

Prospectus



775,000 Common Units, Each Consisting of One Share of Common Stock and a Warrant to Purchase One Share of Common Stock

1,625,000 Pre-funded Units, Each Consisting of a Pre-funded Warrant to Purchase One Share of Common Stock and a Warrant to Purchase One Share of Common Stock

We are offering 775,000 common units (each a “Common Unit”), each Common Unit consisting of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of \$6.00 per whole share of common stock (each a “Warrant”). Each Warrant will be exercisable immediately and will expire five years from the date of issuance.

We are also offering to those purchasers whose purchase of Common Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each a “Pre-funded Unit”) in lieu of Common Units that would otherwise result in the purchaser’s beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each Pre-funded Unit will consist of a pre-funded warrant to purchase one share of our common stock at an exercise price of \$0.01 per share (each a “Pre-funded Warrant”) and a Warrant. The purchase price of each Pre-funded Unit is equal to the price per Common Unit being sold to the public in this offering, minus \$0.01. The Pre-funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-funded Warrants are exercised in full.

We are offering 775,000 Common Units and 1,625,000 Pre-funded Units. Common Units and Pre-funded Units will not be issued or certificated. The shares of common stock or Pre-funded Warrants, as the case may be, and the Warrants included in the Common Units or the Pre-funded Units, can only be purchased together in this offering, but the securities contained in the Common Units or Pre-funded Units will be issued separately and will be immediately separable upon issuance.

Our common stock is listed on The Nasdaq Global Market under the symbol “ALT.” On September 27, 2018, the last reported sale price of our common stock on The Nasdaq Global Market was \$8.78.

There is no established public trading market for the Warrants or the Pre-funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants or the Pre-funded Warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants or the Pre-funded Warrants will be limited.

Investing in our securities involves a high degree of risk, including that the trading price of our common stock has been subject to extreme volatility and investors in this offering may not be able to sell their common stock above the actual offering price or at all. See “Risk Factors” beginning on page 10.

	Per Common Unit	Per Pre-funded Unit	Total
Public offering price	\$ 5.00	\$ 4.99	\$11,983,750
Underwriting discount(1)	\$ 0.35	\$ 0.3493	\$ 838,863
Proceeds to us (before expenses)	\$ 4.65	\$ 4.6407	\$11,144,887

(1) We have agreed to reimburse certain expenses of the underwriter. We have also agreed to issue to the underwriter warrants to purchase up to that number of shares of our common stock equal to 4% of the number of shares of our common stock to be issued and sold in this offering, including the shares of common stock issuable upon the exercise of the Pre-funded Warrants and the Warrants issued to investors in this offering (including shares issued or issuable upon exercise of the over-allotment option described below). See “Underwriting” for a description of the compensation payable to the underwriter.

We have granted the underwriter a 30-day option to purchase additional Common Units, Pre-funded Units, shares of our common stock, Pre-funded Warrants and/or Warrants from us at prices described herein to cover over-allotments, if any, of the Common Units and the Pre-funded Units offered hereby. See “Underwriting.”

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the securities offered hereby is expected to be made on or about October 2, 2018.

Roth Capital Partners

September 28, 2018

TABLE OF CONTENTS

	<u>Page</u>
Summary	1
The Offering	6
Summary Consolidated Financial Data	8
Risk Factors	10
Cautionary Note Regarding Forward-Looking Statements	55
Use of Proceeds	56
Dilution	57
Market Price of Our Common Stock and Related Stockholder Matters	59
Certain Relationships and Related-Party Transactions	60
Principal Stockholders	63
Description of Capital Stock	65
Description of Securities We are Offering	68
Material United States Federal Income Tax Considerations for Holders of Our Common Stock, Pre-funded Warrants and Warrants	72
Underwriting	80
Legal Matters	86
Experts	86
Where You Can Find More Information	87
Incorporation of Documents By Reference	88

You should rely only on the information contained in this prospectus or contained in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not, and the underwriter has not, authorized anyone to provide you with information that is different from that contained in such prospectuses. We and the underwriter are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where such offers and sales are permitted. For investors outside the United States: We have not, and the underwriter has not, taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities covered hereby and the distribution of this prospectus outside the United States. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

SUMMARY

This summary highlights information contained in other parts of this prospectus and in the documents incorporated by reference herein and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus and the documents incorporated by reference herein, including our consolidated financial statements and the related notes, and the information set forth under the sections titled “Risk Factors.” Some of the statements in this prospectus and the documents incorporated by reference herein constitute forward-looking statements that involve risks and uncertainties. See information set forth under the section “Cautionary Note Regarding Forward-Looking Statements.”

Company Overview

We are 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. Our most advanced product candidate is NasoVAX, an intranasally administered recombinant influenza vaccine that 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. We recently completed our first Phase 2 study for NasoVAX. Initial data, released in March 2018, indicated that NasoVAX was well tolerated at all doses tested. Additionally, the achievement of 100% seroprotection at two of the three dose levels studied sets it apart from other intranasally administered vaccines. Strong T-cell responses were observed at the highest dose. This combination of antibody and T-cell responses provides the potential for preventing infection and shedding of the flu virus. Subjects were followed for an additional six months after vaccination to assess durability of the antibody response. These new NasoVAX data, released in September 2018, demonstrate (a) a durable, dose dependent protective immune response, (b) significant mucosal immune response one month after vaccination compared to both placebo and Fluzone, and (c) a clean safety profile. We expect to continue the development of the NasoVAX product candidate in an additional Phase 2 trial in 2019.

We are also developing two government funded assets, NasoShield and SparVax-L. NasoShield is an anthrax vaccine designed to provide rapid, stable protection after a single intranasal administration. 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 the Biomedical Advanced Research and Development Authority (“BARDA”), and with their continued financial and contractual support, we launched a Phase 1 trial with NasoShield in first quarter of 2018. The purpose of the Phase 1 study was to assess the safety and immunogenicity of a single intranasal dose of NasoShield at four dose cohort levels. An additional cohort received a repeated dose of NasoShield at Day 21. Based on initial data from the single-dose cohorts, NasoShield was safe and well-tolerated with no serious adverse events. The study also showed limited immunogenicity, indicating that like other anthrax vaccines, NasoShield may require more than one dose.

With the support of the National Institutes of Allergy and Infectious Diseases, or NIAID, we are developing, 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. We have demonstrated a significant improvement in shelf life (two years at room temperature and six years at refrigerated temperatures) with a lyophilized formulation. Recent preclinical experiments have shown it to be 100% protective with a two-dose regimen (administered on study Days 0 and 14 days) with higher protective (toxin neutralizing) antibodies than the currently licensed vaccine administered under the same schedule. We are seeking additional government funding to continue to move this program forward.

HepTcell, an immunotherapy for patients chronically infected with HBV, has recently completed a Phase 1 trial in the United Kingdom and South Korea. While generally well tolerated, the initial immunogenicity results from this trial in patients with chronic HBV were inconclusive and the Company is awaiting six-month follow up results that will be available in the fourth quarter of 2018, to determine whether to continue with further development of HepTcell, including any further clinical trials.

Risk Factors

An investment in our securities involves a high degree of risk. Any of the factors set forth under “Risk Factors” may limit our ability to successfully execute our business strategy. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under “Risk Factors” in deciding whether to invest in our securities. These risk factors include, among others:

- 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;
- Our profitability depends on our ability to develop and commercialize our current and future product candidates;
- Our ability to continue as a going concern will require us to obtain additional financing to fund our current operations, which may not be available on acceptable terms, or at all;
- We must obtain the approval of our stockholders to amend our Certificate of Incorporation to increase our authorized shares of common stock in order to complete this offering;
- We may be unable to complete the offering if our stockholders do not approve the issuance of shares of our common stock to satisfy our obligations under certain exchange agreements;
- 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;
- 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 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;
- It may be difficult for us to predict the timing and cost of product development. Unforeseen problems may prevent further development or approval of our product candidates;
- 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, our clinical trials could be delayed or halted and we may not be able to obtain regulatory approvals for our product candidates on a timely basis, or at all;
- 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;
- 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; and
- 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.

Recent Developments

Reverse Stock Split

As reported in our Current Report on Form 8-K filed on May 18, 2018, on May 17, 2018, we received notification from the Nasdaq Listing Qualifications department of The Nasdaq Stock Market LLC indicating that our common stock was subject to potential delisting from The Nasdaq Global Market because, for a period of thirty (30) consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under Nasdaq Marketplace Rule 5550(a)(2). The notification had no immediate effect on the listing or trading of our common stock on the Nasdaq Capital Market. Nasdaq stated in its letter that in accordance with the Nasdaq Listing Rules we have been provided an initial period of 180 calendar days, or until November 13, 2018, to regain compliance. If we are unable to regain compliance by November 13, 2018, the Company may be eligible for an additional 180-calendar day compliance period to demonstrate compliance with the bid price requirement.

On September 13, 2018 we amended our Amended and Restated Certificate of Incorporation to effect a reverse stock split at a ratio 1-for-30 (the "Reverse Stock Split"). The Reverse Stock Split was effective on September 13, 2018, and our shares of common stock commenced trading on Nasdaq on a post-Reverse Stock Split basis on September 14, 2018. We believe that the Reverse Stock Split will improve the price level of our common stock so that we are able to maintain compliance with the Nasdaq minimum bid price listing standard. However, the effect of the Reverse Stock Split upon the market price for our common stock cannot be predicted, and the history of similar reverse stock splits for companies in like circumstances is varied. The market price per share of our common stock after the Reverse Stock Split may not rise in proportion to the reduction in the number of shares of our common stock outstanding resulting from the Reverse Stock Split.

Unless otherwise noted, all share and per share numbers in this prospectus, including the number of shares issuable upon the exercise of outstanding options and warrants, shares reserved under incentive plans, exercise prices of outstanding options and warrants, and the per share amount of the special one time cash dividend of PharmAthene, Inc. are reflected on a post-reverse share split basis for all periods presented. As of September 28, 2018, we had 1,720,517 shares of common stock outstanding after giving effect to the Reverse Stock Split.

Exchange Agreements

On June 22, 2018 we entered into exchange agreements with certain holders of our Series B Redeemable Convertible Preferred Stock ("Series B Preferred Stock") and warrants ("Existing Warrants") pursuant to which, we (i) issued an aggregate of 85,356 shares of common stock, (ii) issued convertible notes (the "Exchange Notes") with an aggregate principal value of \$1,500,000, which are initially convertible into up to 73,529 shares of our common stock upon the default by the Company, subject to adjustment under certain circumstances in accordance with the terms of the Exchange Notes, and (iii) paid \$1,100,000 in aggregate cash consideration, all in exchange for Existing Warrants to purchase 53,125 shares of common stock. We refer to these transactions as the "First Exchange".

On July 11, 2018, we entered into exchange agreements with certain holders of our Series B Preferred Stock and Existing Warrants pursuant to which we (i) issued an aggregate of 32,124 shares of common stock and (ii) paid \$22,241 in cash, all in exchange for all of the outstanding shares of our Series B Preferred Stock. We issued an additional 145,038 shares of common stock in exchange for Existing Warrants to purchase 22,523 shares of common stock. We refer to these transactions as the "Second Exchange" and together with the First Exchange as the "Exchanges".

BARDA Amendment

BARDA has modified its existing contract with us by adding \$2.5 million to the \$21.6 million base contract (\$24.1 million total for the modified base contract) and extending the performance period through November

2019. The increase in funding is intended to allow vaccine characterization including key formulation parameters and batch consistency. In addition, we will assay clinical samples from its ongoing Phase 1 clinical trial for a mucosal immune response and compare different methods of intranasal administration of the vaccine in preclinical models.

The NasoShield program is funded through a contract with BARDA (HHSO100201600008C), which runs through September 2021 and, if all options are exercised, an additional \$105 million is expected to provide funding through the end of Phase 2 development. Immunogenicity data for the two-dose cohort is expected to be available in the fourth quarter of this year.

Registered Direct Offering

On September 24, 2018, we sold an aggregate of 286,633 shares of our common stock at a purchase price of \$17.02 per share to certain institutional investors in a registered direct offering (the “Registered Direct Offering”). The net proceeds of the Registered Direct Offering were approximately \$4.3 million, after deducting placement agent fees and estimated offering expenses payable by us.

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 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 of 1986, as amended (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.

Corporate Information

We completed the Mergers between Private Altimmune and PharmAthene in 2017. Our stock is traded on The Nasdaq Global Market under the symbol “ALT”. Our principal executive offices located at 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878. Our telephone number is (240) 654-1450, and our Internet website is www.altimmune.com and our investor relations website is located under the “Investors” tab. The information on, or that can be accessed through, our website is not part of this prospectus and is not incorporated by reference herein.

[Table of Contents](#)

“Altimune,” the Altimune logo and other trademarks, trade names or service marks of Altimune appearing in this prospectus, including NasoVAX, HepTcell, RespirVec, Densigen, NasoShield and Oncosyn, are the property of Altimune. The other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or TM symbols.

THE OFFERING

Common Units offered by us	We are offering 775,000 Common Units at a public offering price of \$5.00 per Common Unit. Each Common Unit will consist of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of \$6.00 per whole share (each a “Warrant”).
Pre-funded Units offered by us	We are also offering to those purchasers whose purchase of Common Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each a “Pre-funded Unit”) in lieu of Common Units that would otherwise result in the purchaser’s beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each Pre-funded Unit will consist of a pre-funded warrant to purchase one share of our common stock at an exercise price of \$0.01 per share (each a “Pre-funded Warrant”) and a Warrant. The purchase price of each Pre-funded Unit is equal to the price per Common Unit being sold to the public in this offering, minus \$0.01. The Pre-funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-funded Warrants are exercised in full. We are offering 775,000 Common Units and 1,625,000 Pre-funded Units. This prospectus also relates to the offering of the shares of our common stock issuable upon exercise of the Pre-funded Warrants.
Warrants offered by us	Warrants to purchase up to 2,400,000 shares of our common stock. Each Warrant included in the Common Units and the Pre-funded Units will have an exercise price of \$6.00 per whole share of common stock, will be immediately exercisable and will be exercisable for five years from the date of issuance. The registration statement of which this prospectus forms a part also covers the shares of common stock that are issuable from time to time upon exercise of the Warrants.
Common stock to be outstanding immediately following this offering	4,120,517 shares assuming all of the Pre-funded Warrants issued in this offering are exercised and assuming that none of the Warrants issued in this offering are exercised.
Over-allotment option(1)	We have granted the underwriter a 30-day option to purchase additional Common Units, Pre-funded Units, shares of our common stock, Pre-funded Warrants, and/or Warrants from us at prices described herein to cover over-allotments, if any, of the Common Units and the Pre-funded Units offered hereby. See “Underwriting.”
Use of proceeds	We estimate that the net proceeds from this offering will be up to approximately \$10.1 million, after deducting the underwriting discount and estimated offering expenses payable by us. We intend to use the net proceeds from this financing for the continued

advancement of development activities for our clinical-stage product pipeline, general corporate purposes, strategic growth opportunities and repayment of our outstanding \$1.5 million in aggregate principal amount of convertible notes. See “Use of Proceeds.”

Risk factors

An investment in our common stock involves a high degree of risk. You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in our securities.

The Nasdaq Global Market symbol

“ALT”. There is no established public trading market for the Warrants or the Pre-funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants or the Pre-funded Warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants or the Pre-funded Warrants will be limited.

- (1) Because the Warrants and the Pre-funded Warrants are not listed on a national securities exchange or other nationally recognized trading market, the underwriter will be unable to satisfy any over-allotment of units without exercising the underwriter’s over-allotment option with respect to the Warrants and, if applicable, the Pre-funded Warrants. The underwriter has informed us that it intends to exercise its over-allotment option for all of the Warrants and Pre-funded Warrants that are over-allotted, if any, at the time of the initial offering of the units. However, because our common stock is publicly traded, the underwriter may satisfy some or all of the over-allotment of shares of our common stock included in the Common Units, if any, by purchasing shares in the open market and will have no obligation to exercise the over-allotment option with respect to our common stock. Assuming no sale of the Pre-funded Units, if the underwriter exercises its over-allotment option with respect to the Warrants in full, but does not exercise its over-allotment option with respect to our common stock, then, the effective warrant coverage for each share of common stock included in the Common Units sold in this offering would increase to 115% instead of the 100% stated on the cover of this prospectus.

The number of shares of common stock to be outstanding after this offering is based on 1,720,517 shares of common stock outstanding at September 28, 2018 and excludes as of such date the following:

- 43,005 shares of common stock issuable upon exercise of outstanding stock options at a weighted-average exercise price of \$94.49 per share;
- 1,767 shares of common stock issuable upon exercise of outstanding warrants at a weighted-average exercise price of \$115.44 per share; and
- 51,103 shares of common stock reserved and available for issuance under our equity compensation plans.

Unless otherwise indicated:

- all historical shares and per share information included in this prospectus have been retroactively adjusted to reflect the closing of the Mergers and the Reverse Stock Split;
- all information in this prospectus assumes no sale of Pre-funded Units in this offering and no exercise of the Warrants being offered in this offering; and
- all information in this prospectus assumes no exercise by the underwriter of its over-allotment option.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated financial data for the years ended December 31, 2016 and 2017 are derived from our audited consolidated financial statements incorporated by reference into this prospectus. 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 or incorporated by reference into this prospectus. The summary consolidated financial data as of June 30, 2018 and for the six months ended June 30, 2017 have been derived from our unaudited condensed consolidated financial statements incorporated by reference into this prospectus. These unaudited condensed consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and, in our opinion, contain all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of such consolidated financial data. You should read this data together with our consolidated financial statements and related notes included elsewhere in, and incorporated by reference into, this prospectus. Our historical results are not necessarily indicative of our future results, and are not necessarily indicative of the results that may be expected for any interim periods, or any future year or period. All share and per share amounts in the table below have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

	Six Months ended June 30, 2018	Six Months ended June 30, 2017	Year Ended December 31,		
			2017	2016	2015
Statements of operations data:					
Revenue	\$ 5,108,121	\$ 3,337,544	\$ 10,738,322	\$ 3,236,175	\$ 4,654,468
Operating expenses:					
Research and development	10,665,890	8,040,851	18,406,329	7,221,460	5,063,650
General and administrative	5,381,917	3,825,026	8,457,557	7,106,378	6,178,829
Goodwill impairment	490,676	—	35,919,695	—	—
Total operating expenses	<u>16,538,483</u>	<u>11,865,877</u>	<u>62,783,581</u>	<u>14,327,838</u>	<u>11,242,479</u>
Loss from operations	(11,430,362)	(8,528,333)	(52,045,259)	(11,091,663)	(6,588,011)
Other (expense) income, net	(3,370,749)	(154,540)	(18,506)	4,851	(60,891)
Net loss before income tax benefit	(14,801,111)	(8,682,873)	(52,063,765)	(11,086,812)	(6,648,902)
Income tax benefit	2,488,731	993,709	5,638,375	—	—
Net loss	(12,312,380)	(7,689,164)	\$(46,425,390)	\$(11,086,812)	\$(6,648,902)
Preferred stock accretion and dividends	(2,591,414)	(163,069)	(4,930,010)	(368,548)	(138,555)
Net loss attributed to common stockholders	<u>\$(14,903,794)</u>	<u>\$(7,852,233)</u>	<u>\$(51,355,400)</u>	<u>\$(11,455,360)</u>	<u>\$(6,787,457)</u>
Weighted-average common shares outstanding, basic and diluted	<u>812,034</u>	<u>319,881</u>	<u>426,837</u>	<u>230,384</u>	<u>191,987</u>
Net loss per share, basic and diluted	<u>\$ (18.35)</u>	<u>\$ (24.55)</u>	<u>\$ (120.32)</u>	<u>\$ (49.72)</u>	<u>\$ (35.35)</u>

[Table of Contents](#)

	<u>June 30,</u> <u>2018</u>	<u>2017</u>	<u>December 31,</u> <u>2016</u>	<u>2015</u>
Balance sheet data:				
Cash, cash equivalents, and restricted cash	\$ 4,762,419	\$12,303,639	\$ 2,876,113	\$ 4,638,711
Working capital	4,799,252	19,626,166	(983,633)	1,820,260
Total assets	52,102,330	63,030,200	38,400,335	48,588,750
Total long-term liabilities	8,715,554	10,512,909	722,289	1,099,991
Redeemable convertible preferred stock	510,083	9,281,767	—	—
Total stockholders' equity	35,809,989	39,395,823	32,207,323	43,134,633

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our consolidated financial statements and the related notes, before deciding to invest in our securities. If any of the following risks actually occurs, our business, financial condition, results of operations and prospects could be materially and adversely affected, the trading price of our common stock could decline and you could lose all or part of your investment.

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

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

Our stock price has been and in the future may be subject to substantial volatility. The volatility of our stock price has increased since we effected the Reverse Stock Split. Since our common stock began trading on a post-Reverse Stock Split based on September 14, 2018, our stock has traded in a range with a low of \$4.07 and a high of \$36.25.

The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. While we believe that some of the volatility may be explained by the Reverse Stock Split, there is no guarantee that this volatility will not continue. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

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

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

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 \$9.1 million for the quarter ended June 30, 2018, 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 June 30, 2018, we have an accumulated deficit of \$90.0 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 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. Our cash on hand at June 30, 2018, our expected tax refunds, and revenue from our research grants and contracts are insufficient to fund our projected operating requirements for a twelve-month period from August 14, 2018, the issuance date of our June 30, 2018 financial statements. 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.

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

[Table of Contents](#)

these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability. If some or all of our product candidates do not prove to be safe, pure and efficacious, then we may have to abandon those product candidates altogether and we will be unable to generate revenues from sales of such products.

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

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

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

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

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

We review our long-lived tangible and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. We test our in-process research and development (“IPR&D”) assets, classified as indefinite-lived intangible assets, for impairment at least annually in the fourth quarter, or when events or changes indicate that the carrying value of our IPR&D assets may exceed their fair value. If our clinical trial results for HepTcell are unsuccessful, if we are unable to obtain further funding for SparVax-L, or if we discontinue our research and development efforts for Oncosyn, and we are unable to identify alternative sale or use for the IPR&D assets associated with these product candidates to recover some or all of the related costs, the carrying value of these IPR&D assets may be impaired and the resulting loss could be material. Any significant writedowns of our long-lived assets in the future could adversely affect our financial position and results of operations.

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

We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in an amount sufficient to fully fund our operations for the foreseeable future. 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 June 30, 2018, our cash balance was \$4.8 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 Q4 2018. However, we do not expect that these funds will be sufficient to enable us to complete the clinical trials needed to seek marketing approval or commercialize any of our product candidates. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

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

Our future capital requirements depend on many factors, including:

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

[Table of Contents](#)

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.

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 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 and SparVax-L product candidates 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, NasoShield 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 platforms, including our leading product candidates, NasoVAX, NasoShield 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, NasoShield 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.

[Table of Contents](#)

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;
- 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 have also recently experienced multiple failures during the manufacturing of clinical materials for use in the upcoming NasoVAX Phase 2 clinical trial.

We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by manufacturing failures or

other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete subsequent clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

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

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. If patients are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

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

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate being tested;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

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

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

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

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

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

In addition, novel vaccine adjuvants, which are included in HepTcell 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, 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 Pfenex, which is developing an anthrax vaccine. 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,

[Table of Contents](#)

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. Although we have entered into employment agreements with each of these members of senior management, the loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We maintain a keyman insurance policy on Mr. Enright for \$2.0 million, 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.

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

On December 22, 2017, President Trump signed into law new tax legislation known as the Tax Cuts and Jobs Act (“TCJA”), which significantly revises the Internal Revenue Code of 1986, as amended. The TCJA, 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 and elimination of net operating loss carrybacks in respect of net operating losses generated during or after 2018, 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 (including reduction of orphan drug tax 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 generated after 2017 that we are permitted to deduct in any taxable year after 2017 to 80% of our taxable income in such year. The TCJA also eliminates the ability to carry back net operating losses generated after 2017 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.

We are subject to taxation in certain foreign jurisdictions due to the ITS acquisition. Any adverse development in the tax laws of such jurisdictions or any disagreement with its tax positions could have a material adverse effect on its business, financial condition or results of operations. In addition, our effective tax rate could change materially as a result of certain changes in its 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 the ITS acquisition. 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 its 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.

Risks Related to the Regulatory Approval Process

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

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

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

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

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

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

Undesirable side effects caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. The most common adverse events in the clinical trials evaluating the safety and tolerability of the 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

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.

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

[Table of Contents](#)

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;

[Table of Contents](#)

- the availability of adequate course and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the restrictions on the use of our products together with other medications, if any.

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

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

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

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

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

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance;
- delays as a result of manufacturing problems or re-prioritization of projects at a third-party manufacturer;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to 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.

[Table of Contents](#)

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. For example, one of our third-party manufacturers has recently failed on multiple occasions to successfully manufacture sufficient quantities of our NasoVAX product candidate. If we and the third party manufacturer are not able to identify and correct the underlying cause(s) of such failure on a timely basis, we may be required to modify or delay some of our planned clinical trials.

Third-party manufacturers may not be able to comply with applicable cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed 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.

[Table of Contents](#)

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 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;

[Table of Contents](#)

- 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 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 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;

[Table of Contents](#)

- 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. Additionally, BARDA will decide in its sole discretion whether to pursue any of the options under the contract and there can be no assurance that BARDA will elect to pursue any of the designated options, which may affect our receipt of the funds.

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

[Table of Contents](#)

funding under the NIAID contract to \$15.3 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 21st Century Cures Act ("Cures Act"), was signed into law on December 13, 2016 and, among other things, includes a provision requiring timely and accurate recommended utilization guidelines for MCMs, including for products in the Strategic National Stockpile. The Cures Act requires HHS to report to the appropriate committees of Congress when funding in the 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.

[Table of Contents](#)

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

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

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

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

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

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

Risks Related to Reimbursement and Government Regulation

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

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

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

[Table of Contents](#)

- 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.

[Table of Contents](#)

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 TCJA 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 distributions with certain FDA-approved products, such as approved vaccines,

with regard to payments or other transfers of value made to certain U.S. health care practitioners, such as physicians and academic medical centers, and with regard to certain ownership interests held by physicians in reporting entities. The CMS publishes information from these reports on a publicly available website, including amounts transferred and the physician and teaching hospital identities.

Under the Physician Payment Sunshine Act, should any of our products be approved for sale, we may be required to collect and report detailed information regarding certain financial relationships we have with physicians 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

[Table of Contents](#)

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 injuries” to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer after they have exhausted their remedies under the compensation program. However, there is no assurance that the Secretary of HHS would issue under this act a declaration to establish a compensation fund.

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

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

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

Our product candidates may also be subject to export control laws within the United Kingdom and European Union resulting in the need for authorization from customs authorities before they can leave the United Kingdom

or European Union customs territories and restrictions on export from these territories to certain countries. Again, such laws could adversely affect our ability to sell to customers in certain countries and non-compliance can result in civil and criminal penalties. Such restrictions exist across the European Union and within its member states individually and may vary between member states.

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

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

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

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

Risks Related to our Securities and the Offering

You will experience immediate dilution in the book value per share of the securities you purchase in this offering and may experience additional dilution upon exercise of the Warrants acquired in this offering.

The public offering prices of the Common Units and the Pre-funded Units are substantially higher than the pro forma net tangible book value per share of our common stock after giving effect to the Registered Direct Offering and the Second Exchange. Therefore, if you purchase securities in this offering, you will pay an effective price per share of common stock you acquire that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Assuming the exercise of all Pre-funded Warrants sold in this offering, that no value is attributed to the Warrants, and that such Warrants are classified as and accounted for as equity, you will experience immediate dilution of \$1.49 per share, representing the difference between the public offering price set forth on the cover of this prospectus and our pro forma as adjusted net tangible book value per share after giving effect to this offering. In addition, if previously issued options to acquire common stock are exercised at prices below the offering price or the Warrants are accounted for as liabilities, you will experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see “Dilution.”

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock or other securities convertible into or exchanged for our common

[Table of Contents](#)

stock in one or more transactions, and in a manner we determine from time to time and at prices that may not be the same as the price per share paid by other investors, and dilution to our stockholders could result. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors. New investors could also receive rights, preferences and privileges senior to those of existing holders of our common stock. In addition, in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock, we may be required to proportionally adjust the conversion price, exercise price or number of shares issuable upon exercise of our outstanding warrants.

A default on our convertible notes could require us to issue additional shares of our common stock, which could result in significant dilution to our stockholders and an adverse effect on the market price of our common stock.

In connection with the First Exchange Agreements, we issued convertible notes (the “Exchange Notes”) with an aggregate principal value of \$1,500,000. The Exchange Notes are convertible into up to 73,529 shares of common stock at the option of the holder on the maturity date, based on a conversion price assuming conversion of the Exchange Notes on the date the First Exchange Agreements were signed. Additionally, the Exchange Notes are convertible in the event of a default, at which time the balance of the Notes increases by 112% and is convertible at a share price equal to the lower of \$20.40 per share or 75% of the weighted average price of our common stock during the twenty consecutive trading day period immediately preceding the event of default. Accordingly, if we were to default under the terms of the notes we could be required to issue a significant number of shares of common stock to satisfy our obligations, resulting in substantial dilution to the 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 increasingly volatile.

We have broad discretion in the use of the net proceeds we receive from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds we receive in this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether our management is using the net proceeds appropriately. Because of the number and variability of factors that will determine our use of our net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest our net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

There is no public market for the Pre-funded Warrants or the Warrants to purchase shares of our common stock being offered in this offering.

There is no established public trading market for the Pre-funded Warrants or the Warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Pre-funded Warrants or the Warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Pre-funded Warrants and the Warrants will be limited.

Holders of the Pre-funded Warrants and the Warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Pre-funded Warrants or Warrants and acquire our common stock.

Until holders of the Pre-funded Warrants or the Warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the

Pre-funded Warrants and the Warrants. Upon exercise of the Pre-funded Warrants or the Warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The Warrants may not have any value.

The Warrants will have an exercise price equal to \$6.00 per share and will expire on the fifth anniversary of their issuance date. In the event our common stock price does not exceed the exercise price of the Warrants during the period when the Warrants are exercisable, the Warrants may not have any value.

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 30% 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 The Nasdaq Global Market, a national securities exchange, which imposes continued listing requirements with respect to listed shares. On May 17, 2018, we received a letter from the Nasdaq Listing Qualifications department, indicating that our common stock was subject to potential delisting from The Nasdaq Global Market because, for a period of thirty (30) consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under Nasdaq Marketplace Rule 5550(a)(2). Nasdaq stated in its letter that in accordance with the Nasdaq Listing Rules, we have been provided an initial period of 180 calendar days, or until November 13, 2018, to regain compliance. The letter states that the Nasdaq Staff will provide written notification that we have achieved compliance with the minimum bid price listing requirement if at any time before November 13, 2018, the bid price of our common stock closes at \$1.00 per share or more for a minimum of ten (10) consecutive business days.

If we fail to regain compliance by November 13, 2018, we may be eligible for an additional 180 calendar day compliance period to demonstrate compliance with the bid price requirement. To qualify for the additional 180 day period, we will be required to meet the continued listing requirement for market value of publicly held shares set forth in Marketplace Rule 5550(a) and all other listing standards for The Nasdaq Capital Market set forth in Marketplace Rule 5505, with the exception of the bid price requirement, and will need to provide written notice to Nasdaq to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not qualify for the second compliance period or we fail to regain compliance during the second 180-day period, then Nasdaq will notify us of its determination to delist our common stock, at which we would have an opportunity to appeal the delisting determination to a Hearings Panel. If our securities are delisted from trading on a Nasdaq exchange, our securities could be quoted on the OTCQB or on The Pink Open Market. As a result, we could face significant adverse consequences, including

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;

[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.

On September 13, 2018 we effected the Reverse Stock Split. We believe that the Reverse Stock Split will improve the price level of our common stock so that we are able to maintain compliance with the Nasdaq minimum bid price listing standard. However, the effect of the Reverse Stock Split upon the market price for our common stock cannot be predicted, and the history of similar reverse stock splits for companies in like circumstances is varied. The market price per share of our common stock after the Reverse Stock Split may not rise in proportion to the reduction in the number of shares of our common stock outstanding resulting from the Reverse Stock Split.

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 \$873 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated herein by reference contain forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. 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 terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus and in the documents incorporated herein by reference are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. These forward-looking statements include, among other things, statements about:

- 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 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 other forward-looking statements detailed under the caption “Risk Factors” in this prospectus and in other reports filed with the Securities and Exchange Commission.

We have based the forward-looking statements included in this prospectus and in the documents incorporated herein by reference on information available to us on the date of this prospectus. 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 Securities and Exchange Commission, 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 or in documents incorporated herein by reference are expressly qualified in their entirety by the cautionary statements contained or referred to elsewhere in this prospectus.

USE OF PROCEEDS

We expect that the net proceeds of this offering will be approximately \$10.1 million, assuming the full exercise of the Pre-funded Warrants sold in this offering, after deducting the underwriting discount and estimated offering expenses payable by us, and excluding the proceeds, if any from the exercise of the Warrants sold in this offering. If the underwriter exercises its over-allotment option in full, we expect that the net proceeds of this offering will be approximately \$11.8 million, assuming the full exercise of the Pre-funded Warrants sold in this offering, after deducting the underwriting discount and estimated offering expenses payable by us, and excluding the proceeds, if any from the exercise of the Warrants sold in this offering.

We intend to use the net proceeds from this financing for the continued advancement of development activities for our clinical-stage product pipeline, general corporate purposes, strategic growth opportunities and repayment of our outstanding \$1.5 million in aggregate principal amount of convertible notes.

The amount and timing of these expenditures will depend on a number of factors, including the progress of our research and development efforts, the progress of any partnering efforts, technological advances and the competitive environment for our product candidates. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be used in a way that does not yield a favorable, or any, return for us. Pending application of the net proceeds as described above, we intend to invest the proceeds in investment grade interest bearing instruments, or will hold the proceeds in interest bearing or non-interest bearing bank accounts.

DILUTION

Dilution in net tangible book value per share to new investors is the amount by which the public offering price paid by the purchasers of the Common Units and Pre-funded Units sold in this offering exceeds the as adjusted net tangible book value per share of common stock after giving effect to the offering, assuming no exercise of the Warrants offered hereby (including the Underwriter's Warrants), that no value is attributed to such Warrants and that such Warrants are classified as and accounted for as equity. Net tangible book value per share is determined by dividing our total tangible assets (total assets less intangible assets), less total liabilities, by the number of shares of our common stock outstanding. All share and per share amounts in this section have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented. Our net tangible book value as of June 30, 2018 was approximately \$(2.0) million, or approximately \$(1.63) per share of common stock.

After giving effect to the sale of 286,633 shares of our common stock in the Registered Direct Offering for estimated net proceeds of \$4.3 million and the issuance of 177,162 shares of our common stock under the Second Exchange that relieved a warrant liability valued at \$2.0 million as of June 30, 2018, our pro forma net tangible book value as of June 30, 2018 would have been approximately \$4.3 million or approximately \$2.49 per share of common stock.

After giving further effect to the sale of 775,000 Common Units in this offering at a public offering price of \$5.00 per Common Unit, a sale of 1,625,000 Pre-funded Units at a public offering price of \$4.99, the exercise of such Pre-funded Warrants included within the Pre-funded Units and no exercise of the Warrants offered hereby, that no value is attributed to such Warrants and that such Warrants are classified as and accounted for as equity, and after deducting the underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2018 would have been approximately \$14.4 million, or approximately \$3.51 per share of common stock. This represents an immediate increase in our pro forma as adjusted net tangible book value of \$1.02 per share to our existing stockholders and an immediate dilution of \$1.49 per share to investors participating in this offering. The following table illustrates this dilution on a per share basis:

Public offering price(1)		\$5.00
Net tangible book value per share as of June 30, 2018		\$(1.63)
Increase in net tangible book value per share attributable to the Registered Direct Offering and Second Exchange		\$ 4.12
Pro forma net tangible book value per shares as of June 30, 2018		\$ 2.49
Increase in pro forma net tangible book value per share attributable to this offering		<u>\$ 1.02</u>
Pro forma as adjusted net tangible book value per share after giving effect to this offering		<u>\$3.51</u>
Dilution per share to new investors		<u>\$1.49</u>

(1) Assumes the exercise of the Pre-funded Warrants sold in this offering at an exercise price of \$0.01 per Pre-funded Warrant.

If the underwriter exercises its over-allotment option in full, our pro forma as adjusted net tangible book value would be approximately \$3.60 per share, an increase in our pro forma as adjusted net tangible book value of approximately \$1.11 per share to existing stockholders and immediate dilution of \$1.40 per share to new investors in this offering, after deducting the underwriting discount and estimated offering expenses payable by us.

Because the Warrants and the Pre-funded Warrants are not listed on a national securities exchange or other nationally recognized trading market, the underwriter will be unable to satisfy any over-allotment of units without exercising the underwriter's over-allotment option with respect to the Warrants and, if applicable, the Pre-funded Warrants. The underwriter has informed us that it intends to exercise its over-allotment option for all of the Warrants and Pre-funded Warrants that are over-allotted, if any, at the time of the initial offering of the units. However, because our common stock is publicly traded, the underwriter may satisfy some or all of the over-allotment of shares of our common stock included in the Common Units, if any, by purchasing shares in the

[Table of Contents](#)

open market and will have no obligation to exercise the over-allotment option with respect to our common stock. Assuming no sale of the Pre-funded Units, if the underwriter exercises its over-allotment option with respect to the Warrants in full, but does not exercise its over-allotment option with respect to our common stock, then, the effective warrant coverage for each share of common stock included in the Common Units sold in this offering would increase to 115% instead of the 100% stated on the cover of this prospectus.

The foregoing discussion and table are based on 1,245,466 shares of common stock outstanding at June 30, 2018 (after giving retroactive effect to the Reverse Stock Split) and excludes as of such date the following:

- 53,846 shares of common stock issuable upon exercise of stock options outstanding at June 30, 2018 at a weighted-average exercise price of \$120.90 per share;
- 25,211 shares of common stock issuable upon exercise of warrants outstanding at June 30, 2018 at a weighted-average exercise price of \$82.50 per share; and
- 38,809 shares of common stock reserved and available for issuance under our equity compensation plans.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

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 1-for-10 reverse stock split effected immediately prior to the Mergers and the 1-for-30 reverse stock split effected on September 13, 2018.

Year Ended December 31, 2018	High	Low
3rd Quarter through September 24, 2018	\$ 36.25	\$ 4.07
2nd Quarter ended June 30	\$ 35.70	\$ 13.50
1st Quarter ended March 31	\$ 60.90	\$ 33.00
Year Ended December 31, 2017	High	Low
4th Quarter ended December 31	\$ 94.80	\$ 45.30
3rd Quarter ended September 30	\$ 102.00	\$ 60.30
2nd Quarter ended June 30	\$ 246.00	\$ 87.00
1st Quarter ended March 31	\$1,050.00	\$141.00*
Year Ended December 31, 2016	High	Low
4th Quarter ended December 31	\$ 990.00	\$810.00
3rd Quarter ended September 30	\$ 876.00	\$726.00
2nd Quarter ended June 30	\$ 747.00	\$573.00
1st Quarter ended March 31	\$ 609.00	\$450.00

* The decrease in share price during the quarter ended March 31, 2017 reflected a one-time special dividend on PharmAthene common stock of \$873 per share paid by PharmAthene on February 3, 2017.

Holders

As of September 24, 2018, we had approximately 155 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 \$873 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.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

The following is a description of transactions, since January 1, 2015, to which we have been a party, in which the amount involved exceeded or will exceed \$120,000, and in which any related person had a direct or indirect material interest.

Review and approval of related party transactions

Our related parties include our directors, director nominees, executive officers, holders of more than five percent of the outstanding shares of our common stock and the foregoing persons' immediate family members. We review relationships and transactions in which the Company and our related parties are participants to determine whether such related persons have a direct or indirect material interest. As required under SEC rules, transactions that are determined to be directly or indirectly material to a related party are disclosed in this Proxy Statement. In addition, the Audit Committee reviews and approves any related party transaction that is required to be disclosed. Set forth below is information concerning transactions with our related parties that is required to be disclosed under SEC rules.

Indemnification agreements

We have entered into an indemnification agreement with each of our outside directors. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Financing Agreement

In connection with the Merger Agreement, on January 28, 2017, Private Altimmune entered into a financing agreement with certain of its stockholders and directors (the "Altimmune Financing Agreement"), including Novartis Bioventures Ltd., HealthCap V LP, OFCO Club V, UFF Innovation 14 FCPI and UFF Innovation 15 FCPI, pursuant to which such stockholders irrevocably committed to: (i) participate in the private placement of Private Altimmune's convertible securities (the "Altimmune Private Placement") in an aggregate amount of not less than \$3.5 million of gross proceeds, and (ii) participate in a private placement after the closing of the Merger (the "Post-Closing Private Placement") to raise an aggregate of not less than \$5.0 million of gross proceeds within 135 days of the closing date of the Merger. However, if the Company completes a public offering of common stock during such 135-day period, then the purchase price of the shares acquired in the Post-Closing Private Placement will be at the same price as the shares sold in such public offering.

Pursuant to the terms of the Altimmune Financing Agreement:

- Novartis Bioventures Ltd. and Novartis International Pharmaceutical Investment Ltd. purchased shares of capital stock with an aggregate purchase price of \$2,081,820 in the Altimmune Private Placement, received a warrant to purchase 15,263 shares of common stock in the Altimmune Private Placement and committed to purchase shares of capital stock with an aggregate purchase price of \$2,918,180 in the Post-Closing Private Placement;
- UFF Innovation 14 FCPI, UFF Innovation 15 FCPI and Truffle Fortune 4 FCPI purchased shares of capital stock with an aggregate purchase price of \$458,000 in the Altimmune Private Placement and committed to purchase shares of capital stock with an aggregate purchase price of \$642,000 in the Post-Closing Private Placement;
- HealthCap V LP and OFCO Club V purchased shares of capital stock with an aggregate purchase price of \$208,180 in the Altimmune Private Placement and committed to purchase shares of capital stock with an aggregate purchase price of \$291,820 in the Post-Closing Private Placement;

[Table of Contents](#)

- David J. Drutz, M.D., one of Altimmune’s directors, agreed to the cancellation of \$274,830 in indebtedness in consideration of the issuance of shares with an equivalent purchase price in the Altimmune Private Placement; and
- Klaus O. Schafer, M.D., MPH, one of Altimmune’s directors, agreed to the cancellation of \$79,330 in indebtedness in consideration of the issuance of shares with an equivalent purchase price in the Altimmune Private Placement.

Securities Purchase Agreement

As previously disclosed, on August 16, 2017, we entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) and a Placement Agent Agreement (the “Placement Agent Agreement”). Pursuant to the terms of the Securities Purchase Agreement, we agreed to sell 15,655,714 shares of our Series B Convertible Preferred Stock, par value \$0.0001 per share (the “Preferred Stock”), which were initially convertible into an aggregate of 195,452 shares of our common stock, and warrants initially exercisable to purchase an aggregate of 78,181 shares of common stock at an exercise price of \$80.10 per share of Common Stock (the “Offering”). The Offering was conducted pursuant to the Company’s existing shelf registration statement on Form S-3 (File No. 333-217034), which was filed with the U.S. Securities and Exchange Commission (the “Commission”) on March 30, 2017 and declared effective by the Commission on April 6, 2017. The Offering closed on August 21, 2017. The Company received net proceeds of approximately \$13.0 million from the Offering, after deducting the placement agent fee, an additional fee related to our completed Merger paid to the placement agent, and our estimated offering expenses.

Pursuant to the terms of the Securities Purchase Agreement:

- Novartis Bioventures Ltd. acquired 3,104.4 shares of our Preferred Stock and warrants to purchase 15,503 shares of our common stock for an aggregate purchase price of \$2,918,180;
- Healthcap V LP acquired 305.79 shares of our Preferred Stock and warrants to purchase 1,527 shares of our common stock for an aggregate purchase price of \$122,314, and OFCO Club V acquired 4.67 shares of our Preferred Stock and warrants to purchase 23 shares of our common stock for an aggregate purchase price of \$4,380; and
- UFF Innovation 14 FCPI, UFF Innovation 15 FCPI, and Truffle Fortune 4 FCPI acquired 682.98 shares of our Preferred Stock and warrants to purchase 3,411 shares of our common stock for an aggregate purchase price of \$642,000.

Stock Purchase Agreement

On March 10, 2015, Altimmune entered into a stock purchase agreement with Novartis Bioventures Ltd., affiliates of HealthCap and affiliates of Truffle Capital, each of which are affiliated with certain of Altimmune’s directors and holders of more than 5% of its capital stock, providing for a \$16.0 million committed financing whereby the investors agreed to purchase, in a private offering, securities for the issuance of up to 53,000 shares of Altimmune’s common stock. These securities include shares of Altimmune’s Class A Common Stock and its Series B Convertible Preferred Stock. The stock purchase agreement also provides for the issuance of warrants to purchase shares of its common stock at an exercise price of \$0.30 per share, with the number of shares issuable thereunder to be based on the number of securities purchased in the financing by Novartis Bioventures Ltd., affiliates of Truffle Capital and affiliates of HealthCap. Altimmune closed the first tranche of this financing immediately after the ITS acquisition, in which Altimmune issued and sold 26,667 shares of its Class A Common Stock to the investors, with total gross proceeds to it of \$8.0 million. Novartis Bioventures Ltd. purchased 11,117 shares for an aggregate purchase price of approximately \$3.3 million, affiliates of Truffle Capital purchased 8,884 shares for an aggregate purchase price of approximately \$2.7 million and affiliates of HealthCap purchased 6,667 shares for an aggregate purchase price of \$2.0 million.

[Table of Contents](#)

On November 6, 2015, January 12, 2016, April 8, 2016 and August 19, 2016, Altimmune issued and sold an aggregate of 800,000 shares of its Series B Convertible Preferred Stock, and issued warrants to purchase an aggregate of 23,940 shares of its common stock at an exercise price of \$0.30 per share, in four closings under the stock purchase agreement, for aggregate proceeds of \$8.0 million. Novartis Bioventures Ltd. purchased 285,738 shares of Altimmune's Series B Convertible Preferred Stock, and received 13,047 common stock warrants, for an aggregate purchase price of approximately \$2.9 million, affiliates of Truffle Capital purchased 238,562 shares of Altimmune's Series B Convertible Preferred Stock, and received 10,893 common stock warrants, for an aggregate purchase price of approximately \$2.4 million, affiliates of HealthCap purchased 150,000 shares of Altimmune's Series B Convertible Preferred Stock at an aggregate purchase price of \$1.5 million.

Exchange Agreements

On June 22, 2018, we entered into substantially similar privately negotiated exchange agreements (the "First Exchange Agreements") with certain investors (the "First Investors"). Pursuant to the terms of the First Exchange Agreements, we (i) issued 85,356 shares of common stock, (ii) issued convertible notes (the "Exchange Notes") with an aggregate principal value of \$1,500,000, which are initially convertible into up to 73,529 shares of our common stock upon the default by the Company, based on a conversion price assuming conversion of the Exchange Notes on the date the First Exchange Agreements were signed, subject to adjustment under certain circumstances in accordance with the terms of the Exchange Notes, and (iii) paid \$1,100,000 in aggregate cash consideration, all in exchange for 53,125 warrants to purchase shares of the common stock held by the First Investors. In addition, the 82,343 shares of our common stock previously issued to the First Investors in connection with the most recent installment payment under our Series B Convertible Preferred Stock were deemed to be issued pursuant to the First Exchange Agreements.

On July 11, 2018, we entered into substantially similar privately negotiated exchange agreements (the "Second Exchange Agreements," and together with the First Exchange Agreements, the "Exchange Agreements") with certain investors (the "Second Investors," and together with the First Investors, the "Investors"). Pursuant to the terms of the Second Exchange Agreements, we issued an aggregate of 32,124 shares of common stock to the Second Investors and paid \$22,241 in cash in exchange for all of the shares of Series B Redeemable Convertible Preferred Stock held by the Second Investors. We issued an additional 145,038 shares of common stock at the second closing of the Second Exchange Agreements in exchange for 22,523 warrants to purchase shares of common stock held by the Second Investors. Pursuant to the terms of the Exchange Agreements:

- Entities affiliated with Hudson Bay Capital Management LP received an aggregate of 69,309 shares of common stock, \$2,812,797 in cash and an Exchange Note for a principal value of \$1,218,000 pursuant to the First Exchange Agreements;
- Novartis Bioventures Ltd. received 22,112 shares of common stock and received an additional 99,833 shares of common stock upon approval by our stockholders pursuant to the Second Exchange Agreements;
- HealthCap V LP has received 2,178 shares of common stock and received an additional 9,834 shares of common stock upon approval by our stockholders, and OFCO Club V has received 33 shares of common stock and received an additional 150 shares of common stock upon approval by our stockholders pursuant to the Second Exchange Agreements; and
- UFF Innovation 14 FCPI, UFF Innovation 15 FCPI and Truffle Fortune 4 FCPI received an aggregate of 4,865 shares of common stock and will receive an additional 21,963 shares of common stock upon approval by our stockholders pursuant to the Second Exchange Agreements.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of the Company's common stock as of September 27, 2018 by (i) each person or group of persons known by us to beneficially own more than five percent of our common stock, (ii) each of our named executive officers, (iii) each of our directors and nominees for director and (iv) all of our directors and executive officers as a group.

The following table gives effect to the shares of common stock issuable within 60 days of September 24, 2018 upon the exercise of all options and other rights beneficially owned by the indicated stockholders on that date. Beneficial ownership is determined in accordance with Rule 13d-3 promulgated under Section 13 of the Securities Exchange Act of 1934, as amended, and includes voting and investment power with respect to shares. Percentage of beneficial ownership is based on 1,720,517 shares of common stock outstanding at the close of business on September 27, 2018. Except as otherwise noted below, each person or entity named in the following table has sole voting and investment power with respect to all shares of our common stock that he, she or it beneficially owns. Stock option and warrant share amounts have been adjusted to reflect the Company's 1-for-30 Reverse Stock Split.

Unless otherwise indicated below, the address for each beneficial owner listed is c/o Altimune, Inc., 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>	
		<u>Before Offering</u>	<u>After Offering</u>
5% or Greater Stockholders:			
Novartis Bioventures Ltd.(1)	278,190	16.46%	
Entities affiliated with Truffle Capital(2)	106,319	6.3%	
Directors and Named Executive Officers:			
William Enright(3)	14,277	1.0%	
Elizabeth Czerepak	—	*	
David Drutz, M.D.(4)	2,126	*	
John M. Gill(5)	3,641	*	
Philip Hodges(6)	20,123	1.2%	
Mitchel Sayare, Ph.D.(7)	2,405	*	
Klaus Schafer, M.D.(8)	1,205	*	
Derace L. Schaffer, M.D.(9)	20,795	1.2%	
Sybil Tasker, M.D., M.P.H.(10)	1,735	*	
Wayne Pisano	—	*	
All Executive Officers and Directors As a Group			
(11 persons)(11)		4.2%	

* Represents beneficial ownership of less than one percent of Altimune's outstanding common stock.

- (1) Consists of 278,172 shares of common stock and options to purchase 18 shares of common stock, all held by Novartis Bioventures Ltd., a Bermuda corporation. The board of directors of Novartis Bioventures Ltd., comprised of Simon Zivi, Michael Jones and Timothy Faries, has sole voting and investment control and power over such shares. None of the members of its board of directors has individual voting and investment power with respect to such shares and disclaims beneficial ownership of such shares. Novartis Bioventures Ltd. is an indirectly owned subsidiary of Novartis AG. The address of Novartis Bioventures Ltd. is 131 Front Street, Hamilton, Bermuda HM 12.
- (2) Consists of 106,301 shares of common stock and options to purchase 18 shares of common stock held by funds managed by Truffle Capital S.A.S., a French société par actions simplifiée. The address of Truffle Capital S.A.S. is c/o Truffle Capital S.A.S., 5, rue de la Baume, 75008 Paris, France.

Table of Contents

- (3) Consists of 12,195 shares of common stock and 2,082 shares that can be acquired upon the exercise of outstanding options within 60 days.
- (4) Consists of 693 shares of common stock and 1,433 shares that can be acquired upon the exercise of outstanding options within 60 days.
- (5) Consists of 2,774 shares of common stock and 867 shares that can be acquired upon the exercise of outstanding options within 60 days.
- (6) Consists of 19,456 shares of common stock and 667 shares that can be acquired upon the exercise of outstanding options within 60 days.
- (7) Consists of 1,088 shares of common stock and 1,317 shares that can be acquired upon the exercise of outstanding options within 60 days.
- (8) Consists of 200 shares of common stock and 1,005 shares that can be acquired upon the exercise of outstanding options within 60 days.
- (9) Consists of 20,062 shares of common stock and 733 shares that can be acquired upon the exercise of outstanding options within 60 days.
- (10) Consists of 1,735 shares of common stock that can be acquired upon the exercise of outstanding options within 60 days.
- (11) Consists of 58,465 shares of common stock and 13,832 shares that can be acquired upon the exercise of outstanding options within 60 days.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock is intended as a summary only. We refer you to our amended and restated certificate of incorporation and restated bylaws, which are incorporated by reference into this prospectus, and to the applicable provisions of the Delaware General Corporation Law. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

Our authorized capital stock consists of 200,000,000 shares of our common stock, par value \$0.0001 per share, and 1,000,000 shares of our preferred stock, par value \$0.0001 per share, all of which preferred stock is undesignated.

Common Stock

Dividend Rights. Holders of outstanding shares of common stock will be entitled to receive dividends out of assets legally available at the times and in the amounts as the board of directors may from time to time determine, subject to preferences that may apply to shares of preferred stock outstanding at the time.

Conversion or Redemption Rights. Our common stock will be neither convertible nor redeemable.

Liquidation Rights. Upon our liquidation, dissolution or winding up, the holders of our common stock will be entitled to receive pro rata our assets which are legally available for distribution, after payment of all debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences. Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 1,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

We have no present plans to issue any additional shares of preferred stock.

Warrants

As of September 24, 2018, warrants to purchase an aggregate of 1,767 shares of our common stock at a weighted-average exercise price of \$115.44 per share were outstanding. We are offering both Warrants and Pre-funded Warrants in this offering. See “Description of Securities we are Offering.” We have agreed to issue to the underwriter in this offering Warrants to purchase up to a number of our shares of common stock equal to 4% of the shares of common stock and the shares of common stock underlying the Warrants sold in this offering. See “Underwriting — Underwriter’s Warrants.”

Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws

Our certificate of incorporation and bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Action by Written Consent; Special Meetings of Stockholders. Our certificate of incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Except as described above, stockholders will not be permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors. Our bylaws provide that our directors may be removed only for cause by the affirmative vote of a majority of the voting power of our outstanding shares of capital stock, voting together as a single class.

Advance Notice Procedures. Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder’s intention to bring that business before the meeting. Although our bylaws does not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum. Our bylaws provide that, subject to limited exceptions, the Court of Chancery in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or

[Table of Contents](#)

other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. The transfer agent and registrar's address is 17 Battery Place, 8th Floor, New York, NY 10004.

Listing

Our common stock is listed on The Nasdaq Global Market under the symbol "ALT."

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 775,000 Common Units, at a public offering price of \$5.00. Each Common Unit will consist of one share of our common stock and one Warrant. We are also offering to those purchasers, if any, whose purchase of Common Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, Pre-funded Units in lieu of Common Units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, each Pre-funded Unit consisting of one Pre-Funded Warrant and one Warrant. We are offering 775,000 Common Units and 1,625,000 Pre-funded Units. Common Units and Pre-funded Units will not be issued or certificated. The shares of common stock or Pre-funded Warrants, as the case may be, and the Warrants included in the Common Units or the Pre-funded Units, can only be purchased together in this offering, but the securities contained in the Common Units or Pre-funded Units will be issued separately and will be immediately separable upon issuance. We are also registering the shares of common stock included in the Common Units and the shares of common stock issuable from time to time upon exercise of the Pre-funded Warrants included in Pre-funded Units and Warrants included in the Common Units and the Pre-funded Units offered hereby.

Common Stock

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption "Description of Capital Stock" in this prospectus.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-funded Warrants included in the Pre-funded Units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-funded Warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Pre-funded Warrant for a complete description of the terms and conditions of the Pre-funded Warrants.

Duration and Exercise Price

Each Pre-funded Warrant offered hereby will have an initial exercise price per share equal to \$0.01. The Pre-funded Warrants will be immediately exercisable and may be exercised at any time until the Pre-funded Warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Pre-funded Warrants will be issued separately from the accompanying Warrants included in the Pre-funded Units.

Exercisability

The Pre-funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of a Pre-funded Warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Pre-funded Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in

[Table of Contents](#)

accordance with the terms of the Pre-funded Warrants. Purchasers of Pre-funded Units in this offering may also elect prior to the issuance of the Pre-funded Units to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If, at the time a holder exercises its Pre-funded Warrants, a registration statement registering the issuance of the shares of common stock underlying the Pre-funded Warrants under the Securities Act of 1933, as amended, or the Securities Act, is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Pre-funded Warrants.

Transferability

Subject to applicable laws, a Pre-funded Warrant may be transferred at the option of the holder upon surrender of the Pre-funded Warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Pre-funded Warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Trading Market

There is no trading market available for the Pre-funded Warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the Pre-funded Warrants is currently listed on the Nasdaq Global Market.

Right as a Stockholder

Except as otherwise provided in the Pre-funded Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Pre-funded Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Pre-funded Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Pre-funded Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of at least 50% of our outstanding common stock, or any person or group becoming the beneficial owner of at least 50% of the voting power represented by our outstanding common stock, the successor entity will assume the Pre-funded Warrant, unless the fundamental transaction is an all-cash sale, in which case we or the successor entity may purchase the Pre-funded Warrants according to a formula set forth in the Pre-funded Warrants based on a Black-Scholes option pricing model (the "Option Value").

Warrants for Common Stock

The following summary of certain terms and provisions of the Warrants included in the Common Units and the Pre-funded Units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Warrant for a complete description of the terms and conditions of the Warrants.

[Table of Contents](#)

Duration and Exercise Price

Each Warrant included in the Common Units and the Pre-funded Units offered hereby will have an initial exercise price of \$6.00 per share. The Warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Warrants will be issued separately from the common stock included in the Common Units, or the Pre-funded Warrants included in the Pre-funded Units, as the case may be. A Warrant to purchase one share of our common stock will be included in each Common Unit or Pre-funded Unit purchased in this offering.

Cashless Exercise

If, at the time a holder exercises its Warrants, a registration statement registering the issuance of the shares of common stock underlying the Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Warrants.

Exercisability

The Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed above). A holder (together with its affiliates) may not exercise any portion of a Warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. Purchasers of Warrants in this offering may also elect prior to the issuance of Warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Transferability

Subject to applicable laws, a Warrant may be transferred at the option of the holder upon surrender of the Warrant to us together with the appropriate instruments of transfer.

Exchange Listing

We do not intend to list the Warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the Warrants is currently listed on The Nasdaq Global Market.

Right as a Stockholder

Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Warrants.

Anti-Dilution

The exercise price and the number and type of securities purchasable upon exercise of the warrants are subject to adjustment upon certain corporate events, including certain combinations, consolidations, recapitalizations, reclassifications, reorganizations, stock dividends and stock splits and certain other events. The warrants contain full ratchet anti-dilution protection upon the issuance or public announcement of the issuance of any common stock, securities convertible into common stock or certain other issuances at a price below the then-existing exercise price of the warrants, with certain exceptions. The terms of the warrants, including these anti-dilution protections, may make it difficult for us to raise additional capital at prevailing market terms in the future.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of at least 50% of our outstanding common stock, or any person or group becoming the beneficial owner of at least 50% of the voting power represented by our outstanding common stock, the successor entity will assume the Warrant, unless (i) the fundamental transaction is an all-cash sale, in which case we or the successor entity may purchase the Warrants according to a formula set forth in the Warrants based on the Option Value, or (ii) the holder of the Warrant elects to receive the Option Value of such Warrant. If the fundamental transaction was not within our control, the holders of the Warrants will be entitled only to receive the same kind and amount of consideration that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, at the Option Value of the unexercised portion of the Warrant.

**MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS FOR HOLDERS OF OUR COMMON STOCK,
PRE-FUNDED WARRANTS AND WARRANTS**

The following discussion is a summary of the material U.S. federal income tax considerations to U.S. Holders and Non-U.S. Holders (each as defined below and, together “Holders”) of the purchase, ownership and disposition of our common stock, Warrants and Pre-funded Warrants. This does not purport to be a complete analysis of all potential tax effects to Holders of purchasing, owning or disposing our common stock, Warrants or Pre-funded Warrants. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not included in this discussion, and Holders should consult their own tax advisors as to these matters. This discussion is based on the Internal Revenue Code of 1986, as amended (the “Code”), final, temporary and proposed Treasury Regulations promulgated thereunder, judicial decisions and administrative pronouncements of the IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change may be applied retroactively in a manner that could adversely affect a Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance that the IRS will not take or that a court will not uphold a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock, Warrants and Pre-funded Warrants.

This discussion is limited to Holders that hold our common stock, Warrants and Pre-funded Warrants as “capital assets” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Holder’s particular circumstances. In addition, it does not address consequences relevant to Holders subject to special rules, including, without limitation:

- banks, insurance companies and other financial institutions;
- real estate investment trusts, regulated investment companies, and other entities treated as conduits for U.S. federal income tax purposes;
- brokers, dealers or traders in securities;
- Holders who are subject to the mark-to-market accounting rules under Section 475 of the Code
- “controlled foreign corporations,” “passive foreign investment companies” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- tax-exempt organizations and governmental organizations or agencies;
- Holders who hold or receive our common stock, Warrants or Pre-funded Warrants pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- U.S. Holders whose functional currency is not the United States dollar;
- Holders holding our common stock, Warrants or Pre-funded Warrants as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment; and
- Holders subject to the alternative minimum tax.

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our common stock, Warrants or Pre-funded Warrants, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner

[Table of Contents](#)

level. Accordingly, partnerships holding our common stock, Warrants or Pre-funded Warrants and the partners in such partnerships should consult their own tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS TAX ADVICE. INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, WARRANTS OR PRE-FUNDED WARRANTS ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Allocation of Purchase Price of Common Unit and Pre-funded Unit

For U.S. federal income tax purposes, the purchase price for each Common Unit and Pre-funded Unit should be allocated between the two components thereof in proportion to their relative fair market values at the time the unit is purchased by the Holder. This allocation of the purchase price for each unit will establish the Holder's initial tax basis for U.S. federal income tax purposes in the share of common stock, Warrant or Pre-funded Warrant, as applicable. The separation (as opposed to the disposition) of the share of common stock, Warrant or Pre-funded Warrant should not be a taxable event for U.S. federal income tax purposes. Each Holder should consult its own tax advisor regarding the allocation of the purchase price for a unit.

Characterization of the Pre-funded Warrants

Although the characterization of the Pre-funded Warrants for U.S. federal income tax purposes is not entirely clear, because the exercise price of the Pre-funded Warrants is a nominal amount, the Company expects to treat the Pre-funded Warrants as common stock of the Company for U.S. federal income tax purposes. Except where noted, the remainder of this discussion assumes that the Pre-funded Warrants will be so treated. Each Holder should consult its own tax advisor regarding the proper characterization of the Pre-funded Warrants for U.S. federal, state and local, and non-U.S. tax purposes, and the consequences to them of such treatment given their individual circumstances. Some portions of the below discussion make reference to potential consequences associated with the purchase, ownership and disposition of the Pre-funded Warrants independent of their potential characterization as common shares.

U.S. Holders

For purposes of this discussion, a "U.S. Holder" is any beneficial owner of Securities that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (ii) has made a valid election under applicable Treasury Regulations to continue to be treated as a U.S. person.

If you are not a U.S. Holder, this section does not apply to you. Please see the discussion under "Non-U.S. Holders" below.

Distributions on Common Stock

As described in the section captioned “Dividend Policy,” we do not anticipate declaring or paying distributions to Holders of our common stock in the foreseeable future. Any cash distributions we make to U.S. Holders of shares of our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. Holder’s adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under “U.S. Holders—Sale or Other Taxable Disposition of Common Stock, Warrants or Pre-funded Warrants” below.

Dividends we pay to a U.S. Holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided the common shares are held for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and certain other holding period requirements are met, dividends we pay to a non-corporate U.S. Holder generally will constitute “qualified dividends” that will be subject to tax at the maximum tax rate accorded to long-term capital gains. Dividends paid by us will generally be treated as income from U.S. sources. U.S. Holders should consult their own tax advisors regarding the holding period and other requirements that must be satisfied in order to qualify for the reduced maximum tax rate on dividends.

Sale or Other Taxable Disposition of Common Stock, Warrants or Pre-funded Warrants

Upon a sale, exchange or other taxable disposition of common stock, Warrants or Pre-funded Warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder’s adjusted tax basis in the common stock, Warrant or Pre-funded Warrant, as the case may be. A U.S. Holder’s adjusted tax basis in the common stock or Warrants generally will equal the U.S. Holder’s acquisition cost of such security less, in the case of common stock (and potentially a Pre-funded Warrant) and as described further above, the amount of any prior distributions treated as a return of capital on such stock. If a U.S. Holder purchases or sells common stock, Warrants and/or Pre-funded Warrants together in a single transaction in which the purchase price for each of the common stock, Warrants and/or Pre-funded Warrants was not separately stated, the U.S. Holder generally would be required to allocate the purchase price among the subject securities so acquired or disposed of, as applicable, based on the relative fair market values of each (at the time of the acquisition or disposition, as applicable). U.S. Holders who purchase or sell common stock, Warrants and/or Pre-funded Warrants in a single transaction should consult with their tax advisors regarding such allocation.

Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. Holder’s holding period for the common stock, Warrants or Pre-funded Warrants disposed of exceeds one year. Long-term capital gains recognized by non-corporate U.S. Holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Exercise or Lapse of a Warrant or a Pre-funded Warrant

A U.S. Holder generally will not recognize taxable gain or loss on the acquisition of common stock upon exercise of a Warrant or a Pre-funded Warrant. The U.S. Holder’s aggregate tax basis in the share of our common stock received upon exercise of a Warrant or a Pre-funded Warrant generally will be an amount equal to the sum of the U.S. Holder’s tax basis in the Warrant or the Pre-funded Warrant prior to exercise and the warrant’s exercise price. The U.S. Holder’s holding period for the common stock received upon exercise of a Warrant will begin on the date following the date of exercise of the Warrant and will not include the period during which the U.S. Holder held the Warrant. If a Pre-funded Warrant is treated as common stock, the holding

[Table of Contents](#)

period of the common stock actually received upon the exercise of a Pre-funded Warrant would include the holding period for the Pre-funded Warrant. If a Warrant or Pre-funded Warrant lapses unexercised, a U.S. Holder generally will recognize a capital loss equal to such Holder's tax basis in the warrant, which will be long-term capital loss if the warrant was held by the U.S. Holder for more than one year. The deductibility of capital losses is subject to limitations.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of Warrants or Pre-funded Warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise is unclear, and the tax consequences of a cashless exercise could differ from the consequences of an exercise described above. For example, the cashless exercise could be treated as a taxable disposition of a portion of the Warrants or the common shares into which they are exercisable. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise.

Certain Adjustments to the Warrants or Pre-funded Warrants and Payments in Respect of the Warrants or Pre-funded Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of the Warrants or Pre-funded Warrants, or an adjustment to the exercise price of the Warrants or Pre-funded Warrants, may be treated as a constructive distribution to a U.S. Holder of the Warrants or Pre-funded Warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of Warrants or Pre-funded Warrants made pursuant to a *bona fide* reasonable adjustment formula that has the effect of preventing dilution of the interest of the U.S. Holder of the Warrants or Pre-funded Warrants generally should not be considered to result in a constructive distribution. Such constructive distribution would be treated as a dividend, return of capital or capital gain as described under the heading "U.S. Holder—Distributions on Common Stock" above. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property.

Net investment income tax

An additional 3.8% tax is imposed on the "net investment income" of non-corporate U.S. Holders, and on the undistributed "net investment income" of certain estates and trusts. Among other items, "net investment income" generally includes dividends paid on our common stock and certain net gain from the sale or other taxable disposition of our common stock, Warrants and Pre-funded Warrants, less certain deductions. U.S. Holders should consult their own tax advisors concerning the potential effect, if any, of this tax on holding our common stock, Warrants and Pre-funded Warrants in such U.S. Holder's particular circumstances.

Backup withholding and information reporting

For non-corporate U.S. Holders, information reporting requirements, on IRS Form 1099, generally will apply to:

- dividend payments or other taxable distributions on our common stock and warrants made to the non-corporate U.S. Holder within the United States or by a United States payor; and
- the payment of proceeds to the non-corporate U.S. Holder from the sale of a share of common stock, Warrants or Pre-funded Warrants effected at a United States office of a broker or through certain U.S.-related financial intermediaries.

Additionally, backup withholding may apply to such payments if the non-corporate U.S. Holder:

- fails to provide an accurate taxpayer identification number;

[Table of Contents](#)

- is notified by the IRS that it has failed to report all interest and dividends required to be shown on its U.S. federal income tax returns; or
- in certain circumstances, fails to comply with applicable certification requirements.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-corporate U.S. Holder's U.S. federal income tax liability (if any), provided the required information is timely furnished to the IRS. U.S. Holders are urged to consult their own tax advisors regarding the application of backup withholding and the availability of and procedure for obtaining an exemption from backup withholding in their particular circumstances.

Non-U.S. Holders

For purposes of this discussion, a Non-U.S. Holder is a beneficial owner of our common stock, Warrants or Pre-funded Warrants that, for U.S. federal income tax purposes, is neither a U.S. Holder (as defined above) nor a partnership or other pass-through entity. If you are not a Non-U.S. Holder, this section does not apply to you.

Distributions on Common Stock

As described in the section captioned "Dividend Policy," we do not anticipate declaring or paying distributions to Holders of our common stock in the foreseeable future. Any distributions we make on our common stock in cash will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles.

Subject to the discussion below regarding backup withholding and payments made to certain foreign accounts, dividends paid to a Non-U.S. Holder of our common stock (including constructive distributions treated as a dividend) that are not effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate as may be specified by an applicable income tax treaty).

Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "Non-U.S. Holders – Sale or Other Taxable Disposition of Common Stock or Warrants."

Non-U.S. Holders may be entitled to a reduction in or an exemption from withholding on dividends as a result of either (i) qualifying for the benefits of an applicable income tax treaty or (ii) the Non-U.S. Holder holding our common stock in connection with the conduct of a trade or business within the United States and dividends being paid in connection with that trade or business. To claim such a reduction in or exemption from withholding, the Non-U.S. Holder must provide the applicable withholding agent with a properly executed (i) IRS Form W-8BEN or W-8BEN-E (or applicable successor form) claiming an exemption from or reduction of the withholding tax under the benefit of an applicable income tax treaty, (ii) IRS Form W-8ECI (or applicable successor form) stating that the dividends are effectively connected with the conduct by the Non-U.S. Holder of a trade or business within the United States, or (iii) a suitable substitute form, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. Holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Subject to the discussion below regarding backup withholding and payments made to certain foreign accounts, if dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S.

Holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although generally exempt from U.S. federal withholding tax (provided the Non-U.S. Holder provides appropriate certification, as described above), the Non-U.S. Holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, a Non-U.S. Holder that is or is treated as a corporation for U.S. federal income tax purposes may be subject to an additional branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their own tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Sale or Other Taxable Disposition of Common Stock, Warrants or Pre-funded Warrants

Subject to the discussion below regarding backup withholding and payments made to certain foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax on any gain recognized upon the sale or other taxable disposition of a share of our common stock, Warrants or Pre-funded Warrants unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a non-resident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- we are or have been a "U.S. real property holding corporation," orUSRPHC, for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. Holder held the common stock, Warrants or Pre-funded Warrants.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A Non-U.S. Holder that is a foreign corporation also may be subject to an additional branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on a portion of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty) on any gain derived from the sale or other taxable disposition, which may be offset by certain U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States) provided the Non-U.S. Holder timely files U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe that we are not, and do not anticipate that we will become, a USRPHC.

The method of determining the amount of gain by a Non-U.S. Holder on disposition of the common stock, Warrants or Pre-funded Warrants generally will correspond to the method of determining the amount of gain (or loss) by a U.S. Holder on disposition of the common stock or Warrants, as described under "U.S. Holders — Sale or Other Taxable Disposition of Common Stock, Warrants or Pre-funded Warrants" above. Non-U.S. Holders should consult their own tax advisors regarding potentially applicable income tax treaties that may provide for different rules, and the potential application of other exceptions to these taxes.

Exercise or Lapse of a Warrant or a Pre-funded Warrant

For certain Non-U.S. Holders engaged in the conduct of a trade or business in the United States, the U.S. federal income tax treatment of the exercise of a Warrant or Pre-funded Warrant, or the lapse of a Warrant or

Pre-funded Warrant, generally will correspond to the U.S. federal income tax treatment of the exercise or lapse of a Warrant by a U.S. Holder, as described under “U.S. Holders — Exercise or Lapse of a Warrant or a Pre-funded Warrant” above. For all other Non-U.S. holders, the exercise or lapse of a Warrant generally will not be a U.S. taxable event.

Certain Adjustments to the Warrants or Pre-funded Warrants and Payments in Respect of the Warrants or Pre-funded Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of the Warrants or Pre-funded Warrants, or an adjustment to the exercise price of the Warrants or Pre-funded Warrants, may be treated as a constructive distribution to a Non-U.S. Holder of the Warrants or Pre-funded Warrants if, and to the extent that, such adjustment has the effect of increasing such Non-U.S. Holder’s proportionate interest in our “earnings and profits” or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of Warrants or Pre-funded Warrants made pursuant to a *bona fide* reasonable adjustment formula that has the effect of preventing dilution of the interest of the Non-U.S. Holder of the Warrants or Pre-funded Warrants generally should not be considered to result in a constructive distribution. Such constructive distribution would be treated as a dividend, return of capital or capital gain as described under the heading “Non-U.S. Holders—Distributions on Common Stock” above. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property.

In addition, regulations governing “dividend equivalents” under Section 871(m) of the Code may apply to the Pre-funded Warrants. Under those regulations, an implicit or explicit payment under the Pre-funded Warrants that references a dividend distribution on our common stock (including an adjustment to the amount due on the Pre-funded Warrant to take into account a dividend distribution on our common stock) would be taxable to a Non-U.S. Holder as described under the heading “Non-U.S. Holders—Distributions on Common Stock” above. Such dividend equivalent amount would be taxable and subject to withholding whether or not there is actual payment of cash or other property, and the Company may satisfy any withholding obligations it has in respect of the Pre-funded Warrants by withholding from other amounts due to the Holder. Non-U.S. holders are encouraged to consult their own tax advisors regarding the application of Section 871(m) of the Code to the Pre-funded Warrants.

Information Reporting and Backup Withholding

Subject to the discussion below regarding payments made to certain foreign accounts, a Non-U.S. Holder generally will not be subject to backup withholding with respect to payments of dividends on our common stock we make to the Non-U.S. Holder, provided the applicable withholding agent does not have actual knowledge or reason to know such Holder is a U.S. person and the Holder certifies its non-U.S. status by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification (or applicable successor form), or otherwise establishes an exception. However, information returns will be filed with the IRS in connection with any dividends or other distributions on our common stock paid to the Non-U.S. Holder (including constructive distributions), regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale of a share of our common stock, Warrants or Pre-funded Warrants within the United States, and information reporting may (although backup withholding will generally not) apply to the proceeds of the sale of a share of our common stock, Warrants or Pre-funded Warrants outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a Non-U.S. person on IRS Form W-8BEN or other applicable form or successor form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability (if any), provided the required information is timely furnished to the IRS. Non-U.S. Holders are urged to consult their own tax advisors regarding the application of backup withholding and the availability of and procedure for obtaining an exemption from backup withholding in their particular circumstances.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under the provisions of the law generally known as the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends or, on or after January 1, 2019, gross proceeds from the sale or other disposition of our common stock, Warrants and Pre-funded Warrants paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial U.S. owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified U.S. persons" or "U.S.-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders. An intergovernmental agreement between the United States and an applicable foreign country, or future Treasury Regulations or other guidance, may modify these requirements.

Under the applicable Treasury Regulations and recent guidance from the IRS, withholding under FATCA generally applies to payments of dividends on our common stock, and will apply to payments of gross proceeds from the sale or other disposition of our common stock, Warrants and Pre-funded Warrants on or after January 1, 2019, and to certain "pass-thru" payments made on or after the later of January 1, 2019 and the date final Treasury Regulations are issued defining such pass-thru payments. The FATCA withholding tax will apply to all withholdable payments without regard to whether the beneficial owner of the payment would otherwise be entitled to an exemption from imposition of withholding tax pursuant to an applicable tax treaty with the United States or U.S. domestic law. We will not pay additional amounts to Holders of our common stock, Warrants or Pre-funded Warrants in respect of any amounts withheld.

Prospective investors should consult their own tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock, Warrants and Pre-funded Warrants.

UNDERWRITING

We have entered into an underwriting agreement with Roth Capital Partners, LLC, acting as the sole underwriter, with respect to the units subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase, the number of Common Units and Pre-funded Units provided below opposite its name.

<u>Underwriter</u>	<u>Number of Common Units</u>	<u>Number of Pre- funded Units</u>
Roth Capital Partners, LLC	775,000	1,625,000
Total	775,000	1,625,000

The underwriter is offering the units subject to its acceptance of the units from us and subject to prior sale. The underwriting agreement provides that the obligations of the underwriter to pay for and accept delivery of the units offered by this prospectus are subject to the approval of certain legal matters by its counsel and to certain other conditions. The underwriter is obligated to take and pay for all of the units if any such units are taken. However, the underwriter is not required to take or pay for the securities covered by the underwriter's over-allotment option described below.

Over-Allotment Option

We have granted the underwriter an option, exercisable for 30 days from the date of this prospectus, to purchase up to 116,250 additional Common Units at a purchase price of \$4.65 per Common Unit, 243,750 additional Pre-funded Units at a purchase price of \$4.6407 per Pre-funded Unit, 116,250 additional shares of common stock at a purchase price of \$4.6407 per share, additional Pre-funded Warrants to purchase up to an additional 243,750 shares of common stock at a purchase price of \$0.0093 per Pre-funded Warrant and/or additional Warrants to purchase up to 360,000 shares of common stock at a purchase price of \$0.0093 per Warrant, to cover over-allotments, if any, in connection with the units offered by this prospectus. If the underwriter exercises this option, the underwriter will be obligated, subject to certain conditions, to purchase such number of additional securities for which the option has been exercised. Because the Warrants and the Pre-funded Warrants are not listed on a national securities exchange or other nationally recognized trading market, the underwriter will be unable to satisfy any over-allotment of units without exercising the underwriter's over-allotment option with respect to the Warrants and, if applicable, the Pre-funded Warrants. The underwriter has informed us that it intends to exercise its over-allotment option for all of the Warrants and Pre-funded Warrants that are over-allotted, if any, at the time of the initial offering of the units. However, because our common stock is publicly traded, the underwriter may satisfy some or all of the over-allotment of shares of our common stock included in the Common Units, if any, by purchasing shares in the open market and will have no obligation to exercise the over-allotment option with respect to our common stock. Assuming no sale of the Pre-funded Units, if the underwriter exercises its over-allotment option with respect to the Warrants in full, but does not exercise its over-allotment option with respect to our common stock, then, the effective warrant coverage for each share of common stock included in the Common Units sold in this offering would increase to 115% instead of the 100% stated on the cover of this prospectus.

Discount, Commissions and Expenses

The underwriter has advised us that it proposes to offer the Common Units and the Pre-funded Units, as the case may be, to the public at the public offering prices set forth on the cover of this prospectus and to certain dealers at that price less a concession not in excess of \$0.175 per unit. After this offering, the public offering prices and concession to dealers may be changed by the underwriter. No such change will change the amount of proceeds to be received by us as set forth on the cover of this prospectus. The units are offered by the underwriter as stated herein, subject to receipt and acceptance by it and subject to its right to reject any order in whole or in part. The underwriter has informed us that it does not intend to confirm sales to any accounts over which it exercises discretionary authority.

[Table of Contents](#)

The following table provides information regarding the amount of the discount to be paid to the underwriter by us, before expenses.

	<u>Per Common Unit</u>	<u>Per Pre-funded Unit</u>	<u>Total</u>
Public offering price	\$ 5.00	\$ 4.99	\$11,983,750
Underwriting discount	\$ 0.35	\$ 0.3493	\$ 838,863

We have agreed to reimburse the underwriter for certain out-of-pocket expenses, including the fees and disbursements of its counsel, up to an aggregate of \$125,000. We estimate that the total expenses payable by us in connection with this offering, other than the underwriting discount referred to above, will be approximately \$1,000,000.

If we decide to pursue another public offering of our equity or equity-linked securities, at any time within six months of the date of this prospectus, we are obligated to offer to the underwriter the right to act as the exclusive placement agent or lead underwriter and sole book runner, as applicable, for the first such offering, under a separate agreement containing customary terms and conditions for such transactions and otherwise similar to the terms described herein, subject to certain exceptions.

Underwriter's Warrants

We have also agreed to issue to the underwriter warrants to purchase a number of our shares of common stock equal to up to 4% of the shares of common stock and the shares of common stock underlying the Pre-funded Warrants and the Warrants sold in this offering. The underwriter warrants will have an exercise price per share equal to 125% of the public offering price per Common Unit in this offering and may be exercised on a cashless basis. The underwriter warrants are not redeemable by us, become exercisable 180 days from the effective date of the registration statement of which this prospectus is a part and will expire on the third anniversary of such effective date. The underwriter warrants will provide for adjustment in the number and price of such underwriter warrants (and the shares of common stock underlying such warrants) in the event of recapitalization, merger or other fundamental transaction. The underwriter warrants and the underlying shares of common stock have been deemed compensation by FINRA and are therefore subject to FINRA Rule 5110(g)(1). In accordance with FINRA Rule 5110(g)(1), neither the underwriter warrants nor any shares of our common stock issued upon exercise of the underwriter warrants may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which the underwriter warrants are being issued, except the transfer of any security:

- by operation of law or by reason of reorganization of the Company;
- to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period;
- if the aggregate amount of securities of the Company held by either an underwriter or a related person do not exceed 1% of the securities being offered;
- that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

In addition, in accordance with FINRA Rule 5110(f)(2)(G), the underwriter warrants may not contain certain terms.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act, and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriter may be required to make in respect of those liabilities.

Lock-up Agreements

We and our officers and directors have agreed, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of the underwriter. The underwriter may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriter of securities in excess of the number of securities the underwriter is obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriter is not greater than the number of securities that it may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriter may close out any covered short position by either exercising its over-allotment option and/or purchasing securities in the open market.
- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriter will consider, among other things, the price of securities available for purchase in the open market as compared to the price at which it may purchase securities through the over-allotment option. If the underwriter sells more securities than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor the underwriter makes any representations that the underwriter will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Passive Market Making

In connection with this offering, the underwriter and any selling group members may engage in passive market making transactions in our common stock on The Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Listing, Transfer Agent and Warrant Agent

Our common stock is listed on The Nasdaq Global Market under the symbol "ALT." The transfer agent of our common stock is Continental Stock Transfer & Trust Company. There is no established public trading market for the Warrants or the Pre-funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants or the Pre-funded Warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants and the Pre-funded Warrants will be limited. We will act as the registrar and transfer agent for the Warrants and the Pre-funded Warrants.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriter, or by its affiliates. Other than this prospectus in electronic format, the information on the underwriter's website and any information contained in any other website maintained by the underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other

From time to time, the underwriter and/or its affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services it has received and, may in the future receive, customary fees. In the course of its businesses, the underwriter and its affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriter and its affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering and except as described below, the underwriter has not provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain the underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus. In connection with the Registered Direct Offering, we entered into a placement agency agreement with the underwriter pursuant to which the underwriter acted as our exclusive placement agent and, in connection therewith, paid the underwriter a cash placement fee of \$341,495 and reimbursed the underwriter for out-of-pocket expenses of \$85,000.

NOTICE TO INVESTORS

Notice to Investors in the United Kingdom

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any such securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) by the underwriter to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of these securities shall result in a requirement for the publication by the issuer or the underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any such securities to be offered so as to enable an investor to decide to purchase any such securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

The underwriter has represented, warranted and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any of the securities in circumstances in which section 21(1) of the FSMA does not apply to the issuer; and
- (b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

European Economic Area

In particular, this document does not constitute an approved prospectus in accordance with European Commission’s Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to such securities which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including

the Relevant Implementation Date, make an offer of securities to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in the last annual or consolidated accounts; or
- in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of securities to the public” in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the units offered hereby are “securities.”

LEGAL MATTERS

The validity of the securities offered in this prospectus will be passed upon for us by Proskauer Rose LLP, Boston, Massachusetts. Lowenstein Sandler LLP, New York, New York, is acting as counsel for the underwriter in connection with this offering.

EXPERTS

The consolidated financial statements of Altimune, Inc. (the Company), appearing in its Annual Report (Form 10-K) for the year ended December 31, 2017, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt regarding the Company's ability to continue as a going concern as described in Note 2 to the consolidated financial statements), included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance on such report given on the authority of said firm as experts in auditing and accounting.

The consolidated financial statements of the Company as of December 31, 2016 and for the year then ended incorporated by reference in this prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and the securities offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and as such we refer you to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The Internet address is www.sec.gov.

We are subject to the information and periodic reporting requirements of the Exchange Act, and we file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at <http://www.altimmune.com>. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus, and any references to this website or any other website are inactive textual references only. You may also request a copy of these filings, at no cost, by writing us at 910 Clopper Road, Suite 201S, Gaithersburg, Maryland or telephoning us at (240) 654-1450.

INCORPORATION OF DOCUMENTS BY REFERENCE

The Securities and Exchange Commission permits us to “incorporate by reference” the information contained in documents we file with the Securities and Exchange Commission, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Information that we file later with the Securities and Exchange Commission will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the Securities and Exchange Commission, and incorporate by reference in this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on April 2, 2018, as amended by Form 10-K/A filed with the SEC on April 30, 2018;
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2018 filed with the SEC on May 15, 2018 and for the quarter ended June 30, 2018 filed with the SEC on August 14, 2018; and
- our definitive proxy statement on Schedule 14A filed on July 26, 2018;
- our Current Reports on Form 8-K filed with the SEC on May 10, 2018, May 18, 2018, June 22, 2018, June 25, 2018, July 16, 2018, August 31, 2018, September 4, 2018, September 12, 2018, September 13, 2018, September 24, 2018 and September 25, 2018.

We also incorporate by reference all additional documents that we file with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the initial filing date of the registration statement of which this prospectus is a part until this offering has been completed. All filings from the date of the initial registration statement and prior to effectiveness of the registration statement shall be deemed to be incorporated by reference into the prospectus. We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with Securities and Exchange Commission rules.

You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

Altimune, Inc.
910 Clopper Road, Suite 201S
Gaithersburg, Maryland 20878
Attn.: Corporate Secretary
Tel: (240) 654-1540

775,000 Common Units, Each Consisting of One Share of Common Stock and a Warrant to Purchase One Share of Common Stock

1,625,000 Pre-funded Units, Each Consisting of a Pre-funded Warrant to Purchase One Share of Common Stock and a Warrant to Purchase One Share of Common Stock



altimmune

PROSPECTUS

Roth Capital Partners

September 28, 2018
