this amount on June 5, 2019. In September 2019, we were notified that €238,229 (\$265,540) was converted into a grant and we recognized this amount as grant revenue for the three and nine months ended September 30, 2019. In addition to the €102,951 amount paid in excess of the allowable funding, we paid €62,500 (total repayments of \$186,940) during the nine months ended September 30, 2019. In October 2019, we paid the remaining balance on the BPI France notes.

#### **Cash Flows**

The following table provides information regarding our cash flows for the years ended December 31, 2020 and 2019:

<i>(in thousands, except percentages)</i>	Year Ended December 31,		
	2020	2019	Increase (Decrease)
Net cash provided by (used in):			
Operating activities	\$ (34,437)	\$ (9,602)	\$ (24,835) (259) %
Investing activities	(72,095)	(28,286)	(43,809) (155) %
Financing activities	213,487	12,532	200,955 1,604 %
Net increase (decrease) in cash and cash equivalents and restricted cash	<u>\$ 106,955</u>	<u>\$ (25,356)</u>	<u>\$ 132,311</u> 522 %

#### *Operating Activities*

Net cash used in operating activities was \$34.4 million for the year ended December 31, 2020 compared to \$9.6 million during the year ended December 31, 2019. Our sources of cash provided by operations during the year ended December 31, 2020 were primarily cash receipts of revenue generated by our BARDA and MTEC contracts. The primary uses of cash from our operating activities include payments for labor and labor-related costs, professional fees, research and development costs associated with our clinical trials, and other general corporate expenditures. The increase in cash used in operations of \$24.8 million year over year is due to an increase in net loss as adjusted for noncash items of \$18.6 million and changes in working capital accounts of \$6.3 million.

#### *Investing Activities*

Net cash used in investing activities was \$72.1 million for the year ended December 31, 2020 compared to \$28.3 million during the year ended December 31, 2019. The net cash used in investing activities during 2020 was primarily due to net purchases and maturities of short-term investments. The net cash used in investing activities in 2019 was primarily due to purchases of short-term investments.

#### *Financing Activities*

Net cash provided by financing activities was \$213.5 million for the year ended December 31, 2020 compared to \$12.5 million during the year ended December 31, 2019. The net cash provided by financing activities during 2020 was primarily the result of the receipt of \$124.0 million in net proceeds from the Public Offering, \$48.2 million in proceeds from the issuance of common stock from the At-the-Market Offering program and \$41.0 million in proceeds from the exercise of warrants. The net cash provided by financing activities in 2019 was primarily the result of the receipt of \$12.7 million in proceeds from the Registered Direct Offering of units that consisted of common stock and warrants.

***Off-Balance Sheet Arrangements***

We do not have any off-balance sheet arrangements.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

We are a smaller reporting company and not required to provide this information.

ALTIMMUNE, INC.

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Shareholders and the Board of Directors of Altimune, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Altimune, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity 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 U.S. generally accepted accounting principles.

### Basis for opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matters

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

#### *Impairment assessment of Indefinite-lived Intangible Assets*

*Description of the Matter*

At December 31, 2020, the Company's indefinite-lived intangible assets consisted of one acquired in-process research and development asset (IPR&D) with a carrying value of approximately \$12.4 million. As explained in Note 2 to the consolidated financial statements, the Company tests IPR&D for impairment at least annually at year end by evaluating qualitative factors which could be indicative of impairment. In evaluating indefinite-lived intangible assets for impairment, the Company considers the current project status, forecasted changes in the timing or amounts required to complete the project, forecasted timing or changes in the future cash flows to be generated by the completed products, probability of success of the ultimate project, and changes to other market-based assumptions, such as discount rates.

Auditing the Company's qualitative impairment assessment was complex and judgmental due to the significant estimation including the evaluation of assumptions that could indicate potential impairment. Management's assumptions that affect the evaluation included the forecasted changes in timing or amounts required to complete the project or in the future expected cash flows to be generated by the completed project

and the probability of success of the ultimate project. These assumptions are forward looking and are sensitive to and affected by economic, industry, and company-specific qualitative factors.

*How We Addressed the Matter in Our Audit*

To assess the Company's evaluation of impairment indicators of the IPR&D asset, we performed audit procedures that included, among others, evaluating the Company's significant assumptions described above. We also, tested the completeness and accuracy of the underlying data. For example, we compared the significant assumptions to current industry, market and economic trends, and to other relevant data. In addition, to evaluate the probability of success, we considered the phase of development of the IPR&D project, the Company's history of obtaining regulatory approval, and third-party data regarding clinical trial success rates. We assessed the historical accuracy of management's estimates and performed sensitivity analyses on significant assumptions to evaluate the effect on the impairment assessment that would result from changes in the assumptions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Baltimore, Maryland  
February 25, 2021

**ALTIMMUNE, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 115,917,807	\$ 8,962,686
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	115,951,981	8,996,860
Short-term investments	100,005,558	28,277,386
Accounts receivable	4,610,202	1,021,179
Tax refund receivable	7,762,793	629,096
Prepaid expenses and other current assets	1,926,675	470,228
Total current assets	230,257,209	39,394,749
Property and equipment, net	1,056,920	1,104,208
Right of use asset	903,825	698,321
Intangible assets, net	12,823,846	12,732,195
Other assets	73,413	128,547
Total assets	<u>\$ 245,115,213</u>	<u>\$ 54,058,020</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 612,293	\$ 18,232
Accrued expenses and other current liabilities	11,408,154	3,904,767
Total current liabilities	12,020,447	3,922,999
Contingent consideration	5,390,000	2,750,000
Other long-term liabilities	1,828,443	1,864,875
Total liabilities	19,238,890	8,537,874
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 37,142,946 and 15,312,381 shares issued; 37,142,946 and 15,312,167 shares outstanding at December 31, 2020 and 2019, respectively	3,697	1,508
Additional paid-in capital	417,337,742	187,914,916
Accumulated deficit	(186,420,599)	(137,376,122)
Accumulated other comprehensive loss, net	(5,044,517)	(5,020,156)
Total stockholders' equity	225,876,323	45,520,146
Total liabilities and stockholders' equity	<u>\$ 245,115,213</u>	<u>\$ 54,058,020</u>

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

ALTIMMUNE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2020	2019
Revenues	\$ 8,185,027	\$ 5,801,401
Operating expenses:		
Research and development	49,774,328	17,765,553
General and administrative	13,209,440	8,500,783
Impairment charge	—	1,000,000
Total operating expenses	62,983,768	27,266,336
Loss from operations	(54,798,741)	(21,464,935)
Other income (expense):		
Changes in fair value of warrant liability	—	30,000
Interest expense	(9,421)	(2,244)
Interest income	322,514	843,409
Other income, net	24,147	15,139
Total other income, net	337,240	886,304
Net loss before income tax benefit	(54,461,501)	(20,578,631)
Income tax benefit	5,417,024	58,500
Net loss	(49,044,477)	(20,520,131)
Other comprehensive (loss) income — unrealized (loss) gain on investments	(24,361)	20,007
Comprehensive loss	\$ (49,068,838)	\$ (20,500,124)
Net loss	\$ (49,044,477)	\$ (20,520,131)
Deemed dividends	—	(452,925)
Net loss attributable to common stockholders	\$ (49,044,477)	\$ (20,973,056)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.91)	\$ (1.60)
Weighted-average common shares outstanding, basic and diluted	25,637,023	13,124,951

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

ALTIMMUNE, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2018</b>	9,078,238	\$ 876	\$ 170,207,844	\$ (116,855,991)	\$ (5,040,163)	\$ 48,312,566
Stock based compensation	—	—	1,264,231	—	—	1,264,231
Vesting of restricted stock awards including withholding, net	(25,691)	6	(47,126)	—	—	(47,120)
Issuance of common stock in registered direct offering, net	4,361,370	436	12,668,348	—	—	12,668,784
Issuance of common stock for acquired in-process research and development	1,887,250	189	3,791,296	—	—	3,791,485
Issuance of common stock upon exercise of warrants	11,000	1	30,323	—	—	30,324
Unrealized gain on short term investments	—	—	—	—	20,007	20,007
Net loss	—	—	—	(20,520,131)	—	(20,520,131)
<b>Balance at December 31, 2019</b>	15,312,167	1,508	187,914,916	(137,376,122)	(5,020,156)	45,520,146
Stock based compensation	—	—	2,576,006	—	—	2,576,006
Issuance of common stock from exercise of stock options	46,966	4	128,892	—	—	128,896
Vesting of restricted stock awards including withholding, net	84,320	16	(262,729)	—	—	(262,713)
Issuance of common stock from Employee Stock Purchase Plan	92,661	8	135,463	—	—	135,471
Issuance of common stock and pre-funded warrants in public offering, net	4,119,564	412	124,027,403	—	—	124,027,815
Issuance of common stock in at-the-market offering, net	5,594,455	560	48,155,512	—	—	48,156,072
Issuance of common stock upon exercise of warrants	10,197,907	1,020	41,037,438	—	—	41,038,458
Issuance of common stock related to contingent consideration liability	1,694,906	169	13,624,841	—	—	13,625,010
Unrealized loss on short term investments	—	—	—	—	(24,361)	(24,361)
Net loss	—	—	—	(49,044,477)	—	(49,044,477)
<b>Balance at December 31, 2020</b>	<u>37,142,946</u>	<u>\$ 3,697</u>	<u>\$ 417,337,742</u>	<u>\$ (186,420,599)</u>	<u>\$ (5,044,517)</u>	<u>\$ 225,876,323</u>

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

ALTIMMUNE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2020	2019
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (49,044,477)	\$ (20,520,131)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash consideration for acquired in-process research and development	—	6,541,485
Changes in fair value of contingent consideration liability	16,265,010	—
Impairment charges	—	1,000,000
Stock-based compensation expense	2,576,006	1,264,231
Depreciation and amortization	298,057	387,321
Unrealized gain on foreign currency exchange	(19,073)	(5,761)
Changes in fair value of warrant liability	—	(30,000)
Changes in operating assets and liabilities:		
Accounts receivable	(3,589,024)	2,440,759
Prepaid expenses and other current assets	(1,371,312)	133,001
Accounts payable	594,060	(354,628)
Accrued expenses and other liabilities	6,987,815	(779,651)
Tax refund receivable	(7,133,698)	379,877
Deferred taxes	—	(58,500)
Net cash used in operating activities	<u>(34,436,636)</u>	<u>(9,601,997)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from sales and maturities of short-term investments	56,406,564	—
Purchases of short-term investments	(128,159,098)	(28,257,379)
Purchases of property and equipment	(203,957)	(1,227)
Cash paid for internally developed patents	(138,464)	(27,772)
Net cash used in investing activities	<u>(72,094,955)</u>	<u>(28,286,378)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Cash paid in conjunction with warrant exchange	—	(25,000)
Proceeds from exercises of warrants	41,038,458	30,324
Proceeds from issuance of common stock in at-the-market offering, net	48,156,072	—
Proceeds from issuance of common stock and pre-funded warrants in public offering, net	124,027,815	—
Proceeds from issuance of common stock in registered direct offering, net	—	12,668,784
Proceeds from issuance of notes payable	632,000	—
Payments of notes payable	(632,000)	(292,002)
Proceeds from conditional economic incentive	—	150,000
Proceeds from issuance of common stock from Employee Stock Purchase Plan	135,471	—
Proceeds from exercises of stock options	128,896	—
Net cash provided by financing activities	<u>213,486,712</u>	<u>12,532,106</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	106,955,121	(25,356,269)
Cash, cash equivalents and restricted cash — beginning of year	8,996,860	34,353,129
Cash, cash equivalents and restricted cash — end of year	<u>\$ 115,951,981</u>	<u>\$ 8,996,860</u>
<b>SUPPLEMENTAL NON-CASH ACTIVITIES:</b>		
Common stock issued related to contingent consideration liability	\$ 13,625,010	\$ —
Common stock issued for acquired in-process research and development	\$ —	\$ 3,791,485
Operating lease liability and right of use asset addition	\$ 338,212	\$ 1,744,128

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**1. Nature of Business and Organization**

Altimmune, Inc., headquartered in Gaithersburg, Maryland, United States, together with its subsidiaries (collectively, the “Company” or “Altimmune”) is a clinical stage biopharmaceutical company incorporated under the laws of the State of Delaware.

The Company is focused on developing intranasal vaccines, immune modulating therapies and treatments for liver disease. The Company’s diverse pipeline includes proprietary intranasal vaccines for COVID-19 (AdCOVID), anthrax (NasoShield) and influenza (NasoVAX); an intranasal immune modulating therapeutic for COVID-19 (T-COVID); and next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell). The Company has not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales.

**2. Summary of Significant Accounting Policies***Basis of Presentation and Principles of Consolidation*

The accompanying consolidated financial statements are prepared in conformity with generally accepted accounting principles in the United States (“U.S. GAAP”) and in accordance with the rules and regulations of the United States Securities and Exchange Commission (“SEC”). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions 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, revenue and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates relied upon in preparing the accompanying consolidated financial statements were related to revenue recognition, the fair value of common stock and other equity instruments, accounting for stock-based compensation, income taxes, useful lives of long-lived assets, fair value of contingent consideration, impairment of long-lived assets, and accounting for project development and certain accruals. The Company assesses the above estimates on an ongoing basis; however, actual results could differ materially from those estimates.

*Comprehensive Loss*

For the years presented, the total comprehensive loss includes net loss and other comprehensive income (loss) which represents unrealized gains or losses on investments.

*Segment*

The Company is managed and operates as a single business focused on the research and development of immunotherapies and vaccines. The Company is managed by a single management team, and consistent with its organizational structure, the Chief Executive Officer manages and allocates resources at a consolidated level. Accordingly, the Company views its business as one operating segment.

*Short-term Investments*

The Company’s short-term investments are comprised of U.S. Treasury, corporate debt securities and certificate of deposit that have original maturities less than or equal to one year and are classified as available-for-sale securities. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported as accumulated other comprehensive income or loss, which is a separate component of stockholders’ equity. Realized gains and losses and declines in value judged to be other-than-temporary, if any, are included in other income in the consolidated results of operations. The Company reviews its investment portfolio for impairment quarterly or more frequently if circumstances warrant. In determining whether a decline in the value of an investment is other-than-temporary, the Company evaluates currently available factors that may include, among others: (1) general market conditions; (2) the duration and extent to which fair value has been less than the carrying value; (3) the investment issuer’s financial condition and business outlook; and (4) its assessment as to whether it is more likely than not that the Company will be required to sell a security prior to recovery of its amortized cost basis. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income are recognized in other income when earned. The cost of

securities sold is calculated using the specific identification method. The Company places all investments with government agencies, or corporate institutions whose debt is rated as investment grade.

### *Intangible Assets*

Intangible assets acquired in a business combination consist primarily of in-process research and development (“IPR&D”) assets. The value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset will be charged to expense. Intangible assets, including patents and licenses, acquired in other transactions are recorded at cost. Intangible assets with finite useful lives consist of legal costs incurred in the course of obtaining patents and license issuance fees for the use of proprietary technologies. Costs incurred for obtaining patents are amortized on a straight-line basis over the estimated useful lives of the assets from the time of approval of the patent. Prior to approval, these costs are carried on the balance sheets and not amortized. In the event approval is denied, the cost of the denied application is expensed. License issuance fees are amortized on a straight-line basis over the estimated useful lives of the underlying licensed technology. Intangible assets with finite useful lives are being amortized over 6 to 20 years. These amortization costs are classified as research and development expenses in the accompanying statements of operations and comprehensive loss.

### *Impairment of Long-lived Assets*

The Company evaluates its long-lived tangible and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Impairment of long-lived assets other than goodwill and indefinite lived intangibles is assessed by comparing the undiscounted cash flows expected to be generated by the asset group to its carrying value.

As mentioned above, the Company’s IPR&D assets are currently non-amortizing. Until such time as the projects are either completed or abandoned, the Company test those assets for impairment at least annually at year end, or more frequently at interim periods, by evaluating qualitative factors which could be indicative of impairment. Qualitative factors being considered include, but are not limited to, the current project status, forecasted changes in the timing or amounts required to complete the project, forecasted changes in timing or changes in the future cash flows to be generated by the completed products, a probability of success of the ultimate project and changes to other market-based assumptions, such as discount rates. If impairment indicators are present as a result of the Company’s qualitative assessment, the Company will test those assets for impairment by comparing the fair value of the assets to their carrying value. Upon completion or abandonment, the value of the IPR&D assets will be amortized to expense over the anticipated useful life of the developed products, if completed, or charged to expense when abandoned if no alternative future use exists.

The Company has one IPR&D asset, HepTcell, that was acquired in 2015. The Company performed a qualitative assessment for the IPR&D impairment testing for 2020 and determined that no impairment indicators were present. During the third quarter of 2019, the Company abandoned its SparVax-L asset and recorded \$1.0 million of impairment to fully write-off the balance of this IPR&D asset. See Note 5 for further details. The Company performed a quantitative assessment for the HepTcell IPR&D impairment test during 2019 and determined that there was no impairment.

### *Fair Value Measurements*

The Company records certain financial assets and liabilities at fair value in accordance with the guidance in Financial Accounting Standards Board (“FASB”) Accounting Standard Codification (“ASC”) 820, *Fair Value Measurements and Disclosures*, which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company can access at the measurement date.

Level 2 — Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term.

Level 3 — Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.



To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, the Company's own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. The Company uses prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may change for many instruments. This condition could cause an instrument to be reclassified within levels in the fair value hierarchy. There were no transfers within the fair value hierarchy during the years ended December 31, 2020 and 2019.

#### *Financial Instruments*

The Company's financial instruments consist of cash, cash equivalents, restricted cash, accounts receivable, short-term investments, notes payable, accounts payable, accrued expenses, contingent consideration, common stock warrants classified as a liability, and common stock warrants classified as equity. The carrying amounts of cash, cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of those financial instruments. Short-term investments are recorded at fair value, with any unrealized holding gains or losses reported as accumulated other comprehensive income or loss. Notes payable, prior to their redemption or cancellation, are recorded at their repayment value which approximates fair value. Contingent payments classified as a liability are recorded at fair value estimated using the Monte Carlo simulation valuation model. Common stock warrants classified as equity is initially recorded at their grant date fair value. For those warrants with a down round feature, if the down round feature is triggered, the Company would remeasure those instruments at that time with changes recorded as a deemed dividend all within equity. Common stock warrants classified as a liability are recorded at fair value and are remeasured every reporting period with the changes in fair value recorded as a component of other income (expenses), net until their settlement or exercise.

#### *Revenue*

Our revenue consists primarily of government and foundation grants and contracts that support the Company's efforts on specific research projects. The Company has determined that the government agencies and foundations providing grants and contracts to the Company are not customers. These grants and contracts generally provide for reimbursement of approved costs as those costs are incurred by the Company. Research grants and contracts and the related accounts receivable are recognized as earned in proportion to when reimbursable expenses are incurred in performance of the contract. Payments received in advance of services being provided are recorded as deferred revenue.

#### *Research and Development*

Research and development costs are expensed as incurred. Research and development costs consist of payroll and personnel expense, consulting costs, external contract research and development expenses, which includes fees paid to other entities that conduct certain research and development activities on the Company's behalf, such as clinical research organizations ("CROs") and contract manufacturing organizations ("CMOs"), raw materials, drug product manufacturing costs, laboratory supplies and allocated overhead, including depreciation and amortization, rent and utilities. Material research and development costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Clinical trial costs are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Material advance payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, the Company analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period.

### *Cash Equivalents*

The Company considers all highly liquid investments purchased with remaining maturities of 90 days or less on the purchase date to be cash equivalents, and include amounts held in money market funds which are actively traded (a Level 1 input).

### *Restricted Cash*

The Company had restricted cash of \$34,174 at both December 31, 2020 and 2019, held in money market savings accounts as collateral. The restricted cash as of December 31, 2020 and 2019 is for the Company's facility lease obligation. Restricted cash is classified as a component of cash, cash equivalents, and restricted cash in the accompanying consolidated balance sheets and consolidated statements of cash flows.

### *Accounts Receivable*

Accounts receivable includes both billed and unbilled amounts. The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not specifically reviewed. The Company's receivables represent amounts reimbursed under its government grants and contracts. The Company believes that credit risks associated with these government grants and contracts is not significant. To date, the Company has not experienced any losses associated with accounts receivable and does not maintain an allowance for doubtful accounts.

### *Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, restricted cash, and accounts receivable. Periodically, the Company maintains deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality. The Company has not experienced any losses in these deposits. The Company recognizes research grants and contracts earned in connection with the services provided on research and development projects. The Company provides credit in the normal course of providing such services based on evaluations of the grantors' financial condition and generally does not require collateral. To manage accounts receivable credit risk, the Company monitors the creditworthiness of its grantors. The U.S. government accounts for 97% and 95% of revenue for the years ended December 31, 2020 and 2019, respectively. The U.S. government accounts for 100% of accounts receivable for both the years ended December 31, 2020 and 2019.

### *Property and Equipment, Net*

The Company records property and equipment at cost less accumulated depreciation and amortization. Expenditures for maintenance and repairs are charged to operations as incurred, whereas major improvements are capitalized as additions to property and equipment. Costs of assets under construction are capitalized but are not depreciated until the construction is substantially complete and the assets being constructed are ready for their intended use.

Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the assets, as follows:

<b>Asset Category</b>	<b>Estimated Useful Life</b>
Computer and telecommunications	3 – 5 years
Software	3 years
Furniture, fixtures and equipment	5 years
Laboratory equipment	7 years
Leasehold improvements	Lesser of lease term or estimated useful lives

### *Warrants*

Common stock warrants issued in connection with the 2018 Unit Offering, the 2018 and 2019 Registered Direct Offerings, and the 2020 Public Offering (all terms defined in Note 10 and Note 11), were classified as a component of permanent equity because they are freestanding financial instruments that were legally detachable and separately exercisable from other debt and equity instruments, are contingently exercisable, do not embody an obligation for the Company to repurchase its shares, and permits the holders to receive a fixed number of common shares upon exercise. In addition, such warrants did not provide any guarantee of value or return. The 2018 Registered Direct Offering and 2019 Registered Direct Offering triggered down round adjustments to the exercise price of warrants issued in connection with the 2018 Unit Offering. In 2019, the Company treated the value of the effect of the reduction in exercise price as a deemed dividend, resulting in a reduction to income available to common shareholders (see Note 11).

There was a reduction in exercise price in 2020 due to the At-the-Market Offering which triggered an anti-dilution provision under the warrant agreement with the Company's holders of redeemable preferred stock (see Note 11).

#### *Stock-based Compensation*

The Company accounts for all stock-based compensation granted to employees and non-employees using a fair value method. Stock-based compensation awarded to employees is measured at the grant date fair value of stock option grants and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures.

If awards are modified, the Company compares the fair value of the affected award measured immediately prior to modification to its value after modification. To the extent that the fair value of the modified award exceeds the original award, the incremental fair value of the modified award is recognized as compensation on the date of modification for vested awards, and over the remaining vesting period for unvested awards.

#### *Income Taxes*

The Company accounts for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. Deferred tax assets and liabilities represent future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities and for loss carryforwards using enacted tax rates expected to be in effect in the years in which the differences reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company also recognizes a tax benefit from uncertain tax positions only if it is "more likely than not" that the position is sustainable based on its technical merits. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date, the Company has not incurred interest and penalties related to uncertain tax positions. Should such costs be incurred, they would be classified as a component of provision for income taxes.

#### *Net Loss per Share*

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period without consideration for potentially dilutive securities.

The Company computes diluted net loss per common share after giving consideration to all potentially dilutive common equivalents, including all unvested restricted stock, common stock warrants, and common stock options outstanding during the period except where the effect of such non-participating securities would be anti-dilutive.

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods.

#### *Leases*

The Company's headquarters lease is the primary lease, accounted for as an operating lease under the new lease accounting guidance, which the Company adopted on January 1, 2019 under the prospective optional transition method. The Company elected the package of practical expedients permitted. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease, (b) whether classification of the operating leases would be different in accordance, or (c) whether the unamortized initial direct costs before transition adjustments would have met the definition of initial direct costs at lease commencement. In addition, the Company does not allocate the consideration between lease and non-lease components.

The Company determines if an arrangement is a lease at inception. Operating leases are recorded as a current and long-term lease obligation, with a corresponding right of use lease assets.

The lease obligations represent the Company's obligation to make lease payments arising from the lease. The right of use lease assets represent the Company's right to use an underlying asset for the lease term. The lease obligations and the operating right of use lease assets are recognized at the commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Short-term leases are leases having a term of twelve months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

Lease incentives and allowance provided by our landlord for the construction of leasehold improvements are recorded as lease incentive obligations as the related construction costs are incurred, up to the maximum allowance.

#### *Contingent Consideration*

The Company records contingent consideration associated with development and regulatory milestones that meets the definition of a liability under ASC 480 at fair value. The fair value model used to calculate this obligation is based on the Monte Carlo simulation that has been risk adjusted based on the probability of achievement of the milestones. The inputs the Company uses for determining the fair value of the contingent consideration associated with development and regulatory milestones are Level 3 fair value measurements. The Company re-evaluates the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the probability of achievement of the milestones, stock price, volatility and the risk-free interest rate.

The change in Company's estimates associated with payments which will become due and payable for development and regulatory milestones will change the fair value of contingent consideration, resulting in a charge or contra expense to research and development expense in the period in which the increase or decrease is determined.

#### *Recently Issued Accounting Pronouncements*

##### Recently Adopted:

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU No. 2018-13"). ASU No. 2018-13 was issued to modify and enhance the disclosure requirements for fair value measurements and eliminates certain disclosure requirements, such as the amount of, and reasons for, transfers between Level 1 and Level 2 of the fair value hierarchy. This ASU adds new disclosure requirements for Level 3 measurements and is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The Company adopted this guidance in the first quarter of 2020, which resulted in expanded disclosures in Note 3 regarding the Company's recurring Level 3 fair value measurements.

##### Not Yet Adopted:

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU No. 2016-13"). ASU No. 2016-13 requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. This update also required enhanced disclosures to help financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an entity's portfolio. This standard is effective for the Company as a smaller reporting company beginning January 1, 2023. Adoption is not expected to have a material impact on the Company's consolidated financial statement disclosure requirements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes* ("ASU No. 2019-12"). ASU 2019-12 amends the approaches and methodologies in accounting for income taxes during interim periods and makes changes to certain income tax classifications. The new standard allows exceptions to the use of the incremental approach for intra-period tax allocation, when there is a loss from continuing operations and income or a gain from other items, and to the general methodology for calculating income taxes in an interim period, when a year-to-date loss exceeds the anticipated loss for the year. The standard also requires franchise or similar taxes partially based on income to be reported as income tax and the effects of enacted changes in tax laws or rates to be included in the annual effective tax rate computation from the date of enactment. Lastly, in any future acquisition, the Company would be required to evaluate when the step-up in the tax basis of goodwill is part of the business combination and when it should be considered a separate transaction. The standard will be effective for the Company beginning January 1, 2021, with early adoption of the amendments permitted. Adoption is not expected to have a material impact on the Company's consolidated financial statement disclosure requirements.

### **3. Fair Value Measurement**

The Company records cash equivalents, short-term investments, contingent consideration, and warrant liability at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants based on assumptions that market participants would use in pricing an asset or liability.

The Company's assets and liabilities measured at fair value on a recurring basis at December 31, 2020 consisted of the following:

	Fair Value Measurement at December 31, 2020			
	Total	Level 1	Level 2	Level 3
Cash equivalents - money market funds	\$ 90,389,473	\$ 90,389,473	\$ —	\$ —
Short-term investments	100,005,558	—	100,005,558	—
Contingent consideration liability (see Note 8)	5,390,000	—	—	5,390,000
Warrant liability	10,000	—	—	10,000

The warranty liability is included in Other long-term liabilities in the consolidated balance sheet at December 31, 2020.

The Company's assets and liabilities measured at fair value on a recurring basis at December 31, 2019 consisted of the following:

	Fair Value Measurement at December 31, 2019			
	Total	Level 1	Level 2	Level 3
Cash equivalents — money market fund	\$ 8,034,640	\$ 8,034,640	\$ —	\$ —
Short-term investments	28,277,386	—	28,277,386	—
Contingent consideration liability (see Note 8)	2,750,000	—	—	2,750,000
Warrant liability	10,000	—	—	10,000

The warranty liability is included in Other long-term liabilities in the consolidated balance sheet at December 31, 2019.

Short-term investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data (Level 2). The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value.

Short-term investments with quoted prices at December 31, 2020 as shown below:

	As of December 31, 2020		
	Amortized Cost	Unrealized Gain	Market Value
United States treasury securities	\$ 20,052,757	\$ 1,843	\$ 20,054,600
Asset-backed and corporate debt securities	54,935,963	(6,197)	54,929,766
Certificates of deposit	25,021,192	—	25,021,192
Total	\$ 100,009,912	\$ (4,354)	\$ 100,005,558

Short-term investments with quoted prices at December 31, 2019 as shown below:

	As of December 31, 2019		
	Amortized Cost	Unrealized Gain	Market Value
United States treasury securities	\$ 3,394,579	\$ 3,228	\$ 3,397,807
Asset-backed and corporate debt securities	24,862,800	16,779	24,879,579
Total	\$ 28,257,379	\$ 20,007	\$ 28,277,386

The fair value of contingent payments classified as a liability is based on the regulatory milestones described in Note 8 and estimated using the Monte Carlo simulation valuation model with Level 3 inputs.

The assumptions used to estimate the fair value of contingent payments that were classified as a liability at December 31, 2020 include the following significant unobservable inputs:

Unobservable input	Value or Range	Weighted Average
Expected volatility	114.9%	114.9%
Risk-free interest rate	0.11%	0.11%
Cost of capital	30%	30%
Discount for lack of marketability	9%-15%	12%
Probability of payment	63%	63%
Projected year of payment	2022	2022

The assumptions used to estimate the fair value of contingent payments that were classified as a liability at December 31, 2019 include the following significant unobservable inputs:

Unobservable input	Value or Range	Weighted Average
Expected volatility	95.3%	95.3%
Risk-free interest rate	1.60%	1.60%
Cost of capital	30%	30%
Discount for lack of marketability	8%-12%	10%
Probability of payment	31%-50%	46%
Projected year of payment	2020-2022	2020

The Company's warrant liability is valued using the Monte Carlo simulation valuation model with Level 3 inputs.

If applicable, the Company will recognize transfers into and out of levels within the fair value hierarchy at the end of the reporting period in which the actual event or change in circumstance occurs. There were no transfers into and out of any of the levels of the fair value hierarchy during 2020 or 2019.

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. Assets recorded at fair value on a non-recurring basis, such as property and equipment and intangible assets are recognized at fair value when they are impaired. During the year ended December 31, 2020, the Company had no significant assets or liabilities that were measured at fair value on a non-recurring basis. During the year ended December 31, 2019, the Company recognized an intangible asset impairment (see Note 5) measured at fair value on a non-recurring basis.

#### 4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2020	2019
Furniture, fixtures and equipment	\$ 125,538	\$ 121,491
Laboratory equipment	959,585	926,590
Computers and telecommunications	220,316	150,517
Software	64,409	25,069
Leasehold improvements	1,285,883	1,228,108
Property and equipment, at cost	2,655,731	2,451,775
Less accumulated depreciation and amortization	(1,598,811)	(1,347,567)
Property and equipment, net	\$ 1,056,920	\$ 1,104,208

Depreciation expense related to property and equipment for the years ended December 31, 2020 and 2019 was \$251,244 and \$239,821, respectively.

## 5. Intangible Assets

The Company's intangible assets consisted of the following:

December 31, 2020					
	Estimated Useful Lives	Gross Carrying Value	Accumulated Amortization	Impairment	Net Book Value
Internally developed patents	6 – 10 years	\$ 884,787	\$ (479,908)	\$ —	\$ 404,879
Acquired licenses	16 – 20 years	285,000	(285,000)	—	—
Total intangible assets subject to amortization		1,169,787	(764,908)	—	404,879
IPR&D assets	Indefinite	12,418,967	—	—	12,418,967
Total		<u>\$ 13,588,754</u>	<u>\$ (764,908)</u>	<u>\$ —</u>	<u>\$ 12,823,846</u>

  

December 31, 2019					
	Estimated Useful Lives	Gross Carrying Value	Accumulated Amortization	Impairment	Net Book Value
Internally developed patents	6 – 10 years	\$ 746,323	\$ (448,874)	\$ —	\$ 297,449
Acquired licenses	16 – 20 years	285,000	(269,221)	—	15,779
Total intangible assets subject to amortization		1,031,323	(718,095)	—	313,228
IPR&D assets	Indefinite	13,418,967	—	(1,000,000)	12,418,967
Total		<u>\$ 14,450,290</u>	<u>\$ (718,095)</u>	<u>\$ (1,000,000)</u>	<u>\$ 12,732,195</u>

Amortization expense of intangible assets subject to amortization totaled \$46,813 and \$147,500 for the years ended December 31, 2020 and 2019, respectively, and was classified as research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

As of December 31, 2020, future estimated amortization expense is as follows:

For the Year Ended December 31,			
2021		\$	26,561
2022			26,561
2023			26,561
2024			22,655
2025			17,187
2026 and thereafter			285,354
Total		<u>\$</u>	<u>404,879</u>

The above future estimated amortization expense does not include potential amortization charges related to the remaining carrying value of IPR&D assets as of December 31, 2020. Those assets, which represent incomplete technologies, will be amortized to expense once the underlying technologies are substantially complete over their estimated useful lives, expected to be 15 to 18 years. In the event that in the future the Company ceases the development of these assets, the remaining carrying value would be written off at that time. IPR&D assets are periodically assessed for impairment by considering the state of completion of the projects, the remaining activities required to complete development, the anticipated market for the completed products, and anticipated future cash required to complete development.

There was no impairment loss during the year ended December 31, 2020. During 2019, as a result of the SparVax-L NIAID contract completion and the U.S. government's funding prioritization of only single dose anthrax vaccine candidates, the Company abandoned the project and concluded that the full remaining net book value of the SparVax-L IPR&D asset was impaired. As a result, \$1.0 million was written off as an impairment charge which was classified as a component of operating expenses during the year ended December 31, 2019.

## 6. Leases

The Company rents office and laboratory space in the United States. The Company also leases office equipment under a non-cancellable equipment lease through December 2022. Rent expense during the years ended December 31, 2020 and 2019 under all of

the Company's operating leases was \$407,200 and \$346,603, respectively, which includes short-term leases and variable lease costs not included in the lease obligation.

The office space lease provides for increases in future minimum annual rental payments as defined in the lease agreements. The office space lease also includes an option to renew the lease as of the end of the term. The Company has determined that the lease renewal option is not reasonably certain of being exercised.

The cash paid for operating lease liabilities for the year ended December 31, 2020 and 2019 was \$391,090 and \$380,805, respectively.

Supplemental balance sheet information related to the operating leases is as follows:

	December 31,	
	2020	2019
Operating lease obligations (see Note 7 and 9)	\$ 1,824,840	\$ 1,744,128
Right of use asset	\$ 903,825	\$ 698,321
Weighted-average remaining lease term	4.33	5.33
Weighted-average discount rate	7.3%	8.0%

Maturities of operating lease liabilities are as follows:

Year ending December 31,		
2021	\$	475,372
2022		484,484
2023		493,868
2024		503,535
2025		168,929
Total operating lease payments		2,126,188
Less: imputed interest		(301,348)
Total operating lease liabilities (see Note 7 and 9)	\$	1,824,840

## 7. Accrued Expenses and Other Current Liabilities

Accrued expense and other current liabilities consist of the following:

	December 31,	
	2020	2019
Accrued professional services	\$ 1,350,194	\$ 429,467
Accrued payroll and employee benefits	2,351,599	1,183,130
Accrued interest	13,016	5,047
Accrued research and development	7,316,876	1,966,111
Lease obligation, current portion (see Note 6)	356,716	259,449
Deferred revenue	19,753	61,563
Total accrued expenses	\$ 11,408,154	\$ 3,904,767

## 8. Contingent Consideration

The Company entered into an Agreement and Plan of Merger and Reorganization, dated July 8, 2019, by and among the Company, Springfield Merger Sub, Inc., Springfield Merger Sub, LLC, Spitfire Pharma, Inc. and David Collier, as the Stockholder Representative (the "Spitfire Merger Agreement") to acquire all of the equity interests of Spitfire Pharma, Inc. ("Spitfire"). Spitfire was a privately held, preclinical pharmaceutical company developing a novel dual GLP-1/glucagon receptor agonist for the treatment of non-alcoholic steatohepatitis.

The transaction closed on July 12, 2019. The Company issued 1,887,250 unregistered shares of its common stock (the "shares") as upfront consideration to certain former securityholders of Spitfire (collectively, the "Spitfire Equityholders"), representing an amount equal to \$5.0 million less working capital and transaction expense adjustment amounts as defined in the agreement.



The acquisition of Spitfire was accounted for as an asset acquisition instead of a business combination because substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset or group of similar identifiable assets, and therefore, the asset was not considered a business. The Company expensed the acquired intellectual property as of the acquisition date as in-process research and development with no alternative future uses. During the year ended December 31, 2019, the Company recorded an in-process research and development expense of \$4.3 million for the upfront consideration, which included the fair value of the common stock transferred and net liabilities assumed. Transaction costs of \$0.7 million was recorded within research and development expense on the Company's consolidated statements of operations and comprehensive loss during the year ended December 31, 2019.

The Spitfire Merger Agreement also includes future contingent payments up to \$88.0 million in cash and shares of the Company's common stock as follows (each, a "Milestone Event"):

- a one-time payment of \$5.0 million (the "IND Milestone Consideration Amount") within sixty days of the submission of an Investigational New Drug Application ("IND") to the United States Food and Drug Administration (the "FDA") or other applicable governmental authority in a foreign jurisdiction, which IND has not been rejected or placed on clinical hold by the FDA or such applicable foreign governmental authority within time specified in the Spitfire Merger Agreement;
- a one-time payment of \$3.0 million (the "Phase 2 Milestone Consideration Amount" and together with the IND Milestone Consideration Amount, the "Regulatory Milestones") within sixty days of the initiation of a human clinical trial of a product candidate anywhere in the world; and
- payments of up to \$80.0 million upon the achievement of specified worldwide net sales (the "Sales Milestones") of all products developed using the technology acquired in the License Agreement within ten years following the approval of a new drug application filed with the FDA.

The Regulatory Milestones will be payable in shares of the Company's Common Stock, with the number of shares of the Company's Common Stock to be issued in connection with each milestone amount, if any, are dependent on the share price at the time of achievement. The number of any shares issued in consideration for the IND Milestone Consideration Amount will be determined based on lower of (A) the average of the closing prices of our Common Stock as reported on the Nasdaq Global Market for the twenty (20) consecutive trading days prior to the IND Reference Date or (B) \$2.95. The value of any shares issued in consideration for the Phase 2 Milestone Consideration Amount shall be determined based the lower of (A) on the average of the closing trading prices of our Common Stock as reported on the Nasdaq Global Market for the twenty (20) consecutive trading days immediately preceding the date of the occurrence of the Phase 2 Milestone Event or (B) \$3.54.

The future contingent payments related to the Regulatory Milestones are stock-based payments accounted for under FASB Accounting Standards Codification Topic 480, *Distinguishing Liabilities From Equity* ("ASC 480"). Such stock-based payments are subject to a lock-up whereby 50% of the shares are released at 3 months and 50% are released at 6 months. The future contingent payments related to the Sales Milestones are predominately cash-based payments accounted for under FASB Accounting Standards Codification Topic 450, *Contingencies*. Accordingly, the Company will recognize the Sales Milestones when the contingency is resolved and the amount is paid or payable.

On November 3, 2020, the Company received acknowledgement from the Australian Government Department of Health on the Company's submitted clinical trial notification ("CTN") which triggered the obligation to settle the IND Milestone payment to the former owners. As a result, on November 19, 2020, the Company issued 1,694,906 shares of its Common Stock valued at \$9.57 per share for the amount value of \$13.6 million to the former Spitfire stockholders. Pursuant to the Spitfire Merger Agreement, the Company issued the shares within sixty days of the submission of the CTN, which was October 29, 2020. From September 30, 2020 through the date of issuance, the Company recognized a decrease in the fair value of the IND Milestone payment of \$5.4 million to research and development expense and reclassified the balance in the contingent consideration liability associated with the fair value of the IND Milestone payment to equity in the Company's consolidated balance sheet.

At the acquisition date, the Company estimated future contingent consideration of \$2.8 million for the Regulatory Milestones which was based upon a Monte Carlo simulation that was risk adjusted based on the probability of achieving the milestones and a discount for lack of marketability, which was expensed to in-process research and development expenses during the third quarter of 2019. The Company remeasures the fair value of contingent consideration at each reporting date, and below is a summary of the contingent consideration activity through December 31, 2020:

	Year Ended December 31,	
	2020	2019
Beginning balance	\$ 2,750,000	\$ —
Acquisition date fair value	—	2,750,000
Cumulative change in fair value	16,265,010	—
Fair value of payments settled in common stock (IND Milestone)	(13,625,010)	—
Ending balance	\$ 5,390,000	\$ 2,750,000

The net increase in fair value throughout 2020 was primarily attributable to an increase in the closing share price of the Company's common stock and in the probability of milestone achievement, partially offset by the fair value of the IND Milestone payment settled in common stock. Any changes in fair value including the initial determination of acquisition date fair value have been recorded within research and development expense during the respective periods presented.

## 9. Notes Payable and Other Liabilities

### Paycheck Protection Program

On April 7, 2020, the Company applied for a loan from ServisFirst Bank, as lender, pursuant to the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") as administered by the U.S. Small Business Administration (the "SBA"). On April 13, 2020, the Loan was approved and the Company received the proceeds from a loan in the amount of \$632,000 (the "PPP Loan").

The PPP Loan, which took the form of a promissory note (the "Promissory Note"), was set to mature on April 7, 2022 and bore interest at a rate of 1% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (discussed below), was to commence on November 7, 2020. The Promissory Note provided for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company could prepay the principal of the PPP Loan at any time without incurring any prepayment charges.

All or a portion of the Loan may be forgiven by the SBA and lender upon application by the Company upon documentation of expenditures in accordance with the SBA requirements. On July 21, 2020, the Company voluntarily extinguished the Promissory Note by paying the outstanding principal and accrued interest in cash.

The Company's other long-term liabilities are summarized as follows:

	December 31,	
	2020	2019
Lease obligation, long-term portion (see Note 6)	\$ 1,468,124	\$ 1,484,679
Conditional economic incentive grants	250,000	250,000
Other	110,319	130,196
Total other long-term liabilities	\$ 1,828,443	\$ 1,864,875

### BPI France Notes

The Company had two non-interest-bearing research and development funding arrangements with BPI France that were entered into in December 2013 to provide up to €750,000 in research funding in the first arrangement and up to €250,000 in the second arrangement. The Company was permitted to draw 50% of the funds upon the signing of the arrangements, an additional 30% contingent upon a financial audit and technical progress report, and the remaining amounts at the completion of the research and development project being funded by the arrangements. In October 2016, the Company and BPI France agreed to extend the term on the arrangement by two years. The total amount advanced under the arrangements was €500,000. In April 2019, the Company was notified that €102,951 exceeded the allowable funding in accordance with the arrangement and made payment of this amount on June 5, 2019. In September 2019, the Company was notified that €238,229 (\$265,540) was converted into a grant and recognized as grant revenue for the year ended December 31, 2019. In October 2019, the Company paid the remaining balance on the BPI France notes. The total repayments during the year ended December 31, 2019 was \$292,002.

### Economic Incentive Grants

The Company has two conditional economic incentive grants for a total of \$250,000 from Montgomery County, Maryland and the State of Maryland. The Montgomery County grant was received in May of 2018, with a term expiring on February 28, 2028. The State of Maryland grant was received in October 2019, with a 10-year term expiring on December 31, 2029. These grants are conditional primarily based on the Company maintaining its current headquarter locations in addition to employing a required number

of employees at different reporting dates through the term of the grant. The Company is accruing 3% interest on both grants and has recorded \$12,625 and \$5,042 in interest expense for the years ended December 31, 2020 and 2019, respectively.

## 10. Common Stock

### *Public Offering*

On July 16, 2020, the Company offered and sold (i) 3,369,564 shares of common stock, at a price to the public of \$23.00 per share, and (ii) pre-funded warrants of the Company to purchase 1,630,436 shares of common stock at an exercise price equal to \$0.0001 per share (the “Pre-Funded Warrants”), at a price to the public of \$22.9999 per share of common stock underlying the Pre-Funded Warrants (equal to the public offering price per share of Common Stock, minus the exercise price of each Pre-Funded Warrant). The Pre-Funded Warrants are exercisable at any time, provided that each Pre-Funded Warrant holder will be prohibited from exercising such Pre-Funded Warrants into shares of the Company’s common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of the Company’s common stock then issued and outstanding, which percentage may change at the holders’ election to any other number less than or equal to 19.99% upon 61 days’ notice to the Company. The gross proceeds of this offering were approximately \$132.2 million, which includes the exercise in full of the underwriters’ option to purchase an additional 750,000 shares of common stock, before deducting underwriting discounts and commissions and offering expenses during the third quarter of 2020. The net proceeds of this offering were approximately \$124.0 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

The Company has assessed the Pre-Funded Warrants for appropriate equity or liability classification and determined that the Pre-Funded Warrants are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to FASB Accounting Standards Codification Topic 815, *Derivatives and Hedging* (“ASC 815”). The Pre-Funded Warrants are indexed to the Company’s common stock and meet all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the Pre-Funded Warrants are classified as equity and are accounted for as a component of additional paid-in capital at the time of issuance.

During the year ended December 31, 2020, no Pre-Funded Warrants were exercised.

### *At-the-Market Offering*

On March 27, 2020, the Company entered into an Equity Distribution Agreement (the “Agreement”) with JMP Securities LLC, serving as placement agent (the “Placement Agent”) with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value \$0.0001 per share (the “Common Stock”), having an aggregate offering price of up to \$50.0 million (the “Shares”) through the Placement Agent (the “Offering”).

Any Shares offered and sold in the Offering were issued pursuant to the Company’s Registration Statement on Form S-3 filed with the Securities and Exchange Commission (the “SEC”) on April 4, 2019, which was declared effective on April 12, 2019, the prospectus supplement relating to the Offering filed with the SEC on March 27, 2020 and any applicable additional prospectus supplements related to the Offering that form a part of the Registration Statement. The aggregate market value of Shares eligible for sale in the Offering and under the Equity Distribution Agreement were subject to the limitations of General Instruction I.B.6 of Form S-3, to the extent required under such instruction. The Company offered Shares having an aggregate offering price of \$18.9 million pursuant to the prospectus supplement filed with the SEC on March 27, 2020. On June 1, 2020, the Company filed an amendment to the Agreement which amended the prospectus supplement dated March 27, 2020 to increase the aggregate offering price to \$50.0 million.

As of December 31, 2020, the Company has sold 5,594,455 shares of Common Stock under the Agreement resulting in \$48.2 million in net proceeds, which concluded this Offering. The Company recorded and recognized approximately \$0.3 million of offering costs which offset the proceeds received from the shares sold associated with this program.

### *Registered Direct Offering*

On March 12, 2019, the Company issued a combined total of 4,361,370 common units and pre-funded units to certain institutional investors in a registered direct offering (the “Registered Direct Offering”). Each common unit in the Registered Direct Offering was sold at a price of \$3.21 and consisted of one share of common stock and 0.70 of a warrant to purchase one share of common stock at an exercise price of \$3.21. Each warrant sold in the Registered Direct Offering was exercisable immediately and expired five years from the date of issuance. Each pre-funded unit in the Registered Direct Offering was sold at a public offering price of \$3.20 and consisted of a pre-funded warrant to purchase one share of common stock at an exercise price of \$0.01 per share and 0.70 of a warrant to purchase one share of common stock at an exercise price of \$3.21. All of the pre-funded warrants were exercised

during 2019. The net proceeds of the Registered Direct Offering were \$12.7 million, after deducting the underwriting discount and estimated offering expenses payable by the Company.

The warrants issued in the Registered Direct Offering were recognized as equity classified freestanding financial instruments. The Registered Direct Offering triggered a down round adjustment to the exercise price of the warrants issued in the 2018 Unit Offering (refer to Note 11) from \$4.1798 to \$2.7568. During the year ended December 31, 2019, the Company treated the value of the effect of the reduction in exercise price as a deemed dividend of \$452,925 which reduced income available to common shareholders. The value of a down round feature is measured as the difference between the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and the financial instrument's fair value (without the down round feature) using the reduced exercise price.

## 11. Warrants

The following common stock warrants were outstanding at December 31, 2020:

	Number of Common Stock Warrants	Per Share Exercise Price	Issuance Date	Expiration Date
Replacement warrants	155	\$ 483.00	March 3, 2012	March 3, 2022
Issued with redeemable preferred stock*	1,420	3.50	August 16, 2017	August 16, 2022
Issued with common units in the 2018 Unit Offering	3,300	2.7568	October 2, 2018	October 2, 2023
Issued with common units in the 2018 Registered Direct Offering	92,300	5.40	October 10, 2018	October 10, 2023
Issued with common units in the 2019 Registered Direct Offering (see Note 10)	50,000	3.21	March 12, 2019	March 12, 2024
Issued with common units in the 2020 Public Offering (see Note 10)	1,630,436	0.0001	July 16, 2020	—
Total	<u>1,777,611</u>			

\*Liability classified warrants

The following common stock warrants were outstanding at December 31, 2019:

	Number of Common Stock Warrants	Per Share Exercise Price	Issuance Date	Expiration Date
Replacement warrants	155	\$ 483.00	March 3, 2012	March 3, 2022
Issued with redeemable preferred stock*	62	80.10	August 16, 2017	August 16, 2022
Issued with common units in 2018 Unit Offering	2,505,250	2.7568	October 2, 2018	October 2, 2023
Underwriter warrant issued in 2018 Unit Offering	196,650	6.25	October 2, 2018	September 28, 2021
Issued with common units in the 2018 Registered Direct Offering	4,629,630	5.40	October 10, 2018	October 10, 2023
Issued with common units in the 2019 Registered Direct Offering (see Note 10)	3,052,959	3.21	March 12, 2019	March 12, 2024
Total	<u>10,384,706</u>			

\*Liability classified warrants

The following is a description of the common stock warrants issued prior to January 1, 2019:

### Replacement Warrants

In May 2017, the Company issued 155 common stock warrants to replace outstanding common stock warrants in connection with the Company's merger with PharmAthene, Inc.

### Redeemable Preferred Stock Warrants

In August 2017, in connection with a redeemable preferred stock issuance, the Company granted warrants to holders of redeemable preferred stock to purchase up to 78,181 shares of the Company's common stock. Warrants issued with the redeemable

preferred stock are classified as a liability and were initially recorded at their grant date fair value, and remeasured on each subsequent balance sheet date. The warrant liability is classified as a component of other long-term liabilities. During the year ended December 31, 2019, the Company exchanged 1,550 of these warrants for a combination of common stock and cash, leaving 62 of these warrants outstanding as of December 31, 2019. During the second quarter of 2020, the 62 common stock warrants were repriced to 1,420 common stock warrants due to the At-the-Market Offering which triggered an anti-dilution provision under the warrant agreement with the Company's holders of redeemable preferred stock.

### 2018 Unit Offering

On October 2, 2018, the Company issued a combined total of 2,400,000 common units and pre-funded units in a public offering (the "2018 Unit Offering"). Each common unit in the 2018 Unit Offering was sold at a public offering price of \$5.00 and consisted of one share of common stock and a warrant to purchase one share of common stock at an exercise price of \$6.00. Each warrant sold in the 2018 Unit Offering was exercisable immediately and expired five years from the date of issuance. Each pre-funded unit in the 2018 Unit Offering was sold at a public offering price of \$4.99 and consisted of a pre-funded warrant to purchase one share of common stock at an exercise price of \$0.01 per share and a warrant to purchase one share of common stock at an exercise price of \$6.00. The pre-funded warrants were immediately exercisable and were able to be exercised at any time until all of the pre-funded warrants were exercised in full. All of the pre-funded warrants were exercised prior to December 31, 2018.

The warrants issued in the 2018 Unit Offering are each subject to anti-dilution protection. Accordingly, to the extent the Company was to issue additional common stock or securities convertible into common stock at an issuance price lower than exercise price of the warrants, the exercise price of the warrants would be adjusted to the lower of (i) the issuance price or (ii) the lowest volume weighted average price of the Company's common stock on the five trading days following the announcement of the new offering.

In conjunction with the 2018 Unit Offering, the Company issued 196,650 warrants to the underwriter. The underwriter warrants had an exercise price per share equal to 125% of the public offering price per common unit in this offering and could be exercised on a cashless basis. As of December 30, 2020, all of the underwriter warrants were exercised in full.

### 2018 Registered Direct Offering

On October 10, 2018, the Company issued a combined total of 4,629,630 common units and pre-funded units to certain institutional investors in a registered direct offering (the "2018 Registered Direct Offering"). Each common unit in the 2018 Registered Direct Offering was sold at a price of \$5.40 and consisted of one share of common stock and a warrant to purchase one share of common stock at an exercise price of \$5.40. Each warrant sold in the 2018 Registered Direct Offering was exercisable immediately and expired five years from the date of issuance. Each pre-funded unit in the 2018 Registered Direct Offering was sold at a public offering price of \$5.39 and consisted of a pre-funded warrant to purchase one share of common stock at an exercise price of \$0.01 per share and a warrant to purchase one share of common stock at an exercise price of \$5.40. The pre-funded warrants were immediately exercisable and were able to be exercised at any time until all of the pre-funded warrants are exercised in full. All of the pre-funded warrants were exercised prior to December 31, 2018.

The 2018 Registered Direct Offering triggered a down round adjustment to the exercise price of the warrants issued in the 2018 Unit Offering from \$6.00 to \$4.1798.

A summary of warrant activity is as follows:

	<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Warrants outstanding, beginning	10,384,706	7,344,297
Issuances	1,631,794	3,052,959
Exercises	(10,238,889)	(12,550)
Warrants outstanding, ending	<u>1,777,611</u>	<u>10,384,706</u>

## **12. Stock-Based Compensation**

### *Stock Options*

The Company established the 2001 Employee Stock Option Plan to provide incentive stock options and non-qualified stock options to employees, and the 2001 Non-employee Stock Option Plan to provide non-qualified stock options to the members of the board of directors and advisory board, and non-employees. The 2001 Employee Stock Option Plan and the 2001 Non-employee Stock Option Plan are collectively referred to as the "2001 Plans." In connection with the PharmAthene Merger Agreement in 2017, the

Company issued options from its 2001 Plans to replace options previously granted. The Company de-designated common stock available for issuance under the 2001 Plans. No additional options or restricted stock will be granted under these plans. Options outstanding and unvested restricted stock granted or replaced under these plans will continue to vest over the remaining vesting period through the earlier of exercise, expiration, or forfeiture no additional options, restricted stock or other awards will be granted under these plans. The replacement options issued after the 2017 mergers will continue to vest over the remaining vesting period through the earlier of exercise, expiration, or forfeiture. Also, in connection with the 2017 mergers, the 2001 Plans were assumed by the Company.

In addition, the Company assumed the PharmAthene, Inc. Amended and Restated 2007 Long-Term Incentive Compensation Plan (the “2007 Plan”). Awards outstanding under the 2007 Plan remained outstanding in accordance with their applicable terms and conditions. No additional awards will be made under the 2007 Plan.

The Company established the 2017 Omnibus Incentive Plan (the “Omnibus Plan”) to provide incentive stock options, non-qualified stock options, restricted stock, and other stock-based awards denominated in shares of the Company’s common stock, and performance-based cash awards to eligible employees, consultants, and directors. In 2018, the Company’s shareholders approved an amendment to the Omnibus Plan to increase the number of shares reserved for issuance from 1,500,000 to 5,000,000. The aggregate share reserve will be increased on January 1 of each year commencing in 2018 and ending on and including January 1, 2027 up to an amount equal to the lowest of (i) 4% of the total number of shares of common stock outstanding on a fully diluted basis as of December 31 of the immediately preceding calendar year, and (ii) such number of shares of common stock, if any, determined by the Company’s board of directors. The maximum shares of common stock that may be granted to each employee or consultant in any fiscal year under the Omnibus Plan is the lesser of 800,000 shares per type of award or a maximum compensation amount of \$5,000,000 under a Black-Scholes valuation model. The maximum common stock that may be granted to directors under the Omnibus Plan during any fiscal year is 500,000 shares.

On November 29, 2018, the Board approved and adopted the Altimune Inc. 2018 Inducement Grant Plan (the “Inducement Plan”). The Inducement Plan provides for the grant of equity or equity-based awards in the form of non-qualified stock options, restricted stock awards, and other stock-based awards. The Inducement Plan was adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules.

The Board has reserved 2,000,000 shares of the Company’s common stock for issuance pursuant to awards granted under the Inducement Plan (subject to customary adjustments in the event of a change in capital structure of the Company), and the Inducement Plan will be administered by the Compensation Committee. In accordance with Rule 5635(c)(4) of the NASDAQ Listing Rules, awards under the Inducement Plan may be only made to an employee who has not previously been an employee or member of the Board or any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary.

The 2001 Plans, the 2007 Plan, the Omnibus Plan, and the Inducement Plan are collectively referred to as the “Plans.” During the year ended December 31, 2020 under the Plans, a total of 708,000 options to purchase shares of common stock were granted. As of December 31, 2020, there were 324,710 and 1,517,001 shares of common stock available for future grants under the Omnibus Plan and the Inducement Plan, respectively.

The fair value of stock option issued to employees was estimated at the date of grant using Black-Scholes with the following weighted-average assumptions:

	For the Year Ended December 31,	
	2020	2019
Expected volatility	102.35%	92.68%
Expected term (years)	5.88	5.89
Risk-free interest rate	1.24%	2.17%
Expected dividend yield	0.00%	0.00%

*Expected volatility:* As there is not sufficient historical volatility for the expected term of the stock options, the Company uses an average historical share price volatility, inclusive of its own volatility, based on an analysis of reported data for a peer group of comparable companies which were selected based upon industry similarities.

*Expected term (years):* Expected term represents the number of years that the Company’s option grants are expected to be outstanding. There is not sufficient historical share exercise data to calculate the expected term of the stock options, therefore, the

Company elected to utilize the simplified method to value option grants. Under this approach, the weighted average expected life is presumed to be the average of the vesting term and the contractual term of the option.

*Risk-free interest rate:* The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the daily U.S. Treasury yield curve rate in effect as of the date of grant.

*Expected dividend yield:* The Company does not anticipate paying any dividends in the foreseeable future.

The fair value of each non-employee stock option is estimated at the date of grant using Black-Scholes with assumptions generally consistent with those used for employee stock options, with the exception of expected term, which is over the contractual life.

A summary of stock option activity under the Plans is presented below:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2019	973,172	\$ 4.36	5.91	\$ —
Granted	708,000	\$ 4.75		
Exercised	(46,966)	\$ 2.74		
Forfeited or expired	(7,454)	\$ 6.48		
Outstanding, December 31, 2020	<u>1,626,752</u>	\$ 4.58	5.90	\$ 12,234,740
Exercisable, December 31, 2020	<u>550,518</u>	\$ 5.93	5.74	\$ 4,104,806
Vested and expected to vest, December 31, 2020	<u>968,611</u>	\$ 3.88	5.98	\$ 8,129,935

The per share weighted-average grant date fair value of stock options granted during the years ended December 31, 2020 and 2019 were \$4.75 and \$2.67 per share, respectively. The total intrinsic value of stock options exercised during the year ended December 31, 2020 was \$0.9 million. There were no shares exercised during the year ended December 31, 2019. The total fair value of awards vested during 2020 and 2019 was \$1.1 million and \$1.0 million, respectively. At December 31, 2020, there was \$2.7 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 2.4 years.

#### *Restricted Stock*

In October 2016, the Company authorized and granted a restricted stock award of 2,651 shares at an aggregate purchase price of \$1,067. The weighted average grant date fair value of the restricted stock award was \$310.80 per share. The restricted stock vests ratably at the end of each quarter over four years starting on December 31, 2016 with 50% of the original issued shares subject to accelerated vesting upon a deemed liquidation event. During the year ended December 31, 2020, 213 of the restricted shares fully vested, which completed the vesting of this share award.

In November 2018, the Company authorized and granted the Chief Executive Officer a restricted stock award of 322,907 shares on his date of hire. The weighted average grant date fair value of the restricted stock award was \$3.59 per share. The restricted stock vests over a four-year period, 25% of the shares vesting on the one-year anniversary, and the remaining 75% vesting in 36 substantially equal monthly installments and will be fully vested on December 1, 2022; provided, however, that the executive officer has not experienced a termination prior to the applicable vesting date. The fair value of the 80,727 restricted shares that vested during the year ended December 31, 2020 totaled \$0.8 million.

In June 2020, the Company authorized and granted 109,525 shares of restricted stock awards which vested over three months. The weighted average grant date fair value of the restricted stock award was \$9.19 per share. The fair value of the 109,525 restricted shares that vested during the year ended December 31, 2020 totaled \$1.3 million.

In September 2020, the Company authorized and granted 15,000 shares of restricted stock units which vested over a four-year period, 25% of the shares vesting on the one-year anniversary, and the remaining 75% vesting in 36 substantially equal monthly installments and will be fully vested on September 22, 2024. The weighted average grant date fair value of the restricted stock award was \$14.35 per share. No restricted shares vested during the year ended December 31, 2020.

A summary of restricted stock activities is presented below:

	Shares		Weighted-average Grant Date Fair Value
Unvested, December 31, 2019	235,666	\$	3.87
Granted	124,525		9.81
Vested	(190,465)		7.15
Unvested, December 31, 2020	<u>169,726</u>	\$	4.54

As of December 31, 2020, total unrecognized compensation expense related to restricted stock awards was \$0.7 million, which the Company expects to recognize over a weighted average period of approximately 2.1 years.

#### *2019 Employee Stock Purchase Plan*

On March 29, 2019, the board of directors adopted the 2019 Employee Stock Purchase Plan (the “2019 ESPP”). A total of 403,500 shares of the Company’s common stock have been reserved for issuance under the 2019 ESPP. Subject to any plan limitations, the 2019 ESPP allows eligible employees to contribute through payroll deductions up to 10% of their earnings for the purchase of the Company’s common stock at a discounted price per share. The offering periods begin in February and August of each year, with the initial offering period started on August 1, 2019. The common shares issuable under the 2019 ESPP were registered pursuant to a registration statement on Form S-8 on April 4, 2019.

Unless otherwise determined by the administrator, the Company’s common stock will be purchased for the accounts of employees participating in the 2019 ESPP at a price per share that is the lesser of 85% of the fair market value of the Company’s common stock on the first trading day of the offering period or 85% of the fair market value of the Company’s common stock on the last trading day of the offering period. The ESPP estimated shares to be purchased fair value is included in the stock-based compensation expense.

Employees have the ability to purchase shares of the Company’s common stock at the lower of the first or last trading day of the offering period, which represents an option and, therefore, the ESPP is a compensatory plan under ASC 718-50, *Employee Stock Purchase Plans*. Accordingly, stock-based compensation expense is determined based on the option’s grant-date fair value, employee contributions, and the Company’s stock price and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model.

During the year ended December 31, 2020, employees purchased 92,661 shares for \$135,466 under the 2019 ESPP. The Company recognized stock-based compensation expense related to this plan of \$158,177 and \$21,608 for the years ended December 31, 2020 and 2019, respectively.

#### *Stock-based Compensation Expense*

Stock-based compensation expense is classified in the accompanying consolidated statements of operations and comprehensive loss for the years ended December 31, 2020 and 2019 as follows:

	Year Ended December 31,	
	2020	2019
Research and development	\$ 357,762	\$ 356,718
General and administrative	2,218,244	907,513
Total	<u>\$ 2,576,006</u>	<u>\$ 1,264,231</u>

### **13. U.S. Government Contracts and Grants**

In June 2020, the Company was awarded \$4.7 million from the U.S. Army Medical Research & Development Command (“USAMRDC”) to fund its Phase 1/2 clinical trial of T-COVID. The competitive award was granted by USAMRDC in collaboration with the Medical Technology Enterprise Consortium (“MTEC”), a 501(c)(3) biomedical technology consortium working in partnership with the Department of Defense (“DoD”). Under the contract, MTEC will pay the Company a firm fixed fee based upon the achievement of certain milestones for conduct and completion of a Phase 1/2 study and research and development work on the replication-deficient adenovirus 5 (“RD-Ad5”) vector vaccine platform. For the year ended December 31, 2020, the Company has recognized \$4.2 million of grant revenue under this contract.



In July 2016, the Company signed a five-year contract with BARDA. The contract, as amended, has a total value of up to \$133.7 million and is used to fund clinical development of NasoShield. Under the contract, BARDA pays the Company a fixed fee and reimburses certain costs for the research and development of an Ad5-vectored, protective antigen-based intranasal anthrax vaccine through cGMP manufacture and conduct of a Phase 1 clinical trial dose ranging assessment of safety and immunogenicity. The contract consists of an initial base performance period providing approximately \$27.8 million in funding for the period July 2016 through June 2021. BARDA has seven options to extend the contract to fund certain continued development and manufacturing activities for the anthrax vaccine, including Phase 2 clinical studies. Each option, if exercised by BARDA, would provide additional funding ranging from approximately \$1.1 million to \$34.4 million for a three-year period beginning in 2021. For the years ended December 31, 2020 and 2019, the Company has recognized \$3.1 million and \$5.3 million of grant revenue under the current BARDA contract, respectively.

#### 14. Employee Benefit Plans

The Company has a 401(k)-retirement plan in which substantially all of our employees in the United States are eligible to participate in. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. During 2020 and 2019, the Company made discretionary plan contributions of \$170,727 and \$131,412, respectively.

#### 15. Income Taxes

The components of net loss before income tax benefit are as follows:

	Year Ended December 31,	
	2020	2019
U.S. operations	\$ (50,735,735)	\$ (18,562,738)
Non-U.S. operations	(3,725,766)	(2,015,893)
Net loss before income tax benefit	<u>\$ (54,461,501)</u>	<u>\$ (20,578,631)</u>

The components of the income tax benefit are as follows:

	Year Ended December 31,	
	2020	2019
U.S. federal		
Current	\$ 4,706,092	\$ —
Deferred	—	45,465
U.S. state and local		
Current	710,932	—
Deferred	—	13,035
Income tax benefit	<u>\$ 5,417,024</u>	<u>\$ 58,500</u>

Reconciliation between the effect of applying the federal statutory rate and the effective income tax rate used to calculate the Company's income tax benefit is as follows:

	Year Ended December 31,	
	2020	2019
Federal statutory rate	21.00%	21.00%
State income taxes, net of federal benefit	4.10	3.12
Research and development tax credit	(0.84)	(1.51)
Acquired in process research and development	(6.27)	(7.03)
CARES Act U.S. federal and state carryback claim	1.81	—
Other	0.29	(2.81)
Change in valuation allowance	(10.14)	(12.49)
Effective tax rate	<u>9.95%</u>	<u>0.28%</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income and for tax carryforwards. Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2020	2019
<b>Deferred tax assets:</b>		
Net operating losses	\$ 18,978,410	\$ 13,493,760
Accrued expenses	495,301	208,604
Amortization	785,523	947,115
Stock compensation	584,507	622,789
Lease liability	502,151	479,940
Other	106,197	117,713
Valuation allowance	(18,671,086)	(13,149,779)
<b>Total deferred tax assets</b>	<b>2,781,003</b>	<b>2,720,142</b>
<b>Deferred tax liabilities:</b>		
IPR&D assets	(2,386,667)	(2,373,304)
Right of use asset	(248,710)	(192,160)
Depreciation	(145,626)	(154,678)
<b>Total deferred tax liabilities</b>	<b>(2,781,003)</b>	<b>(2,720,142)</b>
<b>Total deferred tax liabilities net</b>	<b>\$ —</b>	<b>\$ —</b>

The Company assesses the need for a valuation allowance against our deferred tax assets and considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. This determination requires significant judgment, including assumptions about future taxable income that are based on historical and projected information. The increase in the valuation allowance during the year ended December 31, 2020 primarily relates to increases for current year losses in both the U.S. and foreign locations which the Company concluded needed a full valuation allowance, but was partially offset by the utilization of a portion of the U.S. federal and state losses to offset the Company's 2016 tax liability, due to provisions of the CARES Act enacted in 2020. The Company has recorded a valuation allowance against its gross U.S. deferred tax assets it believes are not more likely than not realizable and the net non-U.S. deferred tax assets, although, a portion of the current year loss was benefited for an additional U.S. Federal carryback from the CARES Act. Deferred tax liabilities, consist primarily of indefinite life IPR&D assets located in a foreign subsidiary, which will be applied in the future to offset against net operating losses ("NOLs") that have an unlimited life.

The Company has U.S. federal and state net operating loss carryforwards of approximately \$45.7 million as of December 31, 2020. Of this amount, \$6.6 million has a 20-year carry forward period that will expire at various dates beginning in 2021. Under current law, the remaining amount of \$39.1 million has an unlimited life. The Company also has foreign net operating loss carryforward of approximately \$30.8 million which carryforward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986, as amended, substantial changes in the Company's ownership may limit the amount of NOLs that can be utilized annually in the future to offset its U.S. federal and state taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of the Company of more than 50% within any three-year period. The amount of the annual limitation is determined based on the value of the Company immediately before the ownership change. The Company has reduced the NOL and related valuation allowance in historical periods and while the Company is in the process of completing its evaluation of whether an equity shift occurred in 2020, it is not expected to require an adjustment to the net NOLs and related valuation allowance. Subsequent ownership changes may further affect the limitation in future years. The Company continues to evaluate its losses for these provisions.

Significant judgment is required in evaluating tax positions and determining the provision for income taxes. The Company establishes liabilities for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes may be due. These liabilities are established when the Company believes that certain positions might be challenged despite its belief that its tax return positions are fully supportable. The Company adjusts these liabilities in light of changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of changes to these liabilities.

The amount of unrecognized tax benefits was \$0.7 million and \$0.0 million as of December 31, 2020 and 2019, respectively. Any changes in the next twelve months are not anticipated to have a significant impact on the results of operations, financial position or cash flows of the Company. All of the Company's uncertain tax positions, if recognized, would affect its income tax expense.

The Company has elected an accounting policy to classify interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2020 and 2019, potential interest and penalties on unrecognized tax benefits were not significant.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits excluding related interest and penalties:

	Year Ended December 31,	
	2020	2019
Beginning of year	\$ —	\$ —
Positions taken in the prior year	710,783	—
End of year	<u>\$ 710,783</u>	<u>\$ —</u>

The Company files income tax returns in the United States, various U.S. states, U.K., and Australia. The Company is still open to examination by the applicable taxing authorities from 2009 forward, although tax attributes that were generated prior to 2009 may still be adjusted upon examination by federal, state, foreign, or local tax authorities if they either have been or will be used in a future period.

#### 16. Net Loss Per Share

Because the Company has reported net loss attributable to common stockholders for the years ended December 31, 2020 and 2019, basic and diluted net loss per share attributable to common stockholders are the same for both years.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average numbers of shares of common stock outstanding for the period. Basic shares outstanding includes the weighted average effect of the Company's outstanding pre-funded warrants, the exercise of which requires little or no consideration for the delivery of shares of common stock.

Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. As such, all unvested restricted stock, common stock warrants, and stock options have been excluded from the computation of diluted weighted average shares outstanding because such securities would have an anti-dilutive impact for all periods presented.

Potential common shares issuable upon conversion, vesting or exercise of unvested restricted stock, common stock warrants, and stock options that are excluded from the computation of diluted weighted-average shares outstanding, as they are anti-dilutive, are as follows:

	December 31,	
	2020	2019
Common stock warrants	147,175	10,384,706
Common stock options	1,631,898	1,001,242
Restricted stock	169,726	235,666

#### 17. Commitments and Contingencies

##### *License Obligations*

##### University of Alabama at Birmingham Research Foundation

The Company had an agreement with the University of Alabama at Birmingham Research Foundation ("UABRF") for the exclusive worldwide license to develop, manufacture, and commercialize certain proprietary technology developed at UABRF. That agreement expired in accordance with its terms in January 2020. Under the terms of the amended and restated agreement, the Company was obligated to pay an annual license fee of \$20,000 and low single digit royalty fees upon the commencement of product sales. Fees incurred under the UABRF agreement totaled \$20,000 for the year ended December 31, 2019 and are classified as a component of research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

##### PER.C6 Cell Line - Janssen Vaccines & Prevention B.V.

The Company has a royalty-bearing, worldwide non-exclusive license agreement with Janssen Vaccines & Prevention B.V. (formerly known as Crucell Holland B.V.) ("Janssen") for use of its vaccine technology. The Company may terminate the license agreement without cause, and the agreement contains customary provisions for either party to terminate prior to the expiration of the

agreement. The amended license agreement expires on a product-by-product and country-by-country basis on the later of the date upon which the last of the licensed patents applicable to the relevant product expires or 15 years from the date of first commercial sale of the relevant product. The Janssen patent rights include patents issued in the United States with an expected expiration date no earlier than April 2020, in each case not giving effect to any potential extensions and assuming payment of all associated fees. Upon expiration of the amended license agreement, or if the Company terminates the amended license agreement for Janssen's material breach, the Company retains the right to exploit the rights granted. Under the agreement, the Company is required to pay an annual license fee and annual royalty fees upon reaching certain milestones in an amount that equals the greater of a low single digit percentage of net sales or \$150,000.

On April 2, 2020, the Company entered into Amendment No. 3 to the Second Restated License Agreement and additionally entered into Amendment No. 4, 5 and 6 throughout 2020 (collectively, the "Amendments"), by and between the Company and Janssen (as amended by Amendment No. 1 to Second Restated License Agreement and Amendment No. 2 to Second Restated License Agreement, together with the Amendments, the "License Agreement"). Pursuant to the Amendment, the field of licenses granted to the Company for the use of the PER.C6 cell line under the License Agreement is expanded to cover COVID-19 caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), in addition to the existing licenses related to Bacillus anthracis and influenza virus. All capitalized terms not defined herein shall have the meanings assigned to them in the Amendment or the License Agreement, as applicable.

Pursuant to the Amendment, the Company agreed to pay certain additional development-based milestone payments through approval of licensed products by the FDA for the treatment or prevention of COVID-19, up to an aggregate amount of \$1.2 million. The Company also agreed to pay royalty payments as a percentage of net sales of products to a royalty stacking reduction and minimum annual royalty payments, until the expiration of the term of the License Agreement, as amended. Fees incurred under the Janssen agreement totaled \$310,502 and \$111,499 for the years ended December 31, 2020 and 2019, respectively, and are included in research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

#### *Spitfire Acquisition*

As disclosed in Note 8, the Company is obligated to make payments of up to \$80.0 million upon the achievement of specified worldwide net sales of all products developed using the technology acquired from Spitfire Pharma Inc. within ten years following the approval of a new drug application filed with the FDA.

#### *Litigation*

In December 2019, a complaint was filed by Dr. De-Chu Christopher Tang ("Plaintiff") against the Company, which the Company removed to the United States District Court for the Eastern District of Texas. The Plaintiff amended the complaint in February 2020 to include Vipin K. Garg and David J. Drutz as defendants, in addition to the Company (Dr. Garg, Dr. Drutz, and the Company are collectively referred to as "Defendants"). In March 2020 the Defendants filed a motion to dismiss the complaint. The Court denied the motion without prejudice and allowed Plaintiff an opportunity to file an amended complaint. Plaintiff's second amended complaint was filed on April 17, 2020, and Defendants filed a motion to dismiss that complaint on May 1, 2020. A hearing on Defendants' motion to dismiss was held on May 20, 2020, and the motion is currently pending. Plaintiff, who is representing himself, alleges five causes of action as follows: (1) Defendants' alleged retention of Plaintiff's lab notebooks after the termination of his employment in 2012; (2) alleged plagiarism based on publishing an article without naming Plaintiff as an author; (3) use of the Adhigh System, which Plaintiff alleges he developed; (4) allegations that Defendants manipulated the Company's stock and caused a decrease in value; and (5) allegations that the Defendants "wast[ed] government grant money and poison[ed] science by leaving data to rot." On September 30, 2020, Plaintiff filed a motion titled "Motion to Proscribe Defendants' Allegedly Illegal Use of Plaintiff's AdHigh System in Altimmune's Human Clinical Trials," to which Defendants filed an opposition on October 13, 2020. The court has not yet ruled on that motion, which also remains pending. On November 6, 2020, Defendants filed a motion for summary judgment on the basis of lack of personal jurisdiction, insufficient service of process, and failure to state a claim. The court has not yet ruled on that motion, which also remains pending. On December 1, 2020, the magistrate judge assigned to the case issued a report and recommendation recommending that Defendants' motion to dismiss of May 1, 2020 be granted and that this action be dismissed for lack of personal jurisdiction. Plaintiff filed objections to the report and recommendation on December 14, 2020, and the resolution of those objections by the district court remains pending. The Company believes the allegations in the complaint are without merit and intends to vigorously defend the litigation. However, the outcome of this legal proceeding is uncertain at this time and the Company cannot reasonably estimate a range of loss, if any. Accordingly, the Company has not accrued any liability associated with this action.

The Company is a party in various other contractual disputes, litigation, and potential claims arising in the ordinary course of business none of which are currently reasonably possible or probable of material loss.

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

## **Item 9A. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as of December 31, 2020. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2020, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act 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 timely decisions regarding required disclosure.

### **Changes in Internal Control Over Financial Reporting**

Our management, including our principal executive and principal financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the year ended December 31, 2020, and has concluded that there was no change that occurred during the year ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an evaluation 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 this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2020.

### **Limitations on Effectiveness of Controls and Procedures**

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

We are a smaller reporting company, and therefore our independent registered public accounting firm has not issued a report on the effectiveness of internal control over financial reporting.

## **Item 9B. Other Information**

None.

**Item 10. Directors, Executive Officers and Corporate Governance****Directors**

Our directors are elected at each annual meeting of stockholders and hold office until the next annual meeting of stockholders and until their successors have been elected and qualified. Our Bylaws provide that the number of Directors constituting the entire Board shall be not less than one nor more than nine as determined by resolution of the Board. Our Board currently has eight Directors, each of whom was elected at the Company's 2020 annual meeting of stockholders.

The names and ages of our directors as of February 25, 2021 are set forth below:

Name	Age	Position
Vipin K. Garg, Ph.D.	63	President, Chief Executive Officer, and Director
Mitchel Sayare, Ph.D.	73	Chairman of the Board
David J. Drutz, M.D.	82	Director
John M. Gill	69	Director
Philip L. Hodges	52	Director
Wayne Pisano	66	Director
Diane Jorkasky, M.D.	69	Director
Klaus O. Schafer, M.D., MPH	71	Director

*Vipin K. Garg, Ph.D.* currently serves as our President and Chief Executive Officer and is a member of the Board of Directors. Dr. Garg joined Altimmune in November 2018 with over three decades of experience in the biotechnology and pharmaceutical industries. He has a proven track record of building and managing both private and publicly traded companies. Before joining Altimmune, from October 2013 to June 2018, he served as President and Chief Executive Officer of Neos Therapeutics, Inc. (Nasdaq: NEOS), where he built a commercial-stage biopharmaceutical company launching three branded therapeutic products including Adzenys XR-ODTTM and Cotempla XR-ODTTM, the first ever XR-ODTTM medications for the treatment of ADHD. Prior to Neos, he served as president and Chief Executive Officer of Tranzyme Pharma where he progressed a discovery-stage, emerging biotech company to a Nasdaq-listed clinical-stage, drug development company. Prior to joining Tranzyme, Dr. Garg served as Chief Operating Officer of Apex Bioscience, Inc. (acquired by Curacyte AG of Munich, Germany), and held senior management positions at DNX Bio-Therapeutics, Inc. (until its acquisition by Baxter Healthcare Corporation), Sunovion Pharmaceuticals, Inc. (formerly known as Sepracor Inc., now a subsidiary of Sumitomo Dainippon Pharma), and Bio-Response Inc. (acquired by Baxter Healthcare Corporation). Dr. Garg received his Ph.D. in Biochemistry in 1982 from the University of Adelaide, Australia, and his M.S. from IARI Nuclear Research Laboratory, New Delhi, India in 1978. We believe that Dr. Garg's extensive experience in the biotechnology and pharmaceutical industries makes him well qualified to serve as a member of our Board of Directors.

*Mitchel Sayare, Ph.D.* has been a member of the Board of Directors since April 2010. Dr. Sayare became Chairman of the Board in January 2018 and served as Executive Chairman from June 2018 to November 2018. Until 2010, Dr. Sayare served as the Chairman of the Board of public company ImmunoGen, Inc. (Nasdaq:IMGN) (a position he had held since 1989). In addition, he served as ImmunoGen's Chief Executive Officer from 1986 to December 31, 2009, and as its President from 1986 to 1992, and from 1994 to July 2008. Prior to joining ImmunoGen, he served as Vice President of Development of Xenogen from 1982 to 1985. Prior to that he was Assistant Professor of Biophysics and Biochemistry at the University of Connecticut. Dr. Sayare earned a Ph.D. in biochemistry from Temple University School of Medicine. Dr. Sayare is a director of Boston IVF, Inc. and Advanced Aesthetic Technologies, Inc., both privately-held companies. We believe that Dr. Sayare's substantial experience as a board member and executive officer of biotechnology companies makes him well qualified to serve as a member of our Board of Directors.

*David J. Drutz, M.D.* has served as a member of our Board of Directors since May 2017, when he was appointed to the Board in connection with the completion of the Merger. Dr. Drutz was first elected to Private Altimmune's Board of Directors in January 2010 and was elected Board Chairman in October 2011. Dr. Drutz is the President of Pacific Biopharma Associates, LLC, a biopharmaceutical consulting company that he founded in 1999. From 2008 to 2015, he held various positions at DARA BioSciences, an oncology supportive care company which was acquired by Midatech Pharma plc, including Director, Chief Executive Officer, Executive Chairman and Chief Medical Officer. He also previously served as Chairman of Tranzyme (Nasdaq:TZYM) from 2000 to 2010; and Director of MethylGene (TSX:MYG) from 2000 to 2010 and Gentris Corporation from 2007 to 2014. From 1999 to 2008 he was a general partner with Pacific Rim Ventures, a Tokyo-based venture capital firm. Dr. Drutz's management experience includes tenures as VP Biological Sciences and VP Clinical Research at Smith Kline & French Laboratories; VP Clinical Development at Daichi Pharmaceutical Corporation; and CEO of Inspire Pharmaceuticals (1995-1998) and Sennes Drug Innovations (1994-1995). Earlier, Dr. Drutz was Professor of Medicine, Chief of the Division of Infectious Diseases, and the founder of the NSF Center for Cell Regulation at the UT Health Science Center, San Antonio. Dr. Drutz received his M.D. from the University of Louisville School of Medicine and postgraduate training in internal medicine and infectious diseases at Vanderbilt University School of Medicine, serving

subsequently as a research medical officer in the U.S. Navy (LCDR, USNR). He is certified by the American Board of Internal Medicine; a fellow of the American College of Physicians and the Infectious Diseases Society of America; a member of Alpha Omega Alpha, the American Society of Clinical Oncology and the American Society for Clinical Investigation; and the author of more than 200 peer-reviewed publications in the area of infectious diseases. We believe Dr. Drutz's significant experience in biotechnology investment and as a physician make him well qualified to serve as a member of our Board of Directors.

*John M. Gill* has served as a member of our Board of Directors since August 2004. Mr. Gill served as PharmAthene's President and Chief Executive Officer from March 2015 until the completion of the Merger in May 2017. From 2003 to 2013, Mr. Gill served as the President, Chief Executive Officer, co-founder and a Director of TetraLogic Pharmaceuticals Corporation, a public biopharmaceutical company. Mr. Gill has previously held positions at 3-Dimensional Pharmaceuticals and SmithKline Beecham. After serving in the United States Marine Corps, Mr. Gill earned a B.A. from Rutgers University. We believe Mr. Gill's executive and board experience in the pharmaceutical industry and his substantial financial knowledge and expertise make him well qualified to serve as a member of our Board of Directors.

*Philip L. Hodges* has served as a member of our Board of Directors since May 2017, when he was appointed to the Board in connection with the completion of the Merger, and was first elected to Private Altimmune's board of directors in September 2003. Mr. Hodges is Managing Partner of Redmont Capital, a private equity firm located in Birmingham, Alabama, which he joined at its inception in 1997. Redmont Capital is a co-founder of Altimmune. Mr. Hodges' investment strategy is focused on high-growth small businesses within the health care, life science and technology sectors. He currently serves as a director for several of the firm's portfolio companies. Mr. Hodges holds a Bachelor of Science in Business Administration from the Brock School of Business at Samford University. We believe Mr. Hodges experience as a life science investor makes him well qualified to serve as a member of our Board of Directors.

*Wayne Pisano* has served as a member of our Board of Directors since August 2018. Mr. Pisano also serves on the board of directors of Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company, since April 2018; and Oncolytics Biotech Inc. (Nasdaq: ONCY), a biotechnology company, since May 2013. Mr. Pisano served on the board of directors of IMV INC. (Nasdaq: IMV) a bio pharmaceutical company from October 2011 until March 2021. Mr. Pisano served as president and Chief Executive Officer of VaxInnate Corporation, a biotechnology company, from January 2012 until November 2016. Mr. Pisano joined Sanofi Pasteur in 1997 and was promoted to President and Chief Executive Officer in 2007, the position he successfully held until his retirement in 2011. He has a Bachelor of Science in biology from St. John Fisher College, New York and an MBA from the University of Dayton, Ohio. We believe Mr. Pisano's depth of experience across the spectrum of commercial operations, public immunization policies and pipeline development makes him well qualified to serve as a member of our Board of Directors.

*Diane Jorkasky, M.D.* has served as a member of our Board of Directors since May 2020. Dr. Jorkasky has served on the board of directors of Alzheon, Inc., a private biopharmaceutical company, since December 2019 and also served on the board of directors of Q Therapeutics, Inc. from September 2013 until August 2016. From June 2014 to August 2019, she served as Executive Vice President, Chief Medical Officer and Head of Development at Complexa Inc., a clinical stated biopharmaceutical company. Dr. Jorkasky received her MD in 1977 from the University of Pennsylvania School of Medicine and is board certified in internal medicine, nephrology and clinical pharmacology. She is a member of the Connecticut Academy of Science and Technology. Dr. Jorkasky is on the faculties of University of California, San Francisco, and Uniformed Service of Health Sciences Medical Schools, with previous faculty appointments at Yale University and the University of Pennsylvania Schools of Medicine. We believe Dr. Jorkasky's executive and board experience in the pharmaceutical industry and as a physician make her well qualified to serve as a member of our Board of Directors.

*Brigadier General (ret.), Klaus O. Schafer, M.D., MPH* has served as a member of our Board of Directors since July 2012. Dr. Schafer has over 35 years of healthcare leadership experience, having held senior positions in government and industry. He previously held the position of Deputy Assistant to the Secretary of Defense for chemical and biological defense, overseeing the Department's \$1.0 billion program for vaccine, therapeutics, medical device and sensor development against biothreats. He retired from the Air Force as a Brigadier General in the role of Assistant Surgeon General for medical readiness, science and technology. He has managed all aspects of large integrated health care delivery systems, from clinical care, to running clinics and hospitals, managing budgets, professional staffs and large science and technology portfolios. He has private sector business experience in imaging technology, as CEO and co-founder of TessArae LLC, a biotech medical device company. Most recently he held the position of Chief Medical Officer and client executive for health at CACI International, an information technology company. He has been an independent consultant since 2002 and has served as advisory board member to a number of biotech and health related companies. Dr. Schafer earned his Doctor of Medicine and Surgery at the University of Iowa, medical boards in family practice and aerospace medicine in the Air Force, a Master of Public Health at the University of Texas, and a Master of Science at the Dwight D. Eisenhower School of National Security and Resource Strategy. We believe Dr. Schafer's broad experience base relevant to Altimmune's core technology makes him well qualified to serve as a member of our Board of Directors.

## Executive Officers

The names and ages of our executive officers as of February 25, 2021 are set forth below:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Vipin K. Garg, Ph.D.	63	President, Chief Executive Officer, and Director
William M. Brown, CPA	39	Chief Financial Officer
M. Scot Roberts, Ph.D.	62	Chief Scientific Officer
M. Scott Harris, M.D.	67	Chief Medical Officer

*Vipin K. Garg, Ph.D.* is our President, Chief Executive Officer and a Director. See Item 10 - “Directors” for a discussion of Dr. Garg’s business experience.

*William M. Brown, CPA* has served as our Chief Financial Officer and Principal Accounting Officer since June 2019, having previously served as the Company’s Acting Chief Financial Officer since May 2018. Prior to his roles at Altimmune, Mr. Brown was a consultant to private and public companies in a variety of accounting and tax matters, both independently and as the managing partner of Redmont CPAs since October 2016. His experience also includes audit roles at PricewaterhouseCoopers LLP and as the Water Heater Division Controller at Rheem Manufacturing. Mr. Brown is a certified public accountant. He has a Bachelor of Science and a Master of Business Administration from Auburn University at Montgomery.

*M. Scot Roberts, Ph.D.* currently serves as Chief Scientific Officer of the Company. Dr. Roberts joined Altimmune in December 2012 and has nearly 20 years of senior technical leadership experience, most recently at ImQuest BioSciences, Inc., where as Chief Scientific Officer from November 2010 until November 2012, he was responsible for managing scientific operations as well as business development opportunities in cancer and antivirals. Dr. Roberts held key positions at Wellstat Biologics Corporation from August 1996 until October 2010, including Director of Research and Development where he was responsible for a portfolio of biologic candidates in oncology including a clinical stage asset. He also led bioassay development efforts for the company and assumed leadership roles in upstream process development and animal pharmacology while at Wellstat. Dr. Roberts has significant experience in both small molecule and biologics drug development with a focus on viral vectors and antiviral therapies. Dr. Roberts completed a post-doctoral fellowship at the National Cancer Institute, Laboratory of Molecular Virology and has numerous patents and publications in peer-reviewed journals, and has been an invited speaker and Chair at numerous international conferences. Dr. Roberts received his Ph.D. from the Johns Hopkins School of Medicine, Department of Pharmacology and Molecular Sciences.

*M. Scott Harris, M.D.* serves as Chief Medical Officer of the Company. Dr. Harris joined Altimmune in July 2019, seasoned medical professional with extensive experience in hepatology and gastroenterology and broad expertise in managing clinical trials from early stage development through successful Phase 3 trials. He has led multidisciplinary forums on drug development and clinical trial design at national and international scientific meetings, and fostered collaborations between professional medical societies and the FDA. Previously, he was co-founder and chief medical officer of Lyric Pharmaceuticals, helping raise a \$21 million Series A round in 2014. He has also served as chief medical officer of Avaxia Biologics, interim chief medical officer of Tranzyme Pharma, and chief medical officer of Ocera Therapeutics. Dr. Harris was also chief medical officer and vice president of Clinical Affairs at Napo Pharmaceuticals where he authored the pivotal clinical study that led to the approval of crofelemer (Mytesi®), the first Phase 2/3 adaptive trial design resulting in a drug approval. Earlier in his career he held senior roles in global clinical development and medical affairs at Otsuka Pharmaceuticals and Abbott. He sits on the faculty of Georgetown University School of Medicine as an Adjunct Professor, where he directs a course on drug development under a grant from the NIH. Dr. Harris has been a consultant on third-world drug development for the Bill and Melinda Gates Foundation and a speaker at national and international forums on drug development. Dr. Harris has an M.D. from Harvard Medical School and an MS in Administrative Medicine and Population Health from the University of Wisconsin Medical School. His post-graduate training includes residencies at John Hopkins Hospital and the University of Pennsylvania, and a Gastroenterology and Hepatology Fellowship at the Yale University School of Medicine.

## How nominees to our Board are selected

Candidates for election to our Board of Directors are nominated by our Nominating and Corporate Governance Committee and ratified by our full Board of Directors for nomination to the stockholders.

The Nominating and Corporate Governance Committee will give due consideration to candidates recommended by stockholders. Stockholders may recommend candidates for the Nominating and Corporate Governance Committee’s consideration by submitting such recommendations directly to the Nominating and Corporate Governance Committee as described below under Communicating with our Board members. However, just because a recommended individual meets the minimum qualification standards does not imply that the Nominating and Corporate Governance Committee will necessarily nominate the person so



recommended by a stockholder. The Nominating and Corporate Governance Committee may also engage outside search firms to assist in identifying or evaluating potential nominees.

There are no family relationships among any of our directors and executive officers.

### **Board leadership structure**

Currently, Dr. Garg is the Company's President and CEO and Dr. Sayare serves as the Chairman of the Board. The Board believes that having different individuals serving in the separate roles of Chairman of the Board and CEO is in the best interest of stockholders in the Company's current circumstances because it reflects the CEO's responsibility over management of the Company's operations and the Chairman's oversight of board functions and strategic development.

### **Board committees**

The Audit Committee of our Board reviews, acts on and reports to our Board with respect to various auditing and accounting matters, including the recommendation of our independent registered public accounting firm, the scope of the annual audits, the fees to be paid to the independent registered public accounting firm, the performance of the independent registered public accounting firm and our accounting practices. The Audit Committee currently consists of Mr. Hodges (Chair) and Dr. Shafer, Mr. Gill, and Mr. Pisano. The Board has determined that each member of the Audit Committee is an independent director in accordance with NASDAQ listing standards. The Board further determined that each of the members of the Audit Committee is able to read and understand fundamental financial statements, including the Company's balance sheet, income statement, and cash flow statement; and that each of Messrs. Hodges and Gill is an "audit committee financial expert", as defined by SEC guidelines and as required by the applicable NASDAQ listing standards.

The Compensation Committee of the Board recommends, reviews and oversees the salaries, benefits and equity incentive plans for our employees, consultants, directors (other than non-employee directors) and other individuals whom we compensate. The Compensation Committee also administers our compensation plans. The Compensation Committee currently consists of Drs. Drutz (Chair), Jorkasky and Schafer, and Mr. Hodges. The Board has determined that each member of the Compensation Committee is an "independent director" in accordance with NASDAQ listing standards, a "non-employee director" under the applicable SEC rules and regulations and an "outside director" under the applicable tax rules. The Compensation Committee may form subcommittees and delegate authority to such subcommittees or individuals as it deems appropriate.

The Nominating and Corporate Governance Committee of the Board selects nominees for director positions to be recommended by our Board for election as directors and for any vacancies in such positions, develops and recommends for our Board the Corporate Governance Guidelines of the Company and oversees the annual review of the performance of the Board, each director and each committee. The Nominating and Corporate Governance Committee currently consists of Mr. Pisano (Chair), and Dr. Drutz and Mr. Gill. The Board has determined that each member of the Nominating and Corporate Governance Committee is an independent director in accordance with NASDAQ listing standards.

### **Meetings and attendance**

During the fiscal year ended December 31, 2020 and after the completion of the Merger, the Board held 17 meetings and the Board Committees held a total of 17 meetings. Each director attended 75% or more of the total number of meetings of the Board and the Board Committees of which he was a member during the period he served as a director in fiscal year 2020. The Company has no specific policy regarding director attendance at our annual meeting of stockholders. Generally, however, a Board meeting is held on the same date as the annual meeting, with directors attending the annual meeting. Our 2020 annual meeting of stockholders was attended by all of the directors recommended for election.

### **Board involvement in risk oversight**

The Company's management is responsible for defining the various risks facing the Company, formulating risk management policies and procedures, and managing the Company's risk exposures on a day-to-day basis. The Board's responsibility is to monitor the Company's risk management processes by informing itself of the Company's material risks and evaluating whether management has reasonable controls in place to address the material risks. The Board is not responsible, however, for defining or managing the Company's various risks.

The Board of Directors monitors management's responsibility for risk oversight through regular reports from management to the Audit Committee and the full Board. Furthermore, the Audit Committee reports on the matters discussed at the committee level to the full Board. The Audit Committee and the full Board focus on the material risks facing the Company, including strategic, operational,

legal and regulatory risks, to assess whether management has reasonable controls in place to address these risks. In addition, the Compensation Committee is charged with reviewing and discussing with management whether the Company's compensation arrangements are consistent with effective controls and sound risk management. Finally, risk management is a factor that the Board and the Nominating and Corporate Governance Committee consider when determining who to nominate for election as a director of the Company and which directors serve on the Audit Committee. The Board believes this division of responsibilities provides an effective and efficient approach for addressing risk management.

#### **Code of Business Conduct and Ethics and other governance documents**

We have adopted a written Code of Business Conduct and Ethics that applies to our Board of Directors and all of our employees, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions. A copy of our code of conduct can be found on our website, <http://www.altimmune.com>. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K and under the applicable the NASDAQ Global Select Market rules by posting such information on our website in accordance with such requirements.

You may also obtain a copy of these documents by writing to Altimmune, Inc., 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878, Attention: Investor Relations.

Copies of the charters of our Board's Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, as well as a copy of the Company's Corporate Governance Guidelines, can be accessed in the Investor Relations — Corporate Governance section of our website. The information on, or that can be accessed through our website is not part of this Annual Report and is not incorporated by reference herein.

#### **Communicating with our Board members**

Although our Board of Directors has not adopted a formal process for stockholder communications with the Board, we make every effort to ensure that the views of stockholders are heard by the Board or by individual directors, as applicable, and we believe that this has been an effective process to date. Stockholders may communicate with the Board by sending a letter to the Altimmune, Inc. Board of Directors, c/o Corporate Secretary, 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878. The Corporate Secretary will receive the correspondence and forward it to the Chairman of the Board, or to any individual director or directors to whom the communication is directed, as appropriate. Notwithstanding the above, the General Counsel has the authority to discard or disregard any communication that is unduly hostile, threatening, illegal or otherwise inappropriate or to take any other appropriate actions with respect to such communications.

In addition, any person, whether or not an employee, who has a concern regarding the conduct of the Company or our employees, including with respect to our accounting, internal accounting controls or auditing issues, may, in a confidential or anonymous manner, communicate that concern in writing by addressing a letter to the Chairman of the Audit Committee, c/o Corporate Secretary, at our corporate headquarters address, which is 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878.

#### **Section 16(a) beneficial ownership reporting compliance and Delinquent Section 16(a) Reports**

The members of our Board of Directors, our executive officers and persons who hold more than 10% of our outstanding Common Stock are subject to the reporting requirements of Section 16(a) of the Securities Exchange Act of 1934, as amended, which requires them to file reports with respect to their ownership of our Common Stock and their transactions in such Common Stock. Based solely upon a review of (i) the copies of Section 16(a) reports that the Company has received from such persons for transactions in our Common Stock and their Common Stock holdings for the 2020 fiscal year and (ii) the written representations of such persons that no annual Form 5 reports were required to be filed by them for the fiscal year, the Company believes that all reporting requirements under Section 16(a) for such fiscal year were met in a timely manner by its directors, executive officers and beneficial owners of more than 10% of its Common Stock, except that each of our non-employee directors other than Dr. Jorkasky were not timely in the filing of one Form 4 during the fiscal year ended December 31, 2020 to report the vesting of restricted stock units.

## Report of the Audit Committee of the Board of Directors

Our Audit Committee has reviewed and discussed our audited financial statements for the fiscal year ended December 31, 2020 with our management. Our Audit Committee has discussed with our independent registered public accounting firm the matters required to be discussed by Auditing Standard No. 1301, *Communications with Audit Committees*, as adopted by the Public Company Accounting Oversight Board (“PCAOB”). Our Audit Committee has also received the written disclosures and the letter from our independent registered public accounting firm required by applicable requirements of the PCAOB regarding the independent accountants’ communications with our Audit Committee concerning independence, and has discussed with our independent registered public accounting firm the accounting firm’s independence. Based on the foregoing, our Audit Committee has recommended to our Board that our audited financial statements be included in this Annual Report.

Submitted by the Audit Committee of the  
Board of Directors:

Philip L. Hodges (Chair)  
John M. Gill  
Wayne Pisano  
Klaus O. Schafer, M.D., MPH

## Item 11. Executive Compensation

Our named executive officers (“Named Executive Officers”) for the year ended December 31, 2020 are:

- Vipin K. Garg, Ph.D., our Chief Executive Officer;
- William M. Brown, CPA, our Chief Financial Officer;
- M. Scot Roberts, Ph.D., our Chief Scientific Officer; and
- M. Scott Harris, M.D., our Chief Medical Officer.

### Elements of Compensation

The compensation arrangement for each Named Executive Officer is intended to encourage performance and to align the Named Executive Officers’ interests with those of our stockholders. In setting compensation for our Named Executive Officers, the Compensation Committee and the Board takes into account the relative amount of compensation that is delivered on a current and long-term basis and in the form of cash and equity. The combination of performance measures for annual bonuses and the equity compensation programs for executive officers, as well as the multi-year vesting schedules for equity awards encourage employees to maintain both a short-term and a long-term view with respect to Company performance.

The Company’s executive compensation program consists of the following elements:

- base salary;
- annual cash bonuses;
- equity awards;
- health and retirement benefits and perquisites; and
- 401(k) plan

### Base Salary

The Named Executive Officers receive a base salary to compensate them for services rendered to our Company. The base salary payable to each Named Executive Officer is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, roles and responsibilities.

### Annual Performance-Based Bonus

The Named Executive Officers are entitled to receive annual performance-based cash bonuses, the amount of which is based on satisfaction of corporate and personal objectives that are established by the Board of Directors or the Compensation Committee. The annual bonuses are intended to encourage the Named Executive Officers to promote the growth of the Company’s business.

### Equity Awards

The Named Executive Officers are eligible to receive equity awards under the Altimune, Inc. 2017 Omnibus Incentive Plan (as amended, the “2017 Plan”). Awards under the 2017 Plan are intended to align the interests of the Named Executive Officers with those of our stockholders and to create a link between executive pay and the long-term performance of our Common Stock.

### Employee Benefits

The Named Executive Officers, like our other employees, participate in health and welfare benefit plans, subject to satisfying eligibility requirements.

## 401(k) Plan

The Company maintains a tax-qualified retirement plan (the “401(k) Plan”) that provides eligible employees (including the Named Executive Officers) with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees are able to participate in the 401(k) Plan as of the first day of the month following the date they meet the 401(k) Plan’s eligibility requirements, and participants are able to defer up to 100% of their eligible compensation subject to applicable annual limits under the Internal Revenue Code of 1986, as amended (the “Code”). All participants’ interests in their deferrals are 100% vested when contributed. The 401(k) Plan permits Altimmune to make matching contributions and profit sharing contributions to eligible participants. Altimmune matches contributions 100% on the first 4% of contributions made by participants.

We believe the benefits described above are necessary and appropriate to provide a competitive compensation package to our Named Executive Officers.

## Summary Compensation Table

The following table sets forth the total compensation that was paid to or earned by the Named Executive Officers for the 2020 and 2019 fiscal years.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)(1)	Option Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)(2)	Total (\$)
Vipin K. Garg, Ph.D. Chief Executive Officer	2020	514,375	—	—	536,705	354,063	—	29,258	1,434,401
	2019	500,000	—	—	—	248,016	—	66,631	814,647
William M. Brown, CPA (3) Chief Financial Officer	2020	339,488	—	—	92,991	169,950	—	19,678	622,106
	2019	192,500	—	—	151,564	89,627	—	190,656	624,347
M. Scot Roberts, Ph.D. Chief Scientific Officer	2020	348,583	—	—	92,991	175,000	—	11,400	627,974
	2019	316,000	—	—	85,605	33,831	—	12,825	448,261
M. Scott Harris, M.D. (4) Chief Medical Officer	2020	377,092	—	—	92,991	188,700	—	11,400	670,183
	2019	115,032	—	—	171,325	95,318	—	1,233	382,908
Sybil Tasker, M.D., MPH (5) Former Chief Medical Officer	2020	—	—	—	—	—	—	—	—
	2019	203,500	—	—	146,103	—	—	6,912	356,515

- (1) Amounts in this column reflect the aggregate grant date fair value of stock awards and stock options granted during the covered year computed in accordance with the provisions of FASB ASC Topic 718. The assumptions used to calculate the amounts for fiscal years 2020 and 2019 are discussed in Item 13, Financial Statements and Supplementary Data.
- (2) Amounts in this column for fiscal year 2019 include payments of \$190,656 for the service of Mr. Brown as Acting Chief Financial Officer prior to June 1, 2019.
- (3) Mr. Brown commenced employment with Altimmune on June 1, 2019.
- (4) Dr. Harris commenced employment with Altimmune on September 9, 2019.
- (5) Dr. Tasker terminated employment with Altimmune on June 30, 2019.

## Narrative to Summary Compensation Table

### Agreements with Named Executive Officers

We have entered into employment agreements with each of Dr. Garg, Mr. Brown, Dr. Roberts and Dr. Harris. The material terms of such agreements are summarized below.

### Employment Agreement with Vipin K. Garg, Ph.D.

On November 16, 2018, the Company entered into an employment agreement with Dr. Garg in connection with his employment as the President and Chief Executive Officer of the Company (the “Employment Agreement”). Pursuant to the Employment Agreement, Dr. Garg commenced employment with the Company on November 30, 2018.

Under the Employment Agreement, Dr. Garg receives a base salary of \$500,000 and, from January 1, 2019, will be eligible to receive an annual discretionary incentive bonus of up to 55% of his base salary based on achievement of performance goals established by the Compensation Committee. In addition, Dr. Garg received a lump sum cash signing bonus of \$100,000, which was

subject to claw-back if Dr. Garg's employment with the Company terminated for any reason other than by the Company without cause or by Dr. Garg for good reason on or prior to November 30, 2019.

Dr. Garg is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives. In addition, the Company pays the premium costs for a term life insurance policy for Dr. Garg with a benefit equal to Dr. Garg's base salary and for short- and long-term disability plans that provide for an annual benefit of at least 60% of Dr. Garg's base salary for as long as the disability continues. In addition, during the term of Dr. Garg's employment, so long as Dr. Garg's primary residence is located within 50 miles of his current residence in North Carolina, the Company will reimburse Dr. Garg an amount not to exceed \$36,000 during any 12-month period to cover Dr. Garg's commuting expenses, which amount will be grossed up for taxes. During the term of Dr. Garg's employment, and subject to applicable securities laws or listing standards, the Company will use its best efforts to cause Dr. Garg to be nominated for election as a member of the Company's board of directors at each annual meeting of stockholders at which Dr. Garg is up for election.

Pursuant to the Employment Agreement, Dr. Garg received the following equity-based awards:

- A grant, pursuant to the Company's 2017 Omnibus Incentive Plan, of an incentive stock option (the "*Incentive Stock Option*") to purchase 111,421 shares of the Company's Common Stock with a grant-date fair value of \$400,000. The Incentive Stock Option has an exercise price of \$3.59. One-fourth of the shares underlying the Incentive Stock Option will vest on the first anniversary of the Grant Date (the "*First Vesting Date*"), and thereafter 1/48th of the shares underlying the Incentive Stock Option will vest monthly commencing on January 1, 2020, such that the shares underlying the Incentive Stock Option will be fully vested on December 1, 2022, in each case, generally subject to Dr. Garg's employment with the Company through the applicable vesting date.
- An inducement grant under Nasdaq Listing Rule 5635(c)(4), of a non-qualified stock option to purchase 211,486 shares of the Company's Common Stock, which will have an exercise price of \$3.59 per share, the last reported sale price of the Company's Common Stock on the date of grant of such award (the "*Grant Date*"). One-fourth of the shares underlying the non-qualified stock option will vest on the First Vesting Date, and thereafter 1/48th of the shares underlying the non-qualified stock option will vest on each monthly anniversary of the First Vesting Date, such that the shares underlying the non-qualified stock option will be fully vested on November 30, 2022, in each case, generally subject to Dr. Garg's employment with the Company through the applicable vesting date.
- An inducement grant under Nasdaq Listing Rule 5635(c)(4), of 322,907 restricted shares of the Company's common stock. One-fourth of the restricted shares will vest on the First Vesting Date, and thereafter 1/48th of the restricted shares will vest on each monthly anniversary of the First Vesting Date, such that the restricted shares will be fully vested on November 30, 2022, in each case, generally subject to Dr. Garg's employment with the Company through the applicable vesting date.

In the event of an employment termination, the Company will pay Dr. Garg his earned but unpaid base salary through the date of termination, accrued but unused vacation pay, unreimbursed business expenses and such employee benefits as may be due to Dr. Garg under the terms of the applicable benefit plans (the "*Accrued Benefits*"). In addition, if the Company terminates Dr. Garg's employment for "cause" (as defined below), Dr. Garg will be entitled to payment of any unpaid prior year's annual bonus.

If the Company terminates Dr. Garg's employment without cause or Dr. Garg resigns his employment for "good reason" (as defined below), in addition to the Accrued Benefits, Dr. Garg will be entitled to receive 12 months of base salary continuation payments, 12 months of continued coverage under the health insurance plans in which Dr. Garg participates at the time of the termination and payment of any unpaid prior year's annual bonus. If such employment termination or resignation occurs within one year following a "change in control" (as defined in the Employment Agreement), Dr. Garg is entitled to receive an amount equal to the sum of 18 months of his base salary plus his target annual discretionary incentive bonus for the year of termination, 18 months of continued coverage under the health insurance plans in which Dr. Garg participates at the time of the termination, payment of any unpaid prior year's annual bonus and, if such termination occurs within the one-year period following a change in control, all of Dr. Garg's outstanding unvested equity awards will become vested. If any payments, whether under Dr. Garg's employment agreement or otherwise, would be subject to the golden parachute excise tax under Section 4999 of the Internal Revenue Code (the "*Code*"), such payments will be reduced to the extent necessary to avoid the excise tax if doing so would result in a greater net after tax payment to Dr. Garg. Dr. Garg is required to execute and not revoke a release of claims in order to be eligible to receive severance payments or benefits, other than the Accrued Benefits.

Under the Employment Agreement, "cause" generally means Dr. Garg's (i) material breach of his fiduciary duties, (ii) material breach of his Employment Agreement, (iii) willful failure or refusal to follow written policies, (iv) conviction of, or plea of guilty or nolo contendere to, a felony, or (v) continuing and willful refusal to act as directed by the Board. Under the Employment Agreement, "good reason" generally means (i) a reduction in Dr. Garg's base salary or target annual bonus opportunity, (ii) a material diminution

in Dr. Garg's authorities, duties or responsibilities, or (iii) a relocation of Dr. Garg's principal place of employment more than 50 miles from Gaithersburg, Maryland.

Dr. Garg is subject to restrictive covenants during the term of his employment and for a period of one year following the termination of his employment. In particular, Dr. Garg will be prohibited from soliciting the Company's customers, clients and employees and from engaging in sales, marketing or related activities on behalf of himself or another entity that directly competes with the Company and does business in the same geographical areas in which the Company does business.

*Employment Agreement with William M. Brown, CPA*

Effective June 1, 2019, the Company entered into an employment agreement with William M. Brown, the Chief Financial Officer. The agreement provided that Mr. Brown would be employed so long as mutually agreeable to Mr. Brown and the Company.

The agreement provided Mr. Brown with an initial base salary of \$330,000. In addition, Mr. Brown was paid a signing bonus of \$60,000. In addition, Mr. Brown is eligible to receive an annual discretionary incentive bonus of up to 30% of base salary based as determined by the Compensation Committee. In addition, Mr. Brown would be granted incentive stock options to purchase 50,000 shares of the Company's common stock, Mr. Brown is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives. In addition, during the term of Mr. Brown's employment, so long as Mr. Brown's primary residence is located within 50 miles of his current residence in Highlands Ranch, Colorado, the Company will reimburse Mr. Brown an amount not to exceed \$18,000 during any 12-month period to cover Mr. Brown's commuting expenses, which amount will be grossed up for taxes.

If, prior to a "change in control" (as defined in the employment agreement), the Company terminates the employment of Mr. Brown without "cause" or if such he resigns for "good reason" (as defined below), in addition to accrued benefits (to which she is entitled on any termination of employment), Mr. Brown will be entitled to receive severance equal to six months of base salary continuation payments, six months of continued coverage under the health insurance plans in which the executive participated at the time of the termination and payment of any unpaid prior year's annual bonus. If such employment termination or resignation occurs within the one-year period following a change in control, he would be entitled to receive a severance amount equal to the sum of 12 months of his base salary plus his target annual discretionary incentive bonus for the year of termination, six months of continued coverage under the health insurance plans in which he participates at the time of termination, payment of any unpaid prior year's annual bonus and, all of his outstanding unvested equity awards will become vested. The agreement also provides that if any payments, whether under the agreement or otherwise, payable to him would be subject to the golden parachute excise tax under Section 4999 of the Code, such payments will be reduced to the extent necessary to avoid the excise tax if doing so would result in a greater net after tax payment to him. Mr. Brown is required to execute and not revoke a release of claims in Altimmune's favor in order to be eligible to receive the severance payments and benefits.

Under the agreement with Mr. Brown, "cause" generally means his (i) material breach of his fiduciary duties to us, (ii) material breach of the agreement, (iii) willful failure or refusal to follow Altimmune's written policies, (iv) conviction of, or plea of guilty or nolo contendere to, a felony or (v) continuing and willful failure to act as directed by Altimmune's board of directors or its chief executive officer. Under the agreement, "good reason" generally means (i) a reduction in Mr. Brown's base salary or target annual bonus opportunity, (ii) a material diminution in authority, duties or responsibilities or (iii) a relocation of his principal place of employment more than 50 miles from Gaithersburg, Maryland.

Under the agreement, Mr. Brown is subject to restrictive covenants during the term of his employment and for a period of six months following termination of employment. In particular, he is prohibited from soliciting the Company's customers, clients and employees and from engaging in sales, marketing or related activities on the executive's behalf or another entity that directly competes with the Company.

*Employment Agreement with M. Scot Roberts, Ph.D.*

On December 31, 2017, the Company entered into an employment agreement with M. Scot Roberts, M.D., the Chief Scientific Officer. The agreement provided that Dr. Roberts would be employed so long as mutually agreeable to Dr. Roberts and the Company.

The agreement provided Dr. Roberts with an initial base salary of \$220,000. In addition, Dr. Roberts is eligible to receive an annual discretionary incentive bonus of up to 30% of base salary based as determined by the Compensation Committee. Dr. Roberts is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives.

If, prior to a “change in control” (as defined in the employment agreement), the Company terminates the employment of Dr. Roberts without “cause” or if such he resigns for “good reason” (as defined below), in addition to accrued benefits (to which he is entitled on any termination of employment), Dr. Roberts will be entitled to receive severance equal to six months of base salary continuation payments, six months of continued coverage under the health insurance plans in which the executive participated at the time of the termination and payment of any unpaid prior year’s annual bonus. If such employment termination or resignation occurs within the one-year period following a change in control, he would be entitled to receive a severance amount equal to the sum of 12 months of his base salary plus his target annual discretionary incentive bonus for the year of termination, six months of continued coverage under the health insurance plans in which he participates at the time of termination, payment of any unpaid prior year’s annual bonus and, all of his outstanding unvested equity awards will become vested. The agreement also provides that if any payments, whether under the agreement or otherwise, payable to him would be subject to the golden parachute excise tax under Section 4999 of the Code, such payments will be reduced to the extent necessary to avoid the excise tax if doing so would result in a greater net after tax payment to him. Dr. Roberts is required to execute and not revoke a release of claims in Altimmune’s favor in order to be eligible to receive the severance payments and benefits.

Under the agreement with Dr. Roberts, “cause” generally means his (i) material breach of his fiduciary duties to us, (ii) material breach of the agreement, (iii) willful failure or refusal to follow Altimmune’s written policies, (iv) conviction of, or plea of guilty or nolo contendere to, a felony or (v) continuing and willful failure to act as directed by Altimmune’s board of directors or its chief executive officer. Under the agreement, “good reason” generally means (i) a reduction in the Dr. Roberts’ base salary or target annual bonus opportunity, (ii) a material diminution in authority, duties or responsibilities or (iii) a relocation of his principal place of employment more than 50 miles from Gaithersburg, Maryland.

Under the agreement, Dr. Roberts is subject to restrictive covenants during the term of his employment and for a period of six months following termination of employment. In particular, he is prohibited from soliciting the Company’s customers, clients and employees and from engaging in sales, marketing or related activities on the executive’s behalf or another entity that directly competes with the Company.

#### *Employment Agreement with M. Scott Harris, M.D.*

On September 9, 2019, the Company entered into an employment agreement with M. Scott Harris, M.D., the Chief Medical Officer. The agreement provided that Dr. Harris would be employed so long as mutually agreeable to Dr. Harris and the Company.

The agreement provided Dr. Harris with an initial base salary of \$370,000. In addition, Dr. Harris is eligible to receive an annual discretionary incentive bonus of up to 30% of base salary based as determined by the Compensation Committee. In addition, Dr. Harris would be granted incentive stock options to purchase 107,000 shares of the Company’s common stock, Dr. Harris is eligible to participate in the Company’s employee benefit plans made available to its similarly situated senior executives.

If, prior to a “change in control” (as defined in the employment agreement), the Company terminates the employment of Dr. Harris without “cause” or if such he resigns for “good reason” (as defined below), in addition to accrued benefits (to which he is entitled on any termination of employment), Dr. Harris will be entitled to receive severance equal to six months of base salary continuation payments, six months of continued coverage under the health insurance plans in which the executive participated at the time of the termination and payment of any unpaid prior year’s annual bonus. If such employment termination or resignation occurs within the one-year period following a change in control, he would be entitled to receive a severance amount equal to the sum of 12 months of his base salary plus his target annual discretionary incentive bonus for the year of termination, six months of continued coverage under the health insurance plans in which he participates at the time of termination, payment of any unpaid prior year’s annual bonus and, all of his outstanding unvested equity awards will become vested. The agreement also provides that if any payments, whether under the agreement or otherwise, payable to him would be subject to the golden parachute excise tax under Section 4999 of the Code, such payments will be reduced to the extent necessary to avoid the excise tax if doing so would result in a greater net after tax payment to the him. Dr. Harris is required to execute and not revoke a release of claims in Altimmune’s favor in order to be eligible to receive the severance payments and benefits.

Under the agreement with Dr. Harris, “cause” generally means his (i) material breach of his fiduciary duties to us, (ii) material breach of the agreement, (iii) willful failure or refusal to follow Altimmune’s written policies, (iv) conviction of, or plea of guilty or nolo contendere to, a felony or (v) continuing and willful failure to act as directed by Altimmune’s board of directors or its chief executive officer. Under the agreement, “good reason” generally means (i) a reduction in the Dr. Harris’ base salary or target annual bonus opportunity, (ii) a material diminution in authority, duties or responsibilities or (iii) a relocation of his principal place of employment more than 50 miles from Gaithersburg, Maryland.

Under the agreement, Dr. Harris is subject to restrictive covenants during the term of his employment and for a period of six months following termination of employment. In particular, he is prohibited from soliciting the Company’s customers, clients and



employees and from engaging in sales, marketing or related activities on the executive's behalf or another entity that directly competes with the Company.

### Outstanding Equity Awards at 2020 Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards of our Named Executive Officers as of December 31, 2020.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Vipin K. Garg, Ph.D.	55,710	55,711	(1)	—	3.59	11/30/2028
	110,149	101,337	(1)	—	3.59	11/30/2028
	—	149,500	(2)	—	1.92	1/2/2030
William M. Brown, CPA	30,000	—	(3)	—	2.60	1/2/2029
	18,750	31,250	(4)	—	2.34	6/10/2029
	—	61,400	(2)	—	1.92	1/2/2030
M. Scot Roberts, Ph.D.	375	—	(5)	—	401.10	4/8/2026
	299	—	(5)	—	77.40	12/4/2024
	299	—	(5)	—	17.40	12/5/2023
	1,361	306	(6)	—	74.40	9/22/2027
	1,152	515	(7)	—	13.35	5/21/2028
	15,625	14,375	(8)	—	2.60	1/2/2029
	16,625	21,375	(9)	—	2.95	3/26/2029
—	61,400	(2)	—	1.92	1/2/2030	
M. Scott Harris, M.D.	33,437	73,563	(10)	—	2.13	9/9/2029
	—	61,400	(2)	—	1.92	1/2/2030

- (1) This option was granted on November 30, 2018 and 25% became vested and exercisable on the first anniversary of the grant date. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on January 1, 2020.
- (2) On January 2, 2020, Dr. Garg, Mr. Brown, Dr. Roberts and Dr. Harris were granted an option to purchase 149,500, 61,400, 61,400 and 61,400, respectively, shares of Common Stock of the Company at an exercise price of \$1.92 per share. 25% on the first anniversary of the grant date and the aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on February 2, 2021.
- (3) On January 2, 2019, Mr. Brown was granted an option to purchase 30,000 shares of Common Stock of the Company at an exercise price of \$2.60 per share. One-hundred percent of the shares underlying the option vested upon the filing of the Company's annual report on Form 10-K for the year ended December 31, 2018.
- (4) This option was granted on June 10, 2019, and 25% became vested and exercisable on June 1, 2020. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on June 1, 2020.
- (5) These options were acquired pursuant to the PharmAthene Merger Agreement on May 4, 2017. These options are fully vested.
- (6) This option was granted on September 22, 2017, and 25% became vested and exercisable on the first anniversary of the grant date. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on September 22, 2018.
- (7) This option was granted on May 21, 2018, and 25% became vested and exercisable on March 1, 2019. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on April 1, 2019.

- (8) This option was granted on January 2, 2019, and 25% became vested and exercisable on the first anniversary of the grant date. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on January 2, 2020.
- (9) This option was granted on March 26, 2019, and 25% became vested and exercisable on the first anniversary of the grant date. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on March 26, 2020.
- (10) This option was granted on September 9, 2019, and 25% became vested and exercisable on the first anniversary of the grant date. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on September 9, 2020.

### Director Compensation

In September 2020, the Company’s Board approved a non-employee director compensation policy effective as of January 1, 2021. Under the program, non-employee directors that qualify under the program receive the cash compensation set forth below, and an additional annual payment of an option to purchase a number of shares of the Company’s Common Stock equal to 62 ½ percentile of the Company’s peer group based on percentage ownership (the “Annual Director Option Grant Amount”), which will be granted immediately following the date of the of each annual meeting of stockholders. Any such option will vest in substantially equal monthly installments for 11 months after the date of grant, with the remaining one-twelfth vesting on the earlier of the one-year anniversary of the date of the grant or the date of the next annual meeting of the Company’s stockholders. In addition, new non-employee directors that qualify under the program receive an initial award in the form of an option to purchase shares of the Company’s Common Stock equal to two times the Annual Director Option Grant Amount upon their election to the board. Any such option shall vest in equal monthly installments during the 36 months following the date upon which the director is first elected to the Board. The vesting of any option grants to our non-employee directors under our non-employee director compensation policy is subject to such non-employee director’s continued service as a director and will accelerate in full upon a change in control of our company.

We also have a policy of reimbursing our directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Under our non-employee director compensation program, each non-employee director that qualifies under the program is eligible to receive compensation for his or her service on our board of directors or committees thereof consisting of annual cash retainers paid quarterly in arrears, as follows:

Position	Retainer
Board Member	\$40,000
Chairperson of the Board	\$30,000
Audit Committee Chairperson	\$17,000
Audit Committee Member	\$7,500
Compensation Committee Chairperson	\$12,000
Compensation Committee Member	\$6,000
Nominating and Corporate Governance Committee Chairperson	\$10,000
Nominating and Corporate Governance Committee Member	\$5,000

The table below sets forth the compensation received by each of the individuals who served as a non-employee director during the fiscal year ended December 31, 2020.

Name	Fees earned or paid in cash (\$)	Stock Awards (\$)(1)(2)	Option Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Mitchel Sayare, Ph.D. (3)	70,000	232,277	244,517	—	—	—	546,794
David J. Drutz, M.D. (4)	56,000	154,852	244,517	—	—	—	455,369
John M Gill (5)	51,500	154,852	244,517	—	—	—	450,869
Philip L. Hodges (6)	60,000	154,852	244,517	—	—	—	459,369
Wayne Pisano (7)	57,500	154,852	244,517	—	—	—	456,869
Diane K. Jorkasky, M.D. (8)	28,104	—	191,158	—	—	—	219,262
Klaus O. Schafer, M.D., MPH (9)	52,500	154,852	244,517	—	—	—	451,869

- (1) Amounts reflect the aggregate grant date fair value of restricted stock unit awards that may be settled for shares of common stock and stock options granted during the covered year computed in accordance with the provisions of FASB ASC Topic 718. The assumptions used to calculate the amounts for fiscal years 2020 are discussed in Item 13, Financial Statements and Supplementary Data.
- (2) The restricted stock unit awards reflected in this column were granted as compensation for services provided in 2019 and paid in 2020 to our non-employees directors who provided services during 2019.
- (3) As of December 31, 2020, Dr. Sayare held unexercised options to purchase an aggregate of 57,401 shares of the Common Stock of the Company.
- (4) As of December 31, 2020, Dr. Drutz held unexercised options to purchase an aggregate of 46,654 shares of the Common Stock of the Company.
- (5) As of December 31, 2020, Mr. Gill held unexercised options to purchase an aggregate of 46,234 shares of the Common Stock of the Company.
- (6) As of December 31, 2020, Mr. Hodges held unexercised options to purchase an aggregate of 46,167 shares of the Common Stock of the Company.
- (7) As of December 31, 2020, Mr. Pisano held unexercised options to purchase an aggregate of 45,500 shares of the Common Stock of the Company.
- (8) As of December 31, 2020, Dr. Jorkasky held unexercised options to purchase an aggregate of 49,500 shares of the Common Stock of the Company.
- (9) As of December 31, 2020, Dr. Schafer held unexercised options to purchase an aggregate of 46,506 shares of the Common Stock of the Company.

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

The following table sets forth certain information regarding the beneficial ownership of the Company's Common Stock as of February 23, 2021 by (i) each person or group of persons known by us to beneficially own more than five percent of our Common Stock, (ii) each of our named executive officers, (iii) each of our directors and nominees for director and (iv) all of our directors and executive officers as a group.

The following table gives effect to the shares of Common Stock issuable within 60 days of February 23, 2021 upon the exercise of all options and other rights beneficially owned by the indicated stockholders on that date. Beneficial ownership is determined in accordance with Rule 13d-3 promulgated under Section 13 of the Securities Exchange Act of 1934, as amended, and includes voting and investment power with respect to shares. Percentage of beneficial ownership is based on 37,150,376 shares of Common Stock outstanding at the close of business on February 23, 2021. Except as otherwise noted below, each person or entity named in the following table has sole voting and investment power with respect to all shares of our Common Stock that he, she or it beneficially owns.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Altimmune, Inc., 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
<b>5% or Greater Stockholders:</b>		
Entities Affiliated with Venrock (1)	4,500,000	12.05%
Velocity Pharmaceutical Holdings, LLC (2)	1,938,335	5.19%
<b>Directors and Named Executive Officers:</b>		
Vipin K. Garg (3)	548,260	1.47%
Will Brown (4)	89,022	*
M. Scot Roberts (5)	69,291	*
M. Scott Harris (6)	66,578	*
Mitchel Sayare, Ph.D. (7)	73,139	*
David J. Drutz, M.D. (8)	53,965	*
John M. Gill (9)	46,808	*
Philip L. Hodges (10)	68,121	*
Klaus O. Schafer, M.D., MPH (11)	44,781	*
Wayne Pisano (12)	43,373	*
Diane K. Jorkasky, M.D. (13)	17,764	*
All Executive Officers and Directors as a Group (12 persons)(14)	1,156,934	3.1%

\* Represents beneficial ownership of less than one percent of Altimmune's outstanding Common Stock.

- (1) This information is based solely on information reported on a Schedule 13D filed with the SEC on June 25, 2020 on behalf of Venrock Healthcare Capital Partners II, L.P., VHCP Co-Investment Holdings II, LLC, Venrock Healthcare Capital Partners III, L.P., VHCP Co-Investment Holdings III, LLC, VHCP Management II, LLC, VHCP Management III, LLC, Nimish Shah and Bong Koh (collectively, the "Venrock Entities"). According to the report, each of the Venrock Entities has shared voting and dispositive power with respect to 4,500,000 shares of the Common Stock of the Company. The principal business address of each of the Venrock Entities is 7 Bryant Park, 23rd Floor, New York, NY 10018.
- (2) Consists of shares of Common Stock issued pursuant to the Spitfire Merger Agreement in payment for the assets of Spitfire Pharma, Inc. at the initial closing and for the achievement of the IND Milestone Event (as defined in the Spitfire Merger Agreement). The principal business address of Velocity Pharmaceutical Holdings, LLC is 400 Oyster Blvd., Suite 202, South San Francisco, CA 94080.
- (3) Consists of 165,179 shares of Common Stock, 147,999 restricted shares of Common Stock over which Dr. Garg has voting control and 235,082 shares of Common Stock which can be acquired upon exercise of outstanding options within 60 days of February 23, 2021.
- (4) Consists of 16,918 shares of Common Stock, and 72,104 shares of Common Stock which can be acquired upon exercise of outstanding options within 60 days of February 23, 2021.
- (5) Consists of 9,861 shares of Common Stock, 15 shares of Common stock owned by his spouse and 59,415 shares of Common Stock which can be acquired upon exercise of outstanding options within 60 days of February 23, 2021.
- (6) Consists of 5,037 shares of Common Stock and 61,541 shares of Common Stock which can be acquired upon exercise of outstanding options within 60 days of February 23, 2021.
- (7) Consists of 26,363 shares of Common Stock and 46,776 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of February 23, 2021.
- (8) Consists of 17,936 shares of Common Stock and 36,029 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of February 23, 2021.
- (9) Consists of 11,199 shares of Common Stock and 35,609 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of February 23, 2021.
- (10) Consists of 32,579 shares of Common Stock and 35,542 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of February 23, 2021.
- (11) Consists of 8,900 shares of Common Stock and 35,881 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of February 23, 2021.

- (12) Consists of 8,498 shares of Common Stock and 34,875 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of February 23, 2021.
- (13) Consists of 17,764 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of February 23, 2021.
- (14) Includes 302,630 shares of Common Stock held by the Company's current directors and executive officers, 147,999 restricted shares of Common Stock over which the Company's current directors and executive officers have voting control and 706,305 shares of Common Stock that can be acquired by the Company's current directors and executive officers upon the exercise of outstanding options within 60 days of February 23, 2021.

### Equity Compensation Plan Information

The following table provides information regarding the number of securities to be issued under our equity plans, the weighted-average exercise price of options issued under our equity plans and the number of securities remaining available for future issuance under our equity plans, in each case as of December 31, 2020:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights (\$)	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	1,430,266	4.67	324,710
Equity compensation plans not approved by security holders	366,212	2.07	1,517,001
Total	1,796,478	4.14	1,841,711

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

#### Director independence

The Board of Directors has determined that each of our current directors, other than Dr. Garg, currently meet the independence requirements contained in the NASDAQ listing standards and applicable tax and securities rules and regulations. None of our non-employee directors has or had a relationship with the Company or its subsidiaries that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In compliance with the NASDAQ listing standards, we have a Board of Directors comprised of a majority of independent directors. The NASDAQ listing standards have both objective tests and a subjective test for determining who is an "independent director." The objective tests state, for example, that a director is not considered independent if he is an employee of the Company or is a partner in or controlling stockholder or executive officer of an entity to which the Company made, or from which the Company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year. The subjective test states that an independent director must be a person who lacks a relationship that, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

None of the non-employee directors were disqualified from "independent" status under the objective tests. In assessing independence under the subjective test, the Board took into account the standards in the objective tests, and reviewed and discussed additional information provided by the directors with regard to each director's business and personal activities as they may relate to Altimmune's management. Based on all of the foregoing, as required by the NASDAQ listing standards, the Board made a substantive determination as to each of the non-employee directors that no relationship exists which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

The Board has not established categorical standards or guidelines to make these subjective determinations, but considers all relevant facts and circumstances.

In addition to Board-level standards for director independence, except as described above under "Item 10 – Board committees," the directors who serve on the Audit Committee and the Compensation Committee each satisfy standards established by the SEC and the NASDAQ listing rules providing that to qualify as "independent" for purposes of membership on the Audit Committee or the Compensation Committee, members of such committees may not accept directly or indirectly any consulting, advisory or other

compensatory fee from the Company other than their director compensation. Also, each of the directors who serve on the Compensation Committee has been determined to be a “non-employee director” for purposes of the applicable SEC rules and regulations and an “outside director” for purposes of the applicable tax rules.

In making its independence determinations, the Board considered transactions occurring since the beginning of 2016 between the Company and entities associated with the independent directors or members of their immediate family. In each case, the Board determined that, because of the nature of the director’s relationship with the entity and/or the amount involved, the relationship did not impair the director’s independence.

The Company does not have a director tenure requirement, as it believes its efforts to regularly refresh the Board with new directors, as well as natural turnover, has achieved the appropriate balance between maintaining longer-term directors with deep institutional knowledge and new directors who bring new perspectives and diversity to the Board. Notwithstanding this belief and the fact that the Company’s corporate governance guidelines and NASDAQ Global Market rules do not deem long-tenured directors to be non-independent, the Board reviews director tenure in connection with its director independence determinations.

#### **Review and approval of related party transactions**

Our related parties include our directors, director nominees, executive officers, holders of more than five percent of the outstanding shares of our Common Stock the foregoing persons’ immediate family members. We review relationships and transactions in which the Company and our related parties are participants to determine whether such related persons have a direct or indirect material interest. As required under SEC rules, transactions since January 1, 2020 that are determined to be directly or indirectly material to a related party are disclosed in this Proxy Statement. In addition, the Audit Committee reviews and approves any related party transaction that is required to be disclosed.

Since January 1, 2020, there have been no related party transactions.

#### **Indemnification agreements**

We have entered into an indemnification agreement with each of our outside directors. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

#### **Item 14. Principal Accountant Fees and Services**

The following table sets forth the aggregate fees billed to the Company for services during the fiscal years ended December 31, 2020 and 2019 by our independent registered public accounting firm, Ernst & Young LLP (“E&Y”):

<b>Fee Category</b>	<b>2020</b>	<b>2019</b>
Audit Fees (1)	\$ 886,499	\$ 670,267
Tax Fees (2)	—	25,000
<b>Total</b>	<b>\$ 886,499</b>	<b>\$ 695,267</b>

- (1) Audit Fees consist of fees billed for professional services rendered for the audit of the Company’s consolidated annual financial statements included in the Company’s Annual Report and review of the interim consolidated financial statements included in the Company’s Quarterly Reports on Form 10-Q, and services that are normally provided by independent registered public accountants in connection with statutory and regulatory filings or engagements.
- (2) Tax Fees were billed for services including assistance with tax compliance and the preparation of tax returns, tax consultation services, assistance in connection with tax audits and tax advice related to mergers, acquisitions and dispositions.

#### **Pre-Approval Policies**

The Audit Committee, or a designated member thereof, pre-approves 100% of all audit, audit-related, tax and other services rendered by the independent registered public accounting firm to the Company or its subsidiaries.

Immediately following the completion of each fiscal year, the Company’s independent registered public accounting firm shall submit to the Audit Committee (and the Audit Committee shall request from the independent registered public accounting firm), as soon as possible, a formal written statement describing: (i) the independent registered public accounting firm’s internal quality-control procedures; and (ii) all relationships between the independent registered public accounting firm and the Company, including at least

the matters set forth in Independence Standards Board Standard No. 1 (Independence Discussion with Audit Committees), in order to assess the independent registered public accounting firm's independence.

Immediately following the completion of each fiscal year, the independent registered public accounting firm also shall submit to the Audit Committee (and the Audit Committee shall request from the independent registered public accounting firm), a formal written statement of the fees billed by the independent registered public accounting firm to the Company in each of the last two fiscal years for each of the following categories of services rendered by the independent registered public accounting firm: (i) the audit of the Company's annual financial statements and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q or services that are normally provided by the independent registered public accounting firm in connection with statutory and regulatory filings or engagements; (ii) assurance and related services not included in clause (i) that are reasonably related to the performance of the audit or review of the Company's financial statements, in the aggregate and by each service; (iii) tax compliance, tax advice and tax planning services, in the aggregate and by each service; and (iv) all other products and services rendered by the independent registered public accounting firm, in the aggregate and by each service.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

#### Financial Statements

Reference is made to the Index to the Consolidated Financial Statements included in Item 8 of this report.

#### Financial Statement Schedules

Required information is included in the notes to the consolidated financial statements.

#### Exhibit Index

Exhibit No.	Description
<a href="#">2.1</a>	<a href="#">Agreement and Plan of Merger and Reorganization, dated July 8, 2019, by and among Altimmune, Inc., Springfield Merger Sub, Inc., Springfield Merger Sub, LLC, Spitfire Pharma, Inc. and David Collier, as the Stockholder Representative (incorporated by reference to Exhibit 2.1 to Registrant's Form 8-K filed on July 9, 2019).</a>
<a href="#">3.1</a>	<a href="#">Amended and Restated Certificate of Incorporation, dated October 17, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on October 18, 2017).</a>
<a href="#">3.2</a>	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding a reverse stock split (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on September 13, 2018).</a>
<a href="#">3.3</a>	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding an increase in authorized shares (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on September 13, 2018).</a>
<a href="#">3.4</a>	<a href="#">Amended and Restated Bylaws of Altimmune, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on October 18, 2017).</a>
<a href="#">3.5</a>	<a href="#">Certificate of Designations of the Series B Convertible Preferred Stock, dated August 21, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on August 21, 2017).</a>
<a href="#">4.1</a>	<a href="#">Form of Warrant in connection with Loan and Security Agreement, dated March 30, 2012 (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on April 3, 2012).</a>
<a href="#">4.2</a>	<a href="#">Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on August 17, 2017).</a>
<a href="#">4.3</a>	<a href="#">Form of Exchange Note (incorporated by reference to Exhibit A to Exhibit 10.1 to the Registrant's Form 8-K filed on June 25, 2018).</a>
<a href="#">4.4</a>	<a href="#">Form of Exchange Note (incorporated by reference to Exhibit A to Exhibit 10.2 to the Registrant's Form 8-K filed on June 25, 2018).</a>
<a href="#">4.5</a>	<a href="#">Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.5 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed on September 26, 2018).</a>
<a href="#">4.6</a>	<a href="#">Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.3 to the Registrant's Post-Effective Amendment on Form S-1 filed on September 28, 2018).</a>
<a href="#">4.7</a>	<a href="#">Form of Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Post-Effective Amendment on Form S-1 filed on September 28, 2018).</a>
<a href="#">4.8</a>	<a href="#">Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on October 9, 2018).</a>
<a href="#">4.9</a>	<a href="#">Form of Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Form 8-K filed on October 9, 2018).</a>
<a href="#">4.10</a>	<a href="#">Description of Registrant's Securities</a>
<a href="#">10.1†</a>	<a href="#">Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 8, 2017).</a>
<a href="#">10.2†</a>	<a href="#">Amendment No. 1 to the Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Appendix A to the Registrant's definitive proxy statement on Schedule 14A filed on July 26, 2018).</a>



Exhibit No.	Description
10.3†	<a href="#">Altimmune, Inc. 2001 Employee Stock Option Plan (incorporated by reference to Exhibit 99.1 to the Registrant’s Form S-8 filed on May 10, 2017)</a>
10.4†	<a href="#">Altimmune, Inc. 2001 Non-Employee Stock Option Plan (incorporated by reference to Exhibit 99.2 to the Registrant’s Form S-8 filed on May 10, 2017)</a>
10.5†	<a href="#">Altimmune, Inc. 2001 Employee Stock Option Plan (incorporated by reference to Exhibit 99.1 to the Registrant’s Form S-8 filed on May 10, 2017)</a>
10.6†	<a href="#">Altimmune, Inc. 2001 Non-Employee Stock Option Plan (incorporated by reference to Exhibit 99.2 to the Registrant’s Form S-8 filed on May 10, 2017)</a>
10.7†	<a href="#">Altimmune, Inc. 2018 Inducement Grant Plan (incorporated by reference to Exhibit 10.3 to the Registrant’s Form 8-K filed on December 3, 2018)</a>
10.8†	<a href="#">Altimmune, Inc. 2019 Employee Stock Purchase Plan (incorporated herein by reference to Appendix A to the Registrant’s Definitive Proxy Statement, filed on August 22, 2019)</a>
10.9†	<a href="#">Altimmune, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.2 to the Registrant’s Form 10-Q, filed on November 9, 2020)</a>
10.10§	<a href="#">Second Restated License Agreement, effective as of October 4, 2005, between Crucell Holland B.V. and Vaxin Inc. (incorporated by reference to Exhibit 10.10 to the Registrant’s Form 10-Q filed on August 14, 2017)</a>
10.11§	<a href="#">Amendment No. 1 to Second Restated License Agreement, effective as of September 25, 2015, between Crucell Holland B.V. and Altimmune, Inc. (incorporated by reference to Exhibit 10.11 to the Registrant’s Form 10-Q filed on August 14, 2017)</a>
10.12§	<a href="#">Amendment No. 2 to Second Restated License Agreement, effective as of September 20, 2016, between Janssen Vaccines &amp; Prevention B.V. (formerly Crucell Holland B.V.) and Altimmune, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant’s Form 10-Q filed on August 11, 2020)</a>
10.13§	<a href="#">Amendment No. 3 to Second Restated License Agreement, effective as of April 2, 2020, between Janssen Vaccines &amp; Prevention B.V. (formerly Crucell Holland B.V.) and Altimmune, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant’s Form 10-Q filed on August 11, 2020)</a>
10.14§	<a href="#">Amendment No. 4 to Second Restated License Agreement, effective as of July 28, 2020, between Janssen Vaccines &amp; Prevention B.V. (formerly Crucell Holland B.V.) and Altimmune, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant’s Form 10-Q filed on November 9, 2020)</a>
10.15	<a href="#">Amendment No. 5 to Second Restated License Agreement, effective as of October 22, 2020, between Janssen Vaccines &amp; Prevention B.V. (formerly Crucell Holland B.V.) and Altimmune, Inc.</a>
10.16§	<a href="#">Amended and Restated Exclusive License Agreement, dated as of June 2, 2014, between the UAB Research Foundation and Vaxin Inc. (incorporated by reference to Exhibit 10.8 to the Registrant’s Form 10-Q filed on August 14, 2017)</a>
10.17§	<a href="#">First Amendment to Amended and Restated Exclusive License Agreement, effective as of October 16, 2015, between UAB Research Foundation and Altimmune, Inc. (f/k/a Vaxin Inc.) (incorporated by reference to Exhibit 10.9 to the Registrant’s Form 10-Q filed on August 14, 2017)</a>
10.18§	<a href="#">Contract with the National Institute of Allergy and Infectious Diseases of the National Institutes of Health for the Development of Vaccine Formulations Effective Against NIAID Priority Pathogens, dated September 9, 2014 (Contract No. HHSN272201400040C) (incorporated by reference to the corresponding exhibit to the Registrant’s quarterly report on Form 10-Q for the quarter ended September 30, 2014 filed on November 6, 2014)</a>
10.19§	<a href="#">Contract Award issued by Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated July 27, 2016 (incorporated by reference to Exhibit 10.6 to the Registrant’s Form 10-Q filed on August 14, 2017)</a>
10.20	<a href="#">Amendment No. 4 to Contract Award issued by the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated September 20, 2018 (incorporated by reference to Exhibit 10.8 to Amendment No. 2 to the Registrant’s Registration Statement on Form S-1 filed on September 26, 2018)</a>

Exhibit No.	Description
<a href="#">10.21§</a>	<a href="#">Amendment No. 5 to Contract Award issued by Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated August 20, 2019 (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q filed on November 13, 2019)</a>
<a href="#">10.22§</a>	<a href="#">Amendment No. 6 to Contract Award issued by the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated December 23, 2020</a>
<a href="#">10.23§</a>	<a href="#">Amended and Restated License Agreement, dated July 12, 2019, by and between Mederis Diabetes, LLC and Spitfire Pharma, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q filed on November 13, 2019)</a>
<a href="#">10.24</a>	<a href="#">Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registrant's Form 10-Q filed on August 14, 2017)</a>
<a href="#">10.25†</a>	<a href="#">Employment Agreement, dated December 7, 2015, between M. Scot Roberts and Altimmune, Inc. (incorporated by reference to Exhibit 10.17 to the Registrant's Form 10-Q filed on August 14, 2017)</a>
<a href="#">10.26</a>	<a href="#">Employment Agreement, dated November 16, 2018 between Dr. Vipin K. Garg and Altimmune, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 27, 2018)</a>
<a href="#">10.27</a>	<a href="#">Employment Agreement, dated June 10, 2019, by and between Altimmune, Inc. and William Brown (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on June 12, 2019)</a>
<a href="#">10.28</a>	<a href="#">Employment Agreement, dated September 3, 2019, by and between Altimmune, Inc. and M. Scott Harris (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q filed on November 13, 2019)</a>
<a href="#">21*</a>	<a href="#">Subsidiaries</a>
<a href="#">23.1*</a>	<a href="#">Consent of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</a>
<a href="#">31.1*</a>	<a href="#">Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)</a>
<a href="#">31.2*</a>	<a href="#">Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)</a>
<a href="#">32.1*</a>	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350</a>
<a href="#">32.2*</a>	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350</a>
101.INS**	Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\* Attached as Exhibit 101 to this Annual Report on Form 10-K are the following materials, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2020 and 2019; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2020 and 2019; (iii) Consolidated Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2020 and 2019; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019; and (vi) Notes to the Consolidated Financial Statements.

† Management contract or compensatory plan or arrangement.

§ Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment.

#### Financial Statements and Schedules of Subsidiaries and Affiliates

None.

#### Item 16. Form 10-K Summary

Not applicable.

## 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, in the city of Gaithersburg, State of Maryland, on the 25<sup>th</sup> day of February 2021.

**ALTIMMUNE, INC.**

By: /s/ Vipin K. Garg

Vipin K. Garg  
Chief Executive Officer

## POWER OF ATTORNEY

BY THESE PRESENTS, each person whose signature appears below constitutes and appoints Vipin K. Garg and Will Brown his true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Vipin K. Garg</u> Vipin K. Garg	President, Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2021
<u>/s/ Will Brown</u> Will Brown	Chief Financial Officer, (Principal Financial Officer and Principal Accounting Officer)	February 25, 2021
<u>/s/ Mitchel Sayare, Ph.D.</u> Mitchel Sayare, Ph.D.	Chairman of the Board	February 25, 2021
<u>/s/ John Gill</u> John Gill	Director	February 25, 2021
<u>/s/ Philip Hodges</u> Philip Hodges	Director	February 25, 2021
<u>/s/ David Drutz, M.D.</u> David Drutz, M.D.	Director	February 25, 2021
<u>/s/ Klaus O. Schafer, M.D.</u> Klaus O. Schafer, M.D.	Director	February 25, 2021
<u>/s/ Wayne Pisano</u> Wayne Pisano	Director	February 25, 2021
<u>/s/ Diane Jorkasky, M.D.</u> Diane Jorkasky, M.D.	Director	February 25, 2021

**Description of the Registrant's Securities Registered Pursuant to  
Section 12 of the Securities Exchange Act of 1934, as amended**

*The summary of the general terms and provisions of the registered securities of Altimune, Inc. ("Altimune" "we," or "our") set forth below does not purport to be complete and is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation, as amended (our "certificate of incorporation") and our Amended and Restated By-laws (our "Bylaws" and, together with our certificate of incorporation, our "Charter Documents"), which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Charter Documents and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL") for additional information.*

**Common Stock**

Under our Amended and Restated Certificate of Incorporation, as amended, to which we refer as our "charter," we are currently authorized to issue 200,000,000 shares of common stock, par value \$0.0001 per share. As of February 23, 2021, we had 37,150,376 shares of common stock outstanding.

Holders of our common stock are entitled to one vote for each share of common stock held of record on all matters to be voted on by stockholders, except as otherwise provided by law or in any preferred stock designation. Our bylaws specify that, except as otherwise required by law or our charter, the presence in person or by proxy of holders of a majority of the shares entitled to vote at a meeting of stockholders will be necessary, and will constitute a quorum, for the transaction of business at such meeting. Our bylaws furthermore specify that all elections of directors will be determined by a plurality of the votes and that, except as otherwise provided by law or in the charter or bylaws, any other matter will be determined by the vote of a majority of the shares which are voted with regard to it. Holders of our common stock have no conversion, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the common stock.

There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voting for the election of directors can elect all of the directors then up for election. Holders of our common stock are entitled to receive dividends when, as and if declared by our board of directors out of funds legally available therefor. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share in all assets remaining which are available for distribution to them after payment of liabilities and after provision has been made for each class of stock, if any, having preference over the common stock.

*Annual Meeting.*

Annual meetings of our stockholders are held on the date designated in accordance with our amended and restated by-laws. Written notice must be mailed to each stockholder entitled to vote not less than ten nor more than 60 days before the date of the meeting. The presence in person or by proxy of the holders of record of a majority of our issued and outstanding shares entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose only by the board of directors pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office. Except as may be otherwise provided by applicable law, our certificate of incorporation or our amended and restated by-laws, all elections of directors shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

*Voting Rights.*

Holders of common stock are entitled to one vote for each share held of record on all matters to be voted upon by stockholders and do not have cumulative voting rights.

*Dividends.*

Subject to the rights, powers and preferences of any outstanding preferred stock that we may designate and issue in the future, and except as provided by law or in our certificate of incorporation, dividends may be declared and paid or set aside for payment on the Common Stock out of legally available assets or funds when and as declared by our board of directors.

### *Liquidation, Dissolution and Winding Up.*

Subject to the rights, powers and preferences of any outstanding preferred stock that we may designate and issue in the future, in the event of our liquidation, dissolution or winding up, our net assets will be distributed pro rata to the holders of Common Stock.

### *Other Rights.*

Holders of Common Stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Holders of Common Stock are not required to make additional capital contributions.

### *Transfer Agent*

The transfer agent and registrar for the common stock is Continental Stock Transfer & Trust Company, New York, New York.

## **Preferred Stock**

Under our charter, we are currently authorized to issue 1,000,000 shares of preferred stock, par value \$.0001 per share. As of December 31, 2020, we had no shares of preferred stock outstanding.

Under our charter, our board of directors is expressly granted authority to issue shares of preferred stock, in one or more series, and to fix for each series such voting powers, full or limited, and such designations, preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions as it may determine in the resolution or resolutions providing for the issue of such series (to which we also refer as a “preferred stock designation”) and as may be permitted by the Delaware General Corporation Law. The number of authorized shares of preferred stock may be increased or decreased (but not below the number of shares of preferred stock then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the then outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, without a separate vote of the holders of the preferred stock, or any series of preferred stock, unless a vote of any such holders is required pursuant to any preferred stock designation.

The rights and terms relating to any new series of preferred stock could adversely affect the voting power or other rights of the holders of the common stock or could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company.

### *Terms*

Our board of directors will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under any prospectus and applicable prospectus supplements in the certificate of designations relating to that series. We will file the form of any certificate of designations that describes the terms of the series of preferred stock we are offering in connection with the issuance of the related series of preferred stock. This description of the preferred stock in the certificate of designations and any applicable prospectus supplement may include:

- the number of shares of preferred stock to be issued and the offering price of the preferred stock;
- the title and stated value of the preferred stock;
- dividend rights, including dividend rates, periods, or payment dates, or methods of calculation of dividends applicable to the preferred stock;
- whether dividends will be cumulative or non-cumulative, and if cumulative the date from which distributions on the preferred stock shall accumulate;

- right to convert the preferred stock into a different type of security;
- voting rights, if any, attributable to the preferred stock;
- rights and preferences upon our liquidation or winding up of our affairs;
- terms of redemption;
- preemption rights, if any;
- the procedures for any auction and remarketing, if any, for the preferred stock;
- the provisions for a sinking fund, if any, for the preferred stock;
- any listing of the preferred stock on any securities exchange;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into our common stock, including the conversion price (or manner of calculation thereof);
- a discussion of federal income tax considerations applicable to the preferred stock, if material;
- the relative ranking and preferences of the preferred stock as to dividend or other distribution rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuance of any series of preferred stock ranking senior to or on a parity with the series of preferred stock being offered as to distribution rights and rights upon the liquidation, dissolution or winding up or our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions of the preferred stock.

#### *Rank*

Shares of our preferred stock may rank, with respect to payment of distributions and rights upon our liquidation, dissolution or winding up, and allocation of our earnings and losses:

- senior to all classes or series of our common stock, and to all of our equity securities ranking junior to the preferred stock;
- equally with all equity securities issued by us, the terms of which specifically provide that these equity securities rank on a parity, or equally, with the preferred stock; or
- junior to all equity securities issued by us, the terms of which specifically provide that these equity securities rank senior to the preferred stock.

#### *Distributions*

Subject to any preferential rights of any outstanding stock or series of stock, holders of our preferred stock may be entitled to receive distributions, when and as authorized by our board of directors, out of legally available funds, and share pro rata based on the number of shares of preferred stock, common stock and other equity securities outstanding.

#### *Voting Rights*

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As indicated in the applicable supplement to a prospectus, and as otherwise required under Delaware law, holders of our preferred stock may or may not have voting rights.

#### *Liquidation Preference*

Upon the voluntary or involuntary liquidation, dissolution or winding up of our affairs, then, before any distribution or payment shall be made to the holders of any common stock or any other class or series of stock ranking junior to the preferred stock in our distribution of assets upon any liquidation, dissolution or winding up, the holders of each series of our preferred stock may be entitled to receive, after payment or provision for payment of our debts and other liabilities, out of our assets legally available for distribution to shareholders, liquidating distributions in the amount of the liquidation preference per share, plus an amount, if applicable, equal to all distributions accrued and unpaid thereon (which shall not include any accumulation in respect of unpaid distributions for prior distribution periods if the preferred stock does not have a cumulative distribution). After payment of the full amount of the liquidating distributions to which they may be entitled, the holders of preferred stock may have no right or claim to any of our remaining assets. In the event that, upon our voluntary or involuntary liquidation, dissolution or winding up, the legally available assets are insufficient to pay the amount of the liquidating distributions on all of our outstanding preferred stock and the corresponding amounts payable on all of our stock of other classes or series of equity security ranking on a parity with the preferred stock in the distribution of assets upon liquidation, dissolution or winding up, then the holders of our preferred stock and all other such classes or series of equity securities may share ratably in the distribution of assets in proportion to the full liquidating distributions to which they would otherwise be respectively entitled.

If the liquidating distributions are made in full to all holders of preferred stock, our remaining assets may be distributed among the holders of any other classes or series of equity security ranking junior to the preferred stock upon our liquidation, dissolution, or winding up, according to their respective rights and preferences and in each case according to their respective number of shares of stock.

#### *Conversion Rights*

The terms and conditions, if any, upon which shares of any series of preferred stock are convertible into, such as common stock, debt securities, warrants or units consisting of one or more of such securities will be set forth in the applicable supplement to a prospectus. These terms will include the amount and type of security into which the shares of preferred stock are convertible, the conversion price (or manner of calculation thereof), the conversion period, provisions as to whether conversion will be at the option of the holders of the preferred stock or us, the events, if any, requiring an adjustment of the conversion price and provisions, if any, affecting conversion in the event of the redemption of that preferred stock.

#### *Redemption*

If so provided in the applicable supplement to a prospectus, our preferred stock will be subject to mandatory redemption or redemption at our option, in whole or in part, in each case upon the terms, at the times and at the redemption prices set forth in such supplement to a prospectus.

### **Warrants**

As of December 31, 2020, we had 1,777,611 shares of our common stock issuable upon the exercise of outstanding warrants. The warrants may be convertible into or exercisable or exchangeable for shares of our common stock, preferred stock or debt securities.

#### *General*

We will describe in the applicable prospectus supplement the terms relating to warrants being offered, which may include:

- the offering price and aggregate number of warrants offered;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant, the price at which these shares may be purchased upon such exercise and whether such exercise may be on a cashless basis;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreements and warrants may be modified;
- federal income tax consequences of holding or exercising the warrants, if material;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will likely not have any of the rights of holders of the securities purchasable upon such exercise, including, in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up of our affairs or to exercise voting rights, if any.

#### *Exercise of Warrants*

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We intend to set forth in any warrant agreement and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of the required payment and any warrant certificate or other form required for exercise properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant or warrant certificate are exercised, then we will issue a new warrant or warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

#### **Provisions of Our Certificate of Incorporation and Amended and Restated By-laws and Delaware Law That May Have Anti-Takeover Effects**

The provisions of Delaware law and our certificate of incorporation and amended and restated by-laws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

#### *Board of Directors*

Our certificate of incorporation and amended and restated by-laws provide for a board of directors divided as nearly equally as possible into three classes. Each class is elected to a term expiring at the annual meeting of



stockholders held in the third year following the year of such election. The number of directors comprising our board of directors is fixed from time to time by the board of directors.

#### *Removal of Directors by Stockholders*

Our amended and restated bylaws provide that members of our board of directors may only be removed for cause by a vote of the holders of a majority of the voting power of the outstanding shares entitled to vote on the election of the directors, voting together as a single class.

#### *Issuance of Preferred Stock*

Our board of directors is authorized, without further action by our stockholders, to issue up to 1,000,000 shares of preferred stock in one or more series, and to fix the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualifications, limitations and restrictions of the shares of each series of preferred stock. The issuance of preferred stock could impede the completion of a merger, tender offer or other takeover attempt.

#### *Stockholder Nomination of Directors*

Our amended and restated bylaws provide that a stockholder must notify us in writing of any stockholder nomination of a director not earlier than 5:00 p.m., Eastern Time, on the 120<sup>th</sup> day and not later than 5:00 p.m., Eastern Time, on the 90<sup>th</sup> day prior to the first anniversary of the preceding year's annual meeting; provided, that if there was no annual meeting in the prior year or if the date of the current year's annual meeting is more than 30 days before or after the anniversary date of the prior year's annual meeting, notice by the stockholder to be timely must be so delivered on or before 10 days after the day on which the date of the current year's annual meeting is first disclosed in a public announcement by us.

#### *No Action By Written Consent*

Our certificate of incorporation provides that our stockholders may not act by written consent and may only act at duly called meetings of stockholders.

#### *Delaware Business Combination Statute*

Section 203 of the General Corporation Law of the State of Delaware, which we refer to as the DGCL, is applicable to us. Section 203 of the DGCL restricts some types of transactions and business combinations between a corporation and a 15% stockholder. A 15% stockholder is generally considered by Section 203 to be a person owning 15% or more of the corporation's outstanding voting stock. Section 203 refers to a 15% stockholder as an "interested stockholder." Section 203 restricts these transactions for a period of three years from the date the stockholder acquires 15% or more of our outstanding voting stock. With some exceptions, unless the transaction is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock of the corporation, Section 203 prohibits significant business transactions such as:

- a merger with, disposition of significant assets to or receipt of disproportionate financial benefits by the interested stockholder, and
- any other transaction that would increase the interested stockholder's proportionate ownership of any class or series of our capital stock.

The shares held by the interested stockholder are not counted as outstanding when calculating the two-thirds of the outstanding voting stock needed for approval.

The prohibition against these transactions does not apply if:

- prior to the time that any stockholder became an interested stockholder, the board of directors approved either the business combination or the transaction in which such stockholder acquired 15% or more of our outstanding voting stock, or
- the interested stockholder owns at least 85% of our outstanding voting stock as a result of a transaction in which such stockholder acquired 15% or more of our outstanding voting stock. Shares held by persons who are both directors and officers or by some types of employee stock plans are not counted as outstanding when making this calculation.

*Choice of forum*

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers or other employees to us or to our stockholders, (iii) any action asserting a claim against us or any of our directors or officers or other employees arising pursuant to any provision of the DGCL or our certificate of incorporation or our amended and restated bylaws (any of which may be amended from time to time), or (iv) any action asserting a claim against us or any of our directors or officers or other employees governed by the internal affairs doctrine.

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**AMENDMENT NO. 5 TO SECOND RESTATED LICENSE AGREEMENT**

This Amendment No. 5 ("**Amendment No. 5**") to the Second Restated License Agreement is made and entered into on the date of the last signature below by and between:

**Janssen Vaccines & Prevention B.V.**, a company under Dutch law with limited liability, with registered address at Archimedesweg 4, 2333 CN Leiden, The Netherlands ("**Janssen Vaccines**"); and

**Altimune, Inc.**, a Delaware corporation, having offices located at 910 Clopper Road, Suite 201S, Gaithersburg Maryland (MD) 20878, United States ("**Altimune**").

Each party hereinafter individually referred to as "Party" and collectively as "Parties".

WHEREAS Altimune (Vaxin) and Janssen Vaccines (Crucell) entered into a Second Restated License Agreement effective as of October 4, 2005 (as amended, the "**Agreement**");

WHEREAS Altimune and Janssen Vaccines entered into the Amendment No. 1 to Second Restated License Agreement effective as of September 25, 2015;

WHEREAS Altimune and Janssen Vaccines entered into the Amendment No. 2 to Second Restated License Agreement effective as of September 20, 2016;

WHEREAS Altimune and Janssen Vaccines entered into the Amendment No. 3 to Second Restated License Agreement effective as of April 2, 2020;

WHEREAS Altimune and Janssen Vaccines entered into the Amendment No. 4 to Second Restated License Agreement effective as of July 28, 2020;

WHEREAS Altimune is adding a STRATEGIC PARTNER; and

WHEREAS Altimune and Janssen Vaccines desire to further amend the Agreement on the terms and conditions set forth below in accordance with Section 14.1 of the Agreement.

NOW THEREFORE, the Parties agree as follows:

1. Definitions and Cross References. Unless otherwise specified herein, each capitalized term shall have the meaning assigned to it in the Agreement and each reference to a Section or Article shall refer to the corresponding Section or Article in the Agreement.
2. Exhibit 1.1 of the Agreement. Exhibit 1.1 of the Agreement (attached hereto) is hereby deleted in its entirety and replaced with a new Exhibit 1.1 as set forth on Exhibit A of this Amendment No. 5, including to add the following under the header Approved STRATEGIC PARTNER:

Lonza Houston Inc.

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3. The Agreement is amended only to the extent necessary to give full effect to this Amendment No. 5. All other terms and conditions of the Agreement shall remain in full force and effect.
4. Each signatory to this Amendment No. 5 personally represents that, to the best of his/her knowledge, he/she has authority to legally bind his/her respective Party to this Amendment No. 5.
5. This Amendment No. 5 may be executed in counterparts and when bearing the signatures of all required parties hereto it shall constitute one and the same Amendment No. 5. The Parties agree that exchanged PDF copies of a signature or any other electronically generated signature used in execution of this Amendment No. 5 (including by means of services such as *Adobe eSign services*) shall constitute a binding original of this Amendment No. 5 for all purposes.

**IN WITNESS WHEREOF**, the Parties hereto have caused this Amendment No. 5 to be duly executed on the dates written below.

**Janssen Vaccines & Prevention B.V. Altimmune, Inc.**

/s/Maarten Santman

/s/Will Brown

Name: Maarten Santman

Name: Will Brown

Function: Legal Director

Function: Chief Financial Officer

Date: Oct 22, 2020

Date: Oct 9, 2020

**Exhibit A**

**EXHIBIT 1.1**

Approved REGISTERED AFFILIATES: none Approved

STRATEGIC PARTNERS:

- Batavia Bioservices B.V.

Manufacturer of the VACCINE for VAXIN in the FIELD of prevention and/or treatment of human infectious diseases caused by infectious agents in Batavia's own facilities

- Fujifilm Diosynth Biotechnologies

Manufacturer of the VACCINE for ALTIMMUNE in the FIELD of prevention and/or treatment of human infectious diseases caused by infectious agents Fujifilm Diosynth Biotechnologies facility located in College Station, TX.

- Emergent BioSolutions

Manufacturer of the VACCINE for ALTIMMUNE in the FIELD of prevention and/or treatment of human infectious diseases caused by infectious agents in Emergent's own facilities located in Baltimore, MD.

- Vigene Biosciences, Inc.

Manufacturer of the VACCINE for ALTIMMUNE in the FIELD of prevention and/or treatment of human infectious diseases caused by infectious agents in Vigene's own facilities located in Rockville, MD.

- Brammer Bio, LLC (aka Patheon Viral Vector Services), part of ThermoFisher Scientific

Manufacturer of the VACCINE for ALTIMMUNE in the FIELD of prevention and/or treatment of human infectious diseases caused by infectious agents in Brammer's own facilities in Alachua, FL and Cambridge and Lexington, MA

- Lonza Houston Inc.

Manufacturer of the VACCINE for ALTIMMUNE in the FIELD of prevention and/or treatment of human infectious diseases caused by infectious agents in Lonza's own facilities located in Houston, Texas, USA.

**CERTAIN INFORMATION IDENTIFIED BY BRACKETED ASTERISKS ([ \* \* ]) HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES 1   6
2. AMENDMENT/MODIFICATION NO. P00006	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	CODE HHS/OS/ASPR/BARDA	7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	CODE ASPR-BARDA02
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)  ALTIMMUNE, INC. 1305044 Attn: WILLIAM BROWN ALTIMMUNE, INC. 910 CLOPPER RD 910 CLOPPER RD STE 201S GAITHERSBURG MD 208781361		(x)	9A. AMENDMENT OF SOLICITATION NO.  9B. DATED (SEE ITEM 11)
CODE 1305044	FACILITY CODE	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600008C  10B. DATED (SEE ITEM 13) 07/27/2016

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**  
 The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended,  is not extended.  
 Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

**12. ACCOUNTING AND APPROPRIATION DATA (If required)**  
 See Schedule

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103(a) - By mutual agreement of the parties
	D. OTHER (Specify type of modification and authority)

**E. IMPORTANT:** Contractor  is not  is required to sign this document and return 1 copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)**

Tax ID Number: 20-  
2726770 DUNS  
Number: 082804936

The purpose of this modification is to:

- 1) Extend the period of performance end date of CLIN0001 without additional cost to the government from 12/31/2020 to 6/30/2021.
  - 2) Revise Article B.2. Estimated Cost and Fixed Fee and Article B.5. Advance Understandings;
  - 3) Revise Section F - Deliveries or Performance; Article F.2. Deliverables;
  - 4) Revise Section G - Contract Administration Data; Article G.1. Replace Contracting Officer; Add Contract Specialist Article G.3. Key Personnel Article G.5. Invoice/Financing Request and Contract Financial Reporting
- Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) Will Brown  CFO	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) KATHLEEN Y. SEARS
15B. CONTRACTOR/OFFEROR /s/ Will Brown <small>(Signature of person authorized to sign)</small> Previous edition unusable	15C. DATE SIGNED Dec 23, 2020
16B. UNITED STATES OF AMERICA /s/ Kathleen Y. Sears <small>(Signature of Contracting Officer)</small>	16C. DATE SIGNED Dec 24, 2020

**CONTINUATION SHEET**

REFERENCE NO. OF DOCUMENT BEING CONTINUED

HHSO100201600008C/P00006

PAGE  
2

OF  
6

NAME OF OFFEROR OR CONTRACTOR  
ALTIMMUNE, INC. 1305044

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 07/27/2016 to 06/30/2021				

Beginning with the effective date of this modification, the Government and the Contractor mutually agree to the following:

**ARTICLE B.2. ESTIMATED COST AND FIXED FEE** – paragraph d. is revised as follows:

d. It is estimated that the amount currently allotted will cover performance of the contract through June 30, 2021.

CLIN	Estimated Period of Performance	Supplies/Services	Estimated Cost	Estimated Fixed Fee	Total Estimated Cost Plus Fixed Fee
0001	July 27, 2016 – June 30, 2021	Perform activities to support the conduct of a Phase 1a clinical study and demonstrate safety and immunogenicity in accordance with Article C.1 Statement of Work Study Reports, development reports, IND	\$[***]	\$[***]	\$[***]

**ARTICLE B.5. ADVANCE UNDERSTANDINGS** – paragraph c. is hereby deleted in its entirety and replaced as follows:

**c. Subcontracts**

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

- **Is of the cost-reimbursement type; or**
  - **Is Fixed-Price and exceeds \$[\*\*\*] or [\*\*\*]% of the total estimated cost of the Contract, whichever value is greater.**

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer within ten (10) calendar days.

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



**SECTION F – DELIVERIES OR PERFORMANCE**

**ARTICLE F.2. DELIVERABLES** – is hereby revised as follows:

**ATTN: Kathleen Sears (Contracting Officer)**  
U.S. Department of Health & Human Services  
Office of the Assistant Secretary for Preparedness and Response Biomedical  
Advanced Research & Development Authority  
200 C Street, S.W.  
Washington, DC 20515  
Email: [Kathleen.Sears@hhs.gov](mailto:Kathleen.Sears@hhs.gov)

**ATTN: Janet Alvanzo (Contract Specialist)**  
U.S. Department of Health & Human Services  
Office of the Assistant Secretary for Preparedness and Response Biomedical  
Advanced Research & Development Authority  
200 C Street, S.W.  
Washington, DC 20515  
Email: [Janet.Alvanzo@hhs.gov](mailto:Janet.Alvanzo@hhs.gov)

**SECTION G - CONTRACT ADMINISTRATION DATA**

**ARTICLE G.1. CONTRACTING OFFICER** - is hereby modified as follows:

The following Contracting Officer (CO) will represent the USG for the purpose of this contract:

**Kathleen Sears (Contracting  
Officer)HHS/ASPR/BARDA**  
200 C Street, S.W.  
Washington, D.C. 20515  
(202) 205-4521  
Email: [Kathleen.Sears@hhs.gov](mailto:Kathleen.Sears@hhs.gov)

**Add Janet Alvanzo as Contract Specialist**

**Janet Alvanzo (Contract Specialist)**  
HHS/ASPR/BARDA  
200 C Street, S.W.  
Washington, D.C. 20515  
(202) 205-5185  
Email: [Janet.Alvanzo@hhs.gov](mailto:Janet.Alvanzo@hhs.gov)

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- 1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
- 2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
- 3) No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.
- 4) The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

**ARTICLE G.3. KEY PERSONNEL** – is hereby modified as follows:

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

#	NAME	ORGANIZATION	TITLE
1	[***]	Altimune, Inc.	[***]
2	[***]	<b>Altimune, Inc.</b>	[***]
3	[***]	Altimune, Inc.	[***]
4	[***]	<b>Altimune, Inc.</b>	[***]

The key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) business days prior to diverting any of the specified individuals to other programs or contracts, including, where practicable, an instance when an individual must be replaced as a result of leaving the employ of the Contractor, the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer.

**ARTICLE G.5. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING** – table, is hereby deleted and replaced as follows:

**Include Program Support Center (PSC) in Receipt of Invoices:**

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<b>Contract No. HHSO100201600008C</b> <b>Modification P00006</b> <b>ALTIMMUNE</b>	<b>Continuation Sheet</b> <b>Block 14</b>	<b>Page 6 of 6</b>
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Documents shall be delivered electronically to the Contracting Officer (CO), the Contracting Specialist (CS), the Contracting Officer's Representative (COR) and PSC. Unless otherwise specified by the Contracting Officer all deliverables and reports furnished to the Government under the resultant contract (including invoices) shall be addressed as follows:

CO	CS	COR	ACOR	PSC
<b>Kathleen Sears</b> <b>HHS/ASPR/BARDA</b> <b>200 C Street, S.W.</b> <b>Washington, D.C. 20515</b> <a href="mailto:Kathleen.Sears@hhs.gov">Kathleen.Sears@hhs.gov</a>	<b>Janet Alvanzo</b> <b>HHS/ASPR/BARDA</b> <b>200 C Street, S.W.</b> <b>Washington, D.C.</b> <b>20515</b> <a href="mailto:Janet.Alvanzo@hhs.gov">Janet.Alvanzo@hhs.gov</a>	<b>Adam Clark</b> <b>HHS/ASPR/AMCG 330</b> <b>Independence Ave.,</b> <b>S.W., Room G640</b> <b>Washington, D.C. 20201</b> <b>Email: <a href="mailto:adam.clark@hhs.gov">adam.clark@hhs.gov</a></b>	<b>Amanda G. Zarrabian</b> <b>CBRN Vaccines</b> <b>BARDA/ASPR/HHS</b> <b>O'Neil House Office</b> <b>Building</b> <b>Washington, D.C. 20201</b> <a href="mailto:Amanda.Zarrabian@hhs.gov">Amanda.Zarrabian@hhs.gov</a>	<a href="mailto:PSC_Invoices@psc.hhs.gov">PSC_Invoices@psc.hhs.gov</a> & "e-Room"

***End of Modification P00006***  
***All other terms and conditions of the contract remain in full force and effect.***

## SIGNIFICANT SUBSIDIARIES

<b>List of Subsidiaries</b>	<b>Jurisdiction of Incorporation or Organization</b>
Altimune, LLC (1)	Delaware
Altimune UK, Limited (1)	United Kingdom
Spitfire Pharma, LLC (1)	Delaware
Altimune AU Pty, Limited (1)	Australia

(1) Wholly owned subsidiary of the Company

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

<b>Form</b>	<b>Registration Number</b>	<b>Date Filed</b>
S-3	333-251858	12/31/2020
S-8	333-248232	8/21/2020
S-8	333-233273	8/14/2019
S-8	333-230722	4/4/2019
S-8	333-228623	11/30/2018
S-8	333-217846	5/10/2017
S-8	333-214765	11/22/2016
S-8	333-156371	12/19/2008

of our report dated February 25, 2021, with respect to the consolidated financial statements of Altimmune, Inc., included in this Annual Report (Form 10-K) of Altimmune, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Baltimore, Maryland  
February 25, 2021

**Certification of Principal Executive Officer  
Pursuant to SEC Rule 13a-14(a)/15d-14(a)**

I, Vipin K. Garg, certify that:

1. I have reviewed this annual report on Form 10-K of Altimmune, Inc. for the year ended December 31, 2020;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 25, 2021

/s/ Vipin K. Garg

Name: Vipin K. Garg

Title: President and Chief Executive Officer

(principal executive officer)

**Certification of Principal Financial Officer  
Pursuant to SEC Rule 13a-14(a)/15d-14(a)**

I, Will Brown, certify that:

1. I have reviewed this annual report on Form 10-K of Altimmune, Inc. for the year ended December 31, 2020;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 25, 2021

/s/ Will Brown

Name: Will Brown

Title: Chief Financial Officer

(principal financial officer)

**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

In connection with the annual report on Form 10-K of Altimmune, Inc. (the "Company") for the year ended December 31, 2020, as filed with the Securities and Exchange Commission (the "Report"), I, Vipin K. Garg, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934.
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Vipin K Garg

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Vipin K Garg

President and Chief Executive Officer

February 25, 2021

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.



**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

In connection with the annual report on Form 10-K of Altimmune, Inc. (the "Company") for the year ended December 31, 2020, as filed with the Securities and Exchange Commission (the "Report"), I, Will Brown, Chief Financial Officer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934.
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Will Brown

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Will Brown

Chief Financial Officer

February 25, 2021

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.