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, 2019

☐ **Transition Report under 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)**	**20-2726770** **(I.R.S. Employer Identification No.)**
910 Clopper Road, Suite 201S, Gaithersburg, MD **(Address of principal executive offices)**	**20878** **(Zip Code)**

Registrant's telephone number, including area code

(240) 654-1450

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the Registrant's common stock held by non-affiliates, based upon the closing price of the Registrant's common stock on the NASDAQ Global Market of $2.38, on June 28, 2019 was approximately $28,792,136.

There were 15,361,660 shares of the Registrant's common stock, $0.0001 par value per share, outstanding on March 26, 2020.

ALTIMMUNE, INC.

ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

PART I

Forward-looking statements

This Annual Report on Form 10-K for the year ended December 31, 2019 (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 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, 2019.

Note regarding trademarks

"Altimmune," our logo and other trademarks, trade names or service marks of the Company appearing in this Annual Report, including, HepTcell, NasoShield, NasoVAX, AdCOVID,, 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.

Item 1. Business.

Overview

Altimmune, Inc. is a clinical stage biopharmaceutical company focused on developing treatments for liver disease, immune modulating therapies, and vaccines. Our diverse pipeline of product candidates includes next generation peptide therapeutics for non-alcoholic steatohepatitis ("NASH ") (ALT-801) and chronic hepatitis B (HepTcell), conjugated immunostimulants for the treatment of cancer (ALT-702) and intranasal vaccines (NasoVAX, NasoShield, and AdCOVID).

Our business is the result of a merger between PharmAthene, Inc. ("PharmAthene") and the business previously known as Altimmune, Inc. ("Private Altimmune"). In May 2017, Private Altimmune merged with PharmAthene pursuant to an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") dated January 18, 2017, among Private Altimmune, PharmAthene, its wholly owned acquisition subsidiaries Mustang Merger Sub Corp I Inc. ("Merger Sub Corp") and Mustang Merger Sub II LLC ("Merger Sub LLC"). Pursuant to the Merger Agreement, Merger Sub LLC agreed to acquire 100% of the outstanding capital stock of Private Altimmune in a reverse triangular merger and reorganization pursuant to section 368(a) of the Internal Revenue Code (the "Mergers"). Prior to the Mergers, PharmAthene was a publicly traded biodefense company engaged in Phase 2 clinical trials.

On May 4, 2017, Private Altimmune and PharmAthene closed the Mergers in accordance with the terms of the Merger Agreement. Upon the closing of the Mergers, (i) Merger Sub Corp merged with and into Private Altimmune, with Private Altimmune remaining as the surviving corporation; (ii) Private Altimmune then merged with and into Merger Sub LLC, with Merger Sub LLC (renamed as "Altimmune LLC") remaining as the surviving entity; and (iii) PharmAthene was renamed as "Altimmune, Inc." Upon closing of the Mergers, all equity instruments of Private Altimmune were exchanged for corresponding equity instruments of PharmAthene. 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.

ALT-801

We completed an acquisition in July 2019 to acquire 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 metabolic dysfunction that causes non-alcoholic steatohepatitis. 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. As observed in a well-established preclinical model of the disease, ALT-801 was capable of inducing significant weight loss with concomitant decreases in liver fat, inflammation and fibrosis. We plan to advance ALT-801 into Phase 1 development in 2020.

HepTcell

HepTcell is an immunotherapeutic product candidate for patients chronically infected with the hepatitis B virus ("HBV"). It 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 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 may allow 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 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 were generally well-tolerated 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 plan to advance HepTcell into Phase 2 development in 2020.

ALT-702

ALT-702 is an investigational tumor immunostimulant designed to act locally to reverse local immunosuppression within the tumor microenvironment and stimulate systemic antitumor immune responses. The ALT-702 technology is a novel synthetic peptide conjugate technology platform designed to retain and concentrate immunostimulants within a tumor potentially leading to enhanced immune stimulation without the risk of systemic inflammation. We believe that ALT-702 represents a new approach in immuno-oncology that may be developed as a monotherapy or be used in conjunction with immune checkpoint inhibitors, oncolytic viruses or other approaches in immuno-oncology or improve their effectiveness. We are currently conducting preclinical studies using an aggressive tumor model based on the murine CT26 colorectal carcinoma cell line. We recently met a key preclinical milestone with the demonstration of systemic antitumor activity following intra-tumoral injection in an individual solid tumor. The aggressive tumor model involved the establishment of a tumor in each flank of a mouse. In the study, three doses of ALT-702 were injected into one tumor mass over five days with concomitant treatment with an anti-CTLA4 antibody immune checkpoint inhibitor administered intraperitoneally. Tumor regression was noted in both injected (88%) and non-injected (38%) lesions, and overall survival in the ALT-702 + anti-CTLA4 group was markedly better than either agent alone. We plan to complete ALT-702's preclinical data set in 2020.

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 plan to commence a Phase 1b trial of NasoShield in 2020. The planned Phase 1b clinical trial builds on the Phase 1a trial completed in 2018 and will evaluate the effect of modified methods of intranasal dosing on NasoShield safety and immunogenicity. Results are expected in the fourth quarter of 2020.

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. We believe 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 evaluating strategic alternatives to fund the development of NasoVAX, such as regional licensing, government funding, or co-development of the program.

AdCOVID

In February 2020, we announced the advancement of AdCOVID, a novel single-dose, intranasal vaccine using our proprietary intranasal vaccine technology, to protect against COVID-19, the disease caused by the SARS-CoV-2 virus. Based on the RespirVec vaccine platform, it is expected that AdCOVID has the potential to activate the mucosal, humoral, and cellular immune arms against the virus that causes COVID-19. We believe the excellent stability of RespirVec vaccines when combined with the simple intranasal route of administration may allow for efficient and inexpensive distribution of the vaccine. We have completed the design and synthesis of the vaccine and are now advancing it toward animal testing and manufacturing. We plan to initiate a Phase 1 clinical study for AdCOVID in the third quarter of 2020.

Our Strategy

Key elements of our strategy include the following;

- *Apply our platform technologies to design and develop immunotherapeutic products tailored to address a wide range of disease indications including NASH, obesity, cancer, 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.

Densigen

Densigen is our synthetic peptide technology platform. HepTcell was developed using our Densigen platform which 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.

RespirVec

NasoShield, NasoVAX and AdCOVID, 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.

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 product 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 for ALT-801, our dual GLP-1/glucagon dual agonist for the treatment of NASH, from companies such as Genfit SA, which is developing a peroxisime proliferator activated receptor agonist; Viking Therapeutics, which is developing a thryroid hormone receptor beta selective agonist; and Intercept Pharmaceuticals, which is developing a farnesoid X receptor agonist. 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. We face competition for ALT-702, our conjugated TLR7/8 agonist for the treatment of cancer, from companies such as Curevac, which is developing a CV8102, a TLR7/8/RIG-1 agonist based on noncoding single stranded RNA for the treatment of solid tumors; and Urogen, which is developing a TLR7 agonist for bladder cancer. We face competition for NasoShield, our single dose intranasal anthrax vaccine product candidate from Emergent Biosolutions, which manufactures the existing anthrax vaccine; and additionally, we generally face substantial competition for government funding from companies that develop products with government contracts and grants. Finally, 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. Any of these smaller companies may develop competing products more rapidly than we do. We also face competition from multiple biotechnology and bio-pharmaceutical companies, such as Moderna, Inovio and Sanofi, that are in the process of developing vaccines against COVID-19 using different vaccine platforms. Certain of these vaccine technologies may develop at a faster rate than AdCOVID or have superior immunogenicity or manufacturability attributes.

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 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, India, 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 an intermediary of the manufacturing process for solubilizing the fluorocarbon antigens, for which we have a patent issued in the United States, Europe, China, South Korea 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 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 and anthrax; the respiratory pathogen COVID-19 in Europe; 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 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.

Topical and Intranasal Application of Adenoviral Vectors Expressing Heterologous Antigen — In-Licensed from the University of Alabama at Birmingham Research Foundation

We were the exclusive licensee of patents owned by the University of Alabama at Birmingham Research Foundation (“UABRF”). That agreement expired in accordance with its terms in January 2020. The patents were directed to topical noninvasive

application of genetic vectors. The patents were issued in the United States and certain European countries, including Great Britain, France, Germany, Italy, Netherlands and Spain, as well as other commercially relevant jurisdictions. The claims were directed to methods of non-invasively inducing a systemic immune response in a bird or mammal against a gene product comprising contacting skin, or intranasal administration, of the bird or mammal with a genetic vector in an amount effective to induce the response.

Under that same agreement with UABRF we were also the exclusive licensee of one issued U.S. patent and a pending patent application owned by the UABRF directed to mucosal administration of genetic vectors. The claims were directed to methods of non-invasive immunization by administering a non-replicating adenovirus vector expressing influenza antigens via intranasal administration. The issued U.S. patent expired in January 2020 and the pending patent application was abandoned.

We entered into the agreement with the UABRF on March 1, 1998, amended and restated the agreement on June 2, 2014 and further amended the agreement as of October 16, 2015. This is the agreement pursuant to which we obtained an exclusive license under the patent rights described above to develop, manufacture and commercialize a non-invasive vaccine technology within the field of use, which includes any diagnostic, vaccine or therapeutic use or methods, in any country in which the licensed patents were pending or had been granted.

In connection with the original license, we paid an up-front license fee of $0.03 million and issued 2,986 shares of common stock to UABRF. We also agreed to make certain payments, including an annual maintenance payment and royalty payments as a percentage of net sales of licensed products covered by valid claims of any licensed patent in the country of sale until the expiration of the last to expire of such patents in such country. The royalty payments were subject to a minimum annual royalty amount following the first commercial sale of a licensed product, ranging from low five figures to low six figures. To date, we have paid UABRF an aggregate of $498,000 under the license agreement consisting of cash and promissory notes to UABRF that have since been repaid, and $94,000 in shares of common stock

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. To date, we have paid Janssen $2.2 million in cash and equity under 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.

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, India, 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 an intermediary of the manufacturing process for solubilizing the fluorocarbon antigens, 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

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

We are the exclusive licensee of patent rights held by Mederis Diabetes, LLC (“Mederis”) to develop and commercialize a dual GLP-1/glucagon dual agonist for the treatment of obesity, metabolic syndrome, insulin resistance, diabetes and cardiovascular disease. Patents under this license 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 License Agreement provides us with a royalty-free, fully paid-up exclusive (even as to Mederis) license under certain Mederis-owned know-how and patents (the “Licensed IP”) to make, use, sell, offer for sale, import and export products worldwide (the “License Grant”). The License Agreement also provides a royalty-free, fully paid-up, non-exclusive license back to Mederis under certain Licensed IP to make, use, sell, offer for sale, import and export certain products outside of the field of incretin-based peptide therapeutics, and variants thereof worldwide (the “Grant Back License”).

We may terminate the License Agreement in its entirety upon sixty (60) days’ written notice to Mederis. Spitfire and Mederis also each have the right to terminate the License Agreement upon the occurrence of a material breach of the License Agreement by the other party, subject to cure provisions. In addition, Spitfire has the right to terminate the Grant Back License portion of the License Agreement upon the occurrence of a material breach of the License Agreement by Mederis, subject to cure provisions.

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, Asia, and India, 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 at least two of the fluorocarbon linked 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.

ALT-702, Immunostimulant for Solid Tumors

We are developing a depot-forming immunostimulant for solid tumors for which we have a patent issued in the United States and patent applications pending in the United States, Canada, Russia, Europe, Japan and Korea. The claims are directed to conjugated immune stimulatory constructs, compositions comprising the constructs and methods of using the constructs 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 2034, not giving effect to any potential extensions and assuming payment of all associated fees.

NasoShield, Anthrax Vaccines

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 US 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. NasoShield is also covered by the patents and patent applications relating to our RespirVec platform technology.

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. NasoVAX is also covered by the patents and patent applications relating to our RespirVec platform technology, including an issued U.S. patent with claims directed to methods of non-invasive immunization by administering a non-replicating adenovirus vector expressing influenza antigens via intranasal administration.

Veterinary Product Candidates

We co-own with Auburn University patents and patent applications covering technology directed to an avian vaccine using human adenovirus vectors for the delivery of avian immunogens and antigens. These patents are issued in the United States and Europe, as well as other commercially relevant jurisdictions; and an application is pending in the United States. The claims are directed to methods for avian (*in ovo* or embryonic) administration of a human adenoviral vector expressing avian influenza antigens. The patents and, if issued, the patent(s) resulting from the patent applications are expected to have an expiration date no earlier than August 2026, not giving effect to any potential extensions and assuming payment of all associated.

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.

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 December 2020. 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. To date, we have received an aggregate of approximately $21.9 million in revenue 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 an anthrax vaccine pursuant to a contract with 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 US government's funding prioritization of only single dose anthrax vaccine candidates, we abandoned the project and impaired the $1.0 million remaining net book value of the SparVax-L IPR&D asset. The carrying value at December 31, 2019 and 2018 is $0 and $1.0 million, respectively.

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 Food and Drug Administration (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, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products. FDA concurrence must be obtained before clinical testing of biological products. FDA approval must be obtained before marketing of biological products. 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 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 ("GLPs"), studies used to support animal rule pathway submissions, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND which must become effective before human clinical trials may begin and which must include approval by an independent Institutional Review Board ("IRB") at each clinical site before the trials may be initiated;
- performance of adequate and well controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices ("GCPs"), 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 substantive evidence of safety, purity and potency from results of preclinical testing and clinical trials, and detailed information about the chemistry, manufacturing and controls for the product candidate, reports of the outcomes and full data sets of the clinical trials and proposed labeling and packaging for the product candidate;
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMPs, to assure that the facilities, methods and controls are adequate to preserve the biological product candidate's identity, strength, quality and purity;
- satisfactory completion of potential FDA audit 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 GLPs.

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 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. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, 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 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 comprising the GCP requirements, including 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. 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*. 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 ratio 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. FDA also permits the administration of investigational biological products to patients under its expanded access regulatory authorities. Under these authorities, patients who are ineligible to meet clinical trial entry criteria may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requesting physician. For 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 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 control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other 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.

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 advanced therapy.

Review and Approval Processes

After the completion of clinical trials of a biological product, the FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human 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 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. In addition, annual reports must be submitted for BLAs for seasonal influenza vaccines.

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. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("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 product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND 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 and deny 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 might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed

to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Requirements

After regulatory approval of a product is obtained, there may be a number of 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 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.

Future FDA inspections may identify 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 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 Medical Countermeasures ("MCMs"). Upon approval of a material threat MCM application, the FDA will award a PRV provided certain criteria are met. When a marketing application receives a priority review designation, the FDA's goal is to take action on that application within 6 months. 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.

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 reduce or prevent serious or life-threatening conditions based on evidence of safety from trial in healthy subjects 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. 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 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 exists 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. 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 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 medical countermeasures 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 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 of HHS, 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 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.

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 and the Health Care and Education Reconciliation Act of 2010 ("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, 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.

FDA Expedited Development and Approval Programs

Certain FDA programs are intended to speed the availability of drugs that treat serious diseases, which could potentially apply to our product candidates, although this cannot be assured, and we do not currently have any products with fast track designation. The FDA fast track designation programs is designed to facilitate the development and review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast track

designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug for a specific indication that receives fast track designation. The sponsor of a product designated as being in a fast track drug development program may engage in close early communication with the FDA, including through timely meetings and feedback on clinical trials. Products in fast track drug development programs also may be eligible for FDA priority review or accelerated approval, if relevant criteria are met. A drug reviewed pursuant to priority review has a six-month review clock instead of a ten-month review clock. Sponsors of drugs with fast track designation may also be able to submit completed portions of an application before the entire application is completed; however, the review clock will not officially begin until the entire completed BLA is submitted to and filed by the FDA. The FDA may notify a sponsor that its program is no longer classified as a fast track development program if the fast track designation is no longer supported by emerging data, the designated drug development program is no longer being pursued, or another product that meets the unmet medical need for the same indication.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor’s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product’s clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review 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 a pediatric trial 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, and so pursuit of this incentive may be relevant.

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, such as with respect to our cancer vaccine activities, and so pursuit of this incentive may be relevant to us.

U.S. Regulations Affecting Health Care Companies

Pharmaceutical manufacturers with products that are reimbursed by U.S. federally funded programs such as Medicare and Medicaid are subject to regulation by the Centers for Medicare & Medicaid Services ("CMS") and enforcement by the HHS Office of Inspector General ("OIG"), and in the event our product candidates are approved, regulation by CMS and enforcement by HHS OIG would be relevant to the Company. Some of these laws, referred to as "false claims laws," prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as "anti-kickback laws," prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for, or recommending ordering, purchasing or leasing of, items or services that are paid for by federal, state and other health care payers and programs.

The federal Anti-Kickback Law prohibits providers and others from knowingly and willingly, directly or indirectly, soliciting, receiving, offering or paying any remuneration with the intent of generating referrals of individuals or purchases, orders, or recommendations for services or items covered by a federal government health care program. Many states have enacted similar laws. 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. There are statutory and regulatory exceptions, or safe harbors, that outline arrangements that are deemed lawful. However, the fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Law. In sum, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose drugs for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from Medicare and Medicaid programs, and arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as payment of consulting fees to health care providers, sponsorship of educational or research grants, charitable donations, interactions with health care providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid the possibility of wrongfully influencing health care providers to prescribe or purchase particular products or as a reward for past prescribing. Violations of the Anti-Kickback Law may be punished by civil and criminal penalties or exclusion from participation in federal health care programs, including Medicare and Medicaid.

The Federal False Claims Act ("FCA") is violated by any entity that "presents or causes to be presented" knowingly false, fictitious, or fraudulent claims for payment to the federal government. In addition, the Health Care Reform Law amended the FCA to create a cause of action against any person who knowingly makes a false statement material to an obligation to pay money to the government or knowingly conceals or improperly decreases an obligation to pay or transmit money or property to the government. For the purposes of these recent amendments, an "obligation" includes an identified overpayment, which is defined broadly to include "any funds that a person receives or retains under Medicare and Medicaid to which the person, after applicable reconciliation, is not entitled…" 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. The fraud and abuse regulations have been subject to varying interpretations, as well as heightened enforcement activity over the past few years, and significant enforcement activity has been the result of "relators," who serve as whistleblowers by filing complaints in the name of the United States (and if applicable, particular states) under federal and state false claims laws. Violations of the FCA can result in treble damages, and each false claim

submitted can be subject to a civil penalty. Most states have adopted similar state false claims laws, and these state laws have their own penalties which may be in addition to federal FCA penalties.

The Health Care Reform Law significantly strengthened the federal 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 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 or indefinite and have not been interpreted by the courts and have been subject to frequent modification and varied 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, or 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 HIPAA without actual knowledge of the statute or specific intent to violate it.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose, among other things, requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that perform services for covered entities them that involve the creation, use, receipt, maintenance or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information.. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

In addition, federal consumer protection and unfair competition laws, broadly regulate marketplace activities and activities that potentially harm consumers.

Analogous state and foreign law equivalents may differ in significant ways. Data privacy and security laws and regulations in foreign jurisdictions such as the General Data Protection Regulation, which became effective in May 2018, are more stringent than laws in the United States. State laws governing the privacy and security of health information in certain circumstances, such as the California Consumer Privacy Act, which went into effect January 1, 2020, increase privacy and security obligations on entities handling personal data.

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 or judicial decisions, or new interpretations of existing laws or decisions, related to health care availability, the method of delivery 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 Patient Protection and Affordable Care Act and the companion Health Care Reform Law. The Health Care Reform Law increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud and abuse, and to provide access to increased health coverage.

The Health Care Reform Law has also imposed substantial changes to the U.S. system for paying for health care, including programs to extend medical benefits to millions of individuals who have lacked insurance coverage. Generally, implementation of the Health Care Reform Law has thus far included significant cost-saving, revenue and payment reduction measures with respect to, for example, several government health care programs that might cover our products in the United States, should they be commercialized, including Medicaid and Medicare. Additional downward pricing pressure associated with the Health Care Reform Law includes that the Health Care Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research, as those terms are defined in the Health Care Reform Law. 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.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Another provision of the Health Care Reform Law, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, has imposed new reporting and disclosure requirements for pharmaceutical and medical device manufacturers and distributors with certain FDA-approved products, such as approved vaccines, with regard to payments or other transfers of value made to certain U.S. health care practitioners, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and academic medical centers, and with regard to certain ownership interests held by physicians and their immediate family members in reporting entities. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. The CMS publishes information from these reports on a publicly available website, including amounts transferred and the physician and teaching hospital identities.

Under the Physician Payment Sunshine Act, should any of our products be approved for sale, we may be required to collect and report detailed information regarding certain financial relationships we have with physicians and teaching hospitals. Our compliance with these rules may also impose additional costs. It is difficult to predict how the new requirements, which also preempt similar state law reporting requirements, may impact our relationships with physicians and teaching hospitals.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. Further, 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. This final rule codified CMS's policy change that was effective January 1, 2019.

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. The continuing efforts of the government, insurance companies, managed care organizations and other payers of health care services to contain or reduce costs of health care 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.

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 President Trump. 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 I (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 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 EMA 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 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 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. 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 adopted regulations governing its acceptance of foreign clinical data not conducted under an IND to support IND applications or marketing authorizations, such as BLAs. The conditions include requirements regarding the ability of the FDA to conduct onsite inspections to validate such data, and compliance with GCPs. 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

As of December 31, 2019, we had 25 full-time employees, 11 of whom hold M.D. or Ph.D. degrees and 8 of whom hold other advanced degrees. Of our total workforce, 15 are engaged primarily in research and development activities and 10 are engaged primarily in executive, finance and accounting, and administrative functions. As of December 31, 2019, 24 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.

Financial Information

Our consolidated contract revenues were approximately $5.8 million and $10.3 million during the years ended December 31, 2019 and 2018, respectively. For the year ended December 31, 2019, we recognized $5.3 million and $0.2 million as revenue from the BARDA and NIAID contracts, respectively. For the year ended December 31, 2018, we recognized $8.3 million and $2.0 million as revenue from the BARDA and NIAID contracts, respectively.

Financial Information by Geographic Area

For the years ended December 31, 2019 and 2018, all revenues were generated in the United States, which is our country of domicile. As of ended December 31, 2019 and 2018, long-lived assets with a net book value of $2.1 million and $2.8 million, respectively, were located in the United States. As of both years ended December 31, 2019 and 2018, long-lived assets with a net book value of $12.4 million were located outside of the United States.

Research and Development

During the years ended December 31, 2019 and 2018, we spent approximately $17.8 million and $18.5 million on research and development activities, respectively.

Corporate 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 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.

Available Information

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) 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.

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. Our public float is currently below $75.0 million and therefore we are currently subject to this limitation. 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, 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 $20.5 million and $39.2 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we have an accumulated deficit of $137.4 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 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 will 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 goodwill and 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, 2019, 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 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, 2019, our cash and short-term investment balance was $37.3 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, 2019 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, 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 and 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;
- 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, 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 with NasoVAX; plan to initiate Phase 2 clinical development of HepTcell in 2020; are in Phase 1 clinical development with NasoShield; and are completing pre-clinical activities on ALT-801 and ALT-702. 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. 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 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 biodefense 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 anthrax vaccine program.

Our product candidates, all of which are biological drug candidates, are subject to extensive governmental regulations relating to, among other things, research, clinical trials, manufacturing, import, export and commercialization. Furthermore, the timing of the marketing approval for our NasoShield product candidate is subject to obtaining continued funding and consent from BARDA, which is uncertain.

Our pursuit of a potential vaccine for the COVID-19 is at an early stage and may never enter into clinical testing or be approved.

In response to the global outbreak of coronavirus, we are pursuing the development of a single-dose vaccine to protect against COVID-19. The development of the vaccine is in very early stages and has not advanced to clinical testing, and we may be unable to produce a vaccine that successfully prevents the virus in a timely manner, if at all. If the outbreak is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture our product candidate, if ever, the commercial viability of such product candidate may be diminished. 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 vaccine may not be effective.

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 in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- delays in obtaining required approvals from the Institutional Revenue 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 in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- 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;
- 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; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

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 subsequent clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

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;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- 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 and the Densigen platform involves synthetic peptide T-cell vaccines. Unforeseen problems with our approaches to vaccines and immunotherapy 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 influenza product candidate 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 having 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. 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.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

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, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing 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 product 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 for ALT-801, our dual GLP-1/glucagon dual agonist product candidate for the treatment of NASH, from companies such as Genfit SA, which is developing a peroxisime proliferator activated receptor agonist; Viking Therapeutics, which is developing a thyroid hormone receptor beta selective agonist; and Intercept Pharmaceuticals, which is developing a farnesoid X receptor agonist. 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. We face competition for ALT-702, our conjugated TLR7/8 agonist

product candidate for the treatment of cancer, from companies such as Curevac, which is developing a CV8102, a TLR7/8/RIG-1 agonist based on noncoding single stranded RNA for the treatment of solid tumors; and Urogen, which is developing a TLR7 agonist for bladder cancer. We face competition for NasoShield, our single dose intranasal anthrax vaccine product candidate from Emergent Biosolutions, which manufactures the existing anthrax vaccine; and additionally we generally face substantial competition for government funding from companies that develop products with government contracts and grants. Finally, 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. Any of these smaller 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.

The market opportunities for any current or future product candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of ALT-702 and any other product candidates we develop as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings

We are heavily dependent on the success of our leading product candidates, ALT-801, HepTcell, and NasoShield. If we ultimately are unable to develop, obtain regulatory approval for or commercialize ALT-801, HepTcell, and NasoShield, 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 ALT-801, HepTcell, and NasoShield, 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, ALT-801, HepTcell, and NasoShield, 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; and
- the prevalence and severity of any side effects.

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

We have conducted clinical trials in the United Kingdom and South Korea for HepTcell, and future clinical trials may be conducted in other foreign jurisdictions. Our ability to successfully initiate, enroll and complete a clinical trial in the United Kingdom or 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 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, as of March 2020, has spread to over 70 countries, including the United States 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 polices 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 epidemic. 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 planned exit of the United Kingdom ("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. However, the terms of the withdrawal have yet to be fully negotiated. The implementation period began February 1, 2020 and will continue until December 31, 2020. During this 11-month period, the UK will continue to follow all of the EU's rules and its trading relationship will remain the same. However, regulations (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations, medicine licensing and regulations, immigration laws and employment laws), have yet to be addressed. 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.

If the U.K. and the EU are unable to negotiate acceptable agreements or if other EU Member States pursue withdrawal, barrier-free access between the UK and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets either during a transitional period or more permanently.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities (including, without limitation, clinical activities for CTX001) in the U.K.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Depending on the terms of the U.K's withdrawal from the EU, the U.K. could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Furthermore, at present, there are no indications of the effect Brexit will have on the pathway to obtaining marketing approval for any of our product candidates in the U.K., or what, if any, role the EMA may have in the approval process. Even prior to any change to the U.K's relationship with the EU, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our common stock.

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

Future changes in tax laws resulting from legislative, administrative or judicial decisions may have adverse tax consequences to a holders of our common stock. Any such change may or may not be retroactive to a time preceding its occurrence.

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 net operating loss carryforwards of approximately $29.6 million as of December 31, 2019. 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 $23.0 million has an unlimited life. As of December 31, 2019, we have recorded a valuation allowance of $13.1 million against our net deferred tax asset. The net operating loss carryforwards are reflective of a 382-limitation related to ownership changes as described below. 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.

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. 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 our this could harm our future operating results by effectively increasing our future tax obligations.

Risks Related to the Regulatory Approval Process

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.

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

Undesirable side effects caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in 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.

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.

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 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 review, which may result in significant additional expense and other restrictions.

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, 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.

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, 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.

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 EMA. 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 Europe 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 Europe 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.

Pediatric exclusivity is another type of regulatory market exclusivity our competitors may pursue. 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 Europe, 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 if the product is authorized across Europe. 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.

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.

Additionally, 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. 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, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. 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 discuss 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 and certain of our product candidates. 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;
- delays as a result of manufacturing problems or re-prioritization of projects at a third-party manufacturer;
- 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 planned multi-valent clinical trials.

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.

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. 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 and when 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 South Korea in the amount of $1.0 million. 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, 2019 and 2018, BARDA funding for the development of NasoShield accounted for approximately 92% and 80% 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 de-prioritized 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 21st 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 President Trump. 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. 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, the laws that may affect our ability to operate include, but are not limited to:

- The federal Health Insurance Portability and Accountability Act of 1996, or 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.
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, and other health privacy measures, which impose requirements on parties with respect to the use and disclosure of individually-identifiable information, such as medical records information, including requirements relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- 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 or judicial decisions, or new interpretations of existing laws or decisions, related to health care availability, the method of delivery 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 Patient Protection and Affordable Care Act and the Health Care Reform Law. The Health Care Reform Law increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud and abuse, and to provide access to increased health coverage.

The Health Care Reform Law has also imposed substantial changes to the U.S. system for paying for health care, including programs to extend medical benefits to millions of individuals who have lacked insurance coverage. Generally, implementation of the Health Care Reform Law has thus far included significant cost-saving, revenue and payment reduction measures with respect to, for example, several government health care programs that might cover our products in the United States, should they be commercialized, including Medicaid and Medicare. Additional downward pricing pressure associated with the Health Care Reform Law includes that the Health Care Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research, as those terms are defined in the Health Care Reform Law. 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.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Another provision of the Health Care Reform Law, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, has imposed new reporting and disclosure requirements for pharmaceutical and medical device manufacturers and distributions with certain FDA approved products, such as approved vaccines, with regard to payments or other transfers of value made to certain U.S. health care practitioners, such as physicians and academic medical centers, and with regard to certain ownership interests held by physicians in reporting entities. The CMS publishes information from these reports on a publicly available website, including amounts transferred and the physician and teaching hospital identities.

Under the Physician Payment Sunshine Act, should any of our products be approved for sale, we may be required to collect and report detailed information regarding certain financial relationships we have with physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. Our compliance with these rules may also impose additional costs. It is difficult to predict how the new requirements, which also preempt similar state law reporting requirements, may impact our relationships between pharmaceutical companies and physicians or teaching hospitals.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. 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. The continuing efforts of the government, insurance companies, managed care organizations and other payers of health care services to contain or reduce costs of health care 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 the FD&C Act, the FCA, the PHS Act, or provisions of the U.S. Social Security Act known as the "Anti-Kickback Law" and the "Civil Monetary Penalties Law," 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.

Some of these laws, referred to as "false claims laws," prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as "anti-kickback laws," prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for, or recommending ordering, purchasing or leasing of, items or services that are paid for by federal, state and other health care payers and programs.

For example, the federal Anti-Kickback Law prohibits providers and others, such as us, from knowingly and willfully, directly or indirectly soliciting, receiving, offering or paying any remuneration with the intent of generating referrals of individuals or purchasers, orders or recommendations for services or items covered by a government health care program. Many states have enacted similar laws. 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. There are statutory and regulatory exceptions, or safe harbors, that outline arrangements that are deemed lawful. However, the fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Law. In sum, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose drugs for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from Medicare and Medicaid programs, and arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as payment of consulting fees to health care providers, sponsorship of educational or research grants, charitable donations, interactions with health care providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid the possibility of wrongfully influencing health care providers to prescribe or purchase particular products or as a reward for past prescribing. Violations of the Anti-Kickback Law may be punished by civil and criminal penalties or exclusion from participation in federal health care programs, including 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 or federal civil money penalties statute.

The FCA is violated by any entity that “presents or causes to be presented” knowingly false, fictitious, or fraudulent claims for payment to the federal government. In addition, the Health Care Reform Law amended the FCA to create a cause of action against any person who knowingly makes a false statement material to an obligation to pay money to the government or knowingly conceals or improperly decreases an obligation to pay or transmit money or property to the government. For the purposes of these recent amendments, an “obligation” includes an identified overpayment, which is defined broadly to include “any funds that a person receives or retains under Medicare and Medicaid to which the person, after applicable reconciliation, is not entitled…”

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. The fraud and abuse regulations have been subject to varying interpretations, as well as heightened enforcement activity over the past few years. Significant enforcement activity has been the result of actions brought by relators, who file complaints in the name of the United States (and if applicable, particular states) under federal and state FCA statutes. The qui tam and whistleblower provisions of the FCA allow private individuals to bring actions on behalf of the government alleging that the government was defrauded, with tremendous potential financial gain to private citizens who prevail. Violations of the FCA can result in treble damages and each false claim submitted can be subject to a civil penalty. Most states have adopted similar state false claims laws, and these state laws have their own penalties which may be in addition to federal FCA penalties.

The bringing of any FCA 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 or indefinite and have not been interpreted by the courts, and have been subject to frequent modification and varied 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.

The FDA and comparable foreign regulatory authorities, 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. In the United States, pharmaceutical companies have, to a limited extent, been recognized by the FDA as permitted to disseminate to physicians certain truthful and accurate information regarding unapproved uses of approved products, or results of studies involving investigational products.

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 Health Care Reform Law significantly strengthened provisions of the FCA, Medicare and Medicaid Anti-Kickback provisions, and other health care fraud provisions, leading to the possibility of greatly increased qui tam suits by relators for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect 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. For example, the federal law, HIPAA, as amended by HITECH and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information, such as information that identifies individuals who participate in our clinical trials as research subjects. HIPAA requires, among other things, the implementation of various recordkeeping, operational, notice and other practices intended to safeguard protected health information, limit its use to allowed purposes, and notify individuals in the event of privacy and security breaches. Failure to comply with these laws and regulations can result in substantial penalties and other liabilities. HITECH created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

In the United Kingdom, the collection and use of "personal data" is primarily governed by the Data Protection Act 1998 ("DPA"), which implemented the EU Directive (95/46/EEC) on data protection. Breach of the United Kingdom data protection laws can result in criminal as well as civil liability. The DPA applies to the "processing" of personal data, or individually identifiable data relating to living individuals. All obligations under the DPA fall on the "data controller" who determines the purposes for which and the manner in which any personal data is, or is to be, processed. A person may be a data controller even if the information is held by a third party. If we are the data controllers for any personal data, including, for example, with respect to clinical trials carried out in the United Kingdom, we will need to comply with the DPA to ensure compliance by any third party who holds any relevant personal data.

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). The GDPR governs the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. 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, obtaining consent of the individuals to whom the personal data relates, 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. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

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. Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has officially left the EU. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

We are also subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. For example, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018 (the "CCPA"), which came into effect on January 1, 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. 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. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. 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.

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, 2019, 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 analysists’ 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;
- recruitment or departure of key personnel; and
- overhang of our convertible securities.

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 14,141 square feet of laboratory and office space. For additional information, see *Commitment and Contingencies*, Note 16 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, we learned of a complaint that had been filed by Dr. De-Chu Christopher Tang ("Plaintiff"). We received a copy of the complaint on January 2, 2020, and on January 24, 2020, we removed the case to the United States District Court for the Eastern District of Texas (No. 4:20-CV-00063-ALM-CAN), where it is currently pending (the "Texas Lawsuit"). Plaintiff amended his complaint on February 25, 2020, naming 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"). Plaintiff, who is representing himself, alleges five causes of action against Defendants, based on (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."

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 March 26, 2020, we had 153 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 and our 1-for-30 reverse stock split effected in September 2018, 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 II, Item 12 of this Annual Report under the heading Equity Compensation Plans and is incorporated herein by reference.

Recent Sales of Unregistered Securities

We entered into a definitive agreement to acquire all of the equity interests of Spitfire Pharma, Inc. ("Spitfire") on July 8, 2019. 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. We 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 $5,000,000 less working capital and transaction expense adjustment amounts as defined in the agreement (the "Closing Consideration"). The number of shares issued as payment of the Closing Consideration was determined based on 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 and including July 8, 2019, the date on which the parties entered into the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"). The Spitfire Equityholders agreed to a lock-up on the upfront consideration pursuant to which 33.3% of the shares will be released at 6 months; 33.3% will be released at 12 months; and 33.3% will be released at 18 months.

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 treatments for liver disease, immune modulating therapies, and vaccines. Our diverse pipeline of product candidates includes next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell), conjugated immunostimulants for the treatment of cancer (ALT-702) and intranasal vaccines (NasoVAX, NasoShield and AdCOVID).

Our business is the result of a merger between PharmAthene, Inc. ("PharmAthene") and the business previously known as Altimmune, Inc. ("Private Altimmune"). In May 2017, Private Altimmune merged with PharmAthene pursuant to an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") dated January 18, 2017, among Private Altimmune, PharmAthene, its wholly owned acquisition subsidiaries Mustang Merger Sub Corp I Inc. ("Merger Sub Corp") and Mustang Merger Sub II LLC ("Merger Sub LLC"). Pursuant to the Merger Agreement, Merger Sub LLC agreed to acquire 100% of the outstanding capital stock of Private Altimmune in a reverse triangular merger and reorganization pursuant to section 368(a) of the Internal Revenue Code (the "Mergers"). Prior to the Mergers, PharmAthene was a publicly traded biodefense company engaged in Phase 2 clinical trials.

ALT-801

We completed an acquisition in July 2019 to acquire 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 metabolic dysfunction that causes non-alcoholic steatohepatitis. NASH, the most severe form of 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. As observed in a well-established preclinical model of the disease, ALT-801 was capable of inducing significant weight loss and treating the obesity and metabolic dysfunction underlying the disorder. We plan to advance ALT-801 into Phase 1 development in 2020.

HepTcell

HepTcell is an immunotherapeutic product candidate for patients chronically infected with the hepatitis B virus ("HBV"). It 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 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 may allow 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 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 were generally well tolerated 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 plan to advance HepTcell into Phase 2 development in 2020.

ALT-702

ALT-702 is an investigational targeted tumor immunostimulant designed to act locally to reverse local immunosuppression within the tumor microenvironment and stimulate systemic antitumor immune responses. The ALT-702 technology is a novel synthetic peptide conjugate technology platform designed to retain and concentrate immunostimulants within a tumor potentially leading to enhanced immune stimulation without the risk of systemic inflammation. We believe that ALT-702 represents a new approach in immuno-oncology that may be developed as a monotherapy or be used in conjunction with immune checkpoint inhibitors, oncolytic viruses or other approaches in immuno-oncology or improve their effectiveness. We are currently conducting preclinical studies using on an aggressive tumor model based on the murine CT26 colorectal carcinoma cell line. We recently met a key pre-

clinical milestone with the demonstration of systemic antitumor activity following intra-tumoral injection in an individual solid tumor. The aggressive tumor model involved the establishment of a tumor in each flank of a mouse. In the study, three doses of ALT-702 were injected into one tumor mass over five days with concomitant treatment with an anti-CTLA4 antibody immune checkpoint inhibitor administered intraperitoneally. Tumor regression was noted in both injected (88%) and non-injected (38%) lesions, and overall survival in the ALT-702 + anti-CTLA4 group was markedly better than either agent alone. We plan to complete ALT-702's pre-clinical data set in 2020.

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 plan to commence a Phase 1b trial of NasoShield in 2020. The planned Phase 1b clinical trial builds on the Phase 1a trial completed in 2018 and will evaluate modified methods of intranasal dosing on NasoShield safety and immunogenicity. Results are expected in the fourth quarter of 2020.

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. We believe 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 greater impact on flu symptoms and shedding of the influenza virus. We are evaluating strategic alternatives to fund the development of NasoVAX, such as regional licensing, government funding, or co-development of the program.

AdCOVID

In February 2020, we announced the advancement of AdCOVID, a novel single-dose, intranasal vaccine using our proprietary intranasal vaccine technology, to protect against COVID-19, the disease caused by the SARS-CoV-2 virus. Based on the RespirVec vaccine platform, it is expected that AdCOVID will be able to activate the mucosal, humoral, and cellular immune arms against the virus that causes COVID-19. We believe the excellent stability of RespirVec vaccines when combined with the simple intranasal route of administration may allow for efficient and inexpensive distribution of the vaccine. We have completed the design and synthesis of the vaccine and are now advancing it toward animal testing and manufacturing. We plan to initiate a Phase I clinical study for AdCOVID in the third quarter of 2020.

Financing

On August 16, 2017, we issued 15,656 shares of Series B redeemable convertible preferred stock, $0.0001 par value, ("redeemable preferred stock") and warrants to purchase up to 78,181 shares of our common stock (the "Existing Warrants") to certain institutional investors in a registered direct offering for total gross proceeds of $14.7 million, and incurred issuance costs totaling $1.7 million. The redeemable preferred stock matured on August 16, 2018. The maturity date was extendable at the option of the holders to ten trading days after the curing of a triggering event (as defined in the Certificate of Designations), or ten business days after the consummation of a change of control. In addition, the redeemable preferred stock agreements required that we reserve a sufficient number of common shares to cover at least 150% of the common shares expected to be issued upon the conversion of the redeemable preferred stock at the then current conversion price, and the exercises of common stock warrants issued in connection with the redeemable preferred stock. The redeemable preferred stock was to be redeemed in nine specified installments. On each of the nine

monthly specified installment dates beginning in December 2017 through maturity, we converted, redeemed, or a combination, one-ninth of the originally issued number of shares of redeemable preferred stock at their stated value of $1,000 per share, for an aggregate value of $1.7 million for each installment. As we elected to convert the installment shares, the conversion price was determined based on the lowest of (i) the then applicable conversion price (initially $2.67 per share), (ii) 85% of the average of the three lowest weighted-average prices of the common stock during the ten trading days up to the installment date, and (iii) 85% of the weighted average price of common stock on the trading day immediately before the installment date. If we elected cash redemption, the redemption amount was $1,000 per share, plus any accrued but unpaid dividends and any accrued but unpaid late charges. During the year ended December 31, 2018, we converted 9,813 shares of the redeemable preferred stock for an aggregate of 502,078 shares of common stock. We redeemed the remaining 2,364 shares of redeemable preferred stock for face value on June 22, 2018 in conjunction with the Exchanges (as defined below).

On June 22, 2018 we entered into separate exchange agreements with certain holders of our redeemable preferred stock and Existing Warrants ("the "First Exchange Holders") pursuant to which, we (i) issued an aggregate of 167,700 shares of common stock to the First Exchange Holders, (ii) issued convertible notes (the "Exchange Notes") to the First Exchange Holders with an aggregate principal value of $1.5 million, which are initially convertible into up to 73,530 shares of our common stock upon the default by the Company or at the holder's option on the maturity date subject to adjustment under certain circumstances in accordance with the terms of the Exchange Notes and (iii) paid $1.1 million in aggregate cash consideration to the First Exchange Holders, all in exchange for Existing Warrants to purchase up to 53,125 shares of common stock held by the First Exchange Holders. We refer to these transactions as the "First Exchange." In addition, the Company agreed to redeem the remaining shares of redeemable preferred stock held by the First Exchange Holders, in cash, at the aggregate face value of $2.4 million.

On July 11, 2018, we entered into exchange agreements with certain other holders of our redeemable preferred stock and Existing Warrants (the "Second Exchange Holders") pursuant to which we (i) issued an aggregate of 32,124 shares of common stock to the Second Exchange Holders and (ii) paid $22,241 in aggregate cash consideration to the Second Exchange Holders, all in exchange for all of the outstanding shares of our redeemable preferred stock held by the Second Exchange Holders. After receiving the approval of our stockholders at our annual meeting of stockholders held on August 30, 2018, we issued an additional 145,038 shares of common stock to the Second Exchange Holders in exchange for Existing Warrants to purchase up to 22,523 shares of common stock held by the Second Exchange Holders. We refer to these transactions as the "Second Exchange."

On September 7, 2018, we entered into exchange agreements with certain other holders of our Existing Warrants ("the Third Exchange Holders") pursuant to which we issued an aggregate of 5,929 shares of common stock to the Third Exchange Holders in exchange for Existing Warrants to purchase up to 921 shares of common stock held by the Third Exchange Holders. We refer to this transaction as the "Third Exchange" and together with the First Exchange and Second Exchange as the "Exchanges."

On September 26, 2018, we issued an aggregate of 286,633 shares of our common stock at a purchase price of $17.02 per share to certain institutional investors in a registered direct offering (the "First Registered Direct Offering"). The net proceeds of the First Registered Direct Offering were approximately $4.3 million, after deducting placement agent fees and estimated offering expenses payable by us.

On October 2, 2018, we issued a combined total of 2,400,000 common units and pre-funded units in an underwritten public offering (the "Unit Offering"). Each common unit in the Offering was sold at a public offering price of $5.00 and consisted of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of $6.00. Each warrant sold in the Unit Offering is exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Unit Offering was sold at a public offering price of $4.99 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 a warrant to purchase one share of our common stock at an exercise price of $6.00. The pre-funded warrants were immediately exercisable and could be exercised at any time until all of the pre-funded warrants are exercised in full. All of the pre-funded warrants were exercised between October 2, 2018 and December 31, 2018. The net proceeds of the Unit Offering were approximately $10.7 million, after deducting the underwriting discount and estimated offering expenses payable by us.

The warrants issued in the Unit Offering are each subject to anti-dilution protection. Accordingly, to the extent we were 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.

On October 10, 2018, we issued a combined total of 4,629,630 common units and pre-funded units to certain institutional investors in a registered direct offering (the "Second Registered Direct Offering"). Each common unit in the offering was sold at a price of $5.40 and consisted of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of $5.40. Each warrant sold in the Second Registered Direct Offering is exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Second 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 our common stock at an exercise price of $0.01 per share and a warrant to purchase one share of our common stock at an exercise price of $5.40. The pre-funded warrants were immediately exercisable and could be exercised at any time until all of the pre-funded warrants were exercised in full. All of the pre-funded warrants were exercised between October 2, 2018 and December 31, 2018. The net proceeds of the Second Registered Direct Offering were approximately $22.4 million, after deducting the underwriting discount and estimated offering expenses payable by us. The Second Registered Direct Offering triggered an adjustment to the exercise price of the warrants issued in the Unit Offering from $6.00 to $4.1798.

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 "Third Registered Direct Offering"). Each common unit in the Third 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 Third Registered Direct Offering was exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Third 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 Third Registered Direct Offering were approximately $12.7 million, after deducting the underwriting discount and estimated offering expenses payable by us. The Third Registered Direct Offering triggered an adjustment to the exercise price of the warrants issued in the Unit Offering from $4.1798 to $2.7568.

Current Resources

We have financed our operations to date principally through proceeds from issuances of our preferred stock, Registered Direct Offerings, and Unit Offering. As described above, the Company secured net proceeds of $12.7 million and $37.4 million through equity sales that occurred during the years ended December 31, 2019 and 2018, respectively. Accordingly, management believes that the Company has sufficient capital to fund its plan of operations for at least a twelve-month period from the issuance date of our December 31, 2019 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 Altimmune, Inc. and Altimmune UK, 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:

- commence a Phase 1b trial of NasoShield;
- commence a Phase 2 clinical trial for HepTcell;
- commence a Phase 1 trial of ALT-801;
- commence the pre-clinical development of AdCOVID;
- complete the pre-clinical development of ALT-702;
- 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 ALT-801, HepTcell, NasoShield, and NasoVAX 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, including IPR&D assets and goodwill, 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 definite lived intangibles is assessed by comparing the undiscounted cash flows expected to be generated by the asset 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 the future cash flows to be generated by the completed products, 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 under a quantitative test 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 or 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.

During 2018, based on the continued decline of our market capitalization following the completion of the equity offerings and a strategic review of our development pipeline at the direction of our new CEO, we concluded under our qualitative assessment that an impairment indicator was present as it related to our three IPR&D assets. Based on our strategic review, management concluded we would discontinue the development of our Oncosyn cancer immunotherapy program and accordingly the entire amount of this IPR&D asset, or $3.1 million, was charged to expense. For our remaining two IPR&D assets related to HepTcell and SparVax-L we calculated fair value using an excess earnings method or discounted cash flow model and compared the fair value to the carrying amount of the indefinite lived asset. Based on our analysis, the fair value of our HepTcell IPR&D asset exceeded its carrying value by an amount greater than 10%. However, we concluded that the fair value of our SparVax-L IPR&D intangible asset was approximately $1.0 million as compared to the current carrying value of the asset of $22.4 million which resulted in an impairment charge of approximately $21.4 million.

During 2019, as a result of the SparVax-L NIAID contract completion and the US 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, resulting in a Q3 impairment charge of $1.0 million.

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 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, 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, 2019 and 2018.

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 income approach (a discounted cash flow model) or a Monte Carlo simulation, if more appropriate, 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 discount rates and updates in the assumed timing of milestone achievement. Any future increase in the fair value of the contingent consideration associated with development and regulatory milestones are based on an increased likelihood that the underlying milestones will be achieved.

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.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 requires a lessee to separate the lease components from the non-lease components in a contract and recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. The standard requires a modified retrospective approach or an optional transition to apply the new guidance in the year of transition rather than at the beginning of the earliest period presented. We adopted ASU 2016-02 in the first quarter of 2019 under the optional transition method. Our existing operating leases were accounted for as operating lease liabilities and right of use assets upon adoption. We have elected the package of practical expedients permitted. Accordingly, we accounted for 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, we do not allocate the consideration between lease and non-lease components. The adjustment resulted in an increase of $756,347 to total assets and total liabilities on the January 1, 2019 consolidated balance sheet. The adoption did not have a material impact on the consolidated statement of operations or consolidated statement of cash flows.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which required 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 our consolidated financial statement disclosure requirements.

In June 2018, FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718)—Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. We adopted ASU 2018-07 in the first quarter of 2019. The adoption of this standard did not have a material impact on our consolidated financial statements.

In August 2018, FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, was issued to modify and enhance the disclosure requirements for fair value measurements. This update is effective in fiscal years, including interim periods, beginning after December 15, 2019, and early adoption is permitted. We are still completing its assessment of the impacts and anticipated adoption date of this guidance. Adoption is not expected to have a material impact on our consolidated financial statement disclosure requirements.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740*), Simplifying the Accounting for Income Taxes*, which 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. The Company is currently evaluating the impact from the adoption of ASU 2019-12 on its consolidated financial statements.

Results of Operations

Year Ended December 31, 2019 Compared to December 31, 2018

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
Revenue	$ 5,801	$ 10,331	$ (4,530)	(44) %
Operating expenses				
Research and development	17,765	18,459	(694)	(4) %
General and administrative	8,501	9,766	(1,265)	(13) %
Impairment charges	1,000	24,941	(23,941)	(96) %
Total operating expenses	27,266	53,166	(25,900)	(49) %
Loss from operations	(21,465)	(42,835)	21,370	(50) %
Other income (expense):				
Changes in fair value of warrant liability	30	(2,878)	2,908	(101) %
Changes in fair value of imbedded derivative	-	185	(185)	(100) %
Interest expense	(2)	(297)	295	(99) %
Interest income	843	227	616	271 %
Other income, net	15	278	(263)	(95) %
Total other (expense) income, net	886	(2,485)	3,371	(136) %
Net loss before tax benefit	(20,579)	(45,320)	24,741	(55) %
Income tax benefit	59	6,150	(6,091)	(99) %
Net loss	(20,520)	(39,170)	18,650	(48) %
Other comprehensive loss — foreign currency translation adjustment	-	(463)	463	(100) %
Other comprehensive income — unrealized gains on investments	20	-	20	100 %
Comprehensive loss	$ (20,500)	$ (39,633)	$ 19,133	(48) %

Revenue

Revenue from grants and contracts for the years ended December 31, 2019 and 2018 consisted primarily of research grants from BARDA and NIAID in the United States for our anthrax vaccine product candidates.

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
Revenue	$ 5,801	$ 10,331	$ (4,530)	(44) %

Revenue decreased by $4.5 million, or 44% for the year ended December 31, 2019 as compared to 2018. The decrease was primarily the result of:

- a decrease of $2.94 million in BARDA revenue due directly to changes in spending on the NasoShield research and development as described below; and
- a decrease of $1.85 million in NIAID revenue due to the activities diminishing under the SparVax-L program as the contract concluded in the third quarter of 2019 with no future funding identified.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2019 and 2018 consisted primarily of expenses related to product candidate development. Research and development expenses for the years ended December 31, 2019 and 2018 are summarized as follows:

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
Research and development	$ 17,765	$ 18,459	$ (694)	(4) %

Research and development expenses decreased by $0.7 million, or 4%, during the year ended December 31, 2019 as compared to 2018. The decreased expense was primarily due to:

- an increase of $7.77 million due to the Spitfire acquisition costs which were recorded as acquired in process research and development;
- an increase of $0.52 million in pre-clinical projects and non-project specific research and development costs including employee compensation and facility costs;
- a decrease of $4.58 million due to development activities decreasing for NasoVAX as management explores strategic options with the program;
- a decrease of $2.09 million due to timing of clinical trial and development activities for NasoShield.
- a decrease of $1.36 million due to timing of a clinical trial and related activities for HepTcell; and
- a decrease of $1.0 million due to reduced development cost for SparVax-L as it the contract concluded in the third quarter of 2019.

General and Administrative Expenses

The following is a summary of general and administrative expenses for the years ended December 31, 2019 and 2018:

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
General and administrative	$ 8,501	$ 9,766	$ (1,265)	(13) %

General and administrative expenses decreased by $1.3 million, or 13%, during the year ended December 31, 2019 as compared to 2018. The decreased expense is primarily due to decreases in compensation, professional services and legal costs; offset by an increase in insurance premiums.

Impairment Charges

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
Impairment charges	$ 1,000	$ 24,941	$ (23,941)	(96) %

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 US 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.

Impairment charges of $24.9 million reported during the year ended December 31, 2018 resulted primarily from a $21.4 million adjustment to the carrying value of the SparVax-L program due to the imminent completion of the NIAID contract discussed above in conjunction with the US government's funding priorities. $3.1 million of impairment is attributable to the 2018 abandonment of our Oncosyn cancer immunotherapy program, and finally $0.5 million is attributable to adjustments effecting goodwill already impaired in 2017 related to the Pharmathene business combination.

Other Income (Expense)

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
Other income (expense):				
Changes in fair value of warrant liability	$ 30	$ (2,878)	$ 2,908	(101) %
Changes in fair value of imbedded derivative	—	185	(185)	(100) %
Interest expense	(2)	(297)	295	(99) %
Interest income	843	227	616	271 %
Other income, net	15	278	(263)	(95) %
Total other (expense) income, net	$ 886	$ (2,485)	$ 3,371	(136) %

Other income (expense) fluctuated by $3.4 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The fluctuation was primarily due to the changes in fair value of our warrant liability as a result of the Exchanges plus interest income related to our short-term investments.

Income Tax Benefit

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
Income tax benefit	$ 59	$ 6,150	$ (6,091)	(99) %

We recorded an income tax benefit of $0.1 million during the year ended December 31, 2019. The $0.1 million discrete tax benefit was a result of the release of deferred tax liabilities associated with the $1.0 million impairment of the IPR&D asset associated with SparVax-L. We recorded an income tax benefit of $6.2 million during the year ended December 31, 2018. The income tax benefit recorded in 2018 represents unlimited lived federal net operating losses ("NOLs") generated in 2018 that we determined to be realizable.

Other Comprehensive Income (Loss)

	For the Year Ended December 31,			
(in thousands except percentages)	2019	2018	Increase (Decrease)	
Other comprehensive loss — foreign currency translation adjustment	$ —	$ (463)	$ 463	(100) %
Other comprehensive income — unrealized gains on investments	20	—	20	100 %
Total other comprehensive income (loss)	$ 20	$ (463)	$ 483	

Unrealized gains on investments are related to our short-term investments comprised of debt securities that have original maturities less than or equal to one year and are classified as available-for-sale securities.

Foreign currency translation adjustment primarily related to the exchange rate differences in the carrying values of our net assets of our foreign subsidiaries. On July 1, 2018, the functional currency for our subsidiaries was changed to U.S. dollars, consequently the

foreign current adjustments only reflect this impact through June 30, 2018. The translation adjustment loss of $0.5 million during the year ended December 31, 2018 was the net effect of a decrease in the British pound as compared to the U.S. dollar. We do not expect there to be further comprehensive income or loss due to these assets to report in future periods. As the functional currency of the subsidiary is now the U.S. dollar, any foreign currency translation effects of cash assets or liabilities domiciled in other currencies will be expensed as incurred in future periods.

Liquidity and Capital Resources

Overview

Our primary sources of cash for the year ended December 31, 2019 was the receipt of $12.7 million in proceeds from the Registered Direct Offering (as discussed below). Our primary sources of cash during the comparable period in 2018 were $37.4 million in net proceeds received from the issuance of common stock and common units. Our cash, cash equivalents, restricted cash, and short-term investments were $37.3 million at December 31, 2019. We believe, based on the operating cash requirements and capital expenditures expected for 2020 and 2021, our cash on hand plus short term investments at December 31, 2019, and revenue from our government sponsored contracts, are sufficient to fund operations for at least a 12-month period from the date our consolidated financial statements are issued.

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 for the years ended December 31, 2019 and 2018 consist primarily of revenues under our contract with BARDA and NIAID for the development of NasoShield and SparVax-L, respectively. We had a $15.3 million NIAID contract that was incrementally funded for the development of SparVax-L. Activities under this contract were completed during the quarter ended September 30, 2019 and no further funding is expected for this program. We have incurred significant losses since we commenced operations. As of December 31, 2019, we had accumulated losses of $137.4 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 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 December 2020. 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, 2019, we have received an aggregate of approximately $21.9 million under the current BARDA contract.

Indebtedness

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.

On June 29, 2018, we issued $1.5 million aggregate principal amount of the Exchange Notes to the First Exchange Holders in conjunction with the First Exchange. The Exchange Notes earned interest at 1% per month and we incurred interest expense of $54,226 for the year ended December 31, 2018. On October 17, 2018, the Company extinguished the Exchange Notes by paying the outstanding principal and accrued interest in cash.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2019 and 2018:

(in thousands, except percentages)	For the Year Ended December 31, 2019	2018	Increase (Decrease)	
Net cash (used in) provided by:				
Operating activities	$ (9,602)	$ (9,389)	$ (213)	2 %
Investing activities	(28,286)	(1,001)	(27,285)	2,726 %
Financing activities	12,532	32,490	(19,958)	(61) %

Operating Activities

Net cash used in operating activities was $9.6 million for the year ended December 31, 2019 compared to $9.4 million during the year ended December 31, 2018. Our sources of cash provided by operations during the year ended December 31, 2019 were primarily cash receipts of revenue generated by our BARDA and NIAID 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 decrease in cash used in operations of $0.2 million year over year is due to an increase in net loss as adjusted for noncash items of $1.1 million offset by changes in working capital accounts of $0.9 million.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2019 was primarily due to purchases of short-term investments. The net cash used in investing activities in 2018 was primarily due to purchases of property and equipment related to the buildout of the Company’s new office and laboratory facilities which was completed in 2018.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2019 of $12.5 million was primarily the result of $12.7 million net proceeds received from Third Registered Direct Offering, offset by the repayment of notes payable and warrant repurchases. Net cash provided by financing activities during the year ended December 31, 2018 of $32.5 million was primarily the result of $37.4 million net proceeds received from the registered direct offerings and unit offerings, offset by $1.1 million paid to Existing Warrant holders in exchange for the Existing Warrants and $2.4 million paid to redeemable preferred stock holders upon redemption of our redeemable preferred stock.

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.

Item 8. Financial Statements and Supplementary Data.

ALTIMMUNE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Altimmune, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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.

/s/ Ernst & Young LLP

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

Baltimore, Maryland
March 27, 2020

ALTIMMUNE, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 8,962,686	$ 33,718,713
Restricted cash	34,174	634,416
Total cash, cash equivalents, and restricted cash	8,996,860	34,353,129
Short-term investments	28,277,386	—
Accounts receivable	1,021,179	3,461,938
Tax refund receivable	629,096	1,008,973
Prepaid expenses and other current assets	470,228	548,094
Total current assets	39,394,749	39,372,134
Property and equipment, net	1,104,208	1,342,802
Right of use asset	698,321	—
Intangible assets, net	12,732,195	13,851,924
Other assets	128,547	183,682
Total assets	$ 54,058,020	$ 54,750,542
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Notes payable	$ —	$ 71,596
Accounts payable	18,232	372,860
Accrued expenses and other current liabilities	3,904,767	4,082,949
Total current liabilities	3,922,999	4,527,405
Deferred income taxes	—	58,500
Contingent consideration	2,750,000	—
Other long-term liabilities	1,864,875	1,852,071
Total liabilities	8,537,874	6,437,976
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 15,312,381 and 9,078,735 shares issued; 15,312,167 and 9,078,238 shares outstanding at December 31, 2019 and 2018, respectively	1,508	876
Additional paid-in capital	187,914,916	170,207,844
Accumulated deficit	(137,376,122)	(116,855,991)
Accumulated other comprehensive loss, net	(5,020,156)	(5,040,163)
Total stockholders' equity	45,520,146	48,312,566
Total liabilities and stockholders' equity	$ 54,058,020	$ 54,750,542

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

ALTIMMUNE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Year Ended December 31,	
	2019	2018
Revenue	$ 5,801,401	$ 10,331,168
Operating expenses		
Research and development	17,765,553	18,459,310
General and administrative	8,500,783	9,765,581
Impairment charges	1,000,000	24,940,687
Total operating expenses	27,266,336	53,165,578
Loss from operations	(21,464,935)	(42,834,410)
Other income (expense)		
Changes in fair value of warrant liability, including loss on exchange	30,000	(2,878,484)
Changes in fair value of embedded derivative	—	184,555
Interest expense	(2,244)	(297,090)
Interest income	843,409	226,597
Other income, net	15,139	277,886
Total other income (expense)	886,304	(2,486,536)
Net loss before income tax benefit	(20,578,631)	(45,320,946)
Income tax benefit	58,500	6,149,794
Net loss	(20,520,131)	(39,171,152)
Other comprehensive loss — foreign currency translation adjustment	—	(463,177)
Other comprehensive income — unrealized gains on investments	20,007	—
Comprehensive loss	$ (20,500,124)	$ (39,634,329)
Net loss	$ (20,520,131)	$ (39,171,152)
Preferred stock accretion and other deemed dividends	(452,925)	(3,307,800)
Net loss attributable to common stockholders	$ (20,973,056)	$ (42,478,952)
Weighted-average common shares outstanding, basic and diluted	13,124,951	2,802,382
Net loss per share attributable to common stockholders, basic and diluted	$ (1.60)	$ (15.16)

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

ALTIMMUNE, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

	Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance, January 1, 2018	12,177	$ 9,281,767	608,499	$ 61	$ 121,657,587	$ (77,684,839)	$ (4,576,986)	$ 39,395,823
Stock based compensation			322,906	—	762,162			762,162
Vesting and accelerated vesting of restricted stock			284	—	11,203			11,203
Exercises of stock options			9,540	1	22,897			22,898
Accretion of Series B redeemable convertible preferred stock		2,894,885			(2,894,885)			(2,894,885)
Conversion of Series B redeemable convertible preferred stock into common stock	(9,813)	(9,790,367)	502,078	50	9,790,317			9,790,367
Redemption of Series B redeemable convertible preferred stock for cash and release of embedded derivative	(2,364)	(2,386,285)			23,292			23,292
Issuance of common stock for the exchange of warrants			318,668	32	3,433,009			3,433,041
Issuance of common stock and units in registered direct offerings, net of offering costs			4,916,263	491	26,734,997			26,735,488
Issuance of common units in public offering, net of offering costs			2,400,000	241	10,667,265			10,667,506
Foreign currency translation adjustments							(463,177)	(463,177)
Net loss						(39,171,152)		(39,171,152)
Balance, December 31, 2018	—	$ —	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 and accelerated vesting of restricted stock, net			(25,691)	6	(47,126)			(47,120)
Issuance of common stock upon exercise of warrants			11,000	1	30,323			30,324
Issuance of common stock in registered direct offering, net of offering costs			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
Unrealized gain on short term investments							20,007	20,007
Net loss						(20,520,131)		(20,520,131)
Balance, December 31, 2019	—	$ —	15,312,167	$ 1,508	$ 187,914,916	$ (137,376,122)	$ (5,020,156)	$ 45,520,146

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

ALTIMMUNE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (20,520,131)	$ (39,171,152)
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	—
Impairment charges	1,000,000	24,940,687
Stock-based compensation	1,264,231	773,248
Depreciation	239,821	218,717
Amortization	147,500	83,652
Unrealized (gain) loss on foreign currency exchange	(5,761)	64,806
Debt discount accretion	—	180,611
Gain from disposal of property and equipment	—	(3,806)
Changes in fair value of warrant liability	(30,000)	2,878,484
Changes in fair value of embedded derivative	—	(184,555)
Changes in operating assets and liabilities:		
Accounts receivable	2,440,759	344,301
Prepaid expenses and other current assets	133,001	499,391
Accounts payable	(354,628)	243,062
Accrued expenses and other current liabilities	(626,193)	17,110
Deferred revenue	22,032	(19,780)
Deferred rent		818,893
Lease obligation	(175,490)	—
Tax refund receivable	379,877	5,077,217
Deferred tax benefit	(58,500)	(6,149,794)
Net cash used in operating activities	(9,601,997)	(9,388,908)
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash paid for short-term investments	(28,257,379)	—
Purchases of property and equipment	(1,227)	(975,407)
Proceeds from sale of property and equipment	—	14,492
Additions to intangible assets	(27,772)	(40,227)
Net cash used in investing activities	(28,286,378)	(1,001,142)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayments of notes payable	(292,002)	(1,549,702)
Redemption of preferred stock	—	(2,386,285)
Cash paid in conjunction with warrant exchange	(25,000)	(1,100,000)
Proceeds from conditional economic incentive	150,000	100,000
Proceeds from issuance of common stock, net of issuance costs	—	4,334,816
Proceeds from issuance of common units, net of issuance costs	12,668,784	33,068,178
Proceeds from exercise of warrants and stock options	30,324	22,898
Net cash provided by financing activities	12,532,106	32,489,905
EFFECT OF EXCHANGE RATES ON CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	—	(50,365)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(25,356,269)	22,049,490
Cash, cash equivalents, and restricted cash — beginning of year	34,353,129	12,303,639
Cash, cash equivalents, and restricted cash — end of year	$ 8,996,860	$ 34,353,129
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for interest	—	57,214
SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES		
Conversion of Series B redeemable convertible preferred stock into common stock	$ —	$ 9,790,367
Common Stock issued for acquired in-process research and development	$ 3,791,485	$ —
Settlement of warrant liability for common stock	$ —	$ 3,345,030
Notes payable issued in conjunction with the exchange of warrants	$ —	$ 1,500,000
Accretion of Series B redeemable convertible preferred stock	$ —	$ 2,894,885

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Nature of Business

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's business is a result of a merger between PharmAthene, Inc. ("PharmAthene") and the business previously known as Altimmune, Inc. ("Private Altimmune"). In May of 2017, Private Altimmune merged with PharmAthene pursuant to an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") dated January 18, 2017. 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.

The Company is focused on developing treatments for liver disease and immune modulating therapies. Our diverse pipeline includes next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™), conjugated immunostimulants for the treatment of cancer (ALT-702) and intranasal vaccines (NasoVAX™ and NasoShield™). 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.

Basis of Presentation

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").

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries, all of which are wholly owned. 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, collectability of accounts receivable, useful lives of long-lived assets, fair value of contingent consideration acquired, impairment of goodwill and other 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 loss which represents unrealized gains on investments and foreign currency translation adjustments.

Foreign Currency Translation

Historically the Company's UK subsidiaries utilized the British pound as their functional currency. The assets and liabilities of these subsidiaries were translated at current exchange rates, while revenue and expenses were translated at the average rates in effect for the period. The related translation gains and losses were included in other comprehensive income or loss within the Consolidated Statements of Operations and Comprehensive Loss. As a result of an analysis which took into account the economic indicators of these subsidiaries from a long-term perspective, the Company changed the functional currency for these subsidiaries from British Pounds to U.S. Dollars effective as of July 1, 2018. The change in the Company's functional currency determination has

been applied on a prospective basis in accordance with ASC 830. Therefore, any translation gains and losses that were previously recorded in accumulated other comprehensive income through June 30, 2018 remain unchanged as of December 31, 2019.

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 reportable operating segment.

Investments

The Company's short-term investments are comprised of U.S. Treasury and corporate debt securities 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. Investments are classified as either current or non-current assets on our consolidated balance sheets based on their contractual maturity dates.

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 and are evaluated separately from indefinite-lived intangible assets for impairment at least annually or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. These amortization costs are classified as research and development expenses in the accompanying statements of operations and comprehensive loss.

Impairment of Long-lived Assets and Goodwill

The Company evaluates our long-lived tangible and intangible assets, including IPR&D assets and goodwill, 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 to its carrying value. Prior to the complete impairment of goodwill in 2018, goodwill was tested for impairment by comparing the estimated fair value of our single reporting unit to its carrying value.

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 in timing or changes in the future cash flows to be generated by the completed products, and changes to other market-based assumptions, such as discount rates. If impairment indicators are present as a result of our 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.

During the fourth quarter of 2018, the Company recorded $24,450,011 of impairments related to IPR&D assets. During 2019, the Company recorded $1,000,000 of impairments related to IPR&D assets. See Note 6 for further details.

During the year ended December 31, 2018, the goodwill impairment charges of $490,676 represented an adjustment recorded to reduce the tax refund receivable acquired in connection with a 2017 business combination. There was no goodwill balance outstanding as of December 31, 2019 and 2018.

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, 2019 and 2018.

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, BPI France notes, contingent consideration, common stock warrants classified as a liability, common stock warrants classified as equity, convertible preferred stock, redeemable convertible preferred stock, and an embedded derivative. 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. The BPI France notes prior to their redemption or cancellation are recorded at their repayment value which approximates fair value. Contingent payments classified as a liability was recorded at fair value estimated using the Monte Carlo simulation valuation model. Redeemable convertible preferred stock until its redemption was classified as temporary equity and its carrying amount accreted over the term of the instrument up to its liquidation and redemption value. Common stock warrants classified as equity and convertible preferred stock classified as temporary equity are 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 and the embedded derivative 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 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

Research and development costs are expensed as incurred. Research and development costs include payroll and personnel expense, consulting costs, external contract research and development expenses, raw materials, drug product manufacturing costs, and allocated overhead, including depreciation and amortization, rent and utilities. 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

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activation, and other information provided to the Company by our vendors.

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 and $634,416 at December 31, 2019 and 2018, respectively held in money market savings accounts as collateral. The restricted cash as of December 31, 2019 is for the Company's facility lease obligation. The restricted cash as of December 31, 2018, was for the Company's facility lease obligation and $600,000 for a legal bond supporting the Company's attempt to collect on amounts previously due from a third-party that was released from restriction in 2019. 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 100% of research grants and contracts and accounts receivable for the years ended December 31, 2019 and 2018. As discussed above, the Company believes that credit risks associated with these government grants and contracts and accounts receivable is not significant.

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:

Asset Category	Estimated Useful Life
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

Preferred Stock

Shares of redeemable preferred stock were issued in August 2017. Redeemable preferred stock was classified as temporary equity and was initially recorded at its original issuance price, net of issuance costs and discounts. Such discounts included common stock warrants issued as part of the financing which were required to be classified as a liability and recorded at fair value (Note 12), an embedded derivative related to certain redemption features which was classified as a liability and recorded at fair value (Note 10), and the intrinsic value of a beneficial conversion feature present in the instrument at issuance (Note 10). The carrying value of the redeemable preferred stock was accreted over the term of the redeemable preferred stock up to its redemption value, using the straight-line method which approximates the effective interest method due to the short-term nature of the redeemable preferred stock terms with the amount of the accretion recorded as a reduction of additional paid-in capital. All redeemable preferred stock was either redeemed or converted during the year ended December 31, 2018.

Warrants

Common stock warrants issued in connection with the redeemable preferred stock in 2017 were classified as a liability because these warrants contained terms which could, in certain circumstances, required the Company to settle the instruments for cash and such circumstances are outside the Company’s control. Common stock warrants classified as a liability are initially recorded at their issuance date fair value and are remeasured on each subsequent balance sheet date with changes in fair value recorded as a component of other income (expenses), net. These common stock warrants were valued using the Monte Carlo simulation valuation model. These warrants were subsequently redeemed in 2018 (Note 12).

Common stock warrants issued in connection with the Unit Offering (as defined in Note 11), the Second Registered Direct Offering (as defined in Note 11), and the Third Registered Direct Offering (as defined in 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 Second Registered Direct Offering and Third Registered Direct Offering triggered down round adjustments to the exercise price of warrants issued in connection with the unit offering. 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 (Note 12).

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. For performance-based awards where the vesting of the options may be accelerated upon the achievement of certain milestones, vesting and the related stock-based compensation is recognized as an expense when it is probable the milestone will be met. For awards containing a market condition, the effect of the market condition is reflected in measuring the grant date fair value of the award and is recognized over the requisite service period, which is usually the vesting period, on a straight-line basis, net of estimated forfeitures.

When 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. Net loss attributable to common stockholders and participating preferred stock is allocated to each share on an as-converted basis as if all of the net loss for the period had been distributed. During periods in which the Company incurred a net loss, the Company does not allocate net loss to participating securities because they do not have a contractual obligation to share in the net loss of the Company.

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

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 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 income approach (a discounted cash flow model) or a Monte Carlo simulation, if more appropriate, 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 discount rates and updates in the assumed timing of milestone achievement. Any future increase in the fair value of the contingent consideration associated with development and regulatory milestones are based on an increased likelihood that the underlying milestones will be achieved.

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 February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 requires a lessee to separate the lease components from the non-lease components in a contract and recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. The standard requires a modified retrospective approach or an optional transition to apply the new guidance in the year of transition rather than at the beginning of the earliest period presented. The Company adopted ASU 2016-02 in the first quarter of 2019 under the optional transition method. The Company's existing operating leases were accounted for as operating lease liabilities and right of use assets upon adoption. The Company has 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 adjustment resulted in an increase of $756,347 to total assets and total liabilities on the January 1, 2019 consolidated balance sheet. The adoption did not have a material impact on the consolidated statement of operations or consolidated statement of cash flows.

In June 2018, FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718)—Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company adopted ASU 2018-07 in the first quarter of 2019. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Pending Adoptions:

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which required 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 August 2018, FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, was issued to modify and enhance the disclosure requirements for fair value measurements. This update is effective in fiscal years, including interim periods, beginning after December 15, 2019, and early adoption is permitted. The Company is still completing its assessment of the impacts and anticipated adoption date of this guidance. 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, which 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. The Company is currently evaluating the impact from the adoption of ASU 2019-12 on its consolidated financial statements.

3. Acquisitions

The Company entered into a definitive agreement to acquire all of the equity interests of Spitfire Pharma, Inc. ("Spitfire") on July 8, 2019. 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 $5,000,000 less working capital and transaction expense adjustment amounts as defined in the agreement (the "closing consideration"). The number of shares issued as payment of the Closing Consideration was determined based on the average of the closing prices of the Company's common stock as reported on the Nasdaq Global Market for the twenty consecutive trading days prior to and including July 8, 2019, the date on which the parties entered into the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"). The Spitfire Equityholders agreed to a lock-up on the upfront consideration pursuant to which 33.3% of the shares will be released at 6 months; 33.3% will be released at 12 months; and 33.3% will be released at 18 months.

The Merger Agreement also includes future contingent payments up to $88,000,000 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 Merger Agreement; plus

- a one-time payment of $3.0 million (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; plus

- 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 Company determined that the acquisition of Spitfire should be accounted for as an asset acquisition instead of a business combination because substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, and therefore, the asset is 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 $4,337,574 for the up-front consideration, which included the fair value of the common stock transferred and net liabilities assumed. The fair value of the common shares transferred was based on the Company's stock price of $2.45 on July 12, 2019, offset by an estimated discount of $832,277 for lack of marketability.

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. 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. As of the acquisition date, the Company estimated future contingent consideration based upon a Monte Carlo simulation that has been risk adjusted based on the probability of achieving the milestone and a discount for lack of marketability. The Company remeasured the fair value of the contingent consideration as of December 31, 2019. During the year ended December 31, 2019, the Company has expensed $2,750,000 to in-process research and development expenses.

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.

Finally, transaction costs associated with the Spitfire acquisition of $680,090 are recorded within research and development expense during the year ended December 31, 2019.

4. Net Loss Per Share

Because the Company has reported net loss attributable to common stockholders for the years ended December 31, 2019 and 2018, basic and diluted net loss per share attributable to common stockholders are the same for both years. All preferred stock, unvested restricted stock, common stock warrants, stock options, and other potentially dilutive shares have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact.

Potential common shares issuable upon conversion, unvested restricted stock, common stock warrants, stock options, and other potentially dilutive shares are excluded from the computation of diluted weighted-average shares outstanding are as follows:

	As of December 31,	
	2019	2018
Common stock warrants	10,384,706	7,344,297
Common stock options	973,172	353,274
Unvested restricted stock	235,666	323,404
Other dilutive securities	28,070	—

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	As of December 31,	
	2019	2018
Furniture, fixtures and equipment	$ 121,491	$ 121,491
Laboratory equipment	926,590	926,590
Computers and telecommunications	150,517	149,290
Software	25,069	25,069
Leasehold improvements	1,228,108	1,228,108
Property and equipment, at cost	2,451,775	2,450,548
Less accumulated depreciation and amortization	(1,347,567)	(1,107,746)
Property and equipment, net	$ 1,104,208	$ 1,342,802

Depreciation expense related to property and equipment for the years ended December 31, 2019 and 2018 was $239,821 and $218,717, respectively.

6. Goodwill and Intangible Assets

The Company’s intangible assets consisted of the following:

	As of 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		$ 14,450,290	$ (718,095)	$ (1,000,000)	$ 12,732,195

	As of December 31, 2018				
	Estimated Useful Lives	Gross Carrying Value	Accumulated Amortization	Impairment	Net Book Value
Internally developed patents	6 – 10 years	$ 718,559	$ (317,172)	$ —	$ 401,387
Acquired licenses	16 – 20 years	285,000	(253,430)	—	31,570
Total intangible assets subject to amortization		$ 1,003,559	$ (570,602)	$ —	$ 432,957
IPR&D assets	Indefinite	37,868,978	—	(24,450,011)	13,418,967
Total		$ 38,872,537	$ (570,602)	$ (24,450,011)	$ 13,851,924

Amortization expense of intangible assets subject to amortization totaled $147,500 and $83,652 for the years ended December 31, 2019 and 2018, respectively, and was classified as research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

As of December 31, 2019, future estimated amortization expense is as follows:

For the Year Ended December 31,	
2020	$ 42,275
2021	26,059
2022	26,059
2023	26,059
2024	22,153
2025 and thereafter	170,623
Total	$ 313,228

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, 2019. 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.

During the fourth quarter of 2018, based on the continued decline of the Company's market capitalization following the completion of the equity offerings and a strategic review of the development pipeline at the direction of a new CEO, the Company concluded under the qualitative assessment that an impairment indicator was present as it related to three IPR&D assets. Based on the Company's strategic review, management concluded it would discontinue development of the Oncosyn cancer immunotherapy program and accordingly the entire amount of this IPR&D asset, or $3,061,011 was charged to expense. For the remaining two IPR&D assets related to HepTcell and SparVax-L, the Company calculated fair value using an excess earnings method or discounted cash flow model and compared the fair value to the carrying amount of the indefinite lived asset. Based on the analysis, the fair value of the Company's HepTcell IPR&D asset exceeded its carrying value by an amount greater than 10%. However, during 2018, the Company concluded that the fair value of the SparVax-L IPR&D intangible asset was approximately $1,000,000 as compared to the current carrying value of the asset of $22,389,000, which resulted in an impairment charge of $21,389,000. Key assumptions used in the analysis included projected cash flows, a probability of success of the ultimate project, and the discount rate.

During 2019, as a result of the SparVax-L NIAID contract completion and the US 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. As a result, of $1,000,000 was written off as an impairment charge which was classified as a component of operating expenses during the year ended December 31, 2019.

During the year ended December 31, 2018, an additional $490,676 of goodwill was written off as an impairment charge. The impairment was an adjustment to reduce the tax refund receivable acquired in connection with a 2017 business combination.

Changes in the carrying amounts of IPR&D assets and goodwill for the years ended December 31, 2019 and 2018 were:

	IPR&D	Goodwill
Balance, January 1, 2018	$ 38,245,871	$ —
Additions	—	490,676
Foreign currency translation adjustments	(376,893)	—
Impairment charges	(24,450,011)	(490,676)
Balance, December 31, 2018	$ 13,418,967	$ —
Impairment charges	(1,000,000)	
Balance, December 31, 2019	$ 12,418,967	$ —

7. Accrued Expenses and Other Current Liabilities

Accrued expense and other current liabilities consist of the following:

	As of December 31,	
	2019	2018
Accrued professional services	$ 429,467	$ 552,619
Accrued payroll and employee benefits	1,183,130	1,257,191
Accrued interest	5,047	1,192
Lease obligation, current portion	259,449	—
Deferred rent, current portion	—	175,490
Accrued research and development	1,966,111	2,076,704
Deferred revenue	61,563	19,753
Total accrued expenses	$ 3,904,767	$ 4,082,949

8. Licenses

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 in each of the years ended December 31, 2019 and 2018 and are classified as a component of research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

Janssen Vaccines & Prevention B.V.

The Company has a royalty-bearing, worldwide non-exclusive license agreement with Janssen Vaccines & Prevention B.V. (“Janssen”) for use of its vaccine technology. We 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 we terminate the amended license agreement for Janssen’s material breach, we retain 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 $100,000. Fees incurred under the Janssen agreement totaled $111,499 and $177,625 for the years ended December 31, 2019 and 2018, respectively, and are included in research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

Auburn University

The Company has an exclusive, world-wide license agreement to develop, manufacture, and commercialize certain vaccine technology developed at Auburn University. The Auburn University agreement expires on the last of the related patent expiration date which may be extended upon patent renewal. The last of the patent expiration date is currently on August 15, 2025. Under the agreement, the Company paid an upfront fee of $1,000 upon signing of the agreement, and is obligated to pay an annual license fee of $5,000, and low single digit royalty fees from net product sales or sublicenses of the technology. Fees incurred under the Auburn University agreement totaled $5,000 in each of the years ended December 31, 2019 and 2018 and are included in research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

9. Notes Payable and Other Liabilities

The Company's current portion of outstanding notes payable are summarized as follows:

	As of December 31,	
	2019	2018
BPI France notes, short-term portion	$ —	$ 71,596
Total notes payable	$ —	$ 71,596

The Company's long-term portion of outstanding notes payable as well as other long-term liabilities are summarized as follows:

	As of December 31,	
	2019	2018
BPI France notes, long-term portion	$ —	$ 501,174
Lease obligation, long-portion (see Note 15)	1,484,679	—
Deferred rent, long-term portion	—	1,045,807
Common stock warrant liability (see Note 12)	10,000	65,000
Economic conditional grants	250,000	100,000
Other	120,196	140,090
Total other long-term liabilities	$ 1,864,875	$ 1,852,071

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 and 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 $5,042 in interest expense for the year ended December 31, 2019.

Exchange Notes

In conjunction with the First Exchange (as defined in Note 12) the Company issued convertible notes (the "Exchange Notes") with an aggregate principal value of $1,500,000, which were initially convertible into up to 73,530 shares of our common stock at the note holder's option on the maturity date. The Exchange Notes were also convertible in the event of default, at which time the balance

of the notes would increase by 112% and was convertible at a share price equal to the lower of $20.40 per share or 75% of the weighted average price of common stock during the twenty consecutive trading day period immediately preceding the event of default. In the event the weighted average price of common stock as defined above is below $4.50 per share, then a supplemental cash payment was due to the note holder.

The conversion and redemption options embedded in the Exchange Notes qualified for derivative accounting under ASC 815-15 “Derivatives and Hedging”. The fair value of the derivative liability at the date of issuance resulted in a discount to the Exchange Notes of $180,611 which was accreted into interest expense over the term of the convertible note. Debt issuance costs of $58,172 were capitalized and was recognized in interest expense over the term of the notes. In addition, the Company paid the holders of the Exchange Notes and additional $54,226 of interest earned. During the year ended December 31, 2018, total interest expense recognized on the Exchange Notes was $293,009.

The Company fully redeemed the Exchange Notes and accrued interest for cash in October 2018.

10. Preferred Stock

Redeemable Convertible Preferred Stock

On August 16, 2017, the Company issued 15,656 shares of $0.0001 par value, redeemable preferred stock and warrants to purchase up to 78,181 shares of common stock (see Note 12), for total gross proceeds of $14,716,370, and incurred issuance costs totaling $1,697,800. The redeemable preferred stock matured on August 16, 2018. In addition, the redeemable preferred stock agreements required that the Company reserve a sufficient number of common shares to cover at least 150% of the common shares expected to be issued upon the conversion of the redeemable preferred stock at the then current conversion price, and the exercises of common stock warrants issued in connection with the redeemable preferred stock.

Because the securities contained contingencies which could require the Company to redeem the shares for cash, and such contingencies were outside the control of the Company, the redeemable preferred stock was classified outside of permanent equity. Because a substantive conversion feature was also present at issuance, the redeemable preferred stock is only contingently redeemable and therefore prior to its redemption or conversion was classified as temporary equity and carried on the balance sheet in between liabilities and equity at its accreted redemption value.

In addition, certain features present in the redeemable preferred stock required separate recognition. For purposes of this evaluation, the Company determined that the redeemable preferred instrument is more akin to a debt host because the installment conversion feature, as the primary settlement mechanism, is indexed to an underlying other than interest rates or credit risk and settles in variable shares. Because the potential contingent redemption price contained a significant premium over the issuance price, the redemption feature is considered to be not clearly and closely related to the debt-like host instrument. All redemption features (including the change of control redemption, triggering event redemption, mandatory redemption, and installment redemption) were determined to be a single, compound embedded derivative financial instrument to be bifurcated and separately accounted for as a liability. The embedded derivative financial instrument was initially recorded at its fair value on the redeemable preferred stock issuance date and was being remeasured on each subsequent balance date with changes in fair value classified as a component of other income (expenses), net. The embedded derivative was classified as a component of other long-term liabilities until its expiration with the conversion of the last amount of redeemable preferred stock.

The redeemable preferred stock also contained a beneficial conversion feature at issuance. The conversion feature was “in-the-money” as of the commitment date as the fair value of the underlying common share was greater than the effective conversion price. The beneficial conversion feature, measured as the intrinsic value of the feature, totaled $1,506,196 on the redeemable preferred stock issuance date, and was classified as a component of additional paid-in capital. The beneficial conversion feature was not remeasured in subsequent periods but was recognized in nine equal amounts corresponding to each of the redeemable preferred stock installments. During the year ended December 31, 2018, the Company recognized $1,338,840 of the beneficial conversion feature.

The fair value used to determine the initial carrying value of the embedded redemption derivative financial instrument was measured using Level 3 inputs and was estimated using the Monte Carlo simulation valuation model. The periodic changes in the fair value of the embedded redemption derivative financial instrument for the year ended December 31, 2018 are as follows:

Balance, January 1, 2018	$	27,236
Changes in fair value		(27,236)
Balance, December 31, 2018	$	—

During the year ended December 31, 2018, the Company converted 9,813 shares of the redeemable preferred stock for an aggregate of 502,078 shares of common stock. In June 2018, the Company additionally agreed to redeem the First Exchange

investors' remaining 2,364 shares of Series B Preferred Stock at their face value of $2,364,044. Since the redemption occurred prior to the stated maturity date, $56,792 of the redemption price is considered a deemed dividend. On July 11, 2018, the Company entered into exchange agreements with certain other holders of the Series B Preferred Stock and warrants (the "Second Exchange") pursuant to which the Company (i) issued an aggregate of 32,124 shares of common stock and (ii) paid $22,241 in cash, in exchange for all of their outstanding shares of our Series B Preferred Stock. Due to the redemption occurring prior to the stated maturity date, this exchange resulted in a deemed contribution of $111,553. As of December 31, 2019 and 2018, there were no remaining Redeemable Convertible Preferred Shares outstanding.

11. Common Stock

On September 26, 2018, the Company issued an aggregate of 286,633 shares of common stock at a purchase price of $17.02 per share to certain institutional investors in a registered direct offering (the "First Registered Direct Offering"). The net proceeds of the First Registered Direct Offering were $4,334,816, after deducting placement agent fees and offering expenses of $543,677.

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 "Unit Offering"). Each common unit in the 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 Unit Offering was exercisable immediately and expired five years from the date of issuance. Each pre-funded unit in the 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 net proceeds of the Unit Offering were $10,667,506, after deducting the underwriting discount and estimated offering expenses payable by the Company. The entire amount of 2,400,000 common shares issued in connection with the Unit Offering are included in common shares outstanding.

The warrants issued in the 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.

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 "Second Registered Direct Offering"). Each common unit in the Second 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 Second Registered Direct Offering was exercisable immediately and expired five years from the date of issuance. Each pre-funded unit in the Second 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 net proceeds of the Second Registered Direct Offering were $22,400,673, after deducting the underwriting discount and estimated offering expenses payable by the Company. The entire amount of 4,629,630 common shares issued in connection with the Unit Offering are included in common shares outstanding.

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 "Third Registered Direct Offering"). Each common unit in the Third 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 Third Registered Direct Offering was exercisable immediately and expired five years from the date of issuance. Each pre-funded unit in the Third 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 prior to March 31, 2019. The net proceeds of the Third Registered Direct Offering were $12,668,784, after deducting the underwriting discount and estimated offering expenses payable by the Company.

The warrants issued in both the Unit Offering and the Second Registered Direct Offering were concluded to be equity classified freestanding financial instruments. The Second Registered Direct Offering triggered a down round adjustment to the exercise price of the warrants issued in the Unit Offering from $6.00 to $4.1798. 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. During the year ended December 31, 2018, the Company treated the value of the effect of the reduction in exercise price as a deemed dividend of $780,038 which reduced income available to common shareholders.

The warrants issued in the Third Registered Direct Offering were also concluded to be equity classified freestanding financial instruments. The Third Registered Direct Offering triggered an additional down round adjustment to the exercise price of the warrants

issued in the Unit Offering 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.

On July 12, 2019, as discussed in Note 3, the Company issued 1,887,250 unregistered shares of its common stock as upfront consideration to certain former Spitfire Equityholders representing the closing consideration.

12. 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 Unit Offering	2,505,250	2.75	October 2, 2018	October 2, 2023
Underwriter warrant issued with public offering	196,650	6.25	October 2, 2018	September 28, 2021
Issued with common units in the Second Registered Direct Offering	4,629,630	5.40	October 10, 2018	October 10, 2023
Issued with common units in the Third Registered Direct Offering	3,052,959	3.21	March 12, 2019	March 12, 2024
Total	10,384,706			

**Liability classified warrants*

The following common stock warrants were outstanding at December 31, 2018:

	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*	1,612	80.10	August 16, 2017	August 16, 2022
Issued with common units in Unit Offering	2,516,250	4.18	October 2, 2018	October 2, 2023
Underwriter warrant issued with public offering	196,650	6.25	October 2, 2018	September 28, 2021
Issued with common units in the Second Registered Direct Offering	4,629,630	5.40	October 10, 2018	October 10, 2023
Total	7,344,297			

**Liability classified warrants*

In May 2017, the Company issued 155 common stock warrants to replace outstanding common stock warrants in connection with the Merger Agreement.

In August 2017, in connection with the redeemable preferred stock issuance (Note 10), 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 are initially recorded at their grant date fair value, to be remeasured on each subsequent balance sheet date. The warrant liability is classified as component of other long-term liabilities. During the years ended December 31, 2019, and 2018, the Company exchanged 1,550 and 76,569, respectively, of these warrants for a combination common stock and cash, leaving 62 of these warrants outstanding as of December 31, 2019.

On June 29, 2018 the Company closed on privately negotiated exchange agreements with certain investors to exchange warrants to purchase 53,125 common shares of the Company (the "First Exchange") in exchange for:

(i) 167,700 shares of the Company's common stock valued at approximately $12.60 per share;

(ii) Convertible notes with an initial aggregate principal balance of $1,500,000 (Note 9), and;

(iii) $1,100,000 in cash consideration.

The total fair value of the consideration given in exchange for the warrants in the First Exchange was $4,727,000, which exceeded the March 31, 2018 fair value of the warrants by $3,467,935. The warrant fair value at March 31, 2018 was determined assuming an orderly transaction between market participants, using a Monte Carlo simulation valuation model. The Company was

compelled to enter into the exchange transaction as management believes the dilutive features of the common stock warrants prevented the Company from obtaining sufficient financing on acceptable terms. Accordingly, the Company recorded a loss on exchange of warrants in the First Exchange of $3,593,082, inclusive of transaction costs of $125,147, which is reported in changes in fair value of warrant liability including loss on exchange on the consolidated statement of operations and comprehensive loss. The Company additionally agreed to redeem the First Exchange investors' remaining shares of Series B Preferred Stock at their face value of $2,364,044 (Note 10).

The value of the shares of the Company's common stock which were part of the First Exchange consideration were valued at a 5% discount to the June 29, 2018 closing price. This amount is considered a marketability discount calculated based on an analysis of the leak out provision provided for in the exchange agreements. The key assumptions used in calculating the marketability discount were:

Holding period, in years	0.03
Risk free rate	1.77%
Dividend yield	0%
Volatility	109.9%

On July 11, 2018, the Company entered into exchange agreements with certain other holders of the redeemable preferred stock and warrants (the "Second Exchange") pursuant to which we (i) issued an aggregate of 32,124 shares of common stock and (ii) paid $22,241 in cash, in exchange for all of the outstanding shares of our Series B Preferred Stock (Note 10). We additionally issued 145,038 shares of common stock in exchange for warrants to purchase 22,523 shares of common stock. Consideration for the Series B Preferred Stock was transferred to the holders on July 11, 2018. Consideration for the warrant exchange was subject to shareholder approval which the Company obtained at its annual shareholder meeting on August 30, 2018, and the shares of common stock were subsequently transferred to the holders on September 12, 2018.

On September 7, 2018, the Company closed on exchange agreements with certain holders of our warrants (the "Third Exchange") pursuant to which we issued 5,929 shares of common stock in exchange for warrants to purchase 921 shares of common stock.

The consideration given for the warrants in the Second and Third Exchange was valued at the closing price of the common stock on the day the transactions closed and the shares were transferred, which was $8.64 and $8.85 per share, respectively. Accordingly, the Company realized a gain on the exchange of warrants of $779,923 based on the fair value of the shares transferred as compared to the last determination of fair value of the warrants performed by the Company as of June 30, 2018, which is reported in changes in fair value of warrant liability including loss on exchange on the consolidated statement of operations and comprehensive loss. The following is a summary of the income statement effect of changes in the Company's outstanding warrants:

	Year Ended December 31,	
	2019	2018
Changes in fair value of warrants	$ 30,000	$ (9,160)
Loss on warrants exchanged	—	(2,688,012)
Transaction costs	—	(181,312)
Change in fair value of warrant liability, including gain (loss) on exchange	$ 30,000	$ (2,878,484)

A summary of warrant activity during the years ended December 31, 2019 and 2018 is as follows:

	Year Ended December 31,	
	2019	2018
Warrants outstanding, January 1	7,344,297	78,336
Issuances	3,052,959	7,342,530
Exercises, conversions, exchanges and repurchases	(12,550)	(76,569)
Warrants outstanding, December 31	10,384,706	7,344,297

The periodic changes in the fair value of the warrant liability is as follows:

Balance, January 1, 2018	$ 3,400,869
Warrants settled upon exchange	(3,345,029)
Changes in fair value	9,160
Balance, December 31, 2018	65,000
Warrant repurchases	(25,000)
Changes in fair value	(30,000)
Balance, December 31, 2019	$ 10,000

The following assumptions were used to estimate the fair value of warrants classified as a liability using the Monte Carlo simulation valuation model with Level 3 inputs at December 31, 2019 and 2018 were as follows:

	As of December 31,	
	2019	2018
Expected volatility	89.87%	93.90%
Expected term (years)	2.63	3.60
Risk-free interest rate	1.61%	2.48%
Expected dividend yield	0.00%	0.00%

13. 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 Merger Agreement in 2017, the Company issued options from its 2001 Plans to replace options previously granted option plans. 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, or 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 Altimmune 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, 2019 under the Plans, a total of 725,000 options to purchase shares of common stock were granted. As of December 31, 2019, there were 83,373 and 1,491,582 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,	
	2019	2018
Expected volatility	92.68%	92.14%
Expected term (years)	5.89	6.07
Risk-free interest rate	2.17%	2.86%
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 activities under the Plans is presented below:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Year)	Weighted-Average Intrinsic Value
Outstanding, January 1, 2019	353,274	$ 10.97	6.04	$ -
Granted	725,000	2.67		
Exercised	—			$ -
Forfeited or expired	(105,102)	14.89		
Outstanding, December 31, 2019	973,172	$ 4.36	5.91	$ -
Exercisable, December 31, 2019	289,518	$ 6.86	5.48	$ -
Expected to vest, December 31, 2019	594,779	$ 3.30	6.09	$ -

The per share weighted-average grant date fair value of stock options granted during the years ended December 31, 2019 and 2018 were $2.67 and $4.63, respectively. At December 31, 2019, there was $1,375,808 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 3.22 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 shared subject to accelerated vesting upon a deemed liquidation event. Fair value of restricted shares that vested during the year ended December 31, 2019 totaled $648. The Company expects the 213 remaining shares to vest during 2020.

On November 30, 2018, the Company authorized and granted one executive officer a restricted stock award of 322,907 shares. 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. Fair value of the 87,454 restricted shares that vested during the year ended December 31, 2019 totaled $159,032.

A summary of restricted stock activities is presented below:

	Shares	Weighted-average Grant Date Fair Value
Unvested, January 1, 2019	323,404	$ 4.06
Vested	(87,738)	4.58
Unvested, December 31, 2019	235,666	$ 3.87

As of December 31, 2019, total unrecognized compensation expense related to restricted stock awards was $843,770, which the Company expects to recognize over a weighted average period of approximately 2.92 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 starting 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 and recognized stock-based compensation expense of $21,608 for the year-ended December 31, 2019.

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, 2019 and 2018 as follows:

	Year-Ended December 31,	
	2019	2018
Research and development	$ 356,718	$ 319,354
General and administrative	907,513	453,894
Total	$ 1,264,231	$ 773,248

14. Income Taxes

The components of net loss before income tax benefit are as follows:

	Year Ended December 31,	
	2019	2018
U.S. operations	$ 18,562,738	$ 38,979,638
Non-U.S. operations	2,015,893	6,341,308
Net loss before income tax benefit	$ 20,578,631	$ 45,320,946

The components of the income tax benefits are as follows:

	Year Ended December 31,	
	2019	2018
U.S. federal		
Current	$ —	$ 271,356
Deferred	45,465	4,309,534
US state and local		
Current	—	(1,464)
Deferred	13,035	1,570,368
Income tax benefit	$ 58,500	$ 6,149,794

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,	
	2019	2018
Federal statutory rate	21.00%	21.00%
State income taxes, net of federal benefit	3.12	4.53
Foreign income tax rate differential	(0.01)	(0.15)
Stock compensation	(0.93)	(0.16)
Research and development tax credit	(1.51)	(1.30)
Acquisition costs	(0.91)	—
Goodwill impairment	—	(0.22)
Acquired in process research and development impairment	(7.03)	—
Loss on warrant exchange and warrant FMV changes	0.03	(1.33)
Permanent differences and other	(0.99)	2.14
Change in valuation allowance	(12.49)	(10.94)
Effective tax rate	0.28%	13.57%

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,	
	2019	2018
Deferred tax assets:		
Domestic NOLs	$ 8,141,204	$ 4,025,587
Foreign NOLs	5,352,556	5,303,154
Accrued expenses	208,604	162,814
Amortization	947,115	1,035,765
Deferred revenue	44,558	38,494
Stock compensation	622,789	568,165
Deferred rent	—	336,070
Lease Liability	479,940	—
Research and development carryforward	73,155	73,156
Total deferred tax assets	15,869,921	11,543,205
Deferred tax liabilities:		
IPR&D assets	(2,373,304)	(2,557,085)
Right of Use Asset	(192,160)	—
Depreciation	(154,678)	(205,859)
IRC §481(a) adjustment	—	—
Total deferred tax liabilities	(2,720,142)	(2,762,944)
Deferred tax assets, net	13,149,779	8,780,261
Valuation allowance	(13,149,779)	(8,838,761)
Total deferred tax liabilities net	$ —	$ (58,500)

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, 2019 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. 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. 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 NOLs that have an unlimited life.

The Company has U.S. federal net operating loss carryforwards of approximately $29,596,042 as of December 31, 2019. Of this amount, $6,576,869 has a 20-year carry forward period that will expire at various dates beginning in 2021. Under current law, the remaining amount of $23,019,173 has an unlimited life.

As of December 31, 2019 and 2018, the Company does not have any material unrecognized tax benefits. The Company files income tax returns in the United States, various U.S. states, U.K., and France. 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. 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 both 2018 and 2019 and subsequent ownership changes may further affect the limitation in future years.

15. Lease Obligations

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, 2019 and 2018 under all of

the Company's operating leases was $346,603 and $632,658, respectively, which includes short-term leases and variable lease costs not included in the lease obligation.

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.

The office space lease provides for increases in future minimum annual rental payments as defined in the lease agreements. The Company has determined the lease renewal option is not reasonably certain.

The office space lease provided the Company tenant improvement incentives and allowances. The Company recorded $164,090 and $115,782 of amortization of lease incentive obligation as a reduction of rent expense for the years ended December 31, 2019 and 2018, respectively.

The cash paid for operating lease liabilities for the year ended December 31, 2019 was $380,805.

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

	December 31, 2019
Operating lease obligations	$ 1,744,128
Right of use asset	$ 698,321
Weighted-average remaining lease term	5.33
Weighted-average discount rate	8.0%

Maturities of lease liabilities are as follows:

Year ending December 31,	
2020	$ 387,079
2021	393,542
2022	400,198
2023	407,054
2024	414,117
2025 and thereafter	138,831
Total lease payments	2,140,821
Less imputed interest	(396,693)
Total	$ 1,744,128

16. Commitments and Contingencies

See Note 8 for the Company's commitments under license agreements.

As disclosed in Note 3, 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.

In December 2019, a complaint was filed by Dr. De-Chu Christopher Tang ("Plaintiff") against the Company in U.S. 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. Subsequently the Plaintiff filed a motion to strike Defendants' motion to dismiss and both motions are currently pending. Plaintiff, who is representing himself, alleges five causes of action as follows: (1) Defendants' alleged retention of Plaintiff's lab notebooks; (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." 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.

The Company does not believe that the resolution of these matters will have a material adverse effect on its financial position or results of operations.

17. 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. As discussed in Note 2, the Company classifies assets and liabilities measured at fair value using the fair value hierarchy per ASC 820.

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
Recurring fair value measurements				
Cash equivalents - money market funds	$ 8,034,640	$ 8,034,640	$ —	$ —
Short-term investments	28,277,386	—	28,277,386	—
Contingent consideration	2,750,000	—	—	2,750,000
Warrant liability	10,000	—	—	10,000

The Company's assets and liabilities measured at fair value on a recurring basis at December 31, 2018 consisted of the following:

	Fair Value Measurement at December 31, 2018			
	Total	Level 1	Level 2	Level 3
Recurring fair value measurements				
Cash equivalents — money market fund	$ 29,375,509	$ 29,375,509	$ —	$ —
Warrant liability	65,000	—	—	65,000

Cash equivalents and short-term investments valued using publicly quoted market prices, data from third party pricing services, and other market observable data at the end of each reporting period. Short-term investments had 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
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 was 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, 2019 were as follows:

Expected volatility	95.3%
Risk-free interest rate	1.6%
Cost of capital	30.0%

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 2019 or 2018.

Assets recorded at fair value on a nonrecurring basis, such as property and equipment, intangible assets, and goodwill are recognized at fair value when they are impaired. During the years ended December 31, 2019 and 2018, the Company recognized goodwill and intangible asset impairments (Note 6) measured at fair value on a nonrecurring basis.

18. 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 2019 and 2018, we made discretionary plan contributions of $131,412 and $139,042, respectively.

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, 2019. 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, 2019, 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, 2019, and has concluded that there was no change that occurred during the year ended December 31, 2019 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, 2019.

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.

PART III

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 seven Directors, each of whom was elected at the Company's 2018 annual meeting of stockholders.

The names and ages of our directors as of March 27, 2020 are set forth below:

Name	Age	Position
Vipin K. Garg, Ph.D.	62	President, Chief Executive Officer, and Director
Mitchel Sayare, Ph.D.	72	Chairman of the Board
David J. Drutz, M.D.	81	Director
Philip L. Hodges	51	Director
John M. Gill	68	Director
Klaus O. Schafer, M.D., MPH	70	Director
Wayne Pisano	65	Director

Vipin K. Garg, Ph.D. currently serves as our President and CEO and is a member of the board of directors. He 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, he served as President and CEO of Neos Therapeutics (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 CEO 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 AGof 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.

Mitchel Sayare, Ph.D. has been a member of the Board of Directors since April 2010. Until 2010, Dr. Sayare served as the Chairman of the Board of public company ImmunoGen, Inc. (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. Dr. Sayare was chosen to serve as a director of Altimmune because of his substantial experience as a board member and executive officer of biotechnology companies.

David J. Drutz, M.D. was appointed to our Board in connection with the completion of the Mergers in May 2017, and first elected to Private Altimmune's board of directors in January 2010 and as Board Chairman in October 2011. Dr. Drutz is the President of Pacific Biopharma Associates, a biopharmaceutical consulting company that he founded in 1999. From 2008-2015, he served variously as Director, CEO, Executive Chairman and Chief Medical Officer of DARA BioSciences (NASDAQ:DARA), an oncology supportive care company located in Raleigh, NC. He served previously as Chairman of Tranzyme (NASDAQ:TZYM; 2000-2010); and Director of MethylGene (TSX:MYG; 2000-2010) and Gentris Corporation (2007-2014). From 1999-2008 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 Daiichi 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. Dr. Drutz brings significant experience in biotechnology investment and as a physician to Altimmune's board of directors.

Philip L. Hodges was appointed to our Board in connection with the completion of the Mergers in May 2017 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. Mr. Hodges brings significant experience as a life science investor and co-founder to Altimmune's board of directors.

John M. Gill served as PharmAthene's President and Chief Executive Officer from March 2015 until the completion of the Mergers in May 2017. Mr. Gill has served on our Board since 2004. 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. Mr. Gill was chosen to serve as a director of Altimmune because of his executive and board experience in the pharmaceutical industry and his substantial financial knowledge and expertise.

Brigadier General (ret.), Klaus O. Schafer, M.D., MPH was appointed to our Board in connection with the completion of the Mergers in May 2017 and was first elected to Private Altimmune's board of directors in July 2012. Dr. Schafer has over 30 years of leadership experience, having held senior positions in government and industry. He was first elected to Altimmune's board of directors in July 2012. As the Deputy Asst. to the Secretary of Defense for chemical and biological defense, a position he held from April 2004 through June 2005, he oversaw the management of the Department of Defense's $1.0 billion program for vaccine, therapeutics, medical device and sensor development. He retired from the Air Force as the Assistant Surgeon General with extensive experience managing all aspects of large integrated health care delivery systems. Prior private sector experience includes VP of business development for Compressus Inc., a telemedicine start-up, former CEO and cofounder of TessArae LLC, a start-up biotech genetic testing company, Chief Medical Officer and VP, business development, Health for CACI International, a publicly traded Fortune 1000 company, and consultant and advisory board member to numerous companies and to the biodefense industry. Dr. Schafer earned his MD at the University of Iowa, Family Practice Boards, Eglin AFB where he was Chief Resident, MPH at the University of Texas and the Master of Science at the Eisenhower School of National Security and Resource Strategy. Dr. Schafer was selected as a director for his board and varied background, including deep understanding of government biotech development strategy, funding, and budgeting, and his commercial industry experiences. Dr. Schafer brings significant experience as a physician and biotechnology investor, in government and as a board member and advisor in the health care biodefense industry to Altimmune's board of directors.

Wayne Pisano was elected to join the company's Board in August of 2018. Mr. Pisano joined the board of directors of Provention Bio, Inc., a biopharmaceutical company, in April of 2018, and has served on the board of directors of IMV Inc., a biopharmaceutical company, since October 2011, and Oncolytics, Inc., a biotechnology company, since May 2013. Mr. Pisano served as president and CEO of VaxInnate, a biotechnology company, from January 2012 until November 2016. Mr. Pisano joined Sanofi Pasteur in 1997 and was promoted to President and CEO in 2007, the position he successfully held until his retirement in 2011. He has a bachelor's degree in biology from St. John Fisher College, New York and an MBA from the University of Dayton, Ohio. The Board believes that Mr. Pisano's depth of experience across the spectrum of commercial operations, public immunization policies and pipeline development will make him a valuable member of our Board of Directors.

Executive Officers

The names and ages of our executive officers as of March 27, 2020 are set forth below:

Name	Age	Position
Vipin K. Garg, Ph.D.	62	President, Chief Executive Officer, and Director
Will Brown	38	Chief Financial Officer
M. Scot Roberts, Ph.D.	61	Chief Scientific Officer
M. Scott Harris, M.D.	66	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.

Will Brown, CPA current serves as the Chief Financial Officer and Principal Accounting Officer of the Company. Prior to joining the Company in 2018, Mr. Brown has been a consultant to several private and public companies in a variety of accounting and tax matters both independently and as the managing partner of Redmont CPAs (from October 2016 to January 2018). He was an audit manager at PwC in both Montgomery, Alabama (from June 2012 through July 2013) and Denver, Colorado (from November 2014 through September 2016). From August 2013 through October 2014, Mr. Brown was the Water Heater Division Controller at Rheem Manufacturing, a private company located in Montgomery, Alabama. Mr. Brown is a CPA licensed in Colorado and Alabama. 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. serv*es 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 of Messrs. Hodges and Pisano and Dr. Shafer is an independent director in accordance with NASDAQ listing standards. The Board also determined that Mr. Gill is not independent solely by virtue of him having served as the Chief Executive Officer of PharmAthene (the predecessor to the Company) prior to the Mergers (*i.e.*, within the past three years) and otherwise has no relationship with the Company that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Accordingly, despite this determination, the Board determined that, due to Mr. Gill's exceptional skills, experience and qualifications, it is in the best interests of the Company and its shareholders for Mr. Gill to be a member of the Audit Committee. 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) 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, 2019 and after the completion of the Merger, the Board held 19 meetings and the Board Committees held a total of 10 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 2019. 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 2019 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

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 2019 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.

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, 2019 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, 2019 are:

- Vipin K. Garg, Ph.D., our Chief Executive Officer;
- Will Brown, our Chief Financial Officer;
- M. Scott Harris, M.D., MPH, our Chief Medical Officer; and
- Sybil Tasker, M.D., MPH, our Former Chief Medical Officer.

Dr. Tasker resigned as Chief Medical Officer on June 30, 2019.

Elements of Compensation

The compensation arrangement for each Named Executive Officer is intended to encourage performance and to align the Named Executive Officer's 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;
- stock options;
- 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 amounts of which are based on satisfaction of Company 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 Altimmune, 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 2018 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. (3)	2019	500,000	—	—	—	—	—	66,631	566,631
Chief Executive Officer	2018	43,590	100,000	1,159,236	887,107	—	—	31	2,189,964
Will Brown (4)	2019	192,500	60,000	—	151,564	—	—	190,656	594,720
Chief Financial Officer	2018	—	—	—	—	—	—	216,000	216,000
M. Scott Harris, M.D. (5)	2019	115,032	—	—	171,325	—	—	1,233	287,590
Chief Medical Officer	2018	—	—	—	—	—	—	—	—
William J. Enright (6)	2019	—	—	—	—	—	—	—	—
Former Chief Executive Officer	2018	410,667	184,800	—	34,463	—	—	7,776	637,706
Elizabeth A. Czerepak (7)	2019	—	—	—	—	—	—	—	—
Former Chief Financial Officer	2018	126,923	—	—	—	—	—	5,076	131,999
Sybil Tasker, M.D., MPH (8)	2019	203,500	107,190	—	146,103	—	—	6,912	463,705
Chief Medical Officer	2018	397,000	—	—	16,705	—	—	7,571	421,276

(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 2019 and 2018 are discussed in Item 13, Financial Statements and Supplementary Data.

(2) Amounts in this column for fiscal year 2019 include payments for the service of Mr. Brown as Acting Chief Financial Officer prior to June 1, 2019 of $190,656. Amounts in this column for fiscal year 2018 include; Mr. Brown payments for his service as Acting Chief Financial Officer of $216,000 and Dr. Tasker, Mr. Enright, and Ms. Czerepak employer contributions of $7,431, $7,776, and $5,076 respectively.

(3) Dr. Garg commenced employment with Altimmune on November 30, 2018.

(4) Mr. Brown commenced employment with Altimmune on June 1, 2019.

(5) Dr. Harris commenced employment with Altimmune on September 9, 2019.

(6) Mr. Enright terminated employment with Altimmune on November 30, 2018.

(7) Ms. Czerepak terminated employment with Altimmune on May 8, 2018.

(8) 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 and Dr. Tasker. 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 will be subject to claw-back if Dr. Garg's employment with the Company terminates 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 will have an exercise price equal to the last reported sale price of the Company's common stock on the Grant Date. 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 she 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 the 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 the 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. 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 she resigns for "good reason" (as defined below), in addition to accrued benefits (to which she 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 2019 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, 2019.

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	27,855	83,566	(1)		3.59	11/30/2028
	57,277	154,209	(1)		3.59	11/30/2028
Will Brown	30,000	—	(2)	—	2.60	1/2/2029
	—	50,000	(3)	—	2.34	6/10/2029
M. Scott Harris, M.D.	—	107,000	(4)	—	2.13	9/9/2029
Sybil Tasker, M.D., MPH	—	—	(5)	—	—	

(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, 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 that vested upon the filing of the Company's annual report of Form 10-K for the year ended December 31, 2018.

(3) On July 10, 2019, Mr. Brown was granted an option to purchase 50,000 shares of Common Stock of the Company at an exercise price of $2.34 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 July 10, 2020. One-hundred percent of the shares underlying the option will vest upon the filing of the Company's annual report on Form 10-K.

(4) 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 October 9, 2020.

(5) Dr. Tasker resigned as Chief Medical Officer on June 30, 2019.

Director Compensation

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, 2019.

Name (1)	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mitchel Sayare, Ph.D.	65,000	—	—	—	—	—	65,000
David J. Drutz, M.D.	54,500	—	—	—	—	—	54,500
John M Gill	47,500	—	—	—	—	—	47,500
Philip L. Hodges	58,000	—	—	—	—	—	58,000
Klaus O. Schafer, M.D., MPH	48,000	—	—	—	—	—	48,000
Wayne Pisano	55,000	—	—	—	—	—	55,000

(1) As of December 31, 2019, each of Altimmune's non-employee directors, held the following stock option awards: Drs. Sayare, Drutz, and Schafer 31,901, 21,433, and 21,006, respectively. And Messrs. Hodges, Pisano and Gill 20,667, 20,000, and 20,734, respectively. As of December 31, 2019, no outstanding stock awards (vested or unvested) were held by these non-employee directors.

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 March 26, 2020 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 March 26, 2020 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 15,361,660 shares of Common Stock outstanding at the close of business on March 26, 2020. 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
5% or Greater Stockholders:		
Velocity Pharmaceutical Holdings (1)	1,887,250	12.29%
Hudson Bay Capital Management (2)	1,704,955	9.99%
Directors and Named Executive Officers:		
Vipin K. Garg (3)	438,554	2.83%
Will Brown (4)	38,061	*
Matthew Scott Harris (5)	—	
Mitchel Sayare, Ph.D. (6)	32,989	*
David J. Drutz, M.D. (7)	22,126	*
John M. Gill (8)	23,508	*
Philip L. Hodges (9)	40,123	*
Klaus O. Schafer, M.D., MPH (10)	21,206	*
Wayne Pisano (11)	22,000	*
All Executive Officers and Directors as a Group (11 persons)(12)	688,765	4.4%

* Represents beneficial ownership of less than one percent of Altimmune's outstanding Common Stock.

(1) Consists of shares of Common Stock issued on June 12, 2019 in payment for the assets of Spitfire Pharma, Inc.

(2) Consists of warrants to purchase Common Stock. It does not include 3,313,501 warrants to purchase common stock which are subject to ownership blocking provisions of the warrant. Information regarding the number of shares beneficially owned by Hudson Bay Capital Management was obtained from a Schedule 13G/A filed by Hudson Bay Capital Management with the SEC. The principal business address of Hudson Bay Capital Management is 777 Third Avenue, 30th Floor, New York, NY 10017.

(3) Consists of 95,615 shares of Common Stock, 228,576 restricted shares of Common Stock over which Dr. Garg has voting control, and 114,363 shares of Common Stock which can be acquired upon exercise of outstanding options within 60 days. Does not include options to purchase 358,044 shares of Common Stock that are not exercisable within 60 days.

(4) Consists of 30,000 shares of Common Stock that can be acquired upon exercise of outstanding options within 60 days. Does not include options to purchase 111,400 shares of common stock that are not exercisable within 60 days.

(5) Does not include options to purchase 168,400 shares of common stock that are not exercisable within 60 days.

(6) Consists of 1,088 shares of Common Stock, and 31,901 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days.

(7) Consists of 693 shares of Common Stock, and 21,433 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days.
(8) Consists of 2,774 shares of Common Stock, and 20,734 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days.
(9) Consists of 19,456 shares of Common Stock, and 20,667 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days.
(10) Consists of 200 shares of Common Stock, and 21,006 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days.
(11) Consists of 2,000 shares of Common Stock, and 20,000 shares of Common Stock that can be acquired upon the exercise of outstanding options.
(12) Consists of 135,582 shares of Common Stock, 228,576 restricted shares of Common Stock over which Dr. Garg has voting control and 324,607 shares of Common Stock that can be acquired upon exercise of outstanding options within 60 days.

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, 2019:

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	761,686	4.58	609,606
Equity compensation plans not approved by security holders	446,939	1.70	1,938,521
Total	1,208,625	3.51	2,548,127

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 and Mr. Gill, currently meet the independence requirements contained in the NASDAQ listing standards and applicable tax and securities rules and regulations. None of these 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. Mr. Gill will become independent upon May 4, 2020, which is the third anniversary of the cessation of his employment with us.

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.

Other than Mr. Gill, 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 and 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 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. Set forth below is information concerning transactions with our related parties that is required to be disclosed under SEC rules.

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, 2019 and 2018 by our independent registered public accounting firm, Ernst & Young LLP ("E&Y"):

Fee Category	2019	2018
Audit Fees (1)	$ 670,267	$ 848,772
Tax Fees (2)	$ 25,000	$ 152,328
Total	$ 695,267	$ 1,001,100

(1) Audit Fees consist of fees billed for professional services rendered for the audit of the Company's and PharmAthene'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
2.1	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)
3.1	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)
3.2	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)
3.3	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)
3.4	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)
3.5	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)
4.1	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)
4.2	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on August 17, 2017)
4.3	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)
4.4	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)
4.5	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)
4.6	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)
4.7	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)
4.8	Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on October 9, 2018)
4.9	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Form 8-K filed on October 9, 2018)
4.10	Description of Registrant's Securities

Exhibit No.	Description
10.1†	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)
10.2†	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)
10.3†	Altimmune, Inc. 2001 Employee Stock Option Plan (incorporated by reference to Exhibit 99.1 filed with the Registrant's Form S-8 filed on May 10, 2017)
10.4†	Altimmune, Inc. 2001 Non-Employee Stock Option Plan (incorporated by reference to Exhibit 99.2 filed with the Registrant's Form S-8 filed on May 10, 2017)
10.5†	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)
10.6†	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)
10.7†	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)
10.8†	Altimmune, Inc. 2019 Employee Stock Purchase Plan, incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement, filed with the Securities and Exchange Commission on August 22, 2019.
10.9§	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)
10.10§	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)
10.11§	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)
10.12§	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)
10.13§	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)
10.14§	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)
10.15§	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)
10.16§	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)
10.17	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)
10.18†	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)
10.19†	Employment Agreement, dated April 4, 2016, between Sybil Tasker and Altimmune, Inc. (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-Q filed on August 14, 2017)
10.20	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)

Exhibit No.	Description
10.21	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)
10.23	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)
21*	Subsidiaries
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)
31.2*	Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350
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, 2019 and 2018; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2019 and 2018; (iii) Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity for the Years Ended December 31, 2019 and 2018; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018; 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 27th day of March 2020.

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.

Signature	Title	Date
/s/ Vipin K. Garg Vipin K. Garg	President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2020
/s/ Will Brown Will Brown	Chief Financial Officer, (Principal Financial Officer and Principal Accounting Officer)	March 27, 2020
/s/ Mitchel Sayare, Ph.D. Mitchel Sayare, Ph.D.	Chairman of the Board	March 27, 2020
/s/ John Gill John Gill	Director	March 27, 2020
/s/ Philip Hodges Philip Hodges	Director	March 27, 2020
/s/ David Drutz, M.D. David Drutz, M.D.	Director	March 27, 2020
/s/ Klaus O. Schafer, M.D. Klaus O. Schafer, M.D.	Director	March 27, 2020
/s/ Wayne Pisano Wayne Pisano	Director	March 27, 2020

Exhibit 4.10

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 Altimmune, Inc. ("Altimmune" "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 March 26, 2020, we had 15,361,660 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 December 31, 2019, 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

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, 2019, we had 10,384,706 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 120th day and not later than 5:00 p.m., Eastern Time, on the 90th 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.

Exhibit 21

SIGNIFICANT SUBSIDIARIES

List of Subsidiaries	Jurisdiction of Incorporation or Organization
Mustang Merger Sub II LLC (1)	Delaware
Altimmune UK Limited (1)	United Kingdom
Spitfire Pharma, LLC (1)	Delaware

(1) Wholly owned subsidiary of the Company

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

Form	Registration Number	Date Filed
S-8	333-233273	8/14/2019
S-3	333-230723	4/4/2019
S-8	333-230722	4/4/2019
S-8	333-228623	11/30/2018
S-3	333-217034	3/30/2017
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 March 27, 2020, 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, 2019.

/s/ Ernst & Young LLP

Baltimore, Maryland
March 27, 2020

Exhibit 31.1

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, 2019;

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 toc 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: March 27, 2020

/s/ Vipin K. Garg
Name: Vipin K. Garg
Title: President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

Certification of Principal Executive 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, 2019;

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: March 27, 2020

/s/ Will Brown
Name: Will Brown
Title: Chief Financial Officer
(principal financial officer)

Exhibit 32.1

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, 2019, 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
Vipin K Garg
President and Chief Executive Officer
March 27, 2020

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.

Exhibit 32.2

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, 2019, 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
Will Brown
Chief Financial Officer
March 27, 2020

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.