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

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**FORM 10-K**

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(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, 2017

**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

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**ALTIMMUNE, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

910 Clopper Road, Suite 201S, Gaithersburg, MD  
(Address of principal executive offices)

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

20878  
(Zip Code)

Registrant's telephone number, including area code

(240) 654-1450

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

Title of Each Class:  
Common Stock, par value \$0.0001 per share

Name of Each Exchange on Which Registered:  
The NASDAQ Global Market

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

None

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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 and posted on its corporate Web site, if any, every Interactive Data file required to be submitted and posted 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 and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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  (Do not check if smaller reporting company)

Smaller Reporting Company

Emerging growth company

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 \$3.20, on June 30, 2017 was approximately \$49.4 million.

There were 22,271,089 shares of the Registrant's common stock, \$0.0001 par value per share, outstanding on March 30, 2018.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive proxy statement related to its 2018 annual meeting of stockholders (the "Proxy Statement") to be filed subsequently are incorporated by reference into Part III of this report. The Proxy Statement or an amendment to this annual report on Form 10-K will be filed within 120 days of the end of the fiscal year covered by this annual report on Form 10-K.

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ALTIMMUNE, INC.

ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

	<u>Page</u>
<b>PART I</b>	
Item 1. <a href="#">Business</a>	2
Item 1A. <a href="#">Risk Factors</a>	43
Item 1B. <a href="#">Unresolved Staff Comments</a>	88
Item 2. <a href="#">Properties</a>	89
Item 3. <a href="#">Legal Proceedings</a>	89
Item 4. <a href="#">Mine Safety Disclosures</a>	89
<b>PART II</b>	
Item 5. <a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	90
Item 6. <a href="#">Selected Financial Data</a>	91
Item 7. <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	93
Item 7A. <a href="#">Quantitative and Qualitative Disclosures about Market Risk</a>	106
Item 8. <a href="#">Financial Statements and Supplementary Data</a>	107
Item 9. <a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>	145
Item 9A. <a href="#">Controls and Procedures</a>	145
Item 9B. <a href="#">Other Information</a>	146
<b>PART III</b>	
Item 10. <a href="#">Directors, Executive Officers and Corporate Governance</a>	147
Item 11. <a href="#">Executive Compensation</a>	147
Item 12. <a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	147
Item 13. <a href="#">Certain Relationships and Related Transactions, and Director Independence</a>	147
Item 14. <a href="#">Principal Accountant Fees and Services</a>	147
<b>PART IV</b>	
Item 15. <a href="#">Exhibits and Financial Statement Schedules</a>	148
Item 16. <a href="#">Form 10-K Summary</a>	151
<a href="#">Signatures</a>	152

## PART I

### Forward-looking statements

*This annual report on Form 10-K 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. We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all forward-looking statements. In addition, other 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. 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:*

- *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 Biomedical Advanced Research and Development Authority (“BARDA”), or our contract with the National Institutes of Allergy and Infectious Diseases (“NIAID”);*
- *our ability to satisfy certain technical milestones under our contracts with BARDA and NIAID that would entitle us to receive additional funding over the period of the agreement;*
- *the preservation of our net operating loss carryforwards (“NOLs”);*
- *the impact of the Tax Cuts and Jobs Act (“TCJA”) passed into law in December of 2017;*
- *delays caused by third parties challenging government contracts awarded to us;*
- *potential payments under government contracts or grants;*
- *potential future government contracts or grant awards;*
- *potential regulatory approvals;*
- *potential consummation of future strategic partnerships or business combinations;*
- *future product advancements;*
- *anticipated financial or operational results;*
- *our ability to obtain additional capital resources;*
- *unforeseen safety and efficacy issues;*
- *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;*

*as well as risks detailed under the caption “Risk Factors” in this annual report on Form 10-K and in our other reports filed with the U.S. Securities and Exchange Commission (“SEC”), from time to time hereafter.*

## [Table of Contents](#)

*We have based the forward-looking statements included in this annual report on Form 10-K 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 directly to you or through 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 cautionary statements contained or referred to elsewhere in this annual report. Unless otherwise indicated, the information in this annual report is as of December 31, 2017.*

### **Item 1. Business.**

#### **Overview**

Altimmune, Inc. is a clinical stage immunotherapeutics company focused on the development of products to stimulate robust and durable immune responses for the prevention and treatment of diseases. We have two proprietary platform technologies, RespirVec and Densigen, each of which has been shown, in preclinical studies and early clinical trials, to activate the immune system in distinctly different ways than traditional vaccine methods. Using these technologies, we have generated clinical product candidates which potentially represent an entirely new approach to harnessing the immune system. We have two programs using the Respirvec recombinant adenovirus technology. NasoVAX, an intranasally administered recombinant influenza vaccine, uses an adenovector to achieve expression of the influenza antigen in the target cell, thereby potentially stimulating a broader and more rapid immune response than traditional influenza vaccines. Our planned Phase 2 program for NasoVAX started in September 2017. Initial data, released in March 2018, indicated that NasoVAX was well tolerated at all doses tested, and achieved 100% seroprotection with the two higher doses. Final data from this study will be available in the third quarter of 2018 and we expect to move forward with continued development of a quadrivalent NasoVAX product candidate which we expect will be ready for clinical evaluation in the first half of 2019. The second RespirVec product, NasoShield, is an anthrax vaccine designed to provide rapid, stable protection after one intranasal administration. We launched a Phase 1 trial for NasoShield in the first quarter of 2018 and anticipate topline data in the third quarter of 2018.

With the support of NIAID, we are developing an alternative anthrax vaccine candidate, SparVax-L, a recombinant protein-based anthrax vaccine designed to require fewer doses and have a longer shelf-life than the only currently licensed anthrax vaccine. The shelf life of the liquid formulation was insufficient to meet the government standards and the product was reformulated in a lyophilized (dry powder) formulation. We have demonstrated a significant improvement (at least two years at room temperature and at least six years at refrigerated temperatures) with the lyophilized formulation. Recent preclinical experiments have shown it to be 100% protective with a two-dose regimen (zero and 14 days) with higher toxin neutralizing antibodies than the currently licensed vaccine.

Based on the Densigen platform, HepTcell is an immunotherapy for patients chronically infected with the hepatitis B virus, or HBV. HepTcell is currently in a Phase 1 trial in the United Kingdom and South Korea in patients with chronic HBV. Preliminary results from this trial were inconclusive. We are awaiting the six month follow up results, which we expect will be available in the third quarter of 2018, to determine whether to continue with further development of HepTcell, including any further clinical trials. Oncosyn, a cancer immunotherapeutic is in preclinical development.

#### **Merger with PharmAthene**

Our business is the 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, among Private Altimmune, PharmAthene, its wholly owned acquisition subsidiaries Mustang

## [Table of Contents](#)

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 in developing a next generation anthrax vaccine.

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.

### ***Our Business***

We are focused on the development of products to stimulate robust and durable immune responses for the prevention and treatment of disease. We have two proprietary platform technologies, RespirVec and Densigen, each of which has been shown, in preclinical studies and early clinical trials, to activate the immune system in distinctly different ways than traditional vaccine methods. Using these technologies, we have generated clinical product candidates which potentially represent an entirely new approach to harnessing the immune system.

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With the support of NIAID, we are developing an alternative anthrax vaccine candidate, SparVax-L, a recombinant protein-based anthrax vaccine designed to require fewer doses and have a longer shelf-life than the only currently licensed anthrax vaccine. The shelf life of the liquid formulation was insufficient to meet the government standards and the product was reformulated in a lyophilized (dry powder) formulation. We have demonstrated a significant improvement (two years at room temperature and six years at refrigerated temperatures) with the lyophilized formulation. Recent preclinical experiments have shown it to be 100% protective with a two-dose regimen (zero and 14 days) with higher toxin neutralizing antibodies than the currently licensed vaccine.

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## Our Strategy

Key elements of our strategy include the following:

- *Develop and commercialize immunotherapeutic products for the prevention and treatment of disease.* We are dedicated to the development of immunotherapeutic pharmaceuticals to prevent and treat infectious disease. Our product candidates seek to engage the immune system in distinctive ways that offer an inherent advantage over existing approaches. We are currently focused on developing our four clinical stage assets against influenza, chronic HBV infections and anthrax, as well as our preclinical oncology program.
- *Apply our platform technologies to expand our pipeline of products.* We intend to apply our platform technologies to various disease states where the immune system is involved in disease resolution. We will employ our technologies, either alone or in combination, in an effort to recruit the appropriate elements of the human immune system for a given disease indication. We are currently applying our technologies to respiratory diseases and chronic infections. We will also opportunistically continue to apply our technologies to areas of national security or public interest where government funding is available for such projects.
- *Partner or out-license certain product candidates at later stages of development.* We intend to manage our organization to be focused on product development. With this focus, depending on indication, we see the benefit of partnering or out-licensing certain products for late stage development. For specific indications, such as influenza, we expect to partner after Phase 2 clinical testing. While there may be limited indications where marketing products independently is reasonable for a company of our size, we anticipate that in most indications, we would seek to out-license or partner to bring our products to market. We will seek partners that have the appropriate development expertise and the distribution and marketing infrastructure required to successfully commercialize our products.
- *In-license or acquire complementary immunotherapeutic technologies and products to expand our pipeline.* We will seek opportunities to expand our pipeline through the in-licensing or acquisition of additional immunotherapeutic technologies or product candidates. In particular, we will seek complementary products or technologies that either improve or extend an existing product candidate or indication in our current pipeline.

## The Human Immune System

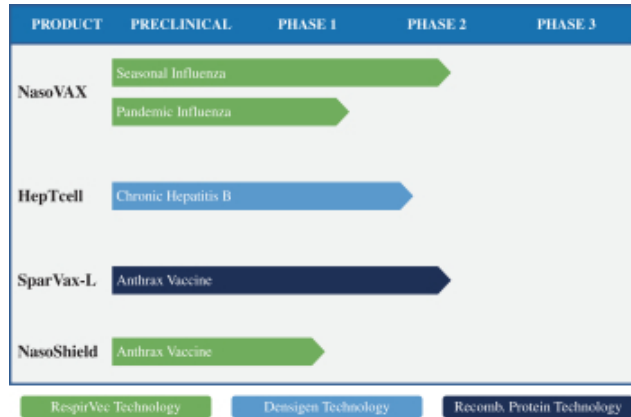
The human immune system consists of a series of specialized structures and cell types that work together to protect the body from disease. The immune system can respond to pathogens in two different ways — via the innate immune response or via the adaptive immune response. Adaptive immunity is developed in response to antigens expressed by a particular pathogen, is highly specific to those antigens, and takes from one to several weeks upon initial recognition of the pathogen to mount an effective response. The adaptive immune system responds to a pathogen through both antibody-mediated and T cell-mediated immunity. The antibody-mediated humoral response is primarily directed toward the neutralization of extracellular pathogens (including viruses), which renders them harmless. T cell-mediated cellular immunity functions to recognize cells that need to be destroyed either because they harbor a pathogen or because the cell has transformed into a cancer cell. The adaptive immune response also includes the mucosal immune system, which is localized to mucosal tissues like the lining of the respiratory tract. The mucosal immune system uses a specialized type of antibody called IgA to block pathogens at the site of entry into the body.

In contrast to the slower, highly specific responses of the adaptive immune response, the innate immune system is designed to provide a rapid and broad response to attacking pathogens. There are numerous types of innate immune cells with specialized functions. Their principal characteristic is the ability to respond quickly when a pathogen is encountered. The innate immune system can recognize viruses, bacteria and fungi, and is

[Table of Contents](#)

initiated immediately upon recognition of an invading organism to provide protection against infection while the adaptive immune response is being developed. In addition to acting directly on the pathogen threat, the innate immune system facilitates and improves the adaptive immune response. Together, the adaptive and innate immune systems provide a concerted response to the control and clear the pathogen from the host.

**Current Product Candidates in Development**



Source: Company data

**NasoVAX**

NasoVAX is an adenovectored influenza vaccine candidate that is delivered intranasally. NasoVAX has demonstrated safety and the ability to induce an immune response against influenza in two Phase 1 trials in healthy volunteers. We completed enrollment of Phase 2 clinical trial program in the fourth quarter of 2017 and reported preliminary data in March 2018. NasoVAX was well tolerated and immunogenic, and we plan to continue development of NasoVAX seasonal influenza vaccine with a quadrivalent study to start in the first half of 2019. Additional development of NasoVAX for the treatment of pandemic influenza is contingent on successful results in the seasonal influenza program and financial support from BARDA or other governmental agencies for additional development of a pandemic vaccine.

**Influenza Overview**

Influenza is one of the most common viral respiratory infections, leading to significant morbidity and mortality. In particular, young children, adults over 65, pregnant women and individuals in long-term care facilities are vulnerable to developing flu-related complications. People with underlying medical conditions such as asthma, obesity, neurological disorders, and chronic lung, heart, liver or kidney problems are also at high risk for complications. The World Health Organization reports that up to 650,000 (<http://www.who.int/mediacentre/news/releases/2017/seasonal-flu/en/>) of those infected with the flu each year die as a result of influenza-related complications. The number of deaths associated with seasonal influenza vary from year to year, based on the severity of circulating strains and the effectiveness of that year’s influenza vaccine. The CDC has posted estimates of seasonal flu deaths and estimates that from the 2010-2011 flu season to the 2013-2014 flu season influenza-associated deaths in the United States ranged from a low of 12,000 (during 2011-2012) to a high of 56,000 (during 2012-2013) ([https://www.cdc.gov/flu/about/disease/us\\_flu-related\\_deaths.htm](https://www.cdc.gov/flu/about/disease/us_flu-related_deaths.htm)). For comparison, the number of deaths from breast cancer in 2017 was approximately 40,000.

It is well known that elderly populations are at greater risk for influenza and influenza-related complications. In the Morbidity and Mortality Weekly Report (“MMWR”) (<https://www.cdc.gov/mmwr/>)

index2018.html), from February 16, 2018, the United States Centers for Disease Control and Prevention (“CDC”), confirmed previous findings that as many as 59% of hospitalizations and 85% of deaths occur among adult age <sup>3</sup>65 years. However, the heightened risk based on age is not confined to senior citizens — for example, a 2014 MMWR report on influenza-associated intensive care unit admissions in the 2013 – 2014 flu season showed that persons aged 41 – 64 years had six times the risk of death and almost four times the risk of intensive care unit admission as those aged 40 or younger, demonstrating that influenza is a real concern for much of the adult population.

There are many influenza strains in circulation during a given flu season and the individual strains are systematically named by: (i) the type of influenza virus, either A or B; (ii) the geographical location where the strain was isolated; (iii) which isolate of potentially many from that location it represents (starting with the number “01”); and (iv) the year it was isolated. For example, an isolate from the pandemic influenza virus known as the swine flu might be called A/California/04/2009. This system of naming virus strains sometimes includes information on the subtype of influenza virus as a suffix at the end of the name, such as A/California/04/2009 (H1N1), where the familiar designation “H1N1” reveals the subunit structure of the virus, designating an influenza subtype comprised of hemagglutinin protein H1 and neuraminidase protein N1.

Vaccination against influenza virus can be an effective way to prevent infections. However, the effectiveness of vaccination can vary greatly from year to year, and the overall level of protection is suboptimal. According to the CDC, the average overall adjusted vaccine effectiveness for influenza seasons has been approximately 40% from 2005 – 2018 (<https://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm>). One reason for vaccine ineffectiveness is the constantly changing nature of influenza virus strains. The viral protein hemagglutinin (HA) is an important target of vaccination, and each type of HA protein, such as H1 or H3, has multiple forms which can vary from year to year. Because the process used to produce over 99% of influenza vaccine doses today requires six months of advance planning, regulatory agencies must commit to the strains to be used well in advance of the start of the flu season. Since each strain is different, an immune response generated against one form of H1 protein may not protect against infection with a virus containing another form of H1 protein. The low estimated 19% overall efficacy of the 2014 – 2015 flu vaccine in the United States was attributed to the fact that more than two-thirds of the H3N2 viruses circulating that season were of a different form than the H3N2 strain included in vaccine production. Worse still, a more dramatic change in influenza virus makeup occasionally arises when an entirely new HA protein emerges, which can result in a human pandemic. Because humans have never encountered the new HA protein they are likely to have little or no immunity, leaving them at much greater risk for serious complications or death. Current vaccines are suboptimal because of their narrow strain specific responses and the long lead times needed for vaccine production that results in mismatches between strains represented in the vaccine and the predominant circulating strains. We have demonstrated in repeated preclinical studies that NasoVAX may provide the type of cross-protection necessary to address a broad variety of HA proteins and has a more rapid production time than the vast majority of currently approved vaccines. Additionally, recent data suggest that glycosylation patterns may also be an important component of increasing vaccine efficacy. It was noted that vaccines that were manufactured in chicken eggs were less efficacious than similar vaccines manufactured in cell culture-based manufacturing processes.

The CDC recommends that everyone in the United States over six months of age receive an annual influenza vaccination. According to the CDC, vaccine manufacturers have projected that the market for influenza vaccines in the United States will be approximately 151 to 166 million doses for the 2017 – 2018 flu season, and have reported approximately 154.7 million doses distributed as of February 17, 2018. Through other market sources we estimate that the substantial majority of these vaccines contain inactivated virus produced in eggs. According to World Health Organization estimates, the U.S. influenza market is expected to be approximately \$2.0 billion in 2018. Despite observations of limited efficacy, the CDC estimates that influenza vaccination prevented approximately 7.2 million illnesses, 3.1 million medically attended illnesses and 90,000 hospitalizations in 2013 – 2014. However, in 2014 – 2015, the CDC estimates that influenza vaccination prevented only 1.9 million illnesses, 966,000 medically attended illnesses and 67,000 hospitalizations,



significantly lower than previous seasons because of the reduced effectiveness of the 2014 – 2015 vaccine against the predominant circulating influenza viruses. New vaccines with improved clinical efficacy and effectiveness are needed to further reduce influenza-related morbidity and mortality. One of the most important improvements needed for influenza vaccines is the ability to provide cross-protection between different HA protein types, which would address the issue created with changing viruses mentioned above. Many companies and laboratories have attempted to develop “universal” influenza vaccines that are directed against viral proteins that are highly conserved in sequence among all viral genetic subtypes of influenza; however, it is not clear that the type of immune response generated against those proteins will be sufficiently effective for approval by the U.S. Food and Drug Administration (“FDA”).

We believe there is an opportunity to develop and market an improved vaccine to prevent influenza given the low overall efficacy of currently approved vaccines, especially in those populations with the highest needs: children under two years of age, adults older than 65 years of age and immunocompromised patients.

### ***Our Solution, NasoVAX***

NasoVAX is an influenza vaccine candidate that consists of a segment of the influenza viral genome packaged in an adenovector that is delivered intranasally. The power of our RespirVec platform, together with the intranasal route of administration, allows NasoVAX to mimic the typical route of infection taken by influenza viruses, potentially stimulating a highly robust and broad immune response as a result.

We believe NasoVAX has a number of important advantages over traditional vaccines, including the potential for:

- Rapid protection in a matter of days, rather than weeks, as demonstrated in preclinical studies
- Broader protection against changing virus strains, as demonstrated in preclinical studies
- Ability to elicit mucosal immunity at the site of influenza infection
- Ability to elicit strong cellular immunity, a T cell response, as demonstrated in Phase 2 clinical trials
- Immune activation at very low doses, as demonstrated in Phase 1 and Phase 2 clinical trials
- Manufacturing process in mammalian cells instead of chicken eggs allows for more appropriate glycosylation, which results in increased efficacy
- Production expected in less than half the time and at anticipated lower costs with greater worker safety compared to traditional egg-based manufacture

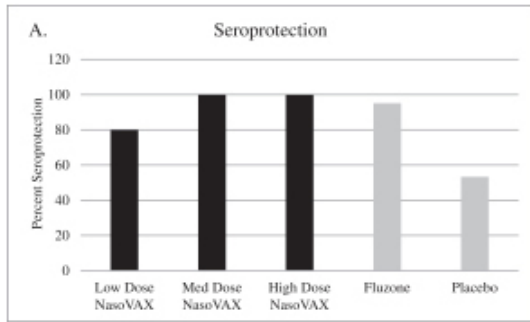
By employing our RespirVec platform and intranasal administration, we mobilize key elements of the adaptive immune system: not just the antibody-based response triggered by traditional vaccines, but also mucosal immunity to provide a first line of defense and cellular immunity to help control and clear the infection. In addition to this adaptive immunity, NasoVAX stimulates the rapidly acting innate immune response. The innate immune response generally occurs within hours of a pathogen invading, as the body’s first line of defense, and complements the longer-lasting pathogen-specific immunity generated by the other components of the immune system. Vaccine developers have long known of the importance of triggering innate immunity. Typically, this is accomplished through the use of adjuvants, which are often crude mixtures that are unrelated to the vaccine product itself. Because it is designed to activate the innate immune response, NasoVAX may act as its own adjuvant, potentially obviating the need for an additional adjuvant component to the vaccine. By triggering innate immunity, NasoVAX may confer rapid protection that complements the longer-lasting protection based on antibodies and cellular immunity.

### ***Clinical Data***

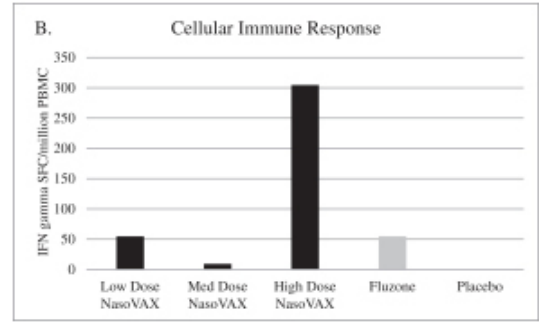
A Phase 2a clinical study of NasoVAX was conducted in 60 healthy young adult volunteers randomized to one of 3 doses of NasoVAX. Immunogenicity measures were also compared to those from 20 similar subjects

vaccinated in an open label study of Fluzone, an injectable influenza vaccine. 100% seroprotection was achieved in the two higher NasoVAX doses, compared to 95% seroprotection after Fluzone. Other antibody measurements were similar for Fluzone and the highest NasoVAX dose, and median cellular immune response 8 days after vaccination was over 5-fold higher with NasoVAX. Rates of local and systemic side effects were not statistically different than in placebo recipients and did not increase with dose.

**Phase 2 clinical results**



**Figure 1A. Seroprotection 28 days post-vaccination**



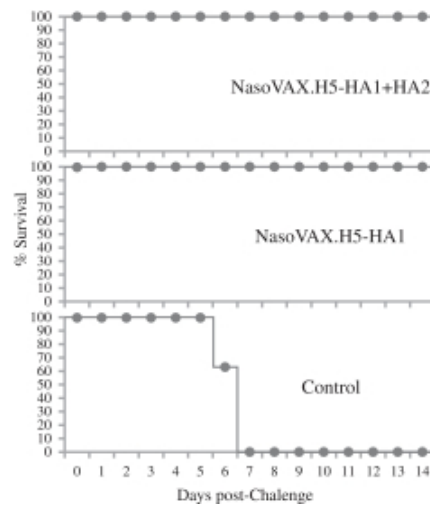
**Figure 1B. T cell immunity 8 days post-vaccination**

Source: Company data

**Preclinical Data**

NasoVAX directed against influenza H5N1, commonly referred to as bird flu, results in 100% survival in a ferret model of H5N1 infection that, in the absence of an effective vaccine, leads to 100% mortality within seven days. We believe that this may potentially translate into better protection for humans as well.

**NasoVAX protects ferrets from H5N1 bird flu**

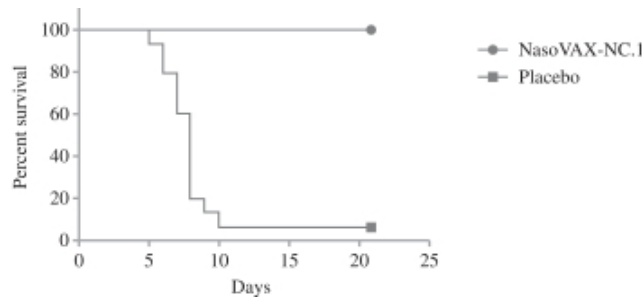


**Figure 2. Protection of ferrets from bird flu H5N1 infection by NasoVAX**

Source: Company data

In preclinical models, NasoVAX vaccines lead to protection against influenza across dissimilar influenza strains. Vaccination of mice with NasoVAX directed against influenza strain A/New Caledonia/20/1999 provided complete protection from a lethal viral challenge using a divergent strain, A/California/04/2009, to which a traditional vaccine for A/New Caledonia/20/1999 would have offered very little cross-protection. This type of activity may potentially provide increased efficacy in flu seasons when the vaccine developed is not a good match for the flu strain actually circulating.

**NasoVAX provides cross-strain protection**

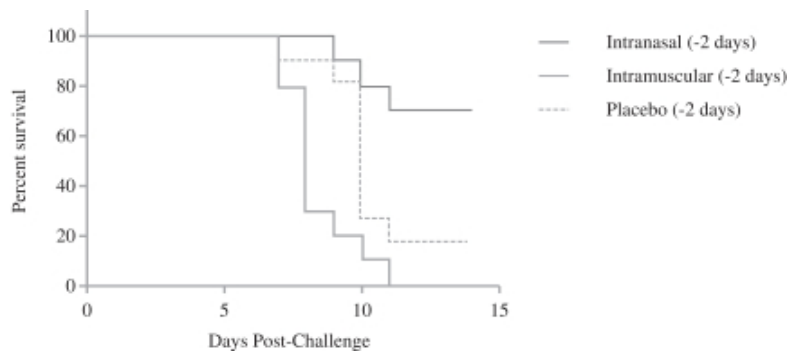


**Figure 3. Protection of mice against a divergent influenza strain not targeted by the vaccine**

Source: Company data

This protection may not only be due to the development of influenza-specific antibodies, but also to the stimulation of the innate immune system by NasoVAX. As shown in the graph below, mice receiving an intranasal administration of NasoVAX had superior rates of survival to the lethal challenge given just two days post-vaccination. These rates of survival at a near-term challenge indicate that NasoVAX activates the innate immune system. In contrast, in intramuscular administration of NasoVAX, the route used for most influenza vaccines, the effect was not observed.

**NasoVAX provides protection from influenza within 2 days**



**Figure 4. Rapid protection of mice from influenza after immunization with NasoVAX**

Source: Company data

The table below highlights certain features of NasoVAX identified during our preclinical studies and Phase 1 clinical trials and compares these with features of certain widely used commercially available influenza vaccines, and certain influenza vaccine product candidates we consider to be potential competitors to NasoVAX. Typically, the injected influenza vaccines that most people receive are either the killed or split vaccines as

illustrated below. The live attenuated vaccine referenced below is currently the only approved intranasal vaccine. The recombinant/virus like particle (“VLP”) vaccine category includes approved and Phase 2 development-stage influenza vaccines, while the bacterial category is another Phase 2 development-stage vaccine. Taken together, these feature comparisons suggest that NasoVAX potentially offers advantages over each of these products and product candidates in speed of response, multi-faceted response, ease and convenience of administration, speed and ease of manufacturing, and ability to protect against a broad range of flu viruses.

**Comparison of influenza vaccine profiles**

Desired Qualities	Killed	Split	Live	Plant-based	Bacterial	Recomb. or VLP	NasoVAX
Cell-based production	-	-/✓	-	-/✓	-/✓	✓	✓
Fast production cycle	-	-	-	✓	-	✓	✓
Non-invasive route	-	-	✓	-	-	-	✓
Mucosal immunity	-	-	✓	-	-	-	✓
Broad strain coverage	-	-	-	-	-/✓	-	✓
Rapid onset of protection	-	-	-	-	-	-	✓
Self-adjuvanting	-	-	✓	-	-	-	✓

**Table 1. Flu vaccine competitive landscape**

*Source: Company and publicly available data. Findings not based on head-to-head comparative preclinical or clinical trials.*

**Clinical Trial Plan for NasoVAX**

Our Phase 2 clinical trial program for NasoVAX for the treatment of seasonal influenza commenced in the third quarter of 2017 completed enrollment in the fourth quarter of 2017 and reported data in the first quarter of 2018. This trial extended the previous dose ranges tested and evaluated both antibody and cellular immune responses. 100% of subjects in the two highest dose groups achieved seroprotective antibody levels to the matched strains and strong cellular immune responses were seen in the highest dose group. Final data to include durability of immune response is expected to be available in mid-2018.

We are also planning two additional trials as part of our Phase 2 program. One is a dose ranging trial of a quadrivalent NasoVAX vaccine in healthy adult subjects stratified by age to include healthy elderly subjects. This vaccine will include H3 and B strains in addition to the H1 influenza strain evaluated in the recent Phase 2a study. The subjects will be assessed for antibody response and other measures of immunogenicity one-month post vaccination, as well as be regularly monitored for duration of response. We anticipate commencing this trial in the first half of 2019 and expect immunogenicity data in the second half of 2019, with additional safety and durability data to follow. We plan to use the results of this trial to select dosing for a larger dose confirmation trial.

**HepTcell**

HepTcell is an immunotherapy product candidate directed against multiple HBV genotypes. HepTcell is a completely synthetic peptide product candidate based on our proprietary Densigen technology which we believe may help the immune system destroy infected cells and clear chronic HBV infection. In July 2015, we commenced a Phase 1 trial of HepTcell in the United Kingdom and South Korea in patients chronically infected

with HBV. HepTcell was well tolerated but elicited HBV specific cellular immune responses were not significantly different than placebo. We plan to complete evaluation of other immune and virologic measures in these study subjects and will report the end of study results later this year.

### ***Chronic Hepatitis B Overview***

Hepatitis is an inflammation of the liver usually caused by a viral infection. There are five main unrelated hepatitis viruses, referred to as types A, B, C, D and E. Hepatitis is categorized as acute when it lasts less than six months and chronic when it persists longer. In particular, types B and C lead to chronic disease in hundreds of millions of people and, together, are the most common cause of liver cirrhosis and liver cancer.

HBV is the most common cause of viral hepatitis and is spread through blood products, contaminated needles or sexual contact, and from mother to infant. HBV infections are particularly endemic in Southeast Asia, sub-Saharan Africa, the Amazon basin, parts of the Middle East and in some Eastern European countries, where 70% – 90% of the population is infected before the age of 40. Even though prophylactic vaccination programs have led to declines in HBV infections in many countries, chronic infection remains a significant problem in certain areas.

Most adults infected with HBV recover naturally; however, according to the Hepatitis B Foundation, five to ten percent of infected adults go on to develop chronic infections. CHB infection is a major worldwide health care challenge with approximately 257 million people worldwide chronically infected, resulting in 857,000 HBV-related deaths per year due to cirrhosis, liver failure and hepatocellular carcinoma.

The management of CHB has improved dramatically in the last 20 years, owing to the development of new small molecule antivirals directed against the HBV polymerase protein. While these therapies can effectively suppress HBV replication, they do not result in eradication of the virus and therefore their administration can rarely be discontinued. They reduce but do not eliminate the risk of HBV related complications.

Therapeutic vaccination is a promising immunotherapeutic approach to induce immune control over the disease. CD4+ and CD8+ T cell responses have been shown to be critical for clearance of acute HBV infection and immune control can be linked to the strength and quality of HBV-specific T cell responses.

CHB patients are known to have profound defects in anti-HBV-specific T cell immune responses, termed immunotolerance, thereby compromising critical protective and disease control mechanisms. We believe that a treatment like HepTcell, which has been shown in preclinical studies to stimulate the HBV-specific T cell response, could help destroy infected cells and clear chronic HBV infections.

### ***Our Solution, HepTcell***

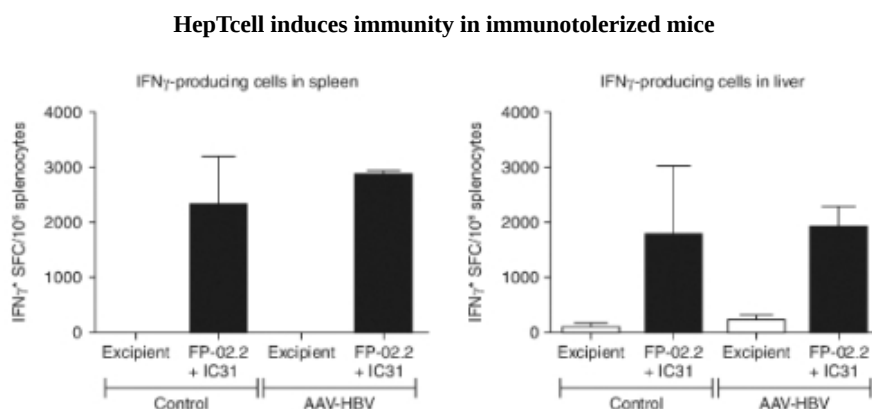
In HepTcell, specific viral peptide sequences, chosen for their ability to elicit broad human leukocyte antigen (“HLA”) type-independent immune responses, are coupled to a fluorocarbon chain so that, upon administration, the immunotherapy creates a short-term depot, which we believe will lead to a strong and sustained activation of the immune system. The final study product consists of a mixture of nine peptides between 32 and 40 amino acids long that are designed to be effective across the full spectrum of HBV genotypes. The peptides were selected using bioinformatics and validated using *in vitro* screening of immune responses from blood of HBV-infected patients. We believe that our synthetic HepTcell product candidate, if approved, could be produced by commodity peptide manufacturers around the world according to a robust and cost-effective process.

Everyone’s immune system responds differently to stimuli due to innate differences in HLA type, a shorthand expression for the proteins that, in part, make up the immune system and that vary from individual to individual. For this reason, organ transplants have to be matched carefully to avoid rejection. The HLA type

determines how each person's unique immune system will react to immunotherapy, leading to differing levels of efficacy. The discovery of the Densigen technology, on which HepTcell is based, has potentially solved the problem of HLA restriction, with the possibility that nearly all patients may benefit from immunotherapy without a need for matching. In addition, we believe that HepTcell has potential advantages over therapeutic vaccines under development for CHB because it is based on the incorporation of highly antigenic sequences that appear to be constant across multiple HBV strains or genotypes.

**Preclinical Data**

In our preclinical studies, mice immunized with HepTcell generated a robust T cell response. In one study, we tested HepTcell in a mouse model that reflects the HBV-induced immunotolerance seen in the clinical setting. Mice in the active arm were infected at week 0 with a vector that expresses all of the HBV proteins (AAV-HBV), and control mice received saline. Both active and control arms were subsequently treated at weeks 12, 14, 16 and 21 with HepTcell immunotherapy combined with the adjuvant IC31. At week 23 strong HBV-specific T cell responses in the spleen and liver were measured through detection of IFN $\gamma$ -secreting T cells.



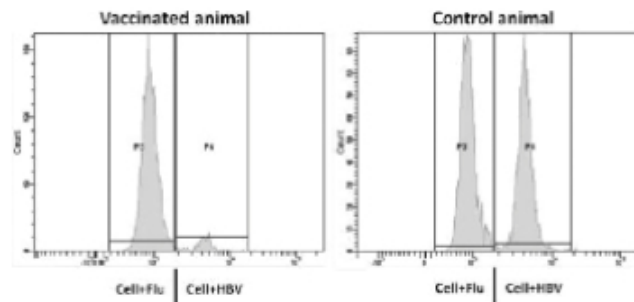
**Figure 5. HepTcell with IC31 adjuvant breaks immune-tolerance and induces a robust immune response in both the spleen and the liver in a murine model of chronic HBV infection**

Source: Company data

The results demonstrate that a robust immune response may be induced by HepTcell independent of HBV-mediated immunotolerance. We believe this response is characterized not just by a sufficiency of activated T cells, but also by the strength of recognition which governs the T cell's ability to effectively eliminate HBV-infected cells. By combining HepTcell together with the adjuvant IC31, we increased the magnitude of the immune response up to three-fold. We chose IC31 because it is a fully synthetic adjuvant consistent with the synthetic nature of HepTcell itself. A synthetic adjuvant provides consistent quality and has a better controlled manufacturing process, in contrast to many adjuvants that, while effective, are comprised of undefined mixtures of natural substances.

HBV replicates only in humans and other primates. Accordingly, we conducted an *in vivo* proof of concept study where it loaded rodent cells with either HBV proteins or proteins from an unrelated pathogen, influenza. We then injected these cells into mice that had been previously administered HepTcell to assess *in vivo* cell killing activity in the treated mice. Within one day, 91.7% of HBV loaded cells were eliminated compared to control cells loaded with proteins from the unrelated pathogen. These preclinical study results show the possibility of HepTcell to recognize and kill cells containing HBV proteins.

### HepTcell induces specific killing of autologous HBV-loaded cells



**Figure 6. HepTcell therapy allows the *in vivo* recognition and cell killing of HBV-loaded cells in mice**

Source: Company data

#### **Clinical Trial Plan for HepTcell**

We launched a Phase 1 trial in July 2015 in the United Kingdom and South Korea and enrolled 60 chronically infected HBV patients with controlled disease under standard of care. The primary objective of the trial was to assess the safety and tolerability of HepTcell. As a secondary objective, the trial measured the immune response induced by HepTcell following administration. The trial evaluated two dose levels, both with and without a novel adjuvant, compared to placebo and adjuvant alone. Each cohort received three doses of HepTcell, at days 1, 29 and 57, and assessed T cell response and HBsAg and HBsAg-antibody levels over a six-month period. We are also measuring the phenotype of cell-mediated immune response that is induced by the immunotherapy. The vaccine was well tolerated and was not associated with hepatic flares. Although the blinded results available at the end of 2017 demonstrated increases in Tcell response in higher dose cohorts, which both contained controls, the unblinded data was inconclusive, with similar results between treated patients and controls. We plan to complete evaluation of additional immunologic and virologic data from these subjects by the end of 2018. There can be no assurances we will continue the development of HepTcell or any other Densigen based product candidate.

#### **Our Anthrax Vaccine Franchise**

NasoShield is a preclinical vaccine product candidate based on our RespirVec technology encoding the *Bacillus anthracis* protective antigen. In a head-to-head comparison with the existing approved anthrax vaccine in a gold-standard animal model, a single dose of NasoShield showed complete protection from inhalation anthrax and was non-inferior to multiple doses of the existing approved anthrax vaccine while providing for a more rapid and stable immune response. We estimate that annual sales in the United States of the existing approved anthrax vaccine are approximately \$300 million. We have developed the product candidate with the support of BARDA, and, subject to their continued financial and other support, we launched a Phase 1 trial with NasoShield in first quarter of 2018 and are anticipating data from this trial midyear 2018. Previous work related to the development of NasoShield was also supported by NIAID.

In addition, we have a second anthrax vaccine candidate, SparVax-L, that is based on a recombinant protein technology encoding the *Bacillus anthracis* protective antigen. In a head-to-head comparison with the existing approved anthrax vaccine in a gold-standard animal model, two doses of SparVax-L showed complete protection from inhalation anthrax and was non-inferior to two doses of the existing approved anthrax vaccine. We have also shown extended shelf life both at room temperature (at least 24 months) and refrigerated temperatures (at least 6 years). The recent preclinical work also showed a greater protective antibody response than the currently licensed vaccine in that head-to-head study.

### **Anthrax Overview**

Anthrax is a disease that arises from infection with a bacterial pathogen, *Bacillus anthracis*. Anthrax can be spread by inhalation of bacterial spores which can be released from infected livestock or livestock products; however, this is extremely rare. The greater fear, and key driver for development of anthrax vaccines, is the potential use of anthrax spores by bioterrorists. The bacterial spores are readily aerosolized and could be used against the military or civilian population. Without timely treatment, inhalation anthrax is almost always fatal, and antibiotic treatment is significantly less effective if not initiated shortly after infection. The U.S. government has made significant investments in ensuring that appropriate countermeasures are in place to prevent and treat these infections. Individuals at high risk, such as active duty military personnel, are routinely vaccinated as a preventative measure, and the government stockpiles adequate doses of vaccine for distribution to the broader population in case of a bioterrorism attack.

Anthrax Vaccine Absorbed trade name BioThrax, is a protein-based vaccine produced from culture filtrates of an avirulent, non-encapsulated strain of *Bacillus anthracis*. For pre-exposure prophylaxis, it is given as a series of three intramuscular injections at zero, one and six months, at which point the vaccinated subject is considered protected. These initial injections are followed by two additional injections over the next year and yearly booster immunizations thereafter. BioThrax is the only anthrax vaccine approved by the FDA and had sales of \$287 million in 2017. In a BioThrax study, approximately 60% to 80% of recipients experienced injection site adverse events following the first dose of the vaccine, primarily tenderness, erythema (skin rash), edema (fluid accumulation under the skin), warmth, induration (skin thickening), pain and itching. BioThrax is currently only given to high risk individuals, such as U.S. military personnel, and a significant number of those individuals have refused the vaccine in past voluntary programs, presumably because of the lengthy immunization procedure and documented adverse events. Thus, we believe that there is a market opportunity for a more effective, safer and more convenient anthrax vaccine to expand beyond the current market.

### **Our Solution, NasoShield**

NasoShield is a vaccine product candidate based on our RespirVec technology encoding the anthrax protective antigen. In a head-to-head comparison with the existing approved anthrax vaccine in a gold-standard animal model, a single dose of NasoShield showed complete protection from inhalation anthrax and was non-inferior to multiple doses of the existing approved anthrax vaccine while providing for a more rapid and stable immune response. We have developed the product candidate with the support of BARDA, and, with their continued financial and other support, we launched a Phase 1 trial with NasoShield in the first quarter of 2018. Previous work related to the development of NasoShield was also supported by NIAID.

NasoShield is an anthrax vaccine product candidate based on the RespirVec platform and contains the coding region for the PA83 protective antigen from *Bacillus anthracis*. We believe NasoShield has advantages over the existing anthrax vaccine, as suggested by our preclinical studies, including the potential for:

- Efficacy with a single intranasal dose versus multiple injections
- Critical threshold of immunity reached in half the time of BioThrax
- Protection for at least one year from a single administration

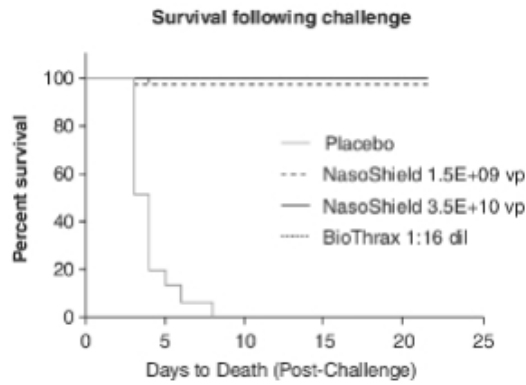
These potential advantages of NasoShield, together with its convenient nasal delivery and robust, scalable manufacturing process, lead us to believe that NasoShield has the potential to be an important next generation anthrax vaccine.

### **Preclinical Data**

Vaccination of animals with a single intranasal dose of NasoShield followed by spores via inhalation after 70 days resulted in statistical non-inferiority for survival relative to two doses of BioThrax, meaning that one



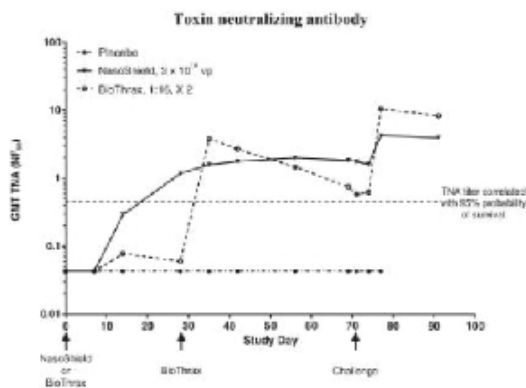
dose of NasoShield provided no worse protection than two doses of BioThrax, with survival rates between 97% and 100%. In these experiments BioThrax was delivered by two intramuscular injections separated by 28 days.



**Figure 7. Non-inferiority of NasoShield vs. BioThrax in a rabbit inhalation anthrax model**

Source: Company data

NasoShield vaccination in this preclinical study also demonstrates an important advantage over BioThrax, because the protective neutralizing antibody titer rises faster and has greater persistence than the immune response induced following vaccination with BioThrax. The level of antibody present within two weeks of NasoShield dosing is consistent with the level associated with 95% probability of survival in this study. As shown in the graph below, NasoShield also leads to the generation of an antibody response that is relatively consistent between 28 and 70 days prior to the lethal anthrax challenge, while the response to BioThrax is much less durable.



**Figure 8. Time course of anthrax antibody development**

Source: Company data

### Clinical Trial Plan for NasoShield

In July 2016, we were awarded a \$120.2 million, five-year contract from BARDA to advance NasoShield into clinical development. The award was increased to \$127.5 million in March 2017. We commenced a Phase 1 trial in the first quarter of 2018 with preliminary data expected midyear 2018. This study is a double-blind placebo controlled dose-escalation study evaluating safety and immunogenicity of NasoShield in healthy volunteers. It will also include a randomized open-label BioThrax comparator arm. The primary endpoint of the

trial is safety; we will also assess immunogenicity as a secondary endpoint. The trial is expected to take approximately 18 months to complete.

**SparVax-L**

In September 2014, we signed a contract with NIAID that funds the preclinical development SparVax-L. Data generated to date demonstrates that the recombinant protective antigen protein can be stably formulated in a lyophilized state for extended storage at room temperature, and even longer at refrigerator temperature. Formulation of SparVax-L for long shelf life also increased the potency of vaccine such that in a preclinical model greater immunogenicity was observed compared to identical doses of a previous formulation of the antigen shown to be well-tolerated and immunogenic in earlier clinical studies. The next phase of the program is a demonstration of the final form of the vaccine in a single unit, dual-chambered syringe designed for simpler storage and ease of use. All of the necessary components of the vaccine will be contained in a single logistics transport and storage will be greatly improved. Animal efficacy studies demonstrated that the vaccine is efficacious even after storage at room temperature, and a repeat dose toxicology study of SparVax-L showed the vaccine to be well-tolerated. These data can be used in support a filing with the FDA to update the SparVax® IND, which is currently on clinical hold, to allow for the commencement of a subsequent clinical trial.

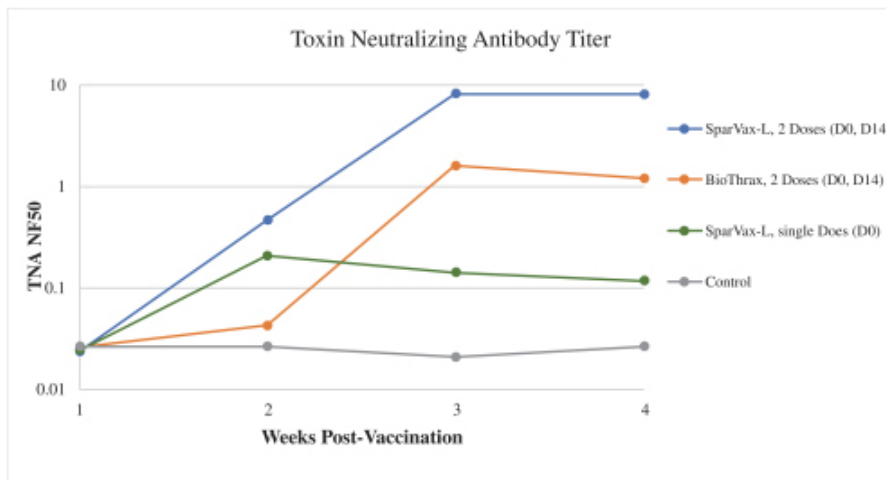
In late 2017, we initiated an additional preclinical study to demonstrate that a two-dose regimen of SparVax-L was able to protect animals at least as well as the currently licensed vaccine. In fact, we showed that a single dose resulted in 67% survival and a two-dose regimen achieved 100% survival, and also induced greater toxin neutralizing (protective) antibodies than the currently licensed vaccine.

**Survival Following Challenge**

Group	Survival at Day 42
SparVax-L, Two Doses (D0, D14)	100
BioThrax, Two Doses (D0, D14)	96
SparVax-L, Single Dose (D0)	67
Control	0

Source: Company data

**Pre-challenge TNA Response to Vaccination**



Source: Company data

## **Our Technology Platforms**

Our product candidates are based on two complementary technology platforms: RespirVec and Densigen. Our respiratory anti-infective product candidates are derived from our RespirVec platform, in which rapid as well as long-term immune protection is elicited by intranasal delivery of adenovectored pathogen sequences. We are targeting chronic diseases using our Densigen platform which recruits T cells to generate a sustained response to intracellular targets.

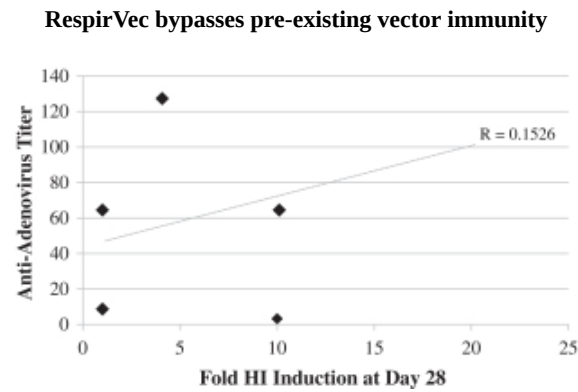
### ***RespirVec***

Our RespirVec platform consists of our proprietary process related to intranasal delivery of replication-deficient adenoviruses and is comprised of patents that we own or license. RespirVec is a viral vector based on a modified version of adenovirus that is used to deliver selected antigens to the immune system so that a robust response can occur. Our RespirVec technology has important potential advantages compared to other vaccine platforms. The ability of vaccines based on the RespirVec platform to induce mucosal immunity, as shown in our preclinical studies, is an important differentiator, as mucosal immunity is generally considered to be desirable for protection against respiratory pathogens. In addition, by using an adenovirus to enter the cell, we trigger the activation of local innate immunity, further boosting the immune recognition and response to the antigen expressed by the vector, essentially creating an adjuvant-like effect. Because the innate immune response can occur very quickly and is broad in its specificity, this immune response has the potential to provide a rapidly developing line of protection against divergent strains of a virus. Unlike most other vaccines, immunotherapies based on RespirVec enter the cells of the upper respiratory tract and express the antigen intracellularly, just as occurs during an actual respiratory infection. This allows the immune system to recognize the pathogen in the same context as a natural infection and as a result a more natural and robust immune response may be elicited that includes not only the humoral response of traditional vaccines, but also activation of the T cell and mucosal components of the immune system. Traditional vaccines are based on proteins rather than a viral vector and consequently rely primarily on the immune system's antibody response, rather than the type of broad immune involvement seen with RespirVec technology.

Key aspects of our RespirVec technology, supported by our preclinical studies and clinical trials, include:

- Intracellular expression of the vaccine antigen for authentic immune presentation;
- Mobilization of the innate, cellular and mucosal immune systems, not just the antibody-based response triggered by conventional injectable vaccines;
- Self-adjuvanting adenovector delivery system with the potential to improve immunogenicity;
- Recombinant vaccine manufactured in cell culture which avoids potential mutations during production and has shown higher efficacy than egg based manufacturing processes;
- Rapid production cycle at anticipated lower costs.

Adenovirus, when unmodified, is one of the causes of the common cold and as such it is well-suited for delivery of antigens using the intranasal route of delivery. One potential disadvantage associated with the use of adenovirus-based vectors is that pre-existing antibodies against the vector, either as a result of previous natural infections or prior therapy with the vector, may interfere with the ability of the vector to express the pathogen. Importantly, these negative effects have been primarily observed following intramuscular injection of similar vectors. Utilizing the intranasal route of delivery seems to bypass this effect, as demonstrated by us and others in preclinical models. We have also observed this in our Phase 1 seasonal influenza trial, where there was no correlation between the amounts of pre-existing adenoviral antibodies in study subjects and the ability of those subjects to generate influenza-specific antibodies when NasoVAX was dosed intranasally.



**Figure 10. Lack of correlation between anti-adenovirus antibody titer and immune response to NasoVAX**

Source: Company data

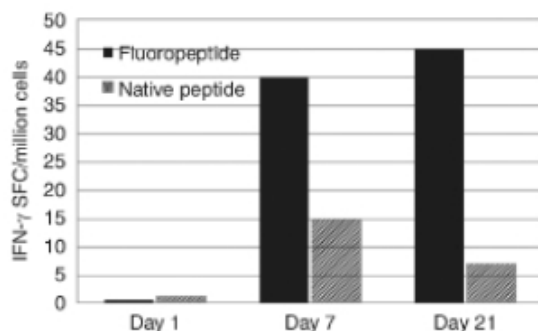
The graph above plots the level of anti-adenovirus titer versus hemagglutinin inhibition, a measure of vaccine activity. If a correlation existed between the level of pre-existing anti-vector antibody and vaccine activity, one would expect the data points in the graph to follow a trend where a point with a high anti-adenovirus titer would also have a low fold HI, yet this was not observed. For example, the two data points with the highest anti-adenovirus antibody level had the highest vaccine activities in one case and one of the lowest vaccine activities in the other case, indicating a lack of association. These results suggest that the presence of adenovirus neutralizing antibodies may not negatively impact the efficacy of intranasally delivered RespirVec-based vaccines.

Our experience suggests that vaccines based on the RespirVec technology can be developed through a simple, fast, safe and relatively inexpensive manufacturing process, which would be an advantage over most other influenza-based vaccine products. Because the manufacturing process uses recombinant DNA to synthesize pathogen-optimized products, manufacturing RespirVec-based products can be done potentially more rapidly than other vaccine types without the need to grow or handle dangerous pathogens. We believe that our RespirVec technology also lends itself to manufacture in smaller scale bioreactors, which may yield millions of doses without the need for large cell culture or egg-based production facilities. The ability to manufacture in cell culture instead of chicken eggs is proving to provide increased efficacy with influenza vaccines.

### **Densigen**

We developed antigens consisting of 30 – 40 amino acid long synthetic peptides that encode a high density of CD4 and CD8 T cell epitopes that are selected to broaden the HLA class reactivity of the product. We refer to these high-density antigens as Densigen, which are covered by patents owned by us. Immunotherapeutic product candidates based on our Densigen technology contain a collection of carefully selected Densigen that are designed to elicit activity across multiple targets for the disease. Synthetic peptide-based antigens have potential advantages over viral or recombinant protein antigens because they may be able to be manufactured at large scale with high purity. However, the development of peptide-based vaccines has been limited due their relatively low immunogenicity in the absence of adjuvants. As demonstrated in preclinical studies, we have enhanced the ability of Densigen peptides to elicit an immune response by attaching a biologically inert fluorocarbon chain to each peptide, resulting in a depot effect. This effect can be seen in the figure below where the T cell immune response is significantly greater in animals treated with the fluorocarbon-containing peptide than in those treated with peptide without the fluorocarbon chain (native peptide).

### Densigen technology improves T cell immunogenicity



**Figure 11. Preclinical demonstration of the depot effect**

*Source: Company data*

This change in the chemical structure, in turn, drives the aggregation of these peptides into micelles, which are more stable and longer-lasting structures than naked peptides. This conformational shift into micelles provides a depot for these peptide antigens and protects them from proteolytic degradation and diffusion, thereby prolonging exposure to the immune system. Our studies also indicate that the aggregation-inducing properties of the fluorocarbon chain can be modified by pH and salt concentrations such that the vaccine product candidate can be maintained in a soluble format until after intramuscular administration.

The following is our illustration of a single Densigen peptide and the aggregate that it forms after intramuscular administration:



*Source: Company graphic*

### Applications of Our Technologies in Animal Health

Highly pathogenic strains of avian and swine influenza threaten the agricultural industry and are potential sources of genetic material that can lead to pandemic influenza outbreaks in humans. We have partnered with leading academic researchers and the United States Department of Agriculture to design and test the potential of our technologies in animal health and are encouraged by the results obtained to date.

We believe that applications in animal health provide potential out-licensing opportunities for our technologies and we continue to pursue animal health research using external sources of funding.

### 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 AstraZeneca, GlaxoSmithKline (“GSK”), Johnson & Johnson and Sanofi Pasteur, among others, compete in the influenza vaccine market. These companies compete with us with their greater experience and expertise in securing government contracts and grants 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 such as Novavax, which is developing an influenza vaccine; Inovio Pharmaceuticals, which is developing an HBV therapeutic vaccine; and Emergent Biosolutions, which manufactures the existing anthrax vaccine, PaxVax and Pfenex which are developing anthrax vaccines. Any of these smaller companies may develop competing products more rapidly than we do. A number of companies of varying sizes are also pursuing the development of a “universal” flu vaccine. In addition, we face substantial competition for government funding, particularly for our anthrax vaccine program.

### **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.

### **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 in the United States, Europe and Japan for influenza; 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 are the exclusive licensee of patents owned by the University of Alabama at Birmingham Research Foundation (“UABRF”). These patents are directed to topical noninvasive application of genetic vectors. These patents are issued in the United States and certain European countries, including Great Britain, France, Germany,

## [Table of Contents](#)

Italy, Netherlands and Spain, as well as other commercially relevant jurisdictions. The claims are 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. The ex-U.S. patents are expected to have an expiration date no earlier than May 2020, not giving effect to any potential extensions and assuming payment of all associated fees. The issued U.S. patents are expected to have an expiration date no earlier than August 2018, not giving effect to any potential extensions and assuming payment of all associated fees.

We are also the exclusive licensee of one issued U.S. patent application owned by the UABRF directed to mucosal application of genetic vectors. The claims are 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 has an expiration date no earlier than January 2020, not giving effect to any potential extensions and assuming payment of all associated fees.

On March 1, 1998, we entered into an exclusive license agreement with the UABRF, which was amended and restated on June 2, 2014 and further amended as of October 16, 2015, 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 are pending or have been granted. The UABRF reserved non-commercial rights customarily reserved by academic licensors and rights outside the field of use. Although the UABRF retained primary responsibility for the filing, prosecution, maintenance and defense of the licensed patents, we have the right to review and comment on all patent protection activities and we agreed to reimburse the UABRF for the cost of such activities.

In connection with the original license, we paid an up-front license fee and issued 119,550 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 are 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 \$478,000 under the agreement, including promissory notes to UABRF in connection with the license agreement that have since been repaid, and an additional \$94,000 in fees that were converted to equity.

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. In addition, UABRF may terminate the agreement if by the earlier of (i) the end of the third calendar year after the first commercial sale of a licensed product and (ii) January 1, 2023 (as extended by the October 2015 amendment), 50% of the minimum royalty payments due in that year does not originate from net sales of licensed products. The agreement expires on the date upon which the last of the licensed patents expires.

### ***Adenovirus Vectored Vaccines — Adjuvant Combination***

We are developing technology directed to non-invasive administration of adenovirus vectored vaccines, for which a patent application is pending in the United States, Europe, Japan other commercially relevant jurisdictions. The claims are directed to methods for increasing immunogenicity of an adenovirus vectored vaccine with a double stranded RNA polynucleotide adjuvant. If issued, the patent(s) resulting from the pending patent application and future patent applications, if any, are expected to have an expiration date no earlier than September 2034, not giving effect to any potential extensions and assuming payment of all associated fees.

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

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

The Janssen patent rights include patents issued in the United States, of which one family of patents is expected to have an expiration date no earlier than March 2017 and another no earlier than April 2020, in each case not giving effect to any potential extensions and assuming payment of all associated fees.

We entered into an amended agreement with Janssen, effective as of October 4, 2005, which amended and restated our prior license agreements with Janssen. Under the amended 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 FDA approval of licensed products, 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 \$2.1 million in cash and equity under the agreement.

We may terminate the Second Restated License Agreement without cause, and the agreement contains customary provisions for either party to terminate prior to the expiration of the agreement. The Second Restated 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. Upon expiration of the amended agreement, or if we terminate the amended agreement for Janssen's material breach, we retain the right to exploit the rights granted.

We further amended our agreement with Janssen, effective as of September 25, 2015, primarily to streamline our manufacturing license arrangements. Prior to this amendment, we entered into three-party manufacturing license agreements with each manufacturer and Janssen. The 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.

## **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, Japan and certain European countries, including the United Kingdom, Germany and France. Additional patents are issued and/or patent applications are pending in other commercially relevant jurisdictions. The claims are directed to the fluorocarbon 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 acetic acid formulations of certain fluorocarbon antigen linked peptides. 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 rPA Platform Technology

Part of our value depends in part on our ability to obtain patents, to protect trade secrets, and to operate without infringing upon the proprietary rights of others. We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to the proprietary technology, inventions and improvements that are important to our business.

The following table identifies each of our material issued and non-abandoned patents and published pending applications, in order of importance to us:

<u>Patent/Patent Application</u>	<u>Patent Number/ Application Number</u>	<u>Country of Issue/Filing</u>	<u>Issue Date/File Date</u>	<u>Expiration Date</u>
Anthrax Vaccine Formulation and Uses Thereof	GB2009/051293	WO	October 2, 2009	October 2, 2029
	12/998245/9,616,117	U.S.	October 2, 2009	October 2, 2029
	2011-529634	Japan	October 2, 2009	October 2, 2029
	EP2344188	Europe	October 2, 2009	October 2, 2029
	2,738,621	Canada	October 2, 2009	October 2, 2029
	2009299615	Australia	October 2, 2009	October 2, 2029
	212118	Israel	October 2, 2009	October 2, 2029

In addition, we are a party to various exclusive and non-exclusive licenses, which provide access to intellectual property and know-how useful for our products. Some of our licenses, which generally extend for the life of any applicable patent, require us to pay royalties on sales of products that may be derived from or produced using the licensed technology.

We recently received trademark designation for SparVax and we also were recently notified of a notice of allowance for SparVax-L from the United States Patent and Trademark Office.

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 Product Candidates

#### *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, 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 a U.S. patent application which has been issued by the United States Patent and Trademark Office (“USPTO”) and includes claims directed to methods of non-invasive immunization by administering a non-replicating adenovirus vector expressing influenza antigens via intranasal administration.

### ***NasoShield and SparVax-L, Anthrax Vaccines***

We are developing a rapid and prolonged immunologic-therapeutic technology for anthrax, for which we have a patent granted in 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 also covered by an allowed US patent application. The allowed 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 resulting from this allowed patent application is expected to have an expiration date no earlier than July 2024, not giving effect to any potential extensions and assuming payment of all associated fees. The claims are directed to intranasal administration of a non-replicating adenovirus vector that contains and expresses anthrax spore protein antigens for use in preventing and treating anthrax infections. If issued, the patent resulting from this patent application is expected to have 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.

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

We are developing an HBV immunotherapy technology directed to compositions comprising fluorocarbon constructs with specific peptide HBV antigen sequences. Our patent applications covering this technology are pending in the United States, Europe and Japan, 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.

### ***Oncosyn, Therapeutic Cancer Vaccine***

We are developing a therapeutic cancer vaccine technology using compositions comprising at least two specific tumor peptide antigens, wherein those sequences comprise T cell epitopes. Our patent applications covering this technology are pending in the United States, Europe, Japan and other commercially relevant jurisdictions. If issued, the patent(s) resulting from the pending patent application and future patent applications, if any, are expected to have an expiration date no earlier than September 2034, not giving effect to any potential extensions and assuming payment of all associated fees. Oncosyn is also covered by the patents and patent applications relating to our Densigen platform technology.

### ***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**

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

On September 7, 2011, we signed a contract with the BARDA pursuant to which we are developing our NasoShield anthrax vaccine. That contract with BARDA was extended through September 2016. In July 2016,

## [Table of Contents](#)

we signed a new contract with BARDA, which was further amended on March 24, 2017. The five-year contract, valued at up to \$127.5 million, will fund clinical development of NasoShield.

Under the 2011 BARDA contract, BARDA paid 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 non-clinical assessment of efficacy, bio-distribution and toxicity, manufacturing process and development as required for IND application, regulatory review, and development of a Phase 1 dose ranging protocol to assess safety and immunogenicity. The 2011 BARDA contract was completed in September 2016. During the term of the 2011 BARDA contract, we received an aggregate of approximately \$17.8 million from BARDA.

Under the current 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 \$21.6 million in funding for the period July 2016 through July 2018. 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 the period July 2018 through July 2021. To date, we have received an aggregate of approximately \$9.3 million in revenue under the current BARDA contract.

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***

As a result of the Mergers on May 4, 2017, we acquired a contract with NIAID that funds the preclinical development SparVax-L. Data generated to date demonstrates that our rPA can be stably formulated in a lyophilized state for room temperature storage. The next phase of the program is a demonstration of the final form of the vaccine in a single unit, dual-chambered syringe designed for simpler storage and ease of use. All of the necessary components of the vaccine will be contained in a single logistics transport and storage will be greatly improved. Animal efficacy studies in 2016 preliminary data indicate that the vaccine is efficacious even after storage at room temperature. Additional non-clinical toxicology studies have been performed, which can support a filing with FDA to update the SparVax® IND to allow for the commencement of a subsequent clinical trial. In late 2017, we initiated an additional preclinical study to demonstrate that a two-dose regimen of SparVax-L was able to protect animals at least as well as the currently licensed vaccine. In fact, we showed that with a single dose, we obtained 67% survival and that with the two-dose regimen not only did we obtain 100% survival, but we obtained much higher toxin neutralizing (protective) antibodies than the currently licensed vaccine.

### **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”), and the Public Health Service (“PHS Act”), 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 approval must be obtained before clinical testing of biological products. FDA approval also 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 approval processes 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 “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 good laboratory practices (“GLPs”), 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 biological licensing 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, reports of the outcomes and full data sets of the clinical trials and proposed labeling and packaging for the product;
- 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’s identity, strength, quality and purity and, if applicable, the FDA’s current good tissue practices (“cGTPs”), for the use of human cells, tissues, and cellular and tissue-based products;

## [Table of Contents](#)

- 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. 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 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.

## [Table of Contents](#)

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, the National Institute of Health (“NIH”) 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.

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.

### **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, 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. 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, BLAs for seasonal influenza vaccines are currently required to be submitted annually, and we would expect the same requirement to be applicable to our influenza product candidate.

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 product fee for biologics and an annual establishment fee on facilities used to manufacture prescription 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, cGTP 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 PRV, the MCM application must be: (i) intended for use to prevent or treat harm from a biological, chemical, radiological, or nuclear agent (or 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 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.

The Animal Rule drug development pathway typically involves costs and time in excess of what would be expended in conducting human vaccine clinical trials not requiring compliance with the Animal Rule. There is an



## [Table of Contents](#)

alternative regulatory pathway available for biological warfare drug candidates, called Emergency use Authorization under the Project BioShield Act of 2004 (“Project BioShield”), which avoids the Animal Rule’s reliance on animal models focused on efficacy. We are seeking to rely upon Emergency Use Authorization, but there can be no assurance that this alternative model will apply to our anthrax vaccine product candidate.

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 detecting, 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.

### ***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 Health Care and Education Reconciliation Act in 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 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.

### ***FDA Fast Track 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 programs, one of which is fast track designation, are 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; in other words, the review cycle may have a six-month review clock instead of a twelvemonth review clock). Sponsors 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.

### ***Pediatric Exclusivity***

Under the BPCIA, which was part of the Health Care Reform Law, 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 under the BPCIA — 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 voluntary completion of a pediatric trial in accordance with an FDA-issued "written request" for such a trial. 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 candidates, and so pursuit of this incentive may be relevant to us.

### ***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 or a meaningfully different mode of administration. 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 Certain Federally Funded Programs, such as Medicare and Medicaid***

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 HHS the Office of the 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 directly or indirectly soliciting, receiving, offering or paying any remuneration with the intent of generating referrals or orders 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.

The Federal False Claims Act (“FCA”) is violated by any entity that “presents or causes to be presented” knowingly false 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. Under the federal FCA, relators can be entitled to receive up to 30% of total recoveries. Violations of the FCA can result in treble damages, and each false claim submitted can be subject to a civil penalty, which, for penalties assessed after January 29, 2018 whose associated violations occurred after November 2, 2015, ranges from a minimum of \$11,181 to a maximum of \$22,363 per claim. 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.

### ***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.

## [Table of Contents](#)

President Trump is seeking to repeal and replace the Health Care Reform Law. Repeal and replace legislation was passed in the House of Representatives, but did not obtain the necessary votes in the Senate. Subsequently, the President has affirmed his intention to repeal and replace the Health Care Reform Law and has taken a number of administrative actions to materially weaken the Health Care Reform Law. For example, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Health Care Reform Law to waive, defer, grant exemptions from, or delay the implementation of any provision of the Health Care Reform Law that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on December 22, 2017, President Trump signed the Tax Cuts and Jobs Act into law, which repealed the individual mandate of the Health Care Reform Law. The uncertain status of the Health Care Reform Law limits our ability to forecast changes that may occur in the future, and its repeal without adequate replacement may have a negative impact 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 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 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 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.

### ***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, including national and local regulations that govern our facility in France. 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. 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 xenogenic 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 xenogenic 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, 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. The agency'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. Applicants also may seek parallel scientific advice from the EMA and FDA. 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 28-member states of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be placed on the market after obtaining a Marketing Authorization, or MA. The MAA 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 marketing authorization:

- 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.
- National MAs, which are issued by the competent authorities of the member states of the EEA (for example, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom) 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. 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, 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 this 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 an NDA to the FDA.

### **U.S. Government Contracts**

Substantially all of our revenues to date have been derived from grants and U.S. 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.

The Company has been audited by BARDA through 2014 and has agreed on final indirect rates with the Defense Contract Audit Agency (“DCAA”) through 2011.

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.

## **Employees**

As of December 31, 2017, we had 30 full-time employees, 14 of whom hold M.D. or Ph.D. degrees and 15 of whom hold other advanced degrees. Of our total workforce, 22 are engaged primarily in research and development activities and eight are engaged primarily in executive, finance and accounting, and administrative functions. As of December 31, 2017, we had 24 employees in the United States and six employees in the United Kingdom. None of our U.S. employees 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 \$10.7 million and \$2.8 million during the years ended December 31, 2017 and 2016, respectively. For the year ended December 31, 2017, we recognized \$8.9 million and \$1.8 million as revenue from the BARDA and NIAID contracts, respectively. All of the contract revenues in 2016 were generated from our contract with BARDA.

## **Financial Information by Geographic Area**

For the years ended December 31, 2017 and 2016, all revenues were generated in the United States, which is our country of domicile. As of December 31, 2017 and 2016, long-lived assets with a net book value of \$23.4 million and \$600,000, respectively, were located in the United States. As of December 31, 2017 and 2016, long-lived assets with a net book value of \$15.9 million and \$33.3 million, respectively, were located outside of the United States.

## **Research and Development**

During the years ended December 31, 2017 and 2016, we spent approximately \$18.4 million and \$7.2 million on research and development activities, respectively.

## **Corporate Information**

We completed the Mergers between Private Altimune and PharmAthene in 2017. 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, with an additional operating site in London, United Kingdom. Our telephone number is (240) 654-1450, and our Internet website is [www.altimmune.com](http://www.altimmune.com) and our investor relations website is located under the “Investors” tab. The information on, or that can be accessed through, our website is not part of this annual report on Form 10-K and is not incorporated by reference herein.

“Altimune,” our logo and other trademarks, trade names or service marks of the Company appearing in this annual report on Form 10-K, including NasoVAX, HepTcell, RespirVec, Densigen, NasoShield and Oncosyn, are the property of the Company. The other trademarks, trade names and service marks appearing in this proxy statement/prospectus/consent solicitation are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this annual report on Form 10-K may appear without the ® or TM symbol.

## **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](http://www.altimmune.com)) as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We also make available on our website reports filed by our executive officers and Directors on Forms 3, 4, and 5 regarding their ownership of our securities. Our Code of Business Conduct and Ethics, and any amendments to our Code of Business Conduct and Ethics, are also available on our website under the “Investors” tab.

## [Table of Contents](#)

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

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

In addition to the other information included in this annual report on Form 10-K, 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.

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

***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 \$46.4 million for the year ended December 31, 2017 and a net loss of \$ 11.1 million for the year ended December 31, 2016. As of December 31, 2017, we have an accumulated deficit of \$77.9 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.

## [Table of Contents](#)

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:

- continues 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 2017, as a result of our declining share price, we tested our goodwill and indefinite-lived intangible assets for impairment both as of interim and at year end. Based on the result of the test, we have determined that that our goodwill was impaired. An aggregate impairment charge of \$35.9 million was recorded for the year, including an impairment charge of \$26.6 million recorded during the three months ended September 30, 2012. Any such significant write-downs of our long-lived assets in the future could adversely affect our balance sheet and results of operations.

***Our ability to continue as a going concern will require us to obtain additional financing to fund our current operations, which may be unavailable on acceptable terms, or at all.***

Our recurring operating losses and current operating plans raise substantial doubt about our ability to continue as a going concern. We expect to incur additional losses in the future in connection with our research

and development activities. As a result, our independent registered public accounting firms included an explanatory paragraph in their reports on our consolidated financial statements as of and for the years ended December 31, 2017 and 2016 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional financing to fund our current operating plans. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us. We believe that the net proceeds from the Mergers, our redeemable preferred stock offering in August of 2017 and our existing cash will be sufficient to fund our projected operating requirements at least through December 2018. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or terminate our research and drug development programs or commercialization efforts.

***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. 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, 2017, our cash balance was \$12.3 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 into the first quarter of 2019. 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;

## [Table of Contents](#)

- 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;
- the timing, receipt and amount of sales of, or royalties or milestone payments on, our future products, if any;
- the extent to which we acquire or license other products or technologies; and
- our ability to utilize net operating loss carryforwards.

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 the Company's 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.

***Conversion of the redeemable preferred stock has significantly diluted our common stock, and the continued installment payments or conversion of the redeemable preferred stock or exercise of the related warrants will further dilute our common stock and may have an adverse effect on the market price of our common stock.***

In August 2017, we issued and sold 15,656 shares of our redeemable preferred stock, initially convertible into 5,863,564 shares of our common stock (without regard to any limitations on conversion governing the redeemable preferred stock). In connection with the issuance of the redeemable preferred stock, we also issued warrants initially exercisable to purchase 2,345,427 shares of our common stock (without regard to any limitations on exercise set forth in the warrants). We cannot predict if and when the holders of redeemable



preferred stock and warrants may sell such shares of converted or exercised common stock. In addition, we owe installment payments to the holders of the redeemable preferred stock starting in December of 2017 and continuing until August of 2018. We have the option, subject to certain conditions, to meet our installment payment obligations with respect to the redeemable preferred stock by issuing shares of our common stock to the holders of the redeemable preferred stock at a conversion price based on the current market price at the time of the installment payment. The conversion price for the installment payments may be less than the fixed conversion price of the redeemable preferred stock of \$2.67 per share, resulting in increased dilution to our common stock. These issuances have resulted in, and, to the extent we continue to issue shares of our common stock to satisfy our installment obligations, will continue to result in substantial dilution to the holders of our common stock and may have an adverse effect on the market price of our common stock. Additionally, the conversion of shares of redeemable preferred stock into shares of common stock or the exercise of warrants for shares of our common stock will result in substantial dilution to holders of our common stock. Further, the sale of a significant amount of these shares of common stock in the open market or the perception that these sales may occur could adversely affect prevailing market prices of our common stock, including causing the market price of our common stock to decline or become highly volatile.

***The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law the TCJA, which significantly revises the Internal Revenue Code of 1986, as amended. The TJCA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse.

***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 \$24.5 million as of December 31, 2017. These net operating loss carryforwards will begin to expire at various dates beginning in 2020. As of December 31, 2017, after giving effect to new corporate tax rates prescribed by the TCJA, we have recorded a valuation allowance of \$13.8 million against our net deferred tax asset. The TCJA limits the amount of net operating losses that we are permitted to deduct in any taxable year to 80% of our taxable income in such year. The TCJA also eliminates the ability to carry back net operating losses to prior years, but allows net operating losses generated after 2017 to be carried forward indefinitely. As such, there is a risk that due to such items, our existing net operating losses could expire or be unavailable to offset future income. These new rules apply regardless of the occurrence of an ownership change.

***A tax examination recently initiated by the Internal Revenue Service could negatively affect our cash on hand or our tax attributes***

The Internal Revenue Service (the "IRS") has notified the Company that the IRS has begun a tax examination of PharmAthene's U.S. federal income tax return for the year ended December 31, 2016. The examination of PharmAthene's U.S. federal income tax return has just begun and so it is difficult to predict the outcome or consequences of such an examination. However, depending on the claims raised by the IRS and the

resolution of the examination, the Company could become responsible for additional tax liabilities, including potentially interest and penalties. Additionally, the examination could result in adjustments to the amount of tax attributes of the Company, including potential reductions in net operating losses of the Company or reductions of the tax basis in the assets of the Company. These consequences could have a material adverse impact on the Company's operations going forward. If we are assessed a significant tax liability, we would be forced to delay, reduce or eliminate some or all of our research and drug development programs or commercialization efforts. We could also be in default on certain of our contractual obligations.

***Because 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 early, small, proof-of-concept clinical trials with our NasoVAX influenza vaccine, and we are in Phase 1 clinical development with HepTcell and late-stage preclinical development with our NasoShield program. 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 vaccine 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 or execute under our NIAID contract acquired and assumed in connection with the Mergers. 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. In order to obtain regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. 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. Also, we may gain regulatory approval for our leading product candidates or our other preclinical product candidates in some but not all of the jurisdictions we seek to obtain regulatory approval. For example, failure to obtain regulatory approval of our products in any of the U.S., European or Japanese markets would materially and adversely affect the Company. Failure to obtain regulatory approval of some but not all of the target indications may result in limited commercial opportunity for the approved product. We may never obtain regulatory approval for these product candidates in any jurisdiction. We also may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy.

***We are heavily dependent on the success of our leading product candidates, NasoVAX and HepTcell, as well as SparVax-L acquired in connection with the Mergers. If we ultimately are unable to develop, obtain regulatory approval for or commercialize NasoVAX, HepTcell, SparVax-L, 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 RespirVec and Densigen platforms, including our leading product candidates, NasoVAX and HepTcell, and to progress those product candidates through clinical development for the treatment of different types of diseases. We are also focused on SparVax L acquired in connection with the Mergers. 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, NasoVAX and HepTcell, would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates.

***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 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 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;

## [Table of Contents](#)

- 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 participant may 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 candidates 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 IND submitted to the FDA.

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 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 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;

## Table of Contents

- 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 and Oncosyn, our product candidates 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. The safety of 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,

## [Table of Contents](#)

rather than in people with disease. As a result, although it is anticipated that HepTcell and Oncosyn are 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 AstraZeneca, GSK, Johnson & Johnson and Sanofi Pasteur, among others, compete in the influenza vaccine market. These companies have greater experience and expertise in securing government contracts and grants 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 have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete.

We also face competition from smaller companies such as Novavax, which is developing a recombinant influenza vaccine; Inovio Pharmaceuticals, which is developing an HBV therapeutic vaccine; Emergent Biosolutions, which manufactures the existing anthrax vaccine; and PaxVax and Pfenex, which are developing anthrax vaccines. Any of these smaller companies may develop competing products more rapidly than we do. A number of companies of varying sizes are also pursuing the development of a “universal” flu vaccine. In addition, we have substantial competition for government funding, particularly for our anthrax vaccine program. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before we do. In addition, any new product that we develop that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

***We 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 William Enright, our President and Chief Executive Officer, Dr. Sybil Tasker, our Chief Medical Officer and Senior Vice President of Clinical Research and Development, and Dr. M. Scot Roberts, our Chief Scientific Officer, as well as Dr. Bertrand Georges, our Chief Technology Officer and a key employee of the Company. 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. We maintain keyman insurance policies on Mr. Enright and Dr. Georges for \$2.0 million and £500,000, respectively, but not for any other member of our senior management or any other employee.

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.

***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.

#### **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.



## [Table of Contents](#)

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 NasoVAX influenza vaccine have been headache, 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 withdrawal 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 filed by the Company 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.

***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, 27 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 as apply to generic non-biologic products so no biosimilar product could be approved or placed on the market during the periods 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 applicable for a biosimilar product, and the twelve-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 voluntary completion of a pediatric trial in accordance with an FDA-issued “written request” for such trial. 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 or a meaningfully different mode of administration.

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, our anthrax vaccine product candidate, 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.

## [Table of Contents](#)

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 is insufficient for approval and require additional non-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those 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 detecting, 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.

***Expanding our operations internationally adds complexity to our operations and poses additional risks to our business.***

We acquired ITS on March 10, 2015 and subsequently renamed it Altimmune UK Limited. By acquiring Altimmune UK, we gained access to the Densigen technology and product candidates based on the Densigen platform, including HepTcell and Oncosyn. Historically, we have been engaged in business activities principally in the United States. Altimmune UK, together with its subsidiary, Altimmune France, marks our first significant direct entry into a foreign market (other than our joint ventures). Our business or financial performance may be adversely affected due to the risks of operating internationally, including but not limited to economic and political instability, failure to comply with foreign laws and regulations and adverse changes in the health care policies of the United Kingdom and European Union, adverse changes in law and regulations affecting the operations of Altimmune UK and Altimmune France going forward and difficulties and costs of staffing and managing our new operations in the United Kingdom and France. Additionally, we may in the future shut down or reduce our international operations, which would result in us incurring additional costs. If any of these events were to materialize, they could lead to disruption of our business, significant expenditures and/or damages to our reputation, which could have a material adverse effect on our results of operations, financial condition or prospects.

***Foreign currency exchange rate fluctuations could materially impact our consolidated financial position and results of operations.***

As a result of the expansion of our operations to the United Kingdom through our acquisition of Altimmune UK, a portion of our expenses and revenues are derived from operations in the United Kingdom, principally with respect to salaries and related personnel expenses associated with our research and development operations. We translate financial results denominated in foreign currency, primarily British pounds, into U.S. dollars for our consolidated financial statements. During periods of a strengthening U.S. dollar, our reported revenues and net income could be reduced because foreign currencies may translate into fewer U.S. dollars. To date, we have not engaged in any hedging strategies, and any such strategies related to transaction exposures, such as forward contracts, options and foreign exchange swaps, that we implement to mitigate this risk may not eliminate our exposure to foreign exchange fluctuations.

In all jurisdictions in which we operate, we are also subject to laws and regulations that govern foreign investment, foreign trade and currency exchange transactions. These laws and regulations may limit our ability to repatriate cash as dividends or otherwise to the United States and may limit our ability to convert foreign currency cash flows into U.S. dollars.

***We are subject to taxation in certain foreign jurisdictions due to the acquisition of Altimmune UK. Any adverse development in the tax laws of such jurisdictions or any disagreement with our tax positions could have a material adverse effect on our business, financial condition or results of operations. In addition, our effective tax rate could change materially as a result of certain changes in our mix of U.S. and foreign earnings and other factors, including changes in tax laws.***

We are subject to taxation in, and to the tax laws and regulations of, certain foreign jurisdictions as a result of our acquisition of Altimmune UK. Adverse developments in these tax laws or regulations, or any change in position regarding the application, administration or interpretation thereof, in any applicable jurisdiction, could have a material adverse effect on our business, financial condition or results of operations. In addition, the tax authorities in any applicable jurisdiction may disagree with the tax treatment or characterization of any of our transactions, which, if successfully challenged by such tax authorities, could have a material adverse effect on

our business, financial condition or results of operations. Certain changes in the mix of our earnings between jurisdictions and assumptions used in the calculation of income taxes, among other factors, could have a material adverse effect on our overall effective tax rate. In addition, legislative proposals to change the U.S. taxation of foreign earnings could also increase our effective tax rate.

#### ***Risks Related to Market Volatility and the Referendum of the United Kingdom's Membership of the European Union***

The United Kingdom held a referendum on June 23, 2016 in which a majority voted for the United Kingdom's withdrawal from the European Union (referred to as "Brexit"). As a result of this vote, negotiations have commenced to determine the terms of the United Kingdom's withdrawal from the European Union as well as its relationship with the European Union going forward, including the terms of trade between the United Kingdom and the European Union. The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Brexit could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and the European Union; however, the full effects of Brexit are uncertain and will depend on any agreements the United Kingdom may make to retain access to European Union markets.

In addition, we expect that Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting our industry, we could face significant new costs. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and European Union. Similarly, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining, maintaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the European Union will cease being enforceable in the United Kingdom absent special arrangements to the contrary, and we are required to refile our trademarks and other intellectual property applications domestically in the United Kingdom.

Lastly, as a result of the Brexit, other European countries may seek to conduct referenda with respect to their continuing membership in the European Union. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, the full extent to which our business, results of operations and financial condition could be adversely affected by Brexit is uncertain.

#### **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. The earliest any of our patents are scheduled to expire is August 2018.

***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. 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 obligations on the Company. 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;

## Table of Contents

- 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 the Company;
- 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 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 products to be disrupted, potentially for extended periods of time. 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 on it, 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 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 the Company. 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. The Company 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

## Table of Contents

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 the Company. 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



## [Table of Contents](#)

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 the Company, 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

## [Table of Contents](#)

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 the Company’s 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. For the years ended December 31, 2017 and 2016, BARDA funding for the development of NasoShield accounted for approximately 83% and 81% 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 in July 2016 we received a new BARDA contract that may fund our NasoShield anthrax vaccine program until 2021, the majority of the funds will be received during the final three years of the contract and are dependent on achieving the following 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.

***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, project tracking and earned-value management 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.

***Prior to the Mergers with PharmAthene, the NIAID notified PharmAthene that it will exercise only one of the additional remaining options under its contract.***

As part of the Mergers, we assumed PharmAthene's contract with NIAID. The NIAID contract is incrementally funded. Over the base period of the contract, PharmAthene was awarded initial funding of approximately \$5.2 million, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestones. NIAID exercised four options under this agreement to provide additional funding of approximately \$8.8 million and an extension of the period of performance through December 31, 2017. The contract has a maximum total value of up to approximately \$28.1 million if all technical milestones were met and all eight contract options were exercised by NIAID. In April 2017, PharmAthene was notified by NIAID that it will exercise only one of the additional remaining options under the contract to provide funding for a rabbit challenge study. Work under all exercised options will bring total committed and final funding under the NIAID contract to \$15.1 million. The recoverability of the acquired IPR&D intangible asset is dependent on future funding to support further development.

***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 21<sup>st</sup> Century Cures Act (“Cures Act”), was signed into law on December 13, 2016 and, among other things, includes a provision requiring timely and accurate recommended utilization guidelines for MCMs, including for products in the Strategic National Stockpile. The Cures Act requires HHS to report to the appropriate committees of Congress when funding in the SRF, available to 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 (“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 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. For example, BARDA audited indirect costs charged with respect to the SparVax® contract for the years 2008 through 2014.

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”);

## [Table of Contents](#)

- 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 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;
- 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 health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

***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.

President Trump is seeking to repeal and replace the Health Care Reform Law. Repeal and replace legislation was passed in the House of Representatives, but did not obtain the necessary votes in the Senate. Subsequently, President Trump affirmed his intention to repeal and replace the Health Care Reform Law and has taken a number of administrative actions to materially weaken the Health Care Reform Law. For example, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Health Care Reform Law to waive, defer, grant exemptions from, or delay the implementation of any provision of the Health Care Reform Law that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on December 22, 2017, President Trump signed the Tax Cuts and Jobs Act into law, which repealed the individual mandate of the Health Care Reform Law. The uncertain status of the Health Care Reform Law affects our ability to plan, and its repeal without replacement could have a material adverse effect on our United States operations.

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 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 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 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 companies such as the Company from directly or indirectly soliciting, receiving, offering or paying any remuneration with the intent of generating referrals or orders 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.

The FCA is violated by any entity that “presents or causes to be presented” knowingly false 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 (up to 30% of the government's recovery plus legal fees) 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, which for penalties assessed after January 29, 2018 whose violations occurred after November 2, 2015, ranges from a minimum of \$11,181 to a maximum of \$22,363 per claim. 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. 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). 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.

***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 Corporate Integrity Agreements and other arrangements, damages, monetary fines, disgorgement, 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

## [Table of Contents](#)

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 Common Stock and Capital Structure**

***Holders of our Series B redeemable convertible preferred stock (“redeemable preferred stock”) and the warrants issued in connection with the redeemable preferred stock have rights that may restrict our ability to operate our business or raise additional capital, and which may be adverse to holders of our common stock.***

The Certificate of Designations governing the redeemable preferred stock, as filed with the Secretary of State of the State of Delaware on August 21, 2017, contains a covenant that until the redeemable preferred stock is no longer outstanding, the Company shall maintain an unrestricted cash balance equal to the lower of \$3,500,000 or the amount of preferred outstanding at any given time. Further, additional provisions contained in the Certificate of Designations limit the Company’s ability to: (i) issue stock senior to or on parity with the redeemable preferred stock, (ii) incur indebtedness, with certain narrow exceptions, (iii) amend, modify, alter or supplement our articles of incorporation or the Certificate of Designations in a manner that would adversely affect the rights, preferences or privileges of the redeemable preferred stock, and (iv) pay distributions on, purchase or redeem our common stock or other capital stock. These restrictions could have a material adverse impact on our ability to operate and sufficiently fund our business.

Additionally, the redeemable preferred shares and the warrants are each subject to full ratchet 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 the conversion price of the redeemable preferred stock or the exercise price of the warrants, the conversion price of the redeemable preferred stock and the exercise price of, and the number of shares underlying, the warrants would be adjusted accordingly. These provisions may prevent us from raising additional capital on favorable terms during the period of time the redeemable preferred stock or the warrants are outstanding, or at all. If we cannot raise funds on acceptable terms, we may not be able to repay debt or other liabilities, develop our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures. Any of these events could adversely affect our ability to achieve our development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

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

During 2017, we completed the sale of our redeemable preferred shares under our “shelf” registration statement on Form S-3. 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



## [Table of Contents](#)

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.

### ***The concentration of the ownership of our common stock may limit the ability of other stockholders of the Company to influence corporate matters.***

Based on information filed with the SEC, the executive officers, directors, five percent or greater stockholders, and their respective affiliated entities beneficially own, in the aggregate, approximately 60% of our outstanding common stock (after giving effect to the maximum ownership limits in the Certificate of Designations and our outstanding warrants). As a result, these stockholders, acting together, may have control over matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other stockholders may view as beneficial.

### ***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, 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 NASDAQ on another exchange, our securities could be quoted on the OTC Marketplace or on the OTC Pink Marketplace. 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;

## [Table of Contents](#)

- 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.

### ***Our stock price is volatile.***

The market price of our common stock has been, and is expected to continue to be, subject to significant volatility. The value of our common stock may decline regardless of our operating performance or prospects. Factors that may affect our market price include:

- our perceived prospects, including but not limited to any changes in U.S. government funding of projects in which we participate;
- variations in our operating results and whether we have achieved key business targets;
- trading patterns by our stock holders;
- overhang of our convertible securities and downward pressure of future installment payments made in connection with our redeemable preferred shares;
- changes in, or our failure to meet, revenue estimates;
- changes in securities analysts' buy/sell recommendations;
- differences between our reported results and those expected by investors and securities analysts;
- announcements of new contracts or other developments by us or our competitors;
- reaction to any acquisitions, merger, joint ventures or strategic investments announced by us or our competitors; and
- general economic, political or stock market conditions.

### ***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 of \$29.10 per share of PharmAthene common stock paid on February 3, 2017, neither Private Altimune 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 6,210 square feet of laboratory and office space. Our lease term expires on October 31, 2018. We also have an office in London, United Kingdom. In June 2017, we entered into a new lease arrangement for 14,141 square feet of laboratory and office space also located in Gaithersburg, Maryland, to be used as our corporate headquarters with office and laboratory facilities. Upon completion of the laboratory and office space, all employees in the United States will relocate to the new headquarters and the lease agreement for the existing headquarters will be terminated. For additional information, see *Commitment and Contingencies*, Note 18 to our Consolidated Financial Statements.

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

**Item 3. Legal Proceedings.**

None.

**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.” The following table sets forth the range of high and low sales prices per share of our common stock for the past two years during the periods shown. The share prices below have been adjusted to reflect PharmAthene’s 10-for-1 reverse stock split effected immediately prior to the Mergers.

<u>Year Ended December 31, 2017</u>	<u>High</u>	<u>Low</u>
4th Quarter ended December 31	\$ 3.16	\$ 1.51
3rd Quarter ended September 30	\$ 3.40	\$ 2.01
2nd Quarter ended June 30	\$ 8.20	\$ 2.90
1st Quarter ended March 31	\$35.00*	\$ 4.70
<u>Year Ended December 31, 2016</u>	<u>High</u>	<u>Low</u>
4th Quarter ended December 31	\$33.00	\$27.00
3rd Quarter ended September 30	\$29.20	\$24.20
2nd Quarter ended June 30	\$24.90	\$19.10
1st Quarter ended March 31	\$20.30	\$15.00

\* The decrease in share price during the quarter ended March 31, 2017 reflected a one-time special dividend on PharmAthene common stock of \$29.10 per share paid by PharmAthene on February 3, 2017.

 **Holders**

As of March 30, 2018, we had 139 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 of \$29.10 per share (amount reflects PharmAthene’s 1-for-10 reverse stock split effected immediately prior to the Mergers) paid by PharmAthene on February 3, 2017, 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 the 2018 proxy statement under the heading “Report of the Compensation Committee of the Board of Directors” and is incorporated herein by reference.

### Recent Sales of Unregistered Securities

We have not sold any securities since the beginning of our most recently completed fiscal year that were not registered under the Securities Act of 1933, as amended. As discussed elsewhere in this annual report on Form 10-K, Private Altimmune completed several unregistered sales of securities prior to the completion of the Mergers.

### Use of Proceeds

Not applicable.

### Purchases of Equity Securities

Not applicable.

### Item 6. Selected Financial Data.

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes included in this annual report on Form 10-K and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this annual report.

We have derived the consolidated statement of operations data for the years ended December 31, 2017 and 2016, and the consolidated balance sheet data as of December 31, 2017 and 2016 from our audited consolidated financial statements, which are included elsewhere in this annual report on Form 10-K. We have derived the consolidated statement of operations data for the year ended December 31, 2015 and the consolidated balance sheet data as of December 31, 2015 from our audited consolidated financial statements that are not included in this annual report on Form 10-K. Our historical results for any prior period are not indicative of results to be expected in any future period.

	Year Ended December 31,		
	2017	2016	2015
<b>Statement of operations data:</b>			
Revenue	\$ 10,738,322	\$ 3,236,175	\$ 4,654,468
Operating expenses			
Research and development	18,406,329	7,221,460	5,063,650
General and administrative	8,457,557	7,106,378	6,178,829
Goodwill impairment charges	35,919,695	—	—
Total operating expenses	62,783,581	14,327,838	11,242,479
Loss from operations	(52,045,259)	(11,091,663)	(6,588,011)
Other (expense) income, net	(18,506)	4,851	(60,891)
Net loss before income tax benefit	(52,063,765)	(11,086,812)	(6,648,902)
Income tax benefit	5,638,375	—	—
Net loss	\$ (46,425,390)	\$ (11,086,812)	\$ (6,648,902)
Preferred stock accretion and dividends	(4,930,010)	(368,548)	(138,555)
Net loss attributed to common stockholders	\$ (51,355,400)	\$ (11,455,360)	\$ (6,787,457)
Weighted-average common shares outstanding, basic and diluted	12,805,095	6,911,534	5,759,615
Net loss per share attributable to common stockholders, basic and diluted	\$ (4.01)	\$ (1.66)	\$ (1.18)

	December 31,		
	2017	2016	2015
<b>Balance sheet data:</b>			
Cash, cash equivalents, and restricted cash	\$12,303,639	\$ 2,876,113	\$ 4,638,711
Working capital	19,626,166	(983,633)	1,820,260
Total assets	63,030,200	38,400,335	48,588,750
Total long-term liabilities	10,512,909	722,289	1,099,991
Redeemable preferred stock	9,281,767	—	—
Total stockholders' equity	39,395,823	32,207,323	43,134,633

## **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 on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. The words “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. We have included important factors in the cautionary statements included in this annual report on Form 10-K, particularly in the section entitled “Risk Factors” in Part I, Item 1A that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.*

*You should read this annual report on Form 10-K and the documents that we have filed as exhibits to this annual report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this annual report on Form 10-K are made as of the date of this annual report on Form 10-K and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.*

### **Overview**

Altimmune, Inc. is a clinical stage immunotherapeutics company focused on the development of products to stimulate robust and durable immune responses for the prevention and treatment of diseases. We have two proprietary platform technologies, RespirVec and Densigen, each of which has been shown, in preclinical studies and early clinical trials, to activate the immune system in distinctly different ways than traditional vaccine methods. Using these technologies, we have generated clinical product candidates which potentially represent an entirely new approach to harnessing the immune system. We have two programs using the Respirvec recombinant adenovirus technology. NasoVAX, an intranasally administered recombinant influenza vaccine, uses an adenovector to achieve expression of the influenza antigen in the target cell, thereby potentially stimulating a broader and more rapid immune response than traditional influenza vaccines. Our planned Phase 2 program for NasoVAX started in September 2017. Initial data, released in March 2018, indicated that NasoVAX was well tolerated at all doses tested, and achieved 100% seroprotection with the two higher doses. Final data from this study will be available in the third quarter of 2018 and we expect to move forward with continued development of a quadrivalent NasoVAX product candidate which we expect will be ready for clinical evaluation in early 2019. The second RespirVec product, NasoShield, is an anthrax vaccine designed to provide rapid, stable protection after one intranasal administration. We launched a Phase 1 trial for NasoShield in the first quarter of 2018 and anticipate topline data the third quarter of 2018.

With the support of NIAID, we are developing an alternative anthrax vaccine candidate, SparVax-L, a recombinant protein-based anthrax vaccine designed to require fewer doses and have a longer shelf-life than the only currently licensed anthrax vaccine. The shelf life of the liquid formulation was insufficient to meet the government standards and the product was reformulated in a lyophilized (dry powder) formulation. We have demonstrated a significant improvement (two years at room temperature and six years at refrigerated temperatures) with the lyophilized formulation. Recent preclinical experiments have shown it to be 100%

protective with a two-dose regimen (zero and 14 days) with higher toxin neutralizing antibodies than the currently licensed vaccine.

From the Densigen platform, HepTcell, an immunotherapy for patients chronically infected with the HBV HepTcell is currently in a Phase 1 trial in the United Kingdom and South Korea in patients with chronic HBV. Preliminary results from this trial were inconclusive and the company is awaiting six-month follow up results which will be available in the third quarter of 2018, to determine whether to continue with further development of HepTcell, including any further clinical trials. Oncosyn, a cancer immunotherapeutic is in preclinical development.

### ***Merger with PharmAthene***

Our business is the result of a merger between PharmAthene and Private Altimmune. In May of 2017, Private Altimmune merged with PharmAthene pursuant to the Merger Agreement dated January 18, 2017, among Private Altimmune, PharmAthene, its wholly owned acquisition subsidiaries Merger Sub Corp and Merger Sub LLC. Pursuant to the Merger Agreement, Merger Sub LLC to acquire 100% of the outstanding capital stock of Private Altimmune in the Mergers. Prior to the Mergers, PharmAthene was a publicly traded biodefense company engaged in Phase 2 clinical trials in developing a next generation anthrax vaccine.

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.”

Prior to and as a condition for the Mergers, in January 2017, Private Altimmune entered into the Note Agreement for the private placement of the Notes for \$8.6 million at 6% to be issued in two separate closings. The initial closing dated March 9, 2017 resulted in \$3,150,630 of gross proceeds. The initial closing also included \$196,496 of certain existing outstanding notes payable and \$881,044 of certain accrued expenses that were modified and became a component of the Notes on February 28, 2017. The second closing contemplated by the Note Agreement was satisfied by the completion of the offering of redeemable preferred stock (“redeemable preferred stock”) in August of 2017. In connection with the offering of the Notes, Private Altimmune issued warrants to purchase 49,776 shares of Private Altimmune common stock to certain noteholders, with an exercise price of \$0.01 per share.

In accordance with the terms of the Merger Agreement, PharmAthene issued 0.749106 (the “share exchange ratio”) of a share of PharmAthene common stock for each share of Private Altimmune common stock outstanding as of the closing date. All historical share and per share information — including common stock, convertible preferred stock, redeemable preferred stock, common stock warrants, restricted stock, and stock options — has been retroactively adjusted to reflect the impact of the share exchange ratio. In addition, Private Altimmune stock options and warrants were also replaced with options and warrants to purchase PharmAthene’s common stock at the same exchange ratio of 0.749106 share. Immediately prior to closing, 599,285 shares of our Series B convertible preferred (“convertible preferred”) stock were converted into Private Altimmune common stock on a 1-for-1 basis. In addition, outstanding principal and accrued interest on the Notes were converted into 316,734 shares of Private Altimmune common stock. Further, 39,758 shares of Private Altimmune common stock were issued pursuant to the accelerated vesting of restricted stock, and 660,715 shares of Private Altimmune common stock were issued as a result of warrant exercises, both in accordance with their original terms. Upon the closing of the Mergers, all outstanding shares of Private Altimmune common stock were exchanged for 6,883,498 shares of PharmAthene common stock.

Following the closing, shareholders of Private Altimmune held 58.2% of the equity interest of the combined entity and assumed control of the combined entity. As a result, the transaction has been accounted for as a reverse merger, and the assets and liabilities of PharmAthene will be recorded at their estimated fair value. The unadjusted purchase price to be allocated to PharmAthene’s assets and liabilities was estimated to be



## [Table of Contents](#)

\$44,742,737 as of the closing date and consisted of the shares of the combined company retained by PharmAthene shareholders, and the estimated fair value of vested PharmAthene stock options and warrants which remained outstanding as of the closing date. Also at the closing, 7,569 shares of PharmAthene outstanding stock options with an estimated fair value of \$15,173 remained subject to vesting and service requirements. These unvested options will be recorded as operating expense in future periods as the services are delivered and the options vest.

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.

### **2017 Financing**

On August 16, 2017, we issued 15,656 shares of \$0.0001 par value, redeemable preferred stock and warrants to purchase up to 2,345,427 shares of our common stock for total gross proceeds of \$14,716,370, and incurred issuance costs totaling \$1,697,800. The redeemable preferred stock matures on August 16, 2018. The maturity date may be extended 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 agreements require 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 will be redeemed in nine specified installments. On each of the nine monthly specified installment dates beginning in December 2017 through maturity, we are required to convert, redeem, or a combination, one-ninth of the originally issued number of redeemable preferred share at their stated value of \$1,000 per share, for an aggregate value of \$1,739,524 for each installment. If we elect to convert the installment shares, the conversion price is 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 elect cash redemption, the redemption amount is \$1,000 per share, plus any accrued but unpaid dividends and any accrued but unpaid late charges. As of December 31, 2017, there are 12,177 shares of redeemable preferred stock still outstanding and we had issued an aggregate of 2,474,480 shares of common stock in connection with the redemption of 3,479 shares of redeemable preferred stock. As of March 30, 2018, there are 6,958 shares of redeemable preferred stock still outstanding.

### **Current Resources**

We have incurred accumulated losses since inception. Our ability to continue as a going concern is dependent upon our ability to raise additional debt and equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us. These factors raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should we be unable to continue as a going concern.

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, in addition to the Notes and the redeemable preferred stock issuance, we must continue to actively pursue additional equity or debt financing.

Adequate financing opportunities might not be available to us, when and if needed, on acceptable terms, or at all. If we are unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, our operating results and prospects will be adversely affected. As of December 31, 2017, the

## [Table of Contents](#)

combination of the net proceeds from the Notes, cash assumed from the Mergers, the anticipated receipt of tax refunds, the August 2017 redeemable preferred stock financing, and revenue from our government sponsored contracts will be insufficient to fund our operations and research and development efforts into the first quarter of 2019.

The consolidated financial information presented below includes the accounts of Altimmune, Inc. Altimmune UK, PharmAthene UK and Altimmune France. All intercompany accounts and transactions have been eliminated in consolidation.

### **Financial Operations Overview**

#### ***Revenue***

To date, we have not generated any product sales. Our revenues have been derived from license agreements and research grants that generally provide for reimbursement of approved costs as those costs are incurred by the Company. We recognize revenue and related accounts receivable from license agreements when the related services are provided, and from research grants when reimbursable expenses are incurred and the earnings process is complete.

#### ***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.

## [Table of Contents](#)

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

- Complete the ongoing Phase 2a trial of NasoVAX monovalent influenza vaccine in which interim data was released in March 2018. Final data is anticipated in Q3 2018;
- commence a Phase 2 dose ranging trial of a quadrivalent formulation of NasoVAX influenza vaccine in early 2019 and a dose confirmation trial to follow;
- additional development of NasoVAX for the treatment of pandemic influenza, contingent on successful results in the treatment of seasonal influenza and non-dilutive funding from BARDA or other governmental agencies;
- complete follow up and data analysis of our Phase 1b clinical trial for HepTcell for the treatment of chronic hepatitis B, which began enrollment in July 2015, initial results were reported at the end of 2017 with additional unblinded results reported in the first quarter of 2018; final data is anticipated by the end of 2018;
- complete enrollment of our ongoing Phase 1 clinical trial for NasoShield anthrax vaccine and present initial data in mid-year 2018. Commence Phase 2 dose confirming trial for NasoShield anthrax vaccine in Q4 2018 (subject to continued funding and other support from BARDA) 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 NasoVAX and HepTcell 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,

## [Table of Contents](#)

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 on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

### ***Business combination***

We use our best estimates and assumptions to assign fair value to the tangible and intangible assets acquired and liabilities assumed at the acquisition date. Our estimates are inherently uncertain and subject to refinement. During the measurement period, which may be up to one year from the acquisition date, we may record adjustments to the fair value of these tangible and intangible assets acquired and liabilities assumed, with the corresponding offset to goodwill. In addition, uncertain tax positions and tax-related valuation allowances are initially established in connection with a business combination as of the acquisition date. We collect information and reevaluates these estimates and assumptions quarterly and records any adjustments to our preliminary estimates to goodwill during the measurement period. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to our consolidated statements of operations and comprehensive loss. Amounts paid for acquisitions are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. We allocate the purchase price in excess of net tangible assets acquired to identifiable intangible assets, including purchased research and development. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management. We allocate any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

Our in-process research and development (“IPR&D”) assets represent the estimated fair value as of the acquisition date of substantive in-process projects that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval. The valuation of IPR&D assets is determined using the discounted cash flow method. In determining the value of IPR&D assets, the Company considers, among other factors, the stage of completion of the projects, the technological feasibility of the projects, whether the projects have an alternative future use and the estimated residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used is determined at the time of acquisition and includes a rate of return which accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized.

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

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 indefinite lived intangibles is assessed by comparing the undiscounted cash flows expected to be generated by the asset to its carrying value. Goodwill is tested for impairment by comparing the estimated fair value of our single reporting unit 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 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. We performed qualitative assessments of our long-lived assets, including IPR&D, and have determined that our long-lived assets, including IPR&D, are not impaired as of December 31, 2017.

Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. We test goodwill for impairment during the fourth quarter of each year, or more frequently if impairment indicators arise. We test goodwill impairment using a one-step quantitative test. If the carrying value of a reporting unit exceeds its fair value, the amount of goodwill impairment is the excess of the reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. We consider multiple methods including both market and income approaches to determine fair value of our one reporting unit, and primarily rely on fair value estimated based on our market capitalization (a Level 2 input) as of or near the testing date, adjusted for an estimated control premium. During the year ended December 31, 2017, we have concluded that our goodwill was impaired and the full amount of its carrying value of \$35,919,695 was written off as an impairment charge.

### ***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, 2017 and 2016.

### ***Research grants and contracts***

Research grants are derived from government and foundation grants and contracts that support our efforts on specific research projects. We have determined that the government agencies and foundations providing grants and contracts to us are not our customers. These grants and contracts generally provide for reimbursement of approved costs as those costs are incurred by the Company. Research grants and the related accounts receivable are recognized as earned when reimbursable expenses are incurred and the earnings process 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 recorded as a prepaid expense and amortized over the service period as the services are provided.

### ***Stock based Compensation***

We account 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. Stock-based compensation awarded to non-employees are subject to revaluation over their vesting terms. 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, we compare 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. We estimate the number of stock-based awards expected to vest, rather than electing to account for forfeitures as they occur to determine the amount of compensation cost to be recognized in each period.

### ***Income Taxes***

We account 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. We also recognize 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. We account for interest and penalties related to uncertain tax positions as part of our provision for income taxes. To date, we have 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. In March 2017, the Internal Revenue Service notified the Company regarding its plans to examine PharmAthene's tax return for the year ended December 31, 2016.

### Recently Issued Accounting Pronouncements

In February 2016, FASB issued 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. It also aligns lease accounting for lessors with the revenue recognition guidance in ASU 2014-09. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and is to be applied at the beginning of the earliest period presented using a modified retrospective approach. We expect the adoption of ASU 2016-02 will not have a material impact on our financial statements.

### Results of Operations

#### Year Ended December 31, 2017 Compared to December 31, 2016

(in thousands except percentages)	Year Ended December 31,			
	2017	2016	Increase (Decrease)	
Revenue				
Research grants and contracts	\$ 10,697	\$ 2,826	\$ 7,871	279%
License revenue	41	410	(369)	(90)%
Total revenue	10,738	3,236	7,502	232%
Operating expenses				
Research and development	18,406	7,222	11,184	155%
General and administrative	8,458	7,106	1,352	19%
Goodwill impairment charges	35,919	—	35,919	100%
Total operating expenses	62,783	14,328	48,455	338%
Loss from operations	(52,045)	(11,092)	(40,953)	(369)%
Other income (expense):				
Changes in fair value of warrant liability	98	—	98	100%
Changes in fair value of imbedded derivative	(7)	—	(7)	(100)%
Interest expense	(162)	(38)	(124)	(326)%
Interest income	47	1	46	4,600%
Other income, net	5	42	(37)	(88)%
Total other (expense) income, net	(19)	5	(24)	(480)%
Net loss before tax benefit	(52,064)	(11,087)	(40,977)	(370)%
Income tax benefit	5,638	—	5,638	100%
Net loss	(46,426)	(11,087)	(35,339)	(319)%
Other comprehensive income (loss) — foreign currency translation adjustments	2,998	(6,805)	9,803	144%
Comprehensive loss	<u>\$(43,428)</u>	<u>\$(17,892)</u>	<u>\$(25,536)</u>	(143)%

## [Table of Contents](#)

### **Revenue**

Revenue from grants and contracts for the years ended December 31, 2017 and 2016 consisted primarily of research grants from BARDA and NIAID in the United States for our anthrax vaccine product candidates.

<i>(in thousands except percentages)</i>	<u>Year Ended December 31,</u>			
	<u>2017</u>	<u>2016</u>	<u>Increase (Decrease)</u>	
Revenue				
Research grants and contracts	\$10,697	\$2,826	\$7,871	279%
License revenue	41	410	(369)	(90)%
Total revenue	<u>\$10,738</u>	<u>\$3,236</u>	<u>\$7,502</u>	232%

Increase in research grants and contracts is the combined results of our signing a five-year contract with BARDA in July 2016 which we amended in March 2017, and revenue from NIAID which we assumed from the Mergers with PharmAthene. Revenue for the year ended December 31, 2016 did not include PharmAthene or the NIAID contract.

### **Research and Development Expenses**

Research and development expenses for the years ended December 31, 2017 and 2016 consisted primarily of expenses related to product candidate development. Research and development expenses for the years ended December 31, 2017 and 2016 are summarized as follows:

<i>(in thousands except percentages)</i>	<u>Year Ended December 31,</u>			
	<u>2017</u>	<u>2016</u>	<u>Increase (Decrease)</u>	
Research and development	<u>\$18,406</u>	<u>\$7,222</u>	<u>\$11,184</u>	155%

Research and development expenses increased by \$11.2 million, or 155%, during the year ended December 31, 2017 as compared to 2016. The increased expense was due to an increase of \$5.1 million for NasoShield in accordance with our BARDA contract, \$3.4 million for NasoVAX to prepare for and start a Phase I clinical trial, \$1.0 million of spending on SparVax-L acquired in the Mergers, \$0.6 million for HepTcell to continue the Phase 2 clinical trials and \$1.6 million in general overhead due to increased activity, offset by \$0.5 million reduced spending on the Oncosyn product. In addition, research and development expenses for the year ended December 31, 2016 did not include PharmAthene or costs incurred under the NIAID contract.

### **General and Administrative Expenses**

The following is a summary of general and administrative expenses for the years ended December 31, 2017 and 2016:

<i>(in thousands except percentages)</i>	<u>Year Ended December 31,</u>			
	<u>2017</u>	<u>2016</u>	<u>Increase (Decrease)</u>	
General and administrative	<u>\$8,458</u>	<u>\$7,106</u>	<u>\$1,352</u>	19%

General and administrative expenses increased by \$1.4 million, or 19%, during the year ended December 31, 2017 as compared to 2016. The increase is due to an increase of \$2.7 million in professional fees related to the Mergers and public company costs, \$0.2 million in labor costs, \$0.4 million in insurance costs and \$0.5 million in stock compensation, offset by \$2.4 million of offering costs incurred in 2016 that did not recur in



## [Table of Contents](#)

2017. Increase in general and administrative expenses in 2017 as compared to 2016 is less significant as compared to the changes in revenue and research and development expenses because we did not retain any general and administrative personnel from PharmAthene or its facilities.

### **Goodwill Impairment Charges**

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2017	2016	Increase (Decrease)	
Goodwill impairment charges	<u>\$35,919</u>	<u>\$—</u>	<u>\$35,919</u>	100%

As a result of the continued decline in our common stock trading price, we had determined that our goodwill was impaired during the year ended December 31, 2017 and the full carrying value of goodwill of \$35.9 million was written off and recorded as impairment charges.

### **Other Income (Expense)**

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2017	2016	Increase (Decrease)	
Other income (expense):				
Changes in fair value of warrant liability	\$ 98	\$—	\$ 98	100%
Changes in fair value of imbedded derivative	(7)	—	(7)	(100)%
Interest expense	(162)	(38)	(124)	(326)%
Interest income	47	1	46	4,600%
Other income, net	5	42	(37)	(88)%
Total other (expense) income, net	<u>\$ (19)</u>	<u>\$ 5</u>	<u>\$ (24)</u>	(480)%

Other expense increased by \$24,000, or 480%, during the year ended December 31, 2017 as compared to the year ended December 31, 2016. The increase was primarily due to an increase in interest expense of \$0.1 million from the issuance of the Notes during 2017, offset by a \$98,000 change in the fair value of warrant liability.

### **Income Tax Benefit**

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2017	2016	Increase (Decrease)	
Income tax benefit	<u>\$5,638</u>	<u>\$—</u>	<u>\$5,638</u>	100%

We recorded an income tax benefit of \$5.4 million during the year ended December 31, 2017, which reflected estimated tax refunds we expect to receive from carrying back the 2017 NOLs to offset the 2016 federal and state income taxes paid by PharmAthene. In March 2017, the Internal Revenue Service notified the Company regarding its plans to examine PharmAthene's tax return for the year ended December 31, 2016.

### **Foreign Currency Translation Adjustments**

<i>(in thousands except percentages)</i>	Year Ended December 31,			
	2017	2016	Increase (Decrease)	
Other comprehensive income (loss) — foreign currency translation adjustments	<u>\$2,998</u>	<u>\$(6,805)</u>	<u>\$9,803</u>	144%

Foreign currency translation adjustment primarily related to the exchange rate differences in the carrying values of IPR&D and goodwill. We had elected to push down assets acquired and liabilities assumed to our U.K. subsidiary whose functional currency is the British pound. The exchange rate as of May 4, 2017, the date of the Mergers was £1.00 = \$1.2916. The exchange rate was £1.00 = \$1.2339 as of December 31, 2016 and £1.00 = \$1.3515 as of December 31, 2017. The translation adjustment gains of \$3.0 million during the year ended December 31, 2017 was the net effect of an increase in the British pound as compared to the U.S. dollar during the year.

## Liquidity and Capital Resources

### Overview

Our primary sources of cash, cash equivalents, and restricted cash for the year ended December 31, 2017 were \$3.0 million in net proceeds received from the issuance of the Notes, \$13.7 million in cash assumed from the Mergers, and \$13.0 million in net proceeds from the issuance of the redeemable preferred stock and warrants. Our primary source of cash during the comparable period in 2016 was \$5.7 million in net proceeds received from the issuance of our convertible preferred stock. Our cash, cash equivalents, and restricted cash were \$12.3 million at December 31, 2017. We believe, based on the operating cash requirements and capital expenditures expected for 2018, our cash on hand at December 31, 2017, expected tax refunds, and revenue from our government sponsored contracts, are insufficient to fund operations for a 12-month period from the date our consolidated financial statements are expected to be issued, and only provide cash into the first quarter of 2019. Our ability to continue as a going concern is dependent upon our ability to raise additional debt and equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us. The current terms of our financing arrangements may make it more difficult to raise additional capital in the future. These factors raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should we be unable to continue as a going concern.

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 consist of revenues under our contract with BARDA and NIAID for the development of NasalShield and SparVax-L, respectively, and to a lesser degree from other licensing arrangements. We have incurred significant losses since we commenced operations. As of December 31, 2017, we had accumulated losses of \$77.7 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.

In July 2016, we signed a five-year contract with BARDA which was amended in March 2017. The contract has a total value of up to \$127.5 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 2 clinical trial dose ranging assessment of safety and immunogenicity. The contract consists of an initial base performance period providing approximately \$21.6 million in funding for the period July 2016 through July 2018. 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 the period July 2018 through July 2021. Through December 31, 2017, we have received an aggregate of approximately \$6.5 million under the current BARDA contract.

As part of the Mergers, we assumed a PharmAthene contract with NIAID. The NIAID contract is incrementally funded. Over the base period of the contract, PharmAthene was awarded initial funding of approximately \$5.2 million, which includes a cost reimbursement component and a fixed fee component payable

## [Table of Contents](#)

upon achievement of certain milestones. NIAID exercised four options under this agreement to provide additional funding of approximately \$8.8 million and an extension of the period of performance through December 31, 2017. In April 2017, PharmAthene was notified by NIAID that it will exercise only one of the additional remaining options under the contract to provide funding for a rabbit challenge study. Work under all exercised options will bring total committed and final funding under the NIAID contract to \$15.1 million.

### **Indebtedness**

As of December 31, 2017, we had outstanding borrowings from a credit facility and two research and development funding arrangements as described in more detail below.

#### *Credit Facility*

We have a secured line of credit agreement with a financial institution that provides for borrowings up to \$250,000 and matures in April 2018. The borrowings are secured by certain assets of the Company. Interest is payable monthly at the financial institution's prime rate (5.00% at December 31, 2017) plus 2.0% per annum with a floor of 5.0%. Accrued interest was \$536 and \$33 as of December 31, 2017 and 2016, respectively. Interest expense for the years ended December 31, 2017 and 2016 totaled \$830 and \$2,956, respectively.

#### *BPI France Notes*

Altimune France has two non-interest-bearing research and development funding arrangements with BPI France that were entered into in December 2013 to provide Altimune France up to €750,000 (\$899,890 at December 31, 2017) in research funding in the first arrangement and up to €250,000 (\$299,963 at December 31, 2017) in the second arrangement. Altimune France is 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 agreed to extend the term on the arrangement by two years. Each of the two obligations is repayable in sixteen quarterly installments from June 2019 through March 2023. The total amount advanced under the arrangements was €500,000 as of December 31, 2017 and 2016 (\$599,927 and \$525,950 as of December 31, 2017 and 2016, respectively).

### **Cash Flows**

The following table provides information regarding our cash flows for the years ended December 31, 2017 and 2016:

<i>(in thousands, except percentages)</i>	<b>Year Ended December 31,</b>			
	<b>2017</b>	<b>2016</b>	<b>Increase (Decrease)</b>	
Net cash (used in) provided by:				
Operating activities	\$(20,214)	\$(6,353)	\$(13,861)	(218)%
Investing activities	13,726	(221)	13,947	6,311%
Financing activities	15,841	4,983	10,858	218%

#### *Operating Activities*

Net cash used in operating activities was \$20.2 million for the year ended December 31, 2017 compared to \$6.4 million during the year ended December 31, 2016.

Net cash used in operating activities during the year ended December 31, 2017 included our net loss of \$46.4 million, adjusted for \$35.9 million in goodwill impairment charges, \$1.4 million in stock-based compensation expense, \$98,000 from the accretion of debt discount and deferred financing costs, a \$98,000

## [Table of Contents](#)

changes in the fair value of warrant liability, a \$1.9 million increase in accounts receivable, a \$2.6 million decrease in accounts payable, a \$0.3 million increase in prepaid expenses and other current assets, a \$0.4 million decrease in accrued expenses, a \$3.4 million increase in tax refunds receivable, a \$2.4 million decrease in deferred tax liability and \$0.1 million from net changes in other balances.

In comparison, net cash used in operating activities of \$6.4 million during the year ended December 31, 2016 included our net loss of \$11.1 million, adjusted for \$1.0 million of stock-based compensation expense; write off of \$2.6 million in deferred offering costs; a \$0.1 million decrease in accounts receivable; an \$0.9 million increase in accounts payable; a \$0.6 million increase in accrued expenses; a \$0.3 million increase in tax refund receivable, and \$0.2 million from net changes in other balances.

### *Investing Activities*

During the year ended December 31, 2017, net cash provided by investing activities of \$13.7 million was primarily the result of \$13.7 million cash assumed from the Mergers with PharmAthene that closed in May 2017.

### *Financing Activities*

Net cash provided by financing activities during the year ended December 31, 2017 was primarily the result of \$3.0 million net proceeds received from the Notes that closed in March 2017 and \$13.0 million net proceeds from the redeemable preferred financing in August 2017, offset by the repayment of notes payable for \$0.2 million.

Net cash provided by financing activities during the year ended December 31, 2016 was primarily the result of \$5.7 million net proceeds received from the issuance of convertible preferred stock in April 2016 offset by payments of deferred offering costs for \$0.6 million.

### *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.

[Table of Contents](#)

**Item 8. Financial Statements and Supplementary Data.**

ALTIMMUNE, INC.

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<a href="#">Report of Independent Registered Public Accounting Firm — Ernst &amp; Young LLP</a>	108
<a href="#">Report of Independent Registered Public Accounting Firm — BDO USA, LLP</a>	109
<a href="#">Consolidated Balance Sheets</a>	110
<a href="#">Consolidated Statements of Operations and Comprehensive Loss</a>	111
<a href="#">Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity</a>	112
<a href="#">Consolidated Statements of Cash Flows</a>	113
<a href="#">Notes to Consolidated Financial Statements</a>	114

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of  
Altimmune, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Altimmune, Inc. (the Company) as of December 31, 2017, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity and cash flows for the year ended December 31, 2017, 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 consolidated financial position of the Company at December 31, 2017, and the consolidated results of its operations and its cash flows for the year ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

**The Company's Ability to Continue as a Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for opinion**

These 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with 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 audit 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 audit 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 supporting the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

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

Baltimore, Maryland  
March 30, 2018

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders  
Altimmune, Inc.  
Gaithersburg, Maryland

We have audited the accompanying consolidated balance sheets of Altimmune, Inc. and subsidiaries (the "Company") as of December 31, 2016 and the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Altimmune, Inc. and subsidiaries as of December 31, 2016, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company has incurred recurring losses, negative cash flows from operations, negative working capital, and losses are expected to continue in the future. These factors raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

McLean, Virginia

March 29, 2017

Except for the effects of the retroactive adjustment to the Company's 2016 equity structure and the related amounts, shares and share-related information resulting from the application of a share exchange ratio discussed in Note 3, as to which the date is March 30, 2018.

## ALTIMMUNE, INC.

## CONSOLIDATED BALANCE SHEETS

	December 31,	
	2017	2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,769,465	\$ 2,876,113
Restricted cash	3,534,174	—
Total cash, cash equivalents, and restricted cash	12,303,639	2,876,113
Accounts receivable	3,806,239	383,046
Tax refunds receivable	6,361,657	807,507
Prepaid expenses and other current assets	994,332	420,424
Total current assets	23,465,867	4,487,090
Property and equipment, net	603,146	177,859
Intangible assets, net	38,722,270	14,954,717
Other assets	238,917	22,248
Goodwill	—	18,758,421
Total assets	<u>\$ 63,030,200</u>	<u>\$ 38,400,335</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity</b>		
Current liabilities:		
Notes payable	\$ 49,702	\$ 458,629
Accounts payable	129,075	2,005,208
Accrued expenses	3,625,257	2,972,745
Current portion of deferred revenue	19,753	19,753
Current portion of deferred rent	15,914	14,388
Total current liabilities	3,839,701	5,470,723
Deferred income taxes	5,938,402	—
Other long-term liabilities	4,574,507	722,289
Total liabilities	<u>14,352,610</u>	<u>6,193,012</u>
Commitments and contingencies (Note 18)		
Series B redeemable convertible preferred stock; \$0.0001 par value; 16,000 shares designated; 12,177 and zero shares issued and outstanding at December 31, 2017 and 2016, respectively; aggregate liquidation and redemption value of \$9,281,767 at December 31, 2017	9,281,767	—
Stockholders' equity:		
Series B convertible preferred stock; \$0.01 par value; zero and 599,285 shares authorized, issued and outstanding at December 31, 2017 and 2016, respectively	—	5,993
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 18,127,119 and 6,991,749 shares issued; 18,103,691 and 6,917,204 shares outstanding at December 31, 2017 and 2016, respectively	1,810	692
Additional paid-in capital	121,655,838	71,034,899
Accumulated deficit	(77,684,839)	(31,259,449)
Accumulated other comprehensive loss — foreign currency translation adjustments	(4,576,986)	(7,574,812)
Total stockholders' equity	39,395,823	32,207,323
Total liabilities and stockholders' equity	<u>\$ 63,030,200</u>	<u>\$ 38,400,335</u>

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



## ALTIMMUNE, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2017	2016
Revenue		
Research grants and contracts	\$ 10,696,819	\$ 2,826,073
License revenue	41,503	410,102
Total revenue	<u>10,738,322</u>	<u>3,236,175</u>
Operating expenses		
Research and development	18,406,329	7,221,460
General and administrative	8,457,557	7,106,378
Goodwill impairment charges	35,919,695	—
Total operating expenses	<u>62,783,581</u>	<u>14,327,838</u>
Loss from operations	<u>(52,045,259)</u>	<u>(11,091,663)</u>
Other income (expense)		
Changes in fair value of warrant liability	97,763	—
Changes in fair value of embedded derivative	(7,379)	—
Interest expense	(162,139)	(38,499)
Interest income	47,579	1,047
Other income, net	5,670	42,303
Total other (expense) income, net	<u>(18,506)</u>	<u>4,851</u>
Net loss before income tax benefit	<u>(52,063,765)</u>	<u>(11,086,812)</u>
Income tax benefit	5,638,375	—
Net loss	<u>(46,425,390)</u>	<u>(11,086,812)</u>
Other comprehensive income (loss) — foreign currency translation adjustments	2,997,826	(6,805,452)
Comprehensive loss	<u>\$ (43,427,564)</u>	<u>\$ (17,892,264)</u>
Net loss	<u>\$ (46,425,390)</u>	<u>\$ (11,086,812)</u>
Preferred stock accretion and dividends	(4,930,010)	(368,548)
Net loss attributable to common stockholders	<u>\$ (51,355,400)</u>	<u>\$ (11,455,360)</u>
Weighted-average common shares outstanding, basic and diluted	12,805,095	6,911,534
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (4.01)</u>	<u>\$ (1.66)</u>

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		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, January 1, 2016	—	\$ —	149,822	\$ 1,498	6,911,189	\$ 691	\$ 64,074,441	\$(20,172,637)	\$ (769,360)	\$ 43,134,633
Stock based compensation							794,582			794,582
Vesting of restricted stock					4,970	1	170,849			170,850
Exercises of stock options					1,045		563			563
Issuance of Series B convertible preferred stock, net of issuance costs and discounts			449,463	4,495			5,994,464			5,998,959
Foreign currency translation adjustments									(6,805,452)	(6,805,452)
Net loss								(11,086,812)		(11,086,812)
Balance, December 31, 2016	—	\$ —	599,285	5,993	6,917,204	692	71,034,899	(31,259,449)	(7,574,812)	32,207,323
Stock based compensation							1,210,499			1,210,499
Vesting and accelerated vesting of restricted stock					51,118	5	233,674			233,679
Exercises of stock options					200,657	20	16,435			16,455
Warrant issuance, net of issuance costs							548,956			548,956
Conversion of Series B convertible preferred stock into common stock			(599,285)	(5,993)	599,285	60	5,933			—
Conversion of convertible notes and accrued interest into common stock					316,734	32	3,645,392			3,645,424
Warrant exercises					660,715	66	(66)			—
Issuance of common stock for the acquisition of subsidiaries					6,883,498	688	44,742,049			44,742,737
Issuance of Series B redeemable convertible preferred stock and warrants, net of issuance costs and discounts	15,656	7,993,885					1,506,196			1,506,196
Accretion of Series B redeemable convertible preferred stock		4,766,942					(4,766,942)			(4,766,942)
Conversion of Series B redeemable convertible preferred stock into common stock	(3,479)	(3,479,060)			2,474,480	247	3,478,813			3,479,060
Foreign currency translation adjustments									2,997,826	2,997,826
Net loss								(46,425,390)		(46,425,390)
Balance, December 31, 2017	<u>12,177</u>	<u>\$ 9,281,767</u>	<u>—</u>	<u>\$ —</u>	<u>18,103,691</u>	<u>\$ 1,810</u>	<u>\$121,655,838</u>	<u>\$(77,684,839)</u>	<u>\$ (4,576,986)</u>	<u>\$ 39,395,823</u>

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

**ALTIMMUNE, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,	
	2017	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (46,425,390)	\$ (11,086,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Goodwill impairment charges	35,919,695	—
Stock-based compensation	1,443,492	965,365
Depreciation	83,834	63,109
Amortization	55,185	72,236
Debt discount and deferred financing charge accretion	98,060	—
Gain from settlement of notes payable	—	(45,573)
Write off of deferred offering costs	—	2,562,377
Loss from disposal of property and equipment	9,182	577
Changes in fair value of warrant liability	(97,763)	—
Changes in fair value of embedded derivative	7,379	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,948,655)	130,630
Prepaid expenses and other current assets	(349,110)	(50,668)
Accounts payable	(2,623,896)	853,886
Accrued expenses	(364,651)	591,562
Deferred revenue	(19,753)	(75,643)
Deferred rent	22,025	(8,876)
Tax refunds receivable	(3,406,633)	(325,178)
Deferred tax liability	(2,617,080)	—
Net cash used in operating activities	<u>(20,214,079)</u>	<u>(6,353,008)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Cash assumed from acquiring subsidiaries	13,684,535	—
Purchases of property and equipment	(112,441)	(124,955)
Proceeds from sale of property and equipment	7,635	—
Additions to intangible assets	(53,886)	(95,615)
Refund of cash held in escrow	200,000	—
Net cash provided by (used in) investing activities	<u>13,725,843</u>	<u>(220,570)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Repayments of notes payable	(212,431)	(81,098)
Proceeds from issuance of notes	—	531
Payments of deferred offering costs	—	(612,218)
Proceeds from issuance of Series B convertible preferred stock and warrants, net of issuance costs	—	5,673,680
Proceeds from issuance of restricted stock	—	1,067
Proceeds from issuance of Series B redeemable convertible preferred stock and warrants, net of issuance costs	13,018,570	—
Proceeds from issuance of convertible notes, net of issuance costs	3,018,780	—
Proceeds from exercise of stock options	16,455	563
Net cash provided by financing activities	<u>15,841,374</u>	<u>4,982,525</u>
<b>EFFECT OF EXCHANGE RATES ON CASH, CASH EQUIVALENTS, AND RESTRICTED CASH</b>	<u>74,387</u>	<u>(171,545)</u>
Net increase (decrease) in cash, cash equivalents, and restricted cash	9,427,526	(1,762,598)
Cash, cash equivalents, and restricted cash — beginning of year	2,876,113	4,638,711
Cash, cash equivalents, and restricted cash — end of year	<u>\$ 12,303,639</u>	<u>\$ 2,876,113</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Cash paid for interest	9,352	4,635
<b>SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES</b>		
Accrued expenses and notes payable replaced with convertible notes	1,077,540	—
Conversion of convertible notes into common stock	3,645,424	—
Common stock warrant issued with convertible notes, net of issuance costs	548,956	—
Addition of property and equipment not yet paid	328,384	—
Billed lease incentive obligations not yet paid	350,076	—
Conversion of Series B convertible preferred stock into common stock	5,993	—
Conversion of Series B redeemable convertible preferred stock into common stock	3,479,060	—
Cashless exercise of common stock warrants	66	—
Accretion of Series B redeemable convertible preferred stock	4,766,942	—
Release of restricted stock liability	686	—
Accumulated dividends on Series B convertible preferred stock	—	368,548
Series B convertible preferred stock subscription reclassified as additional paid-in capital upon issuance of Series B convertible preferred stock	—	325,280

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

ALTIMMUNE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**1. Nature of Business and Basis of Presentation**

*Nature of Business*

Altimune, Inc., headquartered in Gaithersburg, Maryland, United States, together with its subsidiaries (collectively, the “Company” or “Altimune”) is a clinical stage biopharmaceutical company incorporated under the laws of the State of Delaware. The Company is focused on discovering and developing immunotherapies and vaccines to address significant unmet medical needs. Since its inception, The Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital, and has financed its operations through the issuance of common and convertible preferred stock, long-term debt, and proceeds from research grants and government contracts. 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.

The Company’s business is a result of a merger between PharmAthene, Inc. (“PharmAthene”) and the business previously known as Altimune, Inc. (“Private Altimune”). In May of 2017, Private Altimune merged with PharmAthene pursuant to an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) dated January 18, 2017 among Private Altimune, 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 Altimune in a reverse triangular merger and reorganization pursuant to section 368(a) of the Internal Revenue Code (the “Mergers”) (see Note 3). Prior to the Mergers, PharmAthene was a publicly traded biodefense company engaged in Phase 2 clinical trials in developing a next generation anthrax vaccine.

Prior to and as a condition for the Mergers, in January 2017, Private Altimune entered into a Convertible Promissory Note Purchase Agreement (the “Note Agreement”) for the private placement of \$8.6 million of 6% convertible notes (the “Notes”) (See Note 12) to be issued in two separate closings. The initial closing dated March 9, 2017 resulted in \$3,150,630 of gross proceeds. The initial closing also included \$196,496 of certain existing outstanding notes payable and \$881,044 of certain accrued expenses that were modified and became a component of the Notes on March 9, 2017. In connection with the Notes, Private Altimune issued warrants to purchase 49,776 shares of Private Altimune common stock to certain noteholders, with an exercise price of \$0.01 per share. These warrants are classified as permanent equity (see Note 16). The second closing under the Note Agreement was satisfied in connection with the sale of Series B redeemable convertible preferred stock (“redeemable preferred stock”) that closed on August 16, 2017 (see Note 14).

On May 4, 2017, Private Altimune 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 Altimune, with Private Altimune remaining as the surviving corporation; (ii) Private Altimune then merged with and into Merger Sub LLC, with Merger Sub LLC (renamed as “Altimune LLC”) remaining as the surviving entity; and (iii) PharmAthene was renamed as “Altimune, Inc.” Upon closing of the Mergers, all equity instruments of Private Altimune were exchanged for corresponding equity instruments of PharmAthene (see Note 3). Except where the context indicates otherwise, references to “we,” “us,” “our,” “Altimune” or the “Company” refer, for periods prior to the completion of the Mergers, to Private Altimune and its subsidiaries, and for periods following the completion of the Mergers to the combined company and its subsidiaries.

*Basis of Presentation*

The accompanying consolidated financial statements are prepared in conformity with accounting principles general accepted in the United States (“U.S. GAAP”). The consolidated financial statements have been prepared

on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should the Company be unable to continue as a going concern (see Note 2). As more fully described in Note 3, the comparable information included in these consolidated financial statements is that of Altimmune, Inc., the deemed accounting acquirer and in connection with the Mergers, all historical share and per share information including common stock, convertible preferred stock, redeemable preferred stock, common stock warrants, restricted stock and stock options, has been retroactively adjusted to reflect the effect of the share exchange ratio.

#### *Guarantees and Indemnifications*

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through December 31, 2017, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concludes that the fair value of these obligations is negligible, and no related reserves are established.

## **2. Going Concern**

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has experienced recurring losses in past years. The Company incurred a net loss of \$46,425,390 and used \$20,214,079 in cash to fund operations during 2017 and had an accumulated deficit of \$77,684,839 as of December 31, 2017. The Company expects to incur additional losses in the future in connection with research and development activities. Since inception, the Company has financed its activities principally from the issuance of equity and debt securities. The Company's ability to continue as a going concern is dependent upon the Company's ability to raise additional debt and equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern. As of December 31, 2017, the Company does not have sufficient capital to fund its plan of operations for a twelve-month period from the date the 2017 consolidated financial statements are expected to be issued.

In order to address its capital needs, including its planned clinical trials, the Company must continue to actively pursue additional equity or debt financing. The Company has been in ongoing discussions with institutional investors and investment banks with respect to such financing. Adequate financing opportunities might not be available to the Company, when and if needed, on acceptable terms, or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances the Company's operating results and prospects will be adversely affected. As more fully described in Note 12, in January 2017, in connection with the Mergers, the Company entered into a private placement of the Notes. In addition, as more fully described in Note 14, in August 2017, the Company issued shares of redeemable preferred stock and the related common stock warrants for an aggregate net proceeds of \$13,018,570. The Company expects that the combination of the net proceeds from the Notes, cash assumed from the Mergers, the anticipated receipt of tax refunds (Note 17), redeemable preferred financing, and revenue from our government sponsored contracts will be insufficient to fund our operations and research and development efforts for at least twelve months from the expected issuance date of our 2017 financial statements.

## **3. Business Combination**

Pursuant to the Merger Agreement, the Company closed the Mergers with PharmAthene on May 4, 2017. In accordance with the terms of the Merger Agreement, PharmAthene issued 0.749106 (the "share exchange ratio") of a share of PharmaAthene common stock for each share of Private Altimmune's common stock ("common stock") outstanding as of the closing date. All historical share and per share information including common and preferred stock, restricted stock, common stock warrants, and stock options, has been retroactively adjusted to reflect the effect of the share exchange ratio. In addition, Private Altimmune's stock options and warrants were

also replaced with options and warrants to purchase PharmAthene's common stock at the same share exchange ratio of 0.749106 share. Immediately prior to closing, 599,285 shares of Series B convertible preferred stock ("convertible preferred stock") converted into Private Altimmune common stock on a 1-for-1 basis. Due to the convertible preferred stock having unique terms and conditions, the convertible preferred stock outstanding in periods prior to the Mergers continues to be presented separately on our balance sheet for periods prior to conversion. In addition, outstanding principal and accrued interest on the Notes converted into 316,734 shares of Private Altimmune common stock. Further, 39,758 shares of Private Altimmune common stock were issued pursuant to the accelerated vesting of restricted stock, and 660,715 shares of Private Altimmune common stock were issued as a result of warrant exercises, both in accordance with their original terms. Upon the closing of the Mergers, Private Altimmune common stock totaling 6,883,498 shares were exchanged for 6,883,498 shares of PharmAthene common stock.

Although PharmAthene was the issuer of the shares and considered the legal acquirer in the Mergers, following the closing, shareholders of Private Altimmune held 58.2% of the equity interest of the combined entity and assumed control of the combined entity. As a result, the transaction has been accounted for as a reverse merger, with Private Altimmune considered the accounting acquirer, and the assets and liabilities of PharmAthene have been recorded at their estimated fair value. The unadjusted purchase price allocated to PharmAthene's assets and liabilities was estimated to be \$44,742,737 as of the closing date and consisted of the shares of the combined company retained by PharmAthene shareholders, and the estimated fair value of vested PharmAthene stock options and warrants which remained outstanding as of the closing date. Also at the closing, 7,569 outstanding unvested options of PharmAthene with an estimated fair value of \$15,173 remained subject to vesting and service requirements. These unvested options will be recorded as operating expense in future periods as the services are delivered and the options vest.

Headquartered in Annapolis, Maryland, PharmAthene was incorporated in Delaware in April 2005. PharmAthene was a biodefense company engaged in Phase 2 clinical trials in developing a next generation anthrax vaccine. The next generation vaccine is intended to have more rapid time to protection, fewer doses for protection and less stringent requirements for temperature-controlled storage and handling than the currently used vaccine. The Mergers enable the combined company to become a fully integrated, commercially-focused immunotherapeutics company with the ability to create more value than either company could achieve individually. As a publicly listed entity, the Mergers also provide us with additional capital financing alternatives to support the combined entity's planned research and development activities.

In addition to the operating assets and liabilities of PharmAthene, Private Altimmune also acquired PharmAthene's tax attributes, which primarily consisted of a tax refund receivable and \$965,583 of net operating losses ("NOLs") which were limited under Section 382 of the U.S. Internal Revenue Service and were fully reserved, which will expire in 2023. The Company recorded a deferred tax liability related to future tax benefits arising from an in-process research and development asset ("IPR&D") acquired in the Mergers. Goodwill generated from the Mergers is not expected to be deductible for tax purposes.

For accounting purposes, the historical financial statements of Private Altimmune have not been adjusted to reflect the Mergers, other than adjustments to the capital structure of Private Altimmune to reflect the historical capital structure of PharmAthene. Private Altimmune incurred \$2,183,671 of transaction costs, which have been expensed as incurred in the accompanying consolidated financial statements.

## [Table of Contents](#)

The following table lists the various securities of PharmAthene which were outstanding as of May 4, 2017 and whose rights and obligations were assumed by the combined entity following the Mergers:

Outstanding PharmAthene common stock	6,883,498
Outstanding PharmAthene stock options	123,003
Outstanding PharmAthene stock warrants	4,658
Per share fair value of PharmAthene common stock	\$ 6.50
Weighted average per share fair value of PharmAthene stock options, vested and unvested	\$ 0.26
Per share fair value of PharmAthene stock warrants	\$ 0.01
Aggregate fair value of consideration	\$ 44,757,910
Less fair value of unvested common stock options	(15,173)
Total fair value of consideration	<u>\$ 44,742,737</u>

Since the acquisition date, the Company has recorded adjustments to the allocation of the purchase consideration that included a \$44,700 adjustment to increase our tax refund receivable and a \$4,535 adjustment to reduce our deferred tax liabilities, with a total adjustment of \$49,235 resulting in an increase in goodwill. The adjustments were the result of a change in the tax rate being applied from 34% to 35%. These purchase price adjustments were reflected in the accompanying consolidated balance sheet as of December 31, 2017. The adjusted allocation of the purchase consideration to the assets acquired and liabilities assumed of PharmAthene in these financial statements is still preliminary and subject to change as management gathers information regarding these items.

The adjusted allocation of the purchase consideration was as follows:

Cash and cash equivalents	\$ 13,684,535
Accounts receivable	1,124,462
Prepaid expenses and other current assets	597,172
Tax refund receivable	2,047,234
Property and equipment	75,779
IPR&D	22,389,000
Goodwill	15,573,822
Total assets acquired	<u>55,492,004</u>
Accounts payable and accrued expenses	(2,193,785)
Deferred tax liability	(8,555,482)
Total liabilities assumed	<u>(10,749,267)</u>
Net assets acquired	<u>\$ 44,742,737</u>

The Company relied on significant Level 3 unobservable inputs to estimate the fair value of acquired IPR&D assets using management's estimate of future revenue and expected profitability of the products after taking into account an estimate of future expenses, net of contract revenue and other funding, necessary to bring the products to completion. These projected cash flows were then discounted to their present values using a discount rate of 23%, which was considered commensurate with the risks and stages of development of the products.

The operating activities of PharmAthene have been included in the accompanying consolidated financial statements from the date of the Mergers. For the period from May 4, 2017 to December 31, 2017, revenues and net loss of PharmAthene included in the accompanying consolidated financial statements aggregated \$1,765,212 and \$36,003, respectively.

## [Table of Contents](#)

The following unaudited pro forma information for the year ended December 31, 2017 and 2016 gives effect to the acquisition of PharmAthene as if the Mergers had occurred at the beginning of the respective full annual reporting period:

	Year Ended December 31,	
	2017	2016
Pro forma revenue and grants and contracts	\$ 11,844,273	\$ 8,466,371
Pro forma net (loss) income attributable to common stockholders	\$ (52,315,978)	\$ 186,664,464
Pro forma weighted average common shares outstanding, basic	15,547,863	14,368,157
Pro forma net (loss) income per share, basic	\$ (3.36)	\$ 12.99
Pro forma weighted average common shares outstanding, diluted	15,547,863	15,201,819
Pro forma net (loss) income per share, diluted	\$ (3.36)	\$ 12.28

Significant nonrecurring pro forma adjustments included acquisition costs of \$1,512,423 and \$671,248, and PharmAthene stock compensation expenses incurred prior to the Mergers of \$66,180 and \$2,240,015 for the years ended December 31, 2017 and 2016, respectively, that would have been incurred prior to the pro forma acquisition date had the Mergers occurred at the beginning of the respective full annual reporting period.

#### **4. 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.

##### *Reclassification*

Certain 2016 amounts and disclosures have been reclassified to conform to the 2017 presentation. The 2016 amounts and disclosures reclassified include the combining of all noncurrent liabilities, other than deferred income taxes, into other long-term liabilities on the consolidated balance sheets; the combining of other income and other expenses into other income, net in the consolidated statements of operations and comprehensive loss; and the disclosure of additional property and equipment components in Note 6.

##### *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 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 assets acquired and liabilities assumed, 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 foreign currency translation adjustments.



### *Foreign Currency Translation*

Assets and liabilities of Altimmune UK Limited, PharmAthene UK Limited, and Altimmune France SAS, whose functional currencies are the British pound and Euro, respectively, are translated at year end exchange rates, while revenues and expenses are translated at average exchange rates for the year. Translation adjustments are reflected as accumulated other comprehensive loss within stockholders' equity. Translation adjustments from intercompany advances that the Company does not anticipate settling in the foreseeable future are recorded in accumulated other comprehensive loss within stockholders' equity. Gains and losses on foreign currency transactions are included in the consolidated statements of operations and comprehensive loss as a component of operating expenses.

### *Segment*

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment, the research and development of immunotherapies and vaccines.

### *Business Combination*

The Company uses its best estimates and assumptions to assign fair value to the tangible and intangible assets acquired and liabilities assumed at the acquisition date. The Company's estimates are inherently uncertain and subject to refinement. During the measurement period, which may be up to one year from the acquisition date, the Company may record adjustments to the fair value of these tangible and intangible assets acquired and liabilities assumed, with the corresponding offset to goodwill. In addition, uncertain tax positions and tax-related valuation allowances are initially established in connection with a business combination as of the acquisition date. The Company collects information and reevaluates these estimates and assumptions quarterly and records any adjustments to the Company's preliminary estimates to goodwill during the measurement period. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the Company's consolidated statements of operations and comprehensive loss. Amounts paid for acquisitions are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The Company allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets, including purchased research and development. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management. The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

The Company's purchased research and development represents the estimated fair value as of the acquisition date of substantive in-process projects that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval. The valuation of IPR&D assets is determined using the discounted cash flow method. In determining the value of IPR&D assets, the Company considers, among other factors, the stage of completion of the projects, the technological feasibility of the projects, whether the projects have an alternative future use and the estimated residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used is determined at the time of acquisition and includes a rate of return which accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized.

### *Intangible Assets*

Intangible assets acquired in a business combination consist primarily of 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 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.

#### *Acquisition-related Costs*

Acquisition-related costs incurred in connection with the Mergers are expensed as incurred and include direct and incremental costs associated with the acquisition. The \$1,512,423 and \$671,248 of acquisition-related costs incurred in 2017 and 2016, respectively, were primarily professional fees and are classified as general and administrative expenses.

#### *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. Goodwill is tested for impairment by comparing the estimated fair value of our single reporting unit 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 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, we test those assets for impairment by comparing the fair value of the assets to their carrying value. Upon completion or abandonment, the value of the IPR&D assets will be amortized to expense over the anticipated useful life of the developed products, if completed, or charged to expense when abandoned if no alternative future use exists. As of December 31, 2017, our projects continue to progress as originally anticipated, and no significant changes to the estimated timing or amount of cash flows or any other market assumptions have occurred. We believe our assumptions to be reasonable, however development of IPR&D assets are unpredictable and inherently uncertain. Actual future progress may differ from our initial expectations. We performed qualitative assessments of our long-lived assets, including IPR&D, and have determined that our long-lived assets, including IPR&D, are not impaired as of and during the year ended December 31, 2017.

Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. We test goodwill for impairment during the fourth quarter of each year, or more frequently if impairment indicators arise. During the year ended December 31, 2017, we early adopted the Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) No. 2017-04, *Simplifying the Test for Goodwill Impairment* (“ASU 2017-04”), which provides for a one-step quantitative test to simplify our goodwill impairment analysis. If the carrying value of a reporting unit exceeds its fair value, the amount of goodwill impairment is the excess of the reporting unit’s carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. We consider multiple methods

## [Table of Contents](#)

including both market and income approaches to determine fair value of our one reporting unit, and primarily rely on fair value estimated based on our market capitalization (a Level 2 input and non-recurring fair value measurement) as of or near the testing date, adjusted for an estimated control premium.

From the date of the Mergers through December 31, 2017, the Company experienced a significant decline in the trading price of our common stock which indicated potential impairment. We performed interim impairment tests on our goodwill as of September 30, 2017 and December 21, 2017, by estimating our average market capitalization using a volume weighted average price (“VWAP”) (a Level 2 input and non-recurring fair value measurement) as of the testing dates and applying a control premium of 35% (a Level 2 input). Based on the results of our impairment tests, the carrying value of our reporting unit exceeded its estimated fair value by more than the goodwill carrying value. As a result, we have concluded that our goodwill was impaired and the full amount of its carrying value of \$35,919,695 was written off as an impairment charge which was classified as a component of operating expenses.

### *Fair Value Measurements*

The Company follows the guidance in 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, 2017 and 2016.

### *Financial Instruments*

The Company’s financial instruments consist of cash, cash equivalents, restricted cash, accounts receivable, notes payable, accounts payable, accrued expenses, BPI France notes, common stock warrants classified as a liability, common stock warrant classified as equity, convertible preferred stock, redeemable convertible preferred stock, and an embedded derivative. The carrying amounts of cash, cash equivalents, restricted cash,

## [Table of Contents](#)

accounts receivable, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of those financial instruments. The carrying amounts of notes payable approximate their fair value because their stated interest rates approximate the market rates and due to the short-term nature of the notes. BPI France notes are recorded at their repayment value which approximates fair value. Redeemable convertible preferred stock is classified as temporary equity and its carrying amount is accreted over the term of the instrument up to its liquidation and redemption value. Common stock warrant classified as equity and convertible preferred stock classified as permanent equity are initially recorded at their grant date fair value but are not subsequently remeasured. 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.

### *License Revenue*

License revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured. When one or more of the revenue recognition criteria are not met, the Company defers the recognition of revenue until such time that all criteria are met. The Company has granted a license to one of its investors providing for an exclusive right to use, market, sell, and import the Company's potential vaccine products in the territory provided by the license. The terms of the agreement included nonrefundable upfront fees, annual license maintenance fees, and potential royalties from the licensee's sale of the licensed products. The non-refundable upfront fees are deferred and recognized over the license term, which represents the service period, is considered to extend to the expiration of all licensed patents included in the license. Annual license maintenance fees are recognized when due and payable if collection is reasonably assured. Royalty revenue, if any, will be recognized based upon actual and estimated net sales by the licensee in the period sales occur.

### *Research Grants and Contracts*

Research grants and contracts are derived from government and foundation grants and contracts that support the Company's efforts on specific research projects. We have determined that the government agencies and foundations providing grants and contracts to the Company are not our 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 earnings process 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.

## [Table of Contents](#)

### *Cash Equivalents*

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

### *Restricted Cash*

The Company had restricted cash of \$34,174 at December 31, 2017 held in a money market savings account as collateral for the Company's facility lease obligation. In addition, until all the redeemable preferred stock shares have been converted, redeemed, or otherwise satisfied in accordance with their terms, the Company is required to maintain cash on deposit in an unrestricted account with an aggregate amount not less than the lower of \$3,500,000 or the redeemable preferred stock outstanding conversion amount. The Company has elected to record this amount within restricted cash. 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 do 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. Grantors that represented 10% or more of research grants and contracts for the years ended December 31, 2017 and 2016 and grantors that accounted for 10% or more of accounts receivable at December 31, 2017 and 2016, are presented below:

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Research Grants and Contracts</b>		
BARDA	83%	81%
NIAID	17	—
Texas A&M University System	—	19
	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Accounts Receivable</b>		
BARDA	73%	100%
NIAID	27	—

## [Table of Contents](#)

### *Property and Equipment, Net*

Property and equipment are stated at cost. 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:

<u>Asset Category</u>	<u>Estimated Useful Life</u>
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

### *Patent and licensing costs*

Patent and licensing costs that are incurred on behalf of, or reimbursable under, research grant arrangements are capitalized as intangible assets and amortized over the estimated useful lives of the assets. All other patents and licensing costs are expensed as incurred because their realization is uncertain. These costs are classified as research and development expenses in the accompanying statements of operations and comprehensive loss.

### *Preferred Stock*

The Company issued convertible preferred stock under a stock purchase agreement entered into in connection with a 2015 acquisition. Upon a deemed liquidation event, the convertible preferred stock terms permitted holders to vote as a single class to either liquidate or redeem their shares. Upon such an election, all of the Company's stockholders, including the common stock holders, would always be entitled to receive the same form of consideration. As a result, the Company's convertible preferred stock met the limited exception allowed for shares containing such liquidation rights to be classified as permanent equity with net issuance price in excess of par value recorded as additional paid-in capital. In connection with the Mergers, all outstanding shares of convertible preferred stock converted into Private Altimmune common stock on a 1-for-1 basis (see Note 3).

Shares of redeemable preferred stock issued in August 2017 represented the second closing under the Note Agreement (see Notes 1 and 12). 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 16), an embedded derivative related to certain redemption features which was classified as a liability and recorded at fair value (Note 14), and the intrinsic value of a beneficial conversion feature present in the instrument at issuance (Note 14). The carrying value of the redeemable preferred stock will be accreted over the term of the redeemable preferred stock up to its redemption value, using the straight-line method which approximates the 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.

### *Warrants*

Common stock warrants issued in connection with the convertible preferred stock and the Notes were classified as a component of permanent equity because they were freestanding financial instruments that were legally detachable and separately exercisable from other debt and equity instruments, were contingently exercisable, did not embody an obligation for the Company to repurchase our own shares, and permitted the holders to receive a fixed number of common shares upon exercise. In addition, such warrants required physical settlement and did not provide any guarantee of value or return. These warrants were initially recorded at their issuance date allocated fair value and were not subsequently remeasured. These warrants were valued using the Black Scholes option pricing model ("Black-Scholes") and were converted into Private Altimmune common stock according to their original terms upon the Mergers.

## [Table of Contents](#)

Common stock warrants issued in connection with redeemable preferred stock are classified as a liability because these warrants contain terms which could, in certain circumstances, require 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.

### *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. Stock-based compensation awarded to non-employees are subject to revaluation over their vesting terms. 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.

The Company adopted FASB's ASU No. 2016-09, *Compensation – Stock Compensation* ("ASU 2016-09") on January 1, 2017. The adoption of ASU 2016-09 did not have a material impact on the Company's financial statements. The Company elected to adopt the cash flow presentation of the excess tax benefits prospectively, commencing with our statement of cash flows for the three months ended March 31, 2017. We have elected to continue to estimate the number of stock-based awards expected to vest, rather than electing to account for forfeitures as they occur to determine the amount of compensation cost to be recognized in each period. There was no impact to our computation of dilutive EPS as all securities were considered anti-dilutive.

### *Income Taxes*

We account 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. We also recognize 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

## [Table of Contents](#)

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.

### *Lease Incentive Obligations*

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. Lease incentive obligations are classified as a component of deferred rent and are amortized on a straight-line basis over the lease term as a reduction of rent expense.

### *Deferred Rent*

Rent expense from operating leases is recognized on a straight-line basis over the lease term. The difference between rent expense recognized and rental payments is recorded as deferred rent in the consolidated balance sheets.

### *Recently Issued Accounting Pronouncements*

In February 2016, FASB issued 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. It also aligns lease accounting for lessors with the revenue recognition guidance in ASU 2014-09. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and is to be applied at the beginning of the earliest period presented using a modified retrospective approach. We expect the adoption of ASU 2016-02 will not have a material impact on our financial statements.

## **5. Net Loss Per Share**

Because we have reported net loss attributable to common stockholders for both years presented, basic and diluted net loss per share attributable to common stockholders are the same for both years. All convertible preferred stock, redeemable preferred stock, unvested restricted stock, common stock warrants, and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact. As more fully described in Note 3, in connection with the Mergers, all historical share and per share information including common stock, convertible preferred stock, redeemable preferred stock, common stock warrants, unvested restricted stock, and stock options, has been retroactively adjusted to reflect the effect of the share exchange ratio.



## [Table of Contents](#)

The following table sets forth the computation of basic and diluted net loss per share:

	Year Ended December 31,	
	2017	2016
<b>Numerator</b>		
Net loss	\$ (46,425,390)	\$(11,086,812)
Less: preferred stock accretion and dividends	(4,930,010)	(368,548)
Net loss attributable to common stockholders	<u>\$ (51,355,400)</u>	<u>\$(11,455,360)</u>
<b>Denominator</b>		
Weighted-average common shares outstanding, basic and diluted	<u>12,805,095</u>	<u>6,911,534</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>(4.01)</u>	<u>(1.66)</u>

Potential common shares issuable upon conversion, vesting or exercise of convertible preferred stock, redeemable preferred stock, unvested restricted stock, common stock warrants, and stock options that are excluded from the computation of diluted weighted-average shares outstanding are as follows:

	Year Ended December 31,	
	2017	2016
Convertible preferred stock	—	599,285
Redeemable preferred stock	4,560,550	—
Common stock warrants	2,350,085	612,112
Common stock options	1,819,316	1,205,920
Unvested restricted stock	23,428	74,546

## 6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2017	2016
Furniture, fixtures and equipment	\$ 61,121	\$ 60,320
Laboratory equipment	1,001,810	932,065
Computers and telecommunications	81,342	45,837
Software	16,244	595
Leasehold improvements	44,352	44,352
Construction in progress	350,075	—
Property and equipment, at cost	<u>1,554,944</u>	<u>1,083,169</u>
Less accumulated depreciation and amortization	<u>(951,798)</u>	<u>(905,310)</u>
Property and equipment, net	<u>\$ 603,146</u>	<u>\$ 177,859</u>

The presentation of property and equipment at December 31, 2016 has been reclassified to conform to the 2017 presentation. Depreciation expense for the years ended December 31, 2017 and 2016 was \$83,834 and \$63,109, respectively.

[Table of Contents](#)

## 7. Intangible Assets, Net

The Company's intangible assets consisted of the following:

December 31, 2017				
	Estimated Useful Lives	Gross Carrying Value	Accumulated Amortization	Net Book Value
Internally developed patents	6 – 10 years	\$ 678,340	\$ (249,601)	\$ 428,739
Acquired licenses	16 – 20 years	285,000	(237,340)	47,660
Total intangible assets subject to amortization		963,340	(486,941)	476,399
IPR&D assets	Indefinite	38,245,871	—	38,245,871
Total		<u>\$ 39,209,211</u>	<u>\$ (486,941)</u>	<u>\$ 38,722,270</u>

December 31, 2016				
	Estimated Useful Lives	Gross Carrying Value	Accumulated Amortization	Net Book Value
Internally developed patents	6 – 10 years	\$ 624,454	\$ (211,956)	\$ 412,498
Acquired licenses	16 – 20 years	285,000	(219,800)	65,200
Total intangible assets subject to amortization		909,454	(431,756)	477,698
IPR&D assets	Indefinite	14,477,019	—	14,477,019
Total		<u>\$ 15,386,473</u>	<u>\$ (431,756)</u>	<u>\$ 14,954,717</u>

Amortization expense of intangible assets subject to amortization totaled \$55,185 and \$72,236 for the years ended December 31, 2017 and 2016, respectively, and was classified as research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

As of December 31, 2017, future estimated amortization expense is as follows:

Year ending December 31,	
2018	\$ 53,113
2019	48,314
2020	34,868
2021	14,308
2022	14,308
2023 and thereafter	311,488
Total	<u>\$ 476,399</u>

The above future estimated amortization expense does not include potential amortization charges related to the IPR&D assets. 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 the Company ceases the development of these assets, the 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.

## 8. IPR&D and Goodwill

Changes in the carrying amounts of IPR&D assets and goodwill for the years ended December 31, 2017 and 2016 were:

	<u>IPR&amp;D</u>	<u>Goodwill</u>
Balance, January 1, 2016	\$17,366,791	\$ 22,494,691
Foreign currency translation adjustments	(2,889,772)	(3,736,270)
Balance, December 31, 2016	14,477,019	18,758,421
Additions from the Mergers	22,389,000	15,573,822
Foreign currency translation adjustments	1,379,852	1,587,452
Impairment charges	—	(35,919,695)
Balance, December 31, 2017	<u>\$38,245,871</u>	<u>\$ —</u>

## 9. Accrued Expenses

Accrued expenses consist of the following:

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Accrued professional services	\$ 835,326	\$ 689,135
Accrued board of director compensation	—	606,199
Accrued payroll and employee benefits	909,455	957,719
Accrued interest	536	169,790
Accrued construction costs	328,384	—
Accrued research and development	1,551,556	549,902
Accrued expenses	<u>\$ 3,625,257</u>	<u>\$ 2,972,745</u>

As a condition for the Mergers as described in Note 3, the Company entered into the Note Agreement on January 18, 2017. On February 28, 2017, \$881,044 of the Notes were issued upon the conversion of certain accrued expenses that were outstanding as of that date.

## 10. Licenses

### *University of Alabama at Birmingham Research Foundation*

The Company has 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. The UABRF agreement expires on the last of the related patent expiration date which may be extended upon patent renewal. The latest of the patent expiration date is currently on August 7, 2033. Under the terms of the amended and restated agreement, the Company is obligated to pay an annual license fee of \$20,000 and 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, 2017 and 2016, respectively, 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. (Formerly Crucell Holland, 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. The Janssen agreement expires on the last of the related patent expiration date which may be extended upon patent renewal. The latest of the patent expiration date is currently on March 21, 2020. 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 percentage of net sales or \$100,000. Fees incurred under the Janssen agreement totaled \$200,000 and \$100,000 for the years ended December 31, 2017 and 2016, 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 is required to pay an upfront fee of \$1,000 upon signing of the agreement, an annual license fee of \$5,000, and 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, 2017 and 2016 and are included in research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

**11. Notes Payable**

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

	December 31,	
	2017	2016
Line of credit	\$49,702	\$ 49,702
Economic Development Partnership of Alabama ("EDPA") promissory note	—	96,496
Hammond promissory note	—	100,000
Alex Choi promissory note	—	100,000
Frommer, Lawrence and Haug LLP ("FLH") promissory note	—	112,431
Total notes payable	<u>\$49,702</u>	<u>\$458,629</u>

*Line of Credit*

The Company has a secured line of credit agreement with a financial institution that provides for borrowings up to \$250,000 and matures in April 2018. The borrowings are secured by all of the Company's accounts receivable from BARDA. Interest is payable monthly at the financial institution's prime rate (5.00% at December 31, 2017) plus 2.0% per annum with a floor of 5.0%. Accrued interest was \$536 and \$33 as of December 31, 2017 and 2016, respectively. Interest expense for the years ended December 31, 2017 and 2016 totaled \$3,321 and \$2,956, respectively.

*EDPA Promissory Note*

The EDPA promissory note was in default as of December 31, 2016 and was classified as a current liability. The promissory note continued accruing interest at the stated interest rate of 6% per annum, compounded annually, through February 28, 2017 when the outstanding principal and accrued interest were converted into the Notes according to the Note Agreement. Accrued interest was \$34,121 at December 31, 2016. Interest expense on the promissory note was \$1,079 and \$5,621 in 2017 and 2016, respectively.

*Hammond Promissory Note*

The Hammond promissory note was in default as of December 31, 2016 and was classified as a current liability. The promissory note continued accruing interest at the stated default interest rate of 15% per annum through February 28, 2017 when accrued interest was converted into the Notes according to the Note Agreement and the principal was repaid with proceeds from the Notes. Accrued interest was \$94,685 at December 31, 2016. Interest expense on the promissory note was \$4,663 and \$15,000 in 2017 and 2016, respectively.

*Alex Choi Promissory Note*

Alex Choi is one of the Company's stockholders. The Alex Choi promissory note was in default as of December 31, 2016 and was classified as a current liability. The promissory note continued accruing interest at the stated interest

## [Table of Contents](#)

rate of 6% per annum through February 28, 2017 when the outstanding principal and accrued interest were converted into the Notes according to the Note Agreement. Accrued interest was \$40,951 at December 31, 2016. Interest expense on the promissory note was \$1,575 and \$8,149 in 2017 and 2016, respectively.

### *FLH Promissory Note*

The FLH promissory note was in default as of December 31, 2016 and was classified as a current liability. The promissory note was noninterest bearing and was repaid with proceeds from the Notes.

## **12. Other Long-Term Liabilities**

The Company's other long-term liabilities are summarized as follows:

	December 31,	
	2017	2016
Unvested restricted stock (see Note 15)	\$ 315	\$ 1,001
BPI France notes	599,927	525,950
Deferred revenue, long-term portion (see Note 4)	159,671	179,424
Deferred rent, long-term portion	386,489	15,914
Common stock warrant liability (see Note 16)	3,400,869	—
Embedded derivative (see Note 14)	27,236	—
Total other long-term liabilities	<u>\$ 4,574,507</u>	<u>\$ 722,289</u>

### *Note Agreement*

As a condition for the Mergers as described in Note 3, the Company entered into the Note Agreement on January 18, 2017. The Notes bore interest at a rate of 6% per annum, compounded annually. On February 28, 2017, \$196,496 of the Notes were issued upon the conversion of outstanding principal of the EDPA and the Alex Choi promissory notes (see Note 11), and \$174,594 of the Notes were issued upon the conversion of accrued interest on the EDPA, Alex Choi, and Hammond promissory notes. The conversion of these promissory notes and accrued interest into the Notes was accounted for as an extinguishment with no resulting gains or losses being recognized. On March 9, 2017, the remainder of the initial closing of the Notes was issued for an aggregate of \$3,150,630 in gross proceeds. In connection with the issuance of the Notes, we granted a warrant for the purchase of up to 49,776 shares of our common stock to one noteholder. The allocated fair value of the warrant on the issuance date of \$566,793 was accounted for as a debt issuance discount and was accreted over the term of the Notes using the interest method. On May 4, 2017, upon the close of the Mergers, outstanding principal and accrued interest of the Notes, net of unamortized discount and deferred financing costs, totaling \$3,645,424 were converted into 316,734 shares of our common stock. Interest expense incurred on the Notes during 2017 totaled \$136,629.

### *Deferred Rent, Long-Term Portion*

Deferred rent, long-term portion, includes the difference between rent expense recognized and rental payments made, and lease incentive obligations. Lease incentive obligations represent lease incentives and allowances provided by our landlord for the construction of leasehold improvements located at our new office and laboratory facilities. We record lease incentive obligations as construction costs are incurred and billable, up to the maximum allowance amount. Lease incentive obligations are amortized on a straight-line basis over the lease term as a reduction of rent expense. Through December 31, 2017, \$350,076 of construction costs have been incurred and recorded as lease incentive obligation with \$29,854 of amortization recorded as a reduction of rent expense during the year ended December 31, 2017.

*BPI France Notes*

Altimmune France has two non-interest-bearing research and development funding arrangements with BPI France that were entered into in December 2013 to provide Altimmune France up to €750,000 (\$899,890 at December 31, 2017) in research funding in the first arrangement and up to €250,000 (\$299,963 at December 31, 2017) in the second arrangement. Altimmune France is 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 agreed to extend the term on the arrangement by two years. Each of the two obligations is repayable in sixteen quarterly installments from June 2019 through March 2023. The total amount advanced under the arrangements was €500,000 as of December 31, 2017 and 2016 (\$599,927 and \$525,950 as of December 31, 2017 and 2016, respectively).

**13. Common Stock**

As more fully described in Note 3, in connection with the Mergers, all historical share and per share information including common stock, convertible preferred stock, redeemable preferred stock, common stock warrants, restricted stock, and stock options, has been retroactively adjusted to reflect the effect of the share exchange ratio. The Company had 100,000,000 authorized shares of our \$0.0001 par value common stock with 18,103,691 shares and 6,917,204 shares issued and outstanding at December 31, 2017 and 2016, respectively.

The voting, dividend and liquidation rights of the common stockholders are subject to and qualified by the rights, powers and preferences of the preferred stock. Common stockholders are entitled to one vote for each share of common stock held at all meetings of stockholders. Common stockholders are entitled to receive dividends declared out of funds legally available, subject to the payment in full of all preferential dividends to which the holders of preferred stock, if any, are entitled. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, after the payment of all preferential amounts that the holders of preferred stock are entitled, if any, the common stockholders and preferred holders (on an as-converted basis) share ratably in the remaining assets of the Company available for distribution.

As of December 31, 2017, the Company's common stock available for future issuance is summarized as follows:

Common stock authorized	100,000,000
Common stock issued and reserved for future issuance:	
Common stock issued and outstanding	18,103,691
Common stock reserved for the exercises of common stock warrants	3,522,799
Common stock reserved for the conversion of redeemable preferred stock	6,840,818
Common stock reserved for the exercise of options	1,819,316
Common stock reserved for the vesting of unvested restricted stock	23,428
Common stock reserved for future option awards	708,073
Total common stock issued and reserved for future issuance	<u>31,018,125</u>
Unreserved common stock available for future issuance	<u>68,981,875</u>

**14. Preferred Stock**

The Company had 599,285 shares of its \$0.01 par value convertible preferred stock issued and outstanding at December 31, 2016, all of which converted into common stock on a 1-to-1 basis in connection with the Mergers. As more fully described in Note 3, in connection with the Mergers, all historical preferred stock information has been retroactively adjusted to reflect the effect of the share exchange ratio.

On August 16, 2017, we issued 15,656 shares of our \$0.0001 par value, redeemable preferred stock and warrants to purchase up to 2,345,427 shares of our common stock (see Note 16), satisfying the second closing requirement

## [Table of Contents](#)

under the Note Agreement for total gross proceeds of \$14,716,370, and incurred issuance costs totaling \$1,697,800. The redeemable preferred stock matures on August 16, 2018. The maturity date may be extended at the option of the holders to ten trading days after the curing of a triggering event (as defined), or ten business days after the consummation of a change of control. In addition, the redeemable preferred stock agreements require 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 rights, preferences, and privileges of redeemable preferred stock are summarized below:

*Voting* — Holders of redeemable preferred stock have no voting rights, except as required by law.

*Dividends* — Holders of redeemable preferred stock are entitled to participate in dividends, when and if declared by our board of directors, on an as converted basis at the initial conversion price of \$2.67 per share, not to exceed the maximum ownership percentages (as defined).

*Optional conversion* — Holders of redeemable preferred stock have the option to convert redeemable preferred stock into shares of common stock, rounded up to the nearest whole shares, at any time, not to exceed the maximum ownership percentages (as defined), at the conversion rate calculated as (1) whole shares of redeemable preferred shares to be converted at \$1,000 per share, plus any accrued but unpaid dividends, and any accrued but unpaid late charges, divided by (2) the conversion price which is \$2.67 per share initially, or as adjusted for any dilutive events and down rounds.

*Mandatory conversion* — If for any ten consecutive trading days after the redeemable preferred stock issuance date, the weighted average price of our common stock equals or exceeds 200% of the then current conversion price (initially \$2.67 per share, subject to adjustment for stock dividends, stock splits, or a stock combination), we have the option to require all holders of redeemable preferred stock to convert all or a pro rata portion of their outstanding unconverted redeemable preferred stock (plus accrued and unpaid dividends and accrued and unpaid late charges) into common stock at the then current conversion rate (initially \$2.67 per share), up to the maximum ownership percentage (as defined).

*Triggering event conversion* — Upon a triggering event, holders of redeemable preferred stock may elect to convert all, or a portion of, the outstanding conversion amount at the triggering event conversion price determined based on the lowest of (1) the conversion price then in effect (initially \$2.67 per share), (2) 75% of the lowest VWAP during the 20-day period prior to the triggering event conversion date, and (3) 75% of the VWAP on the triggering event conversion date, adjusted for any share dividend, share split, or share combination.

*Installment* — On each of the nine specified installment dates beginning in December 2017 through maturity, we are required to convert, redeem, or a combination, one-ninth of the originally issued number of redeemable preferred shares at their stated value of \$1,000 per share, for an aggregate value of \$1,739,524 at each installment. If we elect to convert the installment shares, the conversion price is 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 elect cash redemption, the redemption amount is \$1,000 per share, plus any accrued but unpaid dividends and any accrued but unpaid late charges.

*Liquidation preference* — In the event of a voluntary or involuntary liquidation, dissolution, or winding up of business involving substantially all of our assets, holders of redeemable preferred stock are entitled to receive cash payments in priority to holders of common stock in the amount that equals the sum of any outstanding shares at \$1,000 per share, plus any accrued and unpaid dividends, and any accrued and unpaid late charges. If

## [Table of Contents](#)

assets available for distribution are insufficient to satisfy the liquidation payment in full, funds available for distribution shall be allocated pari passu among holders of redeemable preferred stock, and other equity classes equal in preference, based on their relative shareholdings. When the holders of redeemable preferred stock are satisfied in full, any excess assets available for distribution will be allocated ratably among holders of common stock and holders of redeemable preferred stock based on the number of common shares held by each holders of redeemable preferred stock on an as-converted basis.

*Mandatory redemption* — Upon maturity, we are required to redeem remaining outstanding redeemable preferred stock, if any, in cash at \$1,000 per share, plus any accrued and unpaid dividends, and any accrued and unpaid late charges.

*Change of control redemption or triggering event redemption* — In the event of a change of control or upon a triggering event, holders of redeemable preferred stock may redeem for cash all or a portion of their outstanding redeemable preferred stock at the greater of (i) 125% of the amount to be redeemed, or (ii) the amount to be redeemed multiplied by the quotient of the highest closing sale price during the period from the earlier of consummation or public announcement of the change of control to the date of the redemption notice, divided by the lowest conversion price in effect during such period. If we are unable to redeem all redeemable preferred stock submitted for redemption, we may be required to pay a penalty until the redemption amount is paid in full.

*Stock purchasing rights* — Holders of redeemable preferred stock are entitled to the same stock purchasing rights granted to holders of common stock.

*Late charges* — We may be required to pay a late charge for any amounts due to the holders of redeemable preferred stock that are not paid timely, at 12% per annum on the unpaid amount, until it is paid in full.

*Affirmative covenants* — Until all the redeemable preferred stock shares have been converted, redeemed, or otherwise satisfied in accordance with their terms, the Company is required to meet certain affirmative covenants that include maintaining its existence as a Delaware corporation, and maintaining cash on deposit in an unrestricted account with an aggregate amount not less than the lower of \$3,500,000 or the redeemable preferred stock outstanding conversion amount.

Because the securities contain contingencies which could require the Company to redeem the shares for cash, and such contingencies are outside the control of the Company, the redeemable preferred stock is classified outside of permanent equity. Because a substantive conversion feature is present at issuance, the redeemable preferred stock is only contingently redeemable and therefore is 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 require separate recognition. For purposes of this evaluation, we have 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 contains 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) have been 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 is being remeasured on each subsequent balance date with changes in fair value classified as a component of other income (expenses), net. The embedded derivative is classified as a component of other long-term liabilities.

The redeemable preferred stock also contains 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



## [Table of Contents](#)

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 is classified as a component of additional paid-in capital. The beneficial conversion feature will not be remeasured in subsequent periods but will be released in nine equal amounts corresponding to each of the redeemable preferred stock installments. Through December 31, 2017, \$167,356 of the beneficial conversion feature has been released within components of additional paid-in capital with a balance of \$1,338,840 remaining at December 31, 2017.

Through December 31, 2017, the Company converted 3,480 shares of redeemable preferred stock which included a scheduled installment due on December 15, 2017 and a pre-installment on December 13, 2017 for the January 2018 scheduled installment.

The net proceeds from the redeemable preferred stock financing were allocated as follows:

Common stock warrant liability (see Note 16)	\$ 3,498,632
Embedded derivative	19,857
Beneficial conversion feature	1,506,196
Initial carrying value of redeemable preferred stock	7,993,885
Net proceeds from redeemable preferred stock issuance	<u>\$ 13,018,570</u>

The periodic changes in the fair value of the embedded redemption derivative financial instrument is as follows:

Balance, January 1, 2017	\$ —
Issuance	19,857
Changes in fair value	7,379
Balance, December 31, 2017	<u>\$27,236</u>

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 assumptions used to estimate the fair value of the embedded redemption derivative financial instrument at December 31, 2017 and as of the redeemable preferred stock issuance date were as follows:

	<u>December 31,</u> <u>2017</u>	<u>August 16,</u> <u>2017</u>
Expected volatility	59.60%	56.40%
Incremental borrowing rate	12.00%	12.00%
Risk-free interest rate	1.59%	1.24%

## 15. 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 Mergers, the Company issued options from its 2001 Plans to replace options previously granted under PharmAthene's option plans. At the close of the Mergers, the Company de-designated common stock available for issuance under the 2001 Plans and the PharmAthene plans. No additional options or restricted stock will be granted under these plans. Options outstanding and unvested restricted stock granted under these plans through the close of the Mergers will continue to vest over the

## [Table of Contents](#)

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 Merger will continue to vest over the remaining vesting period through the earlier of exercise, expiration, or forfeiture. Also, in connection with the Mergers, the 2001 Plans were assumed by the Company.

In addition, PharmAthene had previously established the PharmAthene, Inc. Amended and Restated 2007 Long-Term Incentive Compensation Plan, or the 2007 Plan. Awards outstanding under the 2007 Plan remained outstanding following the Mergers in accordance with their applicable terms and conditions. No additional awards will be made under the 2007 Plan.

Also in connection with the Mergers, 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. Up to 1,500,000 shares of the Company's common stock have initially been reserved and may be issued under the Omnibus Plan. 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) 1,000,000 shares of common stock, (ii) 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 (iii) 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. The maximum common stock that may be granted to directors under the Omnibus Plan during any fiscal year is 500,000 shares.

The 2001 Plans, the 2007 Plan, and the Omnibus Plan are collectively referred to as the "Plans." Under the Plans, a total of 4,500,869 shares of common stock were authorized for issuance. As of December 31, 2017, options to purchase 872,348 shares of common stock have been exercised to date with 708,073 shares of common stock available for future grants.

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:

	Year Ended December 31,	
	2017	2016
Expected volatility	89.17%	76.50%
Expected term (years)	5.84	6.25
Risk-free interest rate	1.95%	2.18%
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 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.

## Table of Contents

*Forfeitures:* Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

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:

	<u>Number of Stock Options</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term (Year)</u>	<u>Weighted- Average Intrinsic Value</u>
Outstanding, January 1, 2017	1,206,104	\$ 3.91	5.79	\$ 8,475,032
Granted	801,927	3.03		
Replacement options issued in connection with the Mergers	123,003	38.76		
Exercised	(200,857)	0.08		\$ 413,623
Forfeited or expired	(110,861)	37.11		
Outstanding, December 31, 2017	<u>1,819,316</u>	\$ 4.27	4.45	\$ 882,103
Exercisable, December 31, 2017	<u>984,666</u>	\$ 3.98	4.47	\$ 863,426
Expected to vest, December 31, 2017	<u>834,650</u>	\$ 4.62	4.42	\$ 18,678

The per share weighted-average grant date fair value of stock options granted during the years ended December 31, 2017 and 2016 were \$2.16 and \$8.92, respectively. The aggregate intrinsic value for stock options exercised during the year ended December 31, 2016 was \$10,273. At December 31, 2017, there was \$2,001,250 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 2.15 years. As more fully described in Note 3, in connection with the Mergers, all historical option information has been retroactively adjusted to reflect the effect of the share exchange ratio.

### *Restricted Stock*

In October 2016, the Company authorized and granted a restricted stock award of 79,516 shares at an aggregate purchase price of \$1,067. The weighted average grant date fair value of the restricted stock award was \$10.36 per share. The restricted stock vests ratably at the end of each quarter over four years starting on December 31, 2016 with 50% of the original issued shares subject to accelerated vesting upon a deemed liquidation event. Fair value of restricted shares that vested during the year ended December 31, 2017 totaled \$331,076. Under certain conditions, the Company has the right to repurchase any unvested shares at a price of \$0.01 per share. Accordingly, the aggregate repurchase price is recorded as a long-term liability to be amortized over the vesting period with the amortization classified as a component of additional paid-in capital. As more fully described in Note 3, in connection with the Mergers, all historical restricted stock information has been retroactively adjusted to reflect the effect of the share exchange ratio (Note 3).

A summary of restricted stock activities is presented below:

	<u>Shares</u>	<u>Weighted- average Grant Date Fair Value</u>	<u>Restricted Stock Repurchase Liability</u>
Unvested, January 1, 2017	74,546	\$ 10.36	\$ 1,001
Vested	(51,118)	10.36	(686)
Unvested, December 31, 2017	<u>23,428</u>	10.36	<u>\$ 315</u>

## [Table of Contents](#)

As of December 31, 2017, total unrecognized compensation expense related to restricted stock awards was \$23,177, which the Company expects to recognize over a weighted average period of approximately 2.75 years.

### *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, 2017 and 2016 as follows:

	Year Ended December 31,	
	2017	2016
Research and development	\$ 327,610	\$ 299,398
General and administrative	1,115,882	665,967
Total	<u>\$ 1,443,492</u>	<u>\$ 965,365</u>

## 16. Warrants

The following common stock warrants were outstanding at December 31, 2017:

	Number of Common Stock Warrants	Per Share Exercise Price	Issuance Date	Expiration Date
Replacement warrants issued in connection with the Mergers	4,658	\$ 16.10	March 3, 2012	March 3, 2022
Issued with redeemable preferred stock	2,345,427	2.67	August 16, 2017	August 16, 2022
Total	<u>2,350,085</u>			

The following common stock warrants were outstanding at December 31, 2016:

	Number of Common Stock Warrants	Per Share Exercise Price	Issuance Date	Expiration Date
Issued in connection with loan guarantees	74,115	\$ 0.08	October 10, 2011	October 10, 2021
Issued with convertible preferred stock	134,499	0.01	November 6, 2015	November 6, 2020
Issued with convertible preferred stock	134,500	0.01	January 12, 2016	November 6, 2020
Issued with convertible preferred stock	134,499	0.01	April 8, 2016	November 6, 2020
Issued with convertible preferred stock	134,499	0.01	August 16, 2016	November 6, 2020
Total	<u>612,112</u>			

As is more fully described in Note 3, in connection with the Mergers, all historical warrant information has been retroactively adjusted to reflect the effect of the share exchange ratio.

In March 2017, we issued warrants to purchase up to 49,776 shares of common stock in connection with the Notes (see Note 1). Those warrants were classified as permanent equity and were recorded at the issuance date using a relative fair value allocation method which were not subsequently remeasured. In connection with the Mergers, 660,652 shares of common stock were issued upon the cashless exercises of 661,888 warrants. In May 2017, we issued 4,658 common stock warrants to replace outstanding PharmAthene common stock warrants in connection with the Mergers.

In August 2017, in connection with the redeemable preferred stock issuance (Note 14), we granted warrants to holders of redeemable preferred stock to purchase up to 2,345,427 shares of our common stock. Warrants issued

## Table of Contents

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.

A summary of warrant activity during the years ended December 31, 2017 and 2016 is as follows:

	Year Ended December 31,	
	2017	2016
Warrants outstanding, January 1	612,112	208,614
Issuances	2,395,203	403,498
Replacement warrants issued in connection with the Mergers	4,658	—
Exercises and conversions	(661,888)	—
Warrants outstanding, December 31	<u>2,350,085</u>	<u>612,112</u>

Warrants outstanding at December 31, 2017 have an aggregate grant date fair value of \$3,498,720 with a weighted average exercise price of \$2.70.

The fair value used to determine the initial carrying value of warrants classified as permanent equity was measured using Level 3 inputs and was estimated using the Black-Scholes option pricing model. The following assumptions were used to estimate the fair value of warrants issued during the years ended December 31, 2017 and 2016 that were classified as permanent equity:

	March 9, 2017 Issuance	August 19, 2016 Issuance	April 8, 2016 Issuance	January 12, 2016 Issuance
Expected volatility	84.40%	71.00%	77.00%	76.00%
Expected term (years)	5.00	4.22	4.58	4.82
Risk-free interest rate	2.13%	1.08%	1.15%	1.65%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

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

Balance, January 1, 2017	\$ —
Issuance	3,498,632
Changes in fair value	<u>(97,763)</u>
Balance, December 31, 2017	<u>\$3,400,869</u>

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, 2017 and as of the redeemable preferred stock issuance date were as follows:

	December 31, 2017	August 16, 2017
Expected volatility	91.30%	86.90%
Expected term (years)	4.60	5.00
Risk-free interest rate	2.16%	1.76%
Expected dividend yield	0.00%	0.00%

## 17. Income Taxes

Pursuant to federal and state tax regulations with respect to carryback periods of certain NOLs, as a result of the Mergers, we anticipate that we will be able to carryback 2017 NOLs to 2016 which we expect will allow us to recover federal and state income taxes previously paid by PharmAthene and other tax credits of \$6,361,657. These anticipated refunds are classified as a component of current assets at December 31, 2017.

## [Table of Contents](#)

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

	Year Ended December 31,	
	2017	2016
U.S. operations	\$ 27,814,653	\$ 8,175,119
Non-U.S. operations	24,249,112	2,911,693
Net loss before income tax benefit	<u>\$ 52,063,765</u>	<u>\$ 11,086,812</u>

The components of the income tax benefits are as follows:

	Year Ended December 31,	
	2017	2016
U.S. federal		
Current	\$ 2,432,088	\$ —
Deferred	2,608,256	—
US state and local		
Current	587,711	—
Deferred	10,320	—
Income tax benefit	<u>\$ 5,638,375</u>	<u>\$ —</u>

Reconciliation between the effect of applying the federal statutory rate and the effective income tax rate used to calculate the Company's income tax benefit is as follows:

	Year Ended December 31,	
	2017	2016
Federal statutory rate	34.00%	34.00%
State income taxes, net of federal benefit	1.20	3.51
Foreign income tax rate differential	(0.05)	(3.50)
Effect of the Tax Cuts and Jobs Act ("TCJA") on tax rates	(2.16)	—
Stock compensation	(2.49)	(0.18)
Research and development tax credit	(2.33)	—
Acquisition costs	(0.77)	(2.05)
Goodwill impairment	(22.69)	—
Permanent differences and other	(0.78)	(6.34)
Change in valuation allowance	6.90	(25.44)
Effective tax rate	<u>10.83%</u>	<u>0.00%</u>

On December 22, 2017, the President of the United States signed into law the TCJA. The TCJA makes significant changes in the U.S. tax code including the following:

- reduction of the corporate federal income tax rate from 35% to 21%;
- repeal of the domestic manufacturing deduction;
- repeal of the corporate alternative minimum tax;
- a one-time transition tax on accumulated foreign earnings (if any);
- a move to a territorial tax system; and
- acceleration of business asset expensing.

## Table of Contents

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for income tax effects of the TCJA. The Company has recognized the provisional tax impacts in 2017, including \$1,125,708 in incremental income tax provision in the fourth quarter of 2017 to re-measure our deferred tax assets to the 21% enacted rate. The final amounts may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the TCJA.

The TCJA provided for a one-time deemed mandatory repatriation of post-1986 undistributed foreign subsidiary earnings and profits through December 31, 2017. Based on the Company’s provisional analysis performed to date, we do not expect to be subject to the one-time transition tax due to our foreign subsidiaries being in a net accumulated deficit position.

While the TCJA provides for a territorial tax system, beginning in 2018, it includes the following new anti-abuse provisions:

- The global intangible low-taxed income (“GILTI”) provisions require the Company to include in our U.S. income tax base foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary’s tangible assets. The Company expects that we will be subject to incremental U.S. tax resulting from GILTI inclusions beginning in 2018. However, our analysis and accounting for the effects of the GILTI provision is incomplete and an accounting policy on whether we will account for impact of GILTI inclusions in the period in which it is incurred or record deferred taxes for anticipated GILTI inclusions has not been made.
- The base-erosion and anti-abuse tax (“BEAT”) provisions in the TCJA impose an alternative minimum tax on taxpayers with substantial base-erosion payments. Our preliminary assessment is that the Company will not be subject to the BEAT; however, our analysis is incomplete and we will continue to analyze the impact of the BEAT provisions to determine if these would be material to the company’s effective tax rate.

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,	
	2017	2016
Deferred tax assets:		
Domestic NOLs	\$ 6,320,893	\$ 6,761,452
Foreign NOLs	8,323,454	4,094,141
Accrued expenses	19,597	793,148
Amortization	1,187,512	254,990
Deferred revenue	49,373	78,565
Stock compensation	589,986	561,749
Deferred rent	110,731	11,954
Depreciation	6,955	(6,081)
Total deferred tax assets	<u>16,608,501</u>	<u>12,549,918</u>
Deferred tax liabilities:		
IPR&D assets	(8,856,561)	(2,607,364)
Prepaid expenses	—	(54,549)
IRC §481(a) adjustment	(20,118)	(32,194)
Total deferred tax liabilities	<u>(8,876,679)</u>	<u>(2,694,107)</u>
Deferred tax assets, net	7,731,822	9,855,811
Valuation allowance	<u>(13,670,224)</u>	<u>(9,855,811)</u>
Total deferred tax liabilities, net	<u>\$ (5,938,402)</u>	<u>\$ —</u>

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 \$3,814,411 net change in the valuation allowance during the year ended December 31, 2017 primarily relates to the Mergers, goodwill impairment, and the re-measurement of our deferred income taxes to the new U.S. statutory tax rate. The Company has recorded a valuation allowance against the majority of its gross U.S. net 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 the U.S. and the U.K., will be applied in the future to offset against NOLs generated after 2017 which will have an unlimited life.

At December 31, 2017, the Company had U.S. federal NOLs totaling approximately \$24,499,476, that will begin to expire in 2020, and U.S. state NOLs of approximately \$18,043,782 that will begin to expire in 2023. Also at December 31, 2017, NOLs for the Company's U.K. subsidiaries and France subsidiary totaled \$18,819,106 and \$845,651, respectively, which do not expire as long as the U.K. and France subsidiaries continue to engage in the same trade or business. 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. Subsequent ownership changes may further affect the limitation in future years. The Company believes that as of December 31, 2017, there was no material limitation on our ability to utilize NOLs and other tax attributes in the future.

As of December 31, 2017 and 2016, we do not have any material unrecognized tax benefits. We file 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. In March 2017, the Internal Revenue Service notified the Company regarding its plans to examine PharmAthene's tax return for the year ended December 31, 2016.

## **18. Commitments and Contingencies**

See Note 10 for the Company's commitments under license agreements.

### *Operating Leases*

The Company rents office and laboratory space in the United States under non-cancelable operating leases, which expire at various dates through October 2018. The leases require a security deposit of \$22,248. The Company also leases office equipment under a non-cancellable equipment lease through June 2019. In addition, the Company rents office and laboratory space in the United Kingdom under a month-to-month arrangement that may be terminated by either the Company or the lessor at any time.

In June 2017, the Company entered into a new lease agreement for our new U.S. headquarters that includes 14,141 square foot of office and laboratory facilities under a noncancelable operating lease commencing on November 1, 2017 for an initial lease term of 90 months. The lease requires a security deposit of \$34,174 which is recorded as a component of other assets. The lease provides for six months of free rent with the first base rent payment of \$17,087 due on May 1, 2018. The base rent is subject to an annual 3% escalation effective on May 1 of each year during lease term. The Company is also required to pay our share of operating expenses billable by the landlord. Aggregate rent over the lease term plus free rent and rent escalation are recognized on a straight-line basis over the lease term with the difference between rent expense and rent payment recorded as deferred rent.



## [Table of Contents](#)

In addition, the lease agreement provides the Company tenant improvement incentives and allowances that include an upfront payment to the Company of \$282,820, and up to \$1,060,575 of additional tenant improvement allowances to be reimbursed by the landlord for construction costs incurred by the Company. Additional tenant improvement allowances, up to the maximum amount of \$1,060,575, will be amortized and added to monthly rent payment beginning on May 1, 2018 and over the remaining lease term, regardless of whether the construction is complete, plus interest at 8.5% per annum. Additional monthly rent payment resulting from additional tenant improvement allowance is not subject to the annual 3% rent escalation applicable to the base rent.

Construction costs incurred are recorded as construction in progress with a corresponding lease incentive obligation which is classified as a component of deferred rent. The amounts to be reimbursed by the landlord are recorded as a component of prepaid expenses and other current assets when billed. Through December 31, 2017, the Company has incurred \$350,076 in construction costs and recorded \$29,854 of amortization of lease incentive obligation as a reduction of rent expense.

Rent expense under all of the Company's operating leases was \$562,840 and \$352,559 for the years ended December 31, 2017 and 2016, respectively. Deferred rent resulting from rent escalation totaled \$82,180 and \$30,302 at December 31, 2017 and 2016, respectively.

Future minimum lease payments for non-cancelable operating leases at December 31, 2017 are as follows:

Year ending December 31,	
2018	\$ 438,409
2019	416,394
2020	422,668
2021	429,131
2022	435,788
2023 and thereafter	<u>1,029,744</u>
Total	<u>\$ 3,172,134</u>

### *Other Contingencies*

We are a party in various contractual disputes, litigation, and potential claims arising in the ordinary course of business. We do not believe that the resolution of these matters will have a material adverse effect on our financial position or results of operations.

## **19. Fair Value Measurement**

The Company records cash equivalents, warrant liability, and an embedded derivative 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 a basis for classifying the fair value measurements, a three-tier fair value hierarchy, which classifies the fair value measurements based on the inputs used in measuring fair value, was established. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The Company's cash equivalents are composed of money market funds which are classified as Level 1 in the fair value hierarchy. The Company's warrant liability and an embedded derivative classified within Level 3 of the fair value hierarchy are valued using the Monte Carlo simulation valuation model. For certain other financial instruments, including accounts receivable, accounts payable, accrued expenses, and notes payable the carrying value approximate their fair value due to the short-term nature of these items. If applicable, the Company will

## [Table of Contents](#)

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 2017. The Company did not have assets or liabilities recorded at fair value on a recurring basis during the year ended December 31, 2016.

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 2017, the Company recognized goodwill impairments measured at fair value on a nonrecurring basis. The Company did not have assets or liabilities recorded at fair value on a nonrecurring basis during the year ended December 31, 2016.

The Company's assets and liabilities measured at fair value on a recurring and nonrecurring basis at December 31, 2017 consisted of the following:

	Fair Value Measurement at December 31, 2017				Total Loss
	Total	Level 1	Level 2	Level 3	
Recurring fair value measurements					
Cash equivalents — money market fund	\$ 259,551	\$ 259,551	\$ —	\$ —	\$ —
Restricted cash — money market fund	3,500,000	3,500,000			
Warrant liability	(3,400,869)			(3,400,869)	
Embedded derivative	(27,236)	—	—	(27,236)	
Nonrecurring fair value measurement					
Goodwill	—	—	—	—	35,919,695

### 20. Employee Benefit Plans

We have a 401(k) retirement plan in which substantially all of our employees in the United States are eligible to participate. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. During 2017 and 2016, we made discretionary plan contributions of \$196,373 and \$73,024, respectively.

### 21. Subsequent Events

None.

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

As previously disclosed, prior to the completion of the Mergers, Ernst & Young LLP (“Ernst & Young”) served as the principal accountant of PharmAthene. On June 22, 2017 (the “Engagement Date”), we engaged Ernst & Young as our independent registered public accounting firm to serve as the principal accountant to audit our financial statements. Prior to May 4, 2017, among other services, Ernst & Young audited PharmAthene’s financial statements for the fiscal years ended December 31, 2016 and 2015, and provided audit opinions with respect to such audited financial statements. During the period starting on May 4, 2017, the last day of Ernst & Young’s engagement as PharmAthene’s auditor, and ending on the Engagement Date, the Company did not consult with Ernst & Young regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company’s financial statements or (ii) any matter that was either the subject of a disagreement (as defined in paragraph (a)(1)(iv) of Item 304 of Regulation S-K and the related instructions thereto) or a reportable event (as described in paragraph (a)(1)(v) of Item 304 of Regulation S-K).

## **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, 2017. 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, 2017, 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, 2017, and has concluded that there was no change that occurred during the year ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except as follows:

On May 4, 2017, we completed the Mergers with PharmAthene as described in Item 1 above.

### **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, 2017.

### **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

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[Table of Contents](#)

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.**

The information required by this Item will be contained in our proxy statement for our 2018 annual stockholders meeting (the “Proxy Statement”) under the headings “Election of Directors,” “Section 16(a) Beneficial Ownership Reporting Compliance,” and “Corporate Governance,” and is incorporated herein by reference. We intend to file the Proxy Statement or amend this annual report on Form 10-K within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

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. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K and under the applicable the NASDAQ Global Market rules by posting such information on our website in accordance with such requirements.

### **Item 11. Executive Compensation.**

The information required by this item is contained in the Proxy Statement (or an amendment to this annual report on Form 10-K) under the headings “Director Compensation” and “Executive Compensation” and is incorporated herein by reference.

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

Information required by this item with respect to stock ownership of certain beneficial owners and management is contained in the Proxy Statement (or an amendment to this annual report on Form 10-K) under the heading “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

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

The information required by this item is contained in the Proxy Statement (or an amendment to this annual report on Form 10-K) under the headings “Certain Relationships and Related Transactions” and “Determination of Independence” and is incorporated herein by reference.

### **Item 14. Principal Accountant Fees and Services.**

The information required by this item is contained in the Proxy Statement (or an amendment to this annual report on Form 10-K) under the heading “Independent Registered Public Accounting Firm Fees and Services” and is incorporated herein by reference.

**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**

<b>Exhibit No.</b>	<b>Description</b>
2.1	<a href="#">Securities Purchase Agreement between Altimmune, Inc. and the purchasers named therein dated August 16, 2017 (incorporated by reference to Exhibit 2.1 to the Registrant's Form 8-K filed on August 17, 2017)</a>
2.2	<a href="#">Agreement and Plan of Merger and Reorganization dated as of January 18, 2017, by and among PharmAthene, Inc., Mustang Merger Sub, Inc., Mustang Merger Sub LLC, Altimmune, Inc. and Shareholder Representative Services LLC, as representative of Altimmune Securityholders (incorporated by reference to Annex A to the Registrant's proxy statement/prospectus/consent solicitation included as part of the Registrant's Registration Statement on Form S-4 (File No. 333-215891) filed with the SEC on February 3, 2017)</a>
3.1	<a href="#">Amended and Restated Certificate of Incorporation, dated October 17, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on October 18, 2017)</a>
3.2	<a href="#">Certificate of Designations of the Series B Convertible Preferred Stock, dated August 21, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on August 21, 2017)</a>
3.3	<a href="#">Amended and Restated Bylaws of Altimmune, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on October 18, 2017)</a>
4.1	<a href="#">Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on August 17, 2017)</a>
4.2	<a href="#">Form of Warrant in connection with Loan and Security Agreement, dated March 30, 2012 (incorporated by reference to the Registrant's Form 8-K filed on April 3, 2012)</a>
10.1†	<a href="#">Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 8, 2017)</a>
10.2†	<a href="#">Form of Incentive Stock Option Agreement under the Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on May 8, 2017)</a>
10.3†	<a href="#">Form of Non-Qualified Stock Option Agreement under the Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on May 8, 2017)</a>
10.3.1†	<a href="#">Incentive Stock Option Agreement under the Altimmune, Inc. 2017 Omnibus Incentive Plan, dated as of September 22, 2017, by and between Altimmune, Inc. and William Enright (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q filed on November 9, 2018)</a>
10.3.2†	<a href="#">Incentive Stock Option Agreement under the Altimmune, Inc. 2017 Omnibus Incentive Plan, dated as of September 22, 2017, by and between Altimmune, Inc. and Elizabeth Czerepak (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q filed on November 9, 2018)</a>

## Table of Contents

<u>Exhibit No.</u>	<u>Description</u>
10.4†	<a href="#"><u>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)</u></a>
10.5†	<a href="#"><u>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)</u></a>
10.6§	<a href="#"><u>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, 2018)</u></a>
10.7§	<a href="#"><u>Amendment No. 1 to Contract Award issued by Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated March 27, 2017 (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-Q filed on August 14, 2018)</u></a>
10.8§	<a href="#"><u>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, 2018)</u></a>
10.9§	<a href="#"><u>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, 2018)</u></a>
10.10§	<a href="#"><u>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, 2018)</u></a>
10.11§	<a href="#"><u>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, 2018)</u></a>
10.12	<a href="#"><u>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, 2018)</u></a>
10.13†	<a href="#"><u>Amended and Restated Employment Agreement, dated December 7, 2015, between William J. Enright and Altimmune, Inc. (incorporated by reference to Exhibit 10.13 to the Registrant's Form 10-Q filed on August 14, 2018)</u></a>
10.14†	<a href="#"><u>Amendment No. 1 to Amended and Restated Employment Agreement, dated January 18, 2017, between William J. Enright and Altimmune, Inc. (incorporated by reference to Exhibit 10.14 to the Registrant's Form 10-Q filed on August 14, 2018)</u></a>
10.15†	<a href="#"><u>Employment Agreement, dated December 7, 2015, between Elizabeth Czerepak and Altimmune, Inc. (incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-Q filed on August 14, 2018)</u></a>
10.16†	<a href="#"><u>Amendment No. 1 to Employment Agreement, dated January 18, 2017, between Elizabeth Czerepak and Altimmune, Inc. (incorporated by reference to Exhibit 10.16 to the Registrant's Form 10-Q filed on August 14, 2018)</u></a>
10.17†	<a href="#"><u>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, 2018)</u></a>
10.18†	<a href="#"><u>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, 2018)</u></a>
10.19	<a href="#"><u>Convertible Promissory Note Purchase Agreement, dated January 18, 2017, by and between Altimmune, Inc. and the purchasers listed therein (incorporated by reference to Exhibit 10.19 to the Registrant's Form 10-Q filed on August 14, 2018)</u></a>

## Table of Contents

<u>Exhibit No.</u>	<u>Description</u>
10.20†	<a href="#">Altimmune, Inc. 2001 Employee Stock Option Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Form S-8 filed on May 10, 2017)</a>
10.21†	<a href="#">Altimmune, Inc. 2001 Non-Employee Stock Option Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Form S-8 filed on May 10, 2017)</a>
10.22	<a href="#">Form of Lock Up Agreement (incorporated by reference to Exhibit D of Exhibit 2.1 to our Form 8-K filed on August 17, 2017)</a>
10.23	<a href="#">Form of Voting Agreement (incorporated by reference to Exhibit E to Exhibit 2.1 to our Form 8-K filed on August 17, 2017)</a>
10.24	<a href="#">Form of PharmAthene Voting Agreement dated as of January 18, 2017 (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 19, 2017)</a>
10.25	<a href="#">Form of PharmAthene Lock-Up Agreement dated as of January 18, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on January 19, 2017)</a>
10.26	<a href="#">Form of Altimmune Lock-Up Agreement dated as of January 18, 2017 (incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on January 19, 2017)</a>
10.27	<a href="#">Phillip MacNeill Retention and Severance Agreement (incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed on January 19, 2017)</a>
10.28	<a href="#">Contract with the National Institute of Allergy and Infectious Diseases of the National Institutes of Health for the Development of Vaccine Formulations Effective Against NIAID Priority Pathogens, dated September 9, 2014 (Contract No. HHSN272201400040C) (incorporated by reference to the corresponding exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2014)</a>
21*	<a href="#">Subsidiaries</a>
23.1*	<a href="#">Consent of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</a>
23.2*	<a href="#">Consent of BDO USA, LLP, Independent Registered Public Accounting Firm</a>
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)</a>
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)</a>
32.1*	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350</a>
32.2*	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350</a>
101.INS	Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document



## [Table of Contents](#)

- \* 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, 2017 and December 31, 2016; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2017 and 2016; (iii) Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity for the Years Ended December 31, 2017 and 2016; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2017 and 2016; and (v) 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 30th day of March 2018.

### ALTIMMUNE, INC.

By: /s/ William Enright  
William Enright  
Chief Executive Officer

## POWER OF ATTORNEY

BY THESE PRESENTS, each person whose signature appears below constitutes and appoints William Enright and Elizabeth A. Czerepak his true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ William Enright</u> William Enright	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2018
<u>/s/ Elizabeth A. Czerepak</u> Elizabeth A. Czerepak	Chief Financial Officer, Executive Vice President of Corporate Development and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 30, 2018
<u>/s/ Mitchel Sayare, Ph.D.</u> Mitchel Sayare, Ph.D.	Chairman of the Board	March 30, 2018
<u>/s/ John Gill</u> John Gill	Director	March 30, 2018
<u>/s/ Philip Hodges</u> Philip Hodges	Director	March 30, 2018
<u>/s/ David Drutz, M.D.</u> David Drutz, M.D.	Director	March 30, 2018
<u>/s/ Klaus Schafer, M.D.</u> Klaus Schafer, M.D.	Director	March 30, 2018
<u>/s/ Derace Schaffer, M.D.</u> Derace Schaffer, M.D.	Director	March 30, 2018

**Exhibit 21**

**SIGNIFICANT SUBSIDIARIES**

<u>List of Subsidiaries</u>	<u>Jurisdiction of Incorporation or Organization</u>
Mustang Merger Sub II LLC (1)	Delaware
Altimune UK Limited (1)	United Kingdom

(1) Wholly owned subsidiary of the Company

**Consent of Independent Registered Public Accounting Firm**

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

<b>Form</b>	<b>Registration Number</b>	<b>Date Filed</b>
S-3	333-217034	3/30/2017
S-8	333-217846	5/10/2017
S-8	333-214765	11/22/2016
S-3	333-176607	9/1/2011
S-3	333-161587	8/27/2009
S-8	333-156371	12/19/2008
S-3	333-155692	11/25/2008
S-3	333-146463	10/2/2007

of our report dated March 30, 2018, with respect to the consolidated financial statements of Altimune, Inc., included in this Annual Report (Form 10-K) of Altimune, Inc. for the year ended December 31, 2017.

/s/ Ernst & Young LLP

Baltimore, Maryland  
March 30, 2018

Consent of Independent Registered Public Accounting Firm

Altimune, Inc.  
Gaithersburg, Maryland

We hereby consent to the incorporation by reference in the following Registration Statements on Form S-3 (File numbers 333-217034, 333-146463, 333-155692, 333-161587, and 333-176607) and Form S-8 (File numbers 333-217846, 333-156371, and 333-214765) of Altimune, Inc. of our report dated March 29, 2017 except for the effects of the retroactive adjustment to the Company's 2016 equity structure and the related amounts, shares and share-related information resulting from the application of a share exchange ratio discussed in Note 3, as to which the date is March 30, 2018, relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

McLean, Virginia  
March 30, 2018

**Certification of Principal Executive Officer  
Pursuant to SEC Rule 13a-14(a)/15d-14(a)**

I, William J. Enright, certify that:

1. I have reviewed this annual report on Form 10-K of Altimmune, Inc. for the year ended December 31, 2017;
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 30, 2018

/s/ William Enright

Name: William Enright

Title: President and Chief Executive Officer  
(principal executive officer)

**Certification of Principal Executive Officer  
Pursuant to SEC Rule 13a-14(a)/15d-14(a)**

I, Elizabeth A. Czerepak, certify that:

1. I have reviewed this annual report on Form 10-K of Altimmune, Inc. for the year ended December 31, 2017;
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 30, 2018

/s/ Elizabeth A. Czerepak

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Name: Elizabeth A. Czerepak

Title: Chief Financial Officer, Executive Vice President of Corporate  
Development and Secretary  
(principal financial officer)

**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

In connection with the annual report on Form 10-K of Altimmune, Inc. (the "Company") for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (the "Report"), I, William Enright, 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/ William Enright

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William Enright  
President and Chief Executive Officer  
March 30, 2018

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.



**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

In connection with the annual report on Form 10-K of Altimmune, Inc. (the "Company") for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (the "Report"), I, Elizabeth A. Czerepak, Chief Financial Officer, Executive Vice President of Corporate Development 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/ Elizabeth A. Czerepak

Elizabeth A. Czerepak  
Chief Financial Officer, Executive Vice President of Corporate  
Development and Secretary  
March 30, 2018

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.