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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2018

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-32587

Altimmune, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-2726770**
State or Other Jurisdiction of Incorporation or Organization	**I.R.S. Employer Identification No.**
910 Clopper Road Suite 201S, Gaithersburg, Maryland	**20878**
Address of Principal Executive Offices	**Zip Code**

(240) 654-1450
Registrant's Telephone Number, Including Area Code

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: The number of shares of the registrant's Common Stock, par value $0.0001 per share, outstanding as of November 13, 2018 was 8,755,260.

ALTIMMUNE, INC.

TABLE OF CONTENTS

Part I—FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements.

ALTIMMUNE, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,964,002	$ 8,769,465
Restricted cash	34,174	3,534,174
Total cash, cash equivalents and restricted cash	7,998,176	12,303,639
Accounts receivable	2,547,402	3,806,239
Tax refund receivable	976,523	6,361,657
Prepaid expenses and other current assets	443,929	994,332
Total current assets	11,966,030	23,465,867
Property and equipment, net	1,407,080	603,146
Intangible assets, net	38,339,086	38,722,270
Other assets	1,149,185	238,917
Total assets	$ 52,861,381	$ 63,030,200
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ 1,467,260	$ 49,702
Accounts payable	150,738	129,075
Accrued expenses and other current liabilities	6,532,924	3,625,257
Current portion of deferred revenue	19,753	19,753
Current portion of deferred rent	173,952	15,914
Total current liabilities	8,344,627	3,839,701
Deferred income taxes	2,891,634	5,938,402
Other long-term liabilities	1,941,932	4,574,507
Total liabilities	13,178,193	14,352,610
Contingencies (Note 16)		
Series B redeemable convertible preferred stock; $0.0001 par value; 16,000 shares designated; 0 and 12,177 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	9,281,767
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 and 100,000,000 shares authorized; 1,726,198 and 609,280 shares issued; 1,725,630 and 608,499 shares outstanding at September 30, 2018 and December 31, 2017, respectively	173	61
Additional paid-in capital	137,071,546	121,657,587
Accumulated deficit	(92,348,368)	(77,684,839)
Accumulated other comprehensive loss – foreign currency translation adjustments	(5,040,163)	(4,576,986)
Total stockholders' equity	39,683,188	39,395,823
Total liabilities and stockholders' equity	$ 52,861,381	$ 63,030,200

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

ALTIMMUNE, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue				
Research grants and contracts	$ 2,629,446	$ 4,565,251	$ 7,727,681	$ 7,892,919
License revenue	4,947	26,689	14,833	36,565
Total revenue	2,634,393	4,591,940	7,742,514	7,929,484
Operating expenses				
Research and development	4,728,726	5,905,552	15,394,616	13,946,403
General and administrative	1,963,733	3,038,756	7,345,651	6,863,782
Goodwill impairment charges	—	26,600,000	490,676	26,600,000
Total operating expenses	6,692,459	35,544,308	23,230,943	47,410,185
Loss from operations	(4,058,066)	(30,952,368)	(15,488,429)	(39,480,701)
Other income (expense):				
Changes in fair value of warrant liability, including gain (loss) on exchange	806,224	(508,316)	(2,874,484)	(508,316)
Changes in fair value of embedded derivatives	185,768	(1,157)	183,638	(1,157)
Interest expense	(166,946)	(2,344)	(169,737)	(160,103)
Interest income	21,100	15,372	78,306	19,538
Other income (expense)	31,378	10,786	289,053	9,839
Total other income (expense)	877,524	(485,659)	(2,493,224)	(640,199)
Net loss before income tax benefit	(3,180,542)	(31,438,027)	(17,981,653)	(40,120,900)
Income tax benefit	829,393	1,532,790	3,318,124	2,526,499
Net loss	(2,351,149)	(29,905,237)	(14,663,529)	(37,594,401)
Other comprehensive income (loss) – foreign currency translation adjustments	—	(1,028,033)	(463,177)	(2,864,839)
Comprehensive loss	$(2,351,149)	$(30,933,270)	$(15,126,706)	$(40,459,240)
Net loss	$(2,351,149)	$(29,905,237)	$(14,663,529)	$(37,594,401)
Preferred stock accretion, contributions, and dividends	64,139	(1,962,072)	(2,527,275)	(2,125,141)
Net loss attributed to common stockholders	$(2,287,010)	$(31,867,309)	$(17,190,804)	$(39,719,542)
Weighted-average common shares outstanding, basic and diluted	1,321,289	517,596	983,651	386,524
Net loss per share attributed to common stockholders, basic and diluted	$ (1.73)	$ (61.57)	$ (17.48)	$ (102.76)

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

ALTIMMUNE, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

	Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, January 1, 2018	12,177	$ 9,281,767	608,499	$ 61	$ 121,657,587	$(77,684,839)	$ (4,576,986)	$ 39,395,823
Stock based compensation					722,451			722,451
Vesting of restricted stock			213	—	(17,909)			(17,909)
Exercises of stock options			9,540	1	22,897			22,898
Conversion of Series B redeemable convertible preferred stock into common stock	(9,813)	(9,790,368)	502,078	50	9,790,317			9,790,367
Redemption of Series B redeemable convertible preferred stock for cash and release of embedded derivative	(2,364)	(2,386,284)			23,292			23,292
Accretion of Series B redeemable convertible preferred stock		2,894,885			(2,894,885)			(2,894,885)
Issuance of common stock for the exchange of warrants			318,667	32	3,433,009			3,433,041
Issuance of common stock in registered direct offering, net of offering costs			286,633	29	4,334,787			4,334,816
Foreign currency translation adjustments							(463,177)	(463,177)
Net loss						(14,663,529)		(14,663,529)
Balance, September 30, 2018	—	$ —	1,725,630	$ 173	$ 137,071,546	$(92,348,368)	$ (5,040,163)	$ 39,683,188

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

ALTIMMUNE, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30, 2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (14,663,529)	$ (37,594,401)
Adjustments to reconcile net loss to net cash used in operating activities:		
Goodwill impairment charge	490,676	26,600,000
Stock-based compensation	704,425	1,137,125
Depreciation	146,299	61,191
Amortization	45,426	40,409
Loss on currency exchange	31,357	—
Debt discount and deferred financing cost accretion	120,024	98,060
(Gain) loss on disposal of property and equipment	(3,806)	3,745
Changes in fair value of warrant liability, including loss on exchange	2,874,484	508,316
Changes in fair value of embedded derivatives	(183,638)	1,157
Changes in operating assets and liabilities:		
Accounts receivable	1,258,837	(1,393,988)
Prepaid expenses and other current assets	589,773	(150,524)
Accounts payable	20,940	(2,273,397)
Accrued expenses and other current liabilities	1,695,296	(34,680)
Deferred revenue	(14,833)	(14,815)
Deferred rent	861,741	(10,085)
Tax refund receivable	4,839,775	(2,142,987)
Deferred taxes	(3,046,768)	(243,056)
Net cash used in operating activities	(4,233,521)	(15,407,930)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash assumed in acquisition	—	13,684,535
Refund of cash held in escrow	—	200,000
Purchase of property and equipment	(968,354)	(89,849)
Proceeds from sale of property and equipment	14,492	7,531
Additions to intangible assets	(39,145)	(47,634)
Net cash (used in) provided by investing activities	(993,007)	13,754,583
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayments of notes payable	—	(212,431)
Proceeds from issuance of convertible notes, net of issuance costs	—	3,018,780
Redemption of preferred stock	(2,386,284)	—
Cash paid in conjunction with warrant exchange	(1,100,000)	—
Proceeds from conditional economic incentive	100,000	
Proceeds from issuance of preferred stock and warrants, net of issuance costs	—	13,018,570
Proceeds from issuance of common stock, net of issuance costs	4,334,816	—
Proceeds from exercise of stock options	22,898	16,455
Net cash provided by financing activities	971,430	15,841,374
EFFECT OF EXCHANGE RATES ON CASH	(50,365)	86,879
Net (decrease) increase in cash and cash equivalents and restricted cash	(4,305,463)	14,274,906
Cash and cash equivalents and restricted cash, beginning of period	12,303,639	2,876,113
Cash and cash equivalents and restricted cash, end of period	$ 7,998,176	$ 17,151,019
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 49,712	$ 5,882
SUPPLEMENTAL NON-CASH FINANCING ACTIVITIES:		
Conversion of Series B redeemable convertible preferred stock into common stock	$ 9,790,368	$ —
Accretion of Series B redeemable convertible preferred stock	$ 2,894,885	$ —
Notes payable issued in conjunction with the exchange of warrants	$ 1,500,000	$ —
Accrued expenses and notes payable modified and replaced with convertible notes	$ —	$ 1,077,540
Conversion of convertible notes into common stock	$ —	$ 3,645,424
Common stock warrants issued in connection with convertible notes	$ —	$ 548,956
Settlement of warrant liability for common stock	$ 3,345,030	$ —

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

ALTIMMUNE, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Altimmune, Inc., headquartered in Gaithersburg, Maryland, together with its subsidiaries (collectively, the "Company" or "Altimmune") is a clinical stage biopharmaceutical company incorporated under the laws of the State of Delaware. The Company is focused on discovering and developing immunotherapies and vaccines to address significant unmet medical needs. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital, and has financed its operations through the issuance of common and preferred stock, long-term debt, and proceeds from research grants and government contracts. The Company has not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales.

The Company's business is a result of a merger between PharmAthene, Inc. ("PharmAthene") and the business previously known as 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 (the "Mergers") (see Note 3). Prior to the Mergers, PharmAthene was a publicly traded biodefense company engaged in Phase 2 clinical trials in developing a next generation anthrax vaccine.

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 (see Note 3). Except where the context indicates otherwise, references to "we," "us," "our," "Altimmune" or the "Company" refer, for periods prior to the completion of the Mergers, to Private Altimmune and its subsidiaries, and for periods following the completion of the Mergers, to the combined company and its subsidiaries.

The accompanying unaudited condensed consolidated financial statements are prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") regarding interim financial reporting. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States for complete consolidated financial statements and should be read in conjunction with our audited consolidated financial statements for the year ended December 31, 2017 included in the annual report on Form 10-K which was filed with the SEC on April 2, 2018. In the opinion of management, we have prepared the accompanying unaudited condensed consolidated financial statements on the same basis as our audited consolidated financial statements, and these condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the results of the interim periods presented. The operating results for the interim periods presented are not necessarily indicative of the results expected for the full year 2018 or any future years or periods.

On September 13, 2018, the Company filed Certificates of Amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware to increase the number of authorized shares of the Company's common stock, par value $0.0001 per share, from 100,000,000 to 200,000,000 shares and to effect a reverse stock split of the Company's common stock at a ratio of 1-for-30 (the "Reverse Stock Split"). All references set forth in this quarterly report to number of shares or per share data have been presented retroactively on a post Reverse Stock Split basis.

The unaudited condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should we be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Segment information

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

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires a lessee to separate the lease components from the non-lease components in a contract and recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. It also aligns lease accounting for lessors with the revenue recognition guidance in ASU 2014-09. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The standard requires a modified retrospective approach however the FASB recently added a transition option to the leases standard that allows entities to apply the new guidance in the year of transition rather than at the beginning of the earliest period presented. The Company has not elected to early adopt this standard and is currently evaluating the impact the adoption of the standard will have on our financial statements.

In July 2017, FASB issued ASU 2017-11 *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This ASU changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. ASU 2017-11 also clarifies existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, ASU 2017-11 requires entities that present earnings per share ("EPS") in accordance with Accounting Standards Codification ("ASC") Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. The new standard is effective for public business entities for fiscal years beginning after December 15, 2018, with early adoption permitted. We early adopted the guidance under ASU 2017-11 during the quarter ended September 30, 2018, as we entered into an Underwriting Agreement to issue warrants with a down round feature on September 28, 2018 (See Note 12). No adjustments were required for the retrospective application of this standard.

In June 2018, FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718)—Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. We are evaluating what impact, if any, the adoption of ASU 2018-07 may have on our financial statements.

Foreign Currencies

Historically the Company's UK subsidiaries utilized the British pound as their functional currency. The assets and liabilities of these subsidiaries were translated at current exchange rates, while revenue and expenses were translated at the average rates in effect for the period. The related translation gains and losses were included in other comprehensive income or loss within the Condensed Consolidated Statements of Operations and Comprehensive Loss. As a result of an analysis which took into account the economic indicators of these subsidiaries from a long-term perspective, the Company changed the functional currency for these subsidiaries from British Pounds to U.S. Dollars effective as of July 1, 2018. The change in the Company's functional currency determination has been applied on a prospective basis in accordance with ASC 830. Therefore, any translation gains and losses that were previously recorded in accumulated other comprehensive income through June 30, 2018 remain unchanged as of September 30, 2018.

Impairment of Long-lived Assets

The Company evaluates our long-lived tangible and intangible assets, including in-process research and development ("IPR&D") assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Our IPR&D assets are currently non-amortizing. Until such time as the projects are either completed or abandoned, we test those assets for impairment at least annually during our fourth quarter, or more frequently at interim periods, by evaluating qualitative factors which could be indicative of impairment. Qualitative factors being considered include, but are not limited to, the current project status, forecasted changes in the timing or amounts required to complete the project, forecasted changes in the timing or amounts of future cash flows to be generated by the completed products, and changes to other market-based assumptions, such as discount rates and overall market capitalization of our Company. Upon completion or abandonment, the value of the IPR&D assets will be amortized to expense over the anticipated useful life of the developed products, if completed, or charged to expense when abandoned if no alternative future use exists.

As of September 30, 2018, our projects continue to progress as originally anticipated. We performed qualitative assessments of our long-lived assets, including IPR&D, and have determined that our long-lived assets, including IPR&D, are not impaired as of and during the period ended September 30, 2018. We believe our assumptions to be reasonable, however development of IPR&D assets are unpredictable and inherently uncertain. Actual future progress may differ from our initial expectations and other market-based assumptions may change over time.

3. Business Combination

Pursuant to the Merger Agreement, the Company closed the Mergers with PharmAthene on May 4, 2017. In accordance with the terms of the Merger Agreement, PharmAthene issued 0.0249702 (the "share exchange ratio") of a share of PharmAthene common stock for each share of Private Altimmune's common stock ("common stock") outstanding as of the closing date. In addition, Private Altimmune's stock options and warrants were

also replaced with options and warrants, to purchase PharmAthene's common stock at

the same share exchange ratio of 0.0249702. All historical share and per share information including common and preferred stock, restricted stock, common stock warrants, and stock options, has been retroactively adjusted to reflect the effect of the share exchange ratio. Immediately prior to closing, 19,976 shares of Series B convertible preferred stock ("convertible preferred stock") converted into Private Altimmune common stock on a 1-for-1 basis. In addition, outstanding principal and accrued interest on the convertible notes that were issued in January 2017 (the "Notes") converted into 10,558 shares of Private Altimmune common stock. Further, 1,325 shares of Private Altimmune common stock were issued pursuant to the accelerated vesting of restricted stock, and 22,024 shares of Private Altimmune common stock were issued as a result of warrant exercises, both in accordance with their original terms. Upon the closing of the Mergers, Private Altimmune common stock totaling 229,450 shares were exchanged for 229,450 shares of PharmAthene common stock.

Although PharmAthene was the issuer of the shares and considered the legal acquirer in the Mergers, following the closing, shareholders of Private Altimmune held 58.2% of the equity interest of the combined entity and assumed control of the combined entity. As a result, the transaction has been accounted for as a reverse merger, with Private Altimmune considered the accounting acquirer, and the assets and liabilities of PharmAthene have been recorded at their estimated fair value. The unadjusted purchase price allocated to PharmAthene's assets and liabilities was estimated to be $44,742,737 as of the closing date and consisted of the shares of the combined company retained by PharmAthene shareholders, and the estimated fair value of vested PharmAthene stock options and warrants which remained outstanding as of the closing date. Also at the closing, 252 outstanding unvested options of PharmAthene with an estimated fair value of $15,173 remained subject to vesting and service requirements. These unvested options will be recorded as operating expense in future periods as the services are delivered and the options vest.

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

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

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

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

Outstanding PharmAthene common stock	229,450
Outstanding PharmAthene stock options	4,100
Outstanding PharmAthene stock warrants	155
Per share fair value of PharmAthene common stock	$ 195.00
Weighted average per share fair value of PharmAthene stock options, vested and unvested	$ 7.80
Per share fair value of PharmAthene stock warrants	$ 0.30
Aggregate fair value of consideration	$44,757,910
Less fair value of unvested common stock options	(15,173)
Total fair value of consideration	$44,742,737

Through December 31, 2017, the Company had recorded adjustments to the allocation of the purchase consideration that included a $44,700 adjustment to increase our tax refund receivable and a $4,535 adjustment to reduce our deferred tax liabilities, with a total adjustment of $49,235 resulting in an increase in goodwill. The adjustments were the result of a change in the tax rate being applied from 34% to 35%. Those purchase price adjustments were reflected in the consolidated balance sheet as of December 31, 2017.

During the nine months ended September 30, 2018, the Company recorded adjustments to the purchase price allocation resulting in a net decrease in tax refunds receivable, with a corresponding net increase in goodwill, of $490,676. The initial tax receivable was recorded based on an estimate of taxable loss for PharmAthene's operations from January 1, 2017 to May 4, 2017 prior to the Mergers. During the preparation of its tax return, management revised its taxable loss calculations for warrant expenses and state tax refunds, resulting in the decrease to tax refunds receivable.

The measurement period ended on the one-year anniversary of the Merger, and accordingly the purchase price allocation is considered final. The final adjusted allocation of the purchase consideration is as follows:

Cash and cash equivalents	$ 13,684,535
Accounts receivable	1,124,462
Prepaid expenses and other current assets	597,172
Tax refunds receivable	1,556,558
Property and equipment	75,779
IPR&D	22,389,000
Goodwill	16,064,498
Total assets acquired	55,492,004
Accounts payable and accrued expenses	(2,193,785)
Deferred tax liability	(8,555,482)
Total liabilities assumed	(10,749,267)
Net assets acquired	$ 44,742,737

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

From the date of the Mergers through December 31, 2017, the Company experienced a significant decline in the trading price of its common stock which indicated potential impairment. Based on the results of our impairment tests performed during 2017, we had concluded that our goodwill was impaired and its full carrying value, including goodwill generated from the Mergers, was written off as an impairment charge during the year ended December 31, 2017. During the three months ended March 31, 2018, the Company recorded an additional goodwill impairment charge of $490,676 as a result of the purchase price allocation adjustments recorded during the period. There was no goodwill balance outstanding at March 31, 2018.

The operating activities of PharmAthene have been included in the accompanying condensed consolidated financial statements from the date of the Mergers. For the nine months ended September 30, 2018, revenues and net income of PharmAthene included in the accompanying condensed consolidated financial statements aggregated $1,743,619 and $56,952, respectively.

The following unaudited pro forma information for the nine months ended September 30, 2017 gives effect to the acquisition of PharmAthene as if the Mergers had occurred on January 1, 2017:

Pro forma revenue	$ 9,035,435
Pro forma net loss attributable to common stockholders	$(39,277,568)
Pro forma weighted-average common shares outstanding, basic and diluted	507,285
Pro forma net loss per share attributable to common stockholders, basic and diluted	$ (77.43)

Significant nonrecurring pro forma adjustments included (i) the reversal of acquisition costs of $2,341,279; (ii) PharmAthene stock compensation expenses of $66,367 for the nine months ended September 30, 2017 that would have been incurred prior to the pro forma acquisition date had the Mergers occurred on January 1, 2017; (iii) exclusion of the change in fair value of derivatives of $90,191, and (iv) reversal of $722,029 of interest expense from notes to be converted.

4. Exchange Agreements

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

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

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

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

The total fair value of the consideration given in exchange for the warrants in the First Exchange was $4,727,000, which exceeded the March 31, 2018 fair value of the warrants by $3,467,935. The warrant fair value at March 31, 2018 was determined assuming an orderly transaction between market participants, using a Monte Carlo simulation valuation model. The Company was compelled to enter into the exchange transaction as management believes the dilutive features of the common stock warrants prevented the Company from obtaining sufficient financing on acceptable terms. Accordingly, the Company recorded a loss on exchange of warrants in the First Exchange of $3,593,082, inclusive of transaction costs of $125,147, which is reported in changes in fair value of warrant liability including gain (loss) on exchange. The Company additionally agreed to redeem the First Exchange investors' remaining shares of Series B Preferred Stock at their face value of $2,364,044. Since the redemption occurred prior to the stated maturity date, $56,792 of the redemption price is considered a deemed dividend.

On July 11, 2018, we entered into exchange agreements with certain other holders of our Series B Preferred Stock and warrants (the "Second Exchange") pursuant to which we (i) issued an aggregate of 32,124 shares of common stock and (ii) paid $22,241 in cash, in exchange for all of the outstanding shares of our Series B Preferred Stock. We additionally issued 145,038 shares of common stock in exchange for warrants to purchase 22,523 shares of common stock. Consideration for the Series B Preferred Stock was transferred to the holders on July 11, 2018, and resulted in a deemed contribution of $111,553. Consideration for the warrant exchange was subject to shareholder approval which the Company obtained at its annual shareholder meeting on August 30, 2018, and the shares of common stock were subsequently transferred to the holders on September 12, 2018.

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

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

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Changes in fair value of warrants	$ 82,466	$ (5,160)
Loss on warrants exchanged Q2 2018	—	(3,467,935)
Gain on warrants exchanged Q3 2018	779,923	779,923
Transaction Costs	(56,165)	(181,312)
Change in fair value of warrant liability, including gain (loss) on exchange	$ 806,224	$ (2,874,484)

In conjunction with the First Exchange the Company issued convertible notes (the "Exchange Notes") with an aggregate principal value of $1,500,000, which are initially convertible into up to 73,530 shares of our common stock at the note holder's option on the maturity date. The Exchange Notes are also convertible in the event of 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 common stock during the twenty consecutive trading day period immediately preceding the event of default. In the event the weighted average price of common stock as defined above is below $4.50 per share, then a supplemental cash payment is due to the note holder.

The Exchange Notes mature on December 29, 2018, when the entire principal and any unpaid interest will be due. These notes earn interest at a stated rate of 1% each month and interest is payable on the last business day of each month.

The conversion and redemption options embedded in the Exchange Notes qualify for derivative accounting under ASC 815-15 "Derivatives and Hedging". The fair value of the derivative liability at the date of issuance resulted in a discount to the Exchange Notes of $180,611 which will be accreted over the term of the convertible note. Additionally, $58,172 in debt issuance costs were capitalized and will be recognized over the term of the notes. During the three and nine months ended September 30, 2018, $120,024 of the debt discount and issuance costs were recognized as interest expense.

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

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

5. Net Loss Per Share

Because we have reported a net loss attributable to common stockholders for all periods presented, basic and diluted net loss per share attributable to common stockholders are the same for all periods presented. For periods presented, all preferred stock, unvested restricted stock, common stock warrants, and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$ (2,351,149)	$ (29,905,237)	$ (14,663,529)	$ (37,594,401)
Less: Preferred stock accretion, contribution, and dividends	64,139	(1,962,072)	(2,527,275)	(2,125,141)
Net loss attributed to common stockholders	$ (2,287,010)	$ (31,867,309)	$ (17,190,804)	$ (39,719,542)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	1,321,289	517,596	983,651	386,524
Net loss per share attributed to common stockholders, basic and diluted	$ (1.73)	$ (61.57)	$ (17.48)	$ (102.76)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Common stock warrants	1,767	78,336	1,767	78,336
Common stock options	45,517	57,334	45,517	57,334
Restricted stock	568	852	568	852

6. Intangible Assets

Our intangible assets consisted of the following:

		September 30, 2018		
	Estimated Useful Lives	Gross Carrying Value	Accumulated Amortization	Net Book Value
Internally developed patents	6-10 years	$ 717,477	$ (282,894)	$ 434,583
Acquired licenses	16-20 years	285,000	(249,474)	35,526
Total intangible assets subject to amortization		1,002,477	(532,368)	470,109
IPR&D assets	Indefinite	37,868,977	—	37,868,977
Total		$38,871,454	$ (532,368)	$38,339,086

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

Changes in the carrying amounts of IPR&D assets for the nine months ended September 30, 2018 were:

Balance, beginning of period	$38,245,871
Foreign currency translation adjustments	(376,894)
Balance, end of period	$37,868,977

As disclosed in Note 2, the functional currency of the UK subsidiary changed to US dollars as of July 1, 2018. Accordingly, the Company's UK based IPR&D assets are now measured in US dollars at the June 30, 2018 historical rate and will not result in a foreign currency gain or loss subsequent to the date of the change.

Amortization expense of intangible assets subject to amortization totaled $15,972 and $14,257 for the three months ended September 30, 2018 and 2017, respectively, and $45,426 and $40,406 for the nine months ended September 30, 2018 and 2017, respectively. Amortization expense was classified as research and development expenses in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss.

As of September 30, 2018, future estimated amortization expense is as follows:

Years ending December 31,	
The remainder of 2018	$ 14,844
2019	59,377
2020	45,930
2021	25,371
2022	25,371
2023 and thereafter	299,216
Total	$470,109

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	September 30, 2018	December 31, 2017
Accrued professional services	$ 1,830,499	$ 835,326
Accrued payroll and employee benefits	973,917	909,455
Accrued interest	533	536
Accrued construction costs	—	328,384
Accrued research and development costs	3,727,975	1,551,556
Total	$ 6,532,924	$ 3,625,257

8. Other Long-Term Liabilities

Other long-term liabilities consist of the following:

	September 30, 2018	December 31, 2017
Unvested restricted stock	$ 227	$ 315
BPI France notes	544,758	599,927
Conditional Grants	100,000	—
Deferred revenue, long-term portion	144,838	159,671
Deferred rent, long-term portion	1,090,192	386,489
Common stock warrant liability	61,000	3,400,869
Embedded derivatives	917	27,236
Total	$ 1,941,932	$ 4,574,507

9. Beneficial Conversion Feature

A summary of the periodic changes in beneficial conversion feature embedded in the redeemable preferred stock as of September 30, 2018 is as follows:

Balance, beginning of period	$ 1,338,840
Amount released during the period	(1,338,840)
Balance, end of period	$ —

All redeemable preferred stock previously outstanding was either redeemed or converted by September 30, 2018.

10. Embedded Derivatives

A summary of the periodic changes in the fair value of the derivative financial instruments embedded in the redeemable preferred stock and Exchange Notes (see Note 4) as of September 30, 2018 is as follows:

	Derivatives embedded in:	
	Redeemable Preferred	Exchange Notes
Balance, beginning of period	$ 27,236	$ —
Issuance of derivatives with Exchange Notes	—	180,611
Derivative released on redemption of preferred stock	(29,366)	—
Changes in fair value	2,130	(179,694)
Balance, end of period	$ —	$ 917

The fair value used to determine the carrying value of the derivative financial instruments embedded in the Exchange Notes at September 30, 2018 were measured using Level 3 inputs and were estimated by weighting an early payoff scenario and a hold to maturity scenario. The hold to maturity scenario fair value was estimated using the Monte Carlo simulation valuation model. The key assumptions used to estimate the fair value of the embedded redemption and conversion derivatives embedded in the Exchange Notes were as follows:

Estimated annual equity volatility	103.2%
Default factor	5.0%
Risk-free interest rate	2.2%
Hold to maturity probability	10%

11. Notes Payable

On July 27, 2018, the Company renewed its existing line of credit agreement for a six-month term with an increase to the borrowing capacity from $250,000 to $1,750,000 subject to a minimum liquidity requirement equal to the outstanding balance of the line. As of September 30, 2018, the outstanding balance on this credit facility was $49,701 with an annual interest rate of 7.75% and incurred interest expense of $979 and $2,769 for the three and nine months ended September 30, 2018, respectively.

On June 29, 2018, the company issued $1,500,000 of convertible notes to certain stockholders (See Note 4). These notes earn interest at 1% per month and incurred interest expense of $45,000 and $46,000 for the three and nine months ended September 30, 2018, respectively. On October 17, 2018, the Company extinguished these notes by paying the outstanding principal and accrued interest in cash.

12. Common Stock

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 "First Registered Direct Offering"). The net proceeds of the First Registered Direct Offering were $4.3 million, after deducting placement agent fees and offering expenses of $0.5 million.

On September 28, 2018 we entered into an Underwriting Agreement to sell a combined total of 2,400,000 common units and pre-funded units in a public offering (the "Unit Offering"). The transaction subsequently closed on October 2, 2018. Each common unit in the Unit Offering was sold at a public offering price of $5.00 and consisted of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of $6.00. Each warrant sold in the Unit Offering is exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Unit Offering was sold at a public offering price of $4.99 and consisted of a pre-funded warrant to purchase one share of our common stock at an exercise price of $0.01 per share and a warrant to purchase one share of our common stock at an exercise price of $6.00. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The net proceeds of the Unit Offering were approximately $10.1 million, after deducting the underwriting discount and estimated offering expenses payable by us.

At September 30, 2018 the Underwriting Agreement represents a forward sale contract that is not in scope of ASC 480 and does not meets the definition of a derivative under ASC 815 as the contract does not provide or allow for a net settlement. Accordingly, the Unit Offering will be recorded in Q4 2018.

On October 10, 2018, we sold a combined total of 4,629,630 common units and pre-funded units to certain institutional investors in a registered direct offering (the "Second Registered Direct Offering"). Each common unit in the Second Registered Direct Offering was sold at a price of $5.40 and consisted of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of $5.40. Each warrant sold in the Second Registered Direct Offering is exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Second Registered Direct Offering was sold at a public offering price of $5.39 and consisted of a pre-funded warrant to purchase one share of our common stock at an exercise price of $0.01 per share and a warrant to purchase one share of our common stock at an exercise price of $5.40. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The net proceeds of the Second Registered Direct Offering were approximately $22.6 million, after deducting the underwriting discount and estimated offering expenses payable by us.

The warrants issued in both the Unit Offering and the Second Registered Direct Offering were concluded to be equity classified freestanding financial instruments. The Second Registered Direct Offering triggered a down round adjustment to the exercise price of the warrants issued in the Unit Offering from $6.00 to $4.1798. The value of a down round feature is measured as the difference between the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and the financial instrument's fair value (without the down round feature) using the reduced exercise price. The Company will treat the value of the effect of the reduction in exercise price. The Company will treat the value of the effect of the reduction in exercise price as a deemed dividend and reduction to income available to common shareholders during the fourth quarter.

13. Warrants

A summary of warrant activity during the three and nine months ended September 30, 2018 and 2017 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Warrants outstanding, beginning of period	25,211	155	78,336	20,559
Issuances	—	78,181	—	79,840
Exchanges	(23,444)	—	(76,569)	—
Exercises and conversions	—	—	—	(22,063)
Warrants outstanding, end of period	1,767	78,336	1,767	78,336

For warrants classified as a liability, the following is a summary of the periodic changes in their fair value by quarter through September 30, 2018:

Balance, beginning of year	$ 3,400,869
Changes in fair value (Monte Carlo simulation valuation)	(1,547,982)
Balance, March 31, 2018	1,852,887
Warrants settled in First Exchange	(1,259,065)
Changes in fair value of warrants (Negotiated value)	1,635,609
Balance, June 30, 2018	2,229,431
Warrants settled in Second and Third Exchange	(2,085,965)
Changes in fair value of warrants (Monte Carlo simulation valuation)	(82,466)
Balance, end of period	$ 61,000

14. Stock-Based Compensation

Stock Options

The Company's stock option awards generally vest over four years and typically have a contractual life of ten years. At September 30, 2018, there was $846,697 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 2.2 years. During the three and nine months ended September 30, 2018, the Company issued 0 and 9,540 shares of common stock, respectively, as a result of option exercises.

Information related to stock options outstanding at September 30, 2018 is as follows:

	Number of Stock Options	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding	44,813	$ 89.76	4.96	$ 3,324
Exercisable	19,520	$ 113.65	5.05	$ 3,324
Expected to vest	25,293	$ 71.32	4.89	$ —

Restricted Stock

At September 30, 2018, we had unvested restricted stock of 568 shares with total unrecognized compensation expense of $784, which we expect to recognize over a weighted average period of approximately 2.0 years. During the three and nine months ended September 30, 2018, the Company released 71 and 213 shares of common stock from restriction, respectively, as a result of the vesting of restricted stock.

Stock-based compensation expense

Stock-based compensation expense is classified in the unaudited condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$39,405	$ 93,821	$236,717	$ 250,061
General and administrative	56,186	359,216	467,708	887,064
Total	$95,591	$453,037	$704,425	$1,137,125

15. Income Taxes

The Company recorded an income tax benefit of $829,393 and $3,318,124 for the three and nine months ended September 30, 2018, respectively. Income taxes for the nine months ended September 30, 2018 included discrete tax benefits of $18,351 related to excess tax benefits associated with share-based compensation, and $271,356 related to a change in estimate. Excluding discrete items, the Company's annual effective tax rate through September 30, 2018 was 20.31% which includes a $2.1 million benefit due to the Company's projected 2018 unlimited lived federal net operating loss ("NOL") that we have determined to be realizable and a $1.0 million tax benefit due to the ability to carry forward Maryland state NOLs generated in 2018. The effective tax rate deviates from the statutory rate primarily due to permanent tax adjustments related to changes in fair value of warrant liability, including loss on exchange described in Note 4.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Act ("SAB 118") which allows the Company to record provisional amounts during a measurement period not to extend beyond one year from the enactment date. Since the Tax Cuts and Jobs Act ("TCJA") was passed in December 2017, additional regulatory guidance and accounting interpretation are expected to be released over the next year, and significant data and analysis will be required to finalize amounts recorded pursuant to TCJA. The Company considers the accounting for the deferred tax re-measurements and other items to be incomplete due to the forthcoming guidance and its ongoing analysis of final year-end data and tax positions. The Company expects to complete its analysis within the measurement period in accordance with SAB 118. The Company did not change any provisional estimates recognized in 2017 which would impact the statement of operations. Any adjustments to these amounts will be recorded to current tax expense in 2018 when the analysis is complete.

The Company has significant U.S. Federal and State tax attribute carryforwards related to net operating losses. Pursuant to IRC §382, and §383, a Company may be limited on the amount of income tax attributes utilized in the current or prospective year(s) if an ownership change resulted within certain shareholders of the Company. For Section 382 purposes, a change in ownership occurs when there is a purchase, sale or reissuance of equity, and there is a 50 percent increase in ownership by 5 percent of the shareholders during a three-year testing period.

As a result of the equity financings that were completed in the 4th quarter of 2018, the Company performed a Section 382 study in order to identify any potential ownership shifts. The Company identified an ownership change as of August 2017 in connection with the issuance of Series B Preferred shares which resulted in a reduction of its pre-2018 NOL DTAs of approximately $3.0 million and a corresponding decrease to the valuation allowance of the same amount. The Company is in the process of evaluating its ownership changes and the NOLs that existed as of the date of the equity financings that could become limited under Section 382. As the equity financings were completed subsequent to the balance sheet date any limitation on the $3.3 million of NOLs generated in 2018 that can no longer be benefited, which could be material, will be recognized in the period in which the financing occurred as a reduction to income tax benefit.

16. Contingencies

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

17. Subsequent events

As disclosed in Note 11, the Company repaid and extinguished its $1,500,000 convertible note on October 17, 2018.

As disclosed in Note 12, the Company closed on an underwritten public offering on October 2, 2018 and a registered direct offering on October 10, 2018.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes appearing elsewhere in this quarterly report on Form 10-Q and our consolidated financial statements and related notes for the year ended December 31, 2017 included in the Company's annual report on Form 10-K, which was filed with the Securities and Exchange Commission on April 2, 2018. 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 (as defined below) and its subsidiaries, and for periods following the completion of the Mergers (as defined below), to the combined company and its subsidiaries.

This quarterly report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. The words "expect," "anticipate," "intend," "plan," "believe," "estimate," "may," "will," "should," "could," "target," "strategy," "intend," "project," "guidance," "likely," "usually," "potential," or the negative of these words or variations of such words, similar expressions, or comparable terminology are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this quarterly report on Form 10-Q, particularly in the section entitled "Risk Factors" in Part II, Item 1A, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

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

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 continued clean safety profile.

We are also developing two government funded assets, NasoShield and SparVax-L. NasoShield is an anthrax vaccine designed to provide rapid, stable protection after 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 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, possibly indicating that NasoShield may require more than one dose for robust immunity.

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 Hepatitis B ("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.

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

In accordance with the terms of the Merger Agreement, PharmAthene issued 0.0249702 (the "share exchange ratio") of a share of PharmAthene common stock for each share of Private Altimmune common stock outstanding as of the closing date. All historical share and per share information — including common stock, convertible preferred stock, redeemable preferred stock, common stock warrants, restricted stock, and stock options — has been retroactively adjusted to reflect the impact of the share exchange ratio. In addition, Private Altimmune stock options and warrants were also replaced with options and warrants to purchase PharmAthene's common stock at the same exchange ratio of 0.0249702. Immediately prior to closing, 19,976 shares of our convertible preferred stock were converted into Private Altimmune common stock on a 1-for-1 basis. In addition, outstanding principal and accrued interest on the Notes were converted into 10,558 shares of Private Altimmune common stock. Further, 1,325 shares of Private Altimmune common stock were issued pursuant to the accelerated vesting of restricted stock, and 22,024 shares of Private Altimmune common stock were issued as a result of warrant exercises, both in accordance with their original terms. Upon the closing of the Mergers, all outstanding shares of Private Altimmune common stock were exchanged for 229,450 shares of PharmAthene common stock.

Following the closing, shareholders of Private Altimmune held 58.2% of the equity interest of the combined entity and assumed control of the combined entity. As a result, the transaction has been accounted for as a reverse merger, and the assets and liabilities of PharmAthene have been recorded at their estimated fair value. The unadjusted purchase price to be allocated to PharmAthene's assets and liabilities was estimated to be $44,742,737 as of the closing date and consisted of the shares of the combined company retained by PharmAthene shareholders, and the estimated fair value of vested PharmAthene stock options and warrants which remained outstanding as of the closing date. Also at the closing, 252 shares of PharmAthene outstanding stock options with an estimated fair value of $15,173 remained subject to vesting and service requirements. These unvested options will be recorded as operating expense in future periods as the services are delivered and the options vest.

Except where the context indicates otherwise, references to "we," "us," "our," "Altimmune" or the "Company" refer, for periods prior to the completion of the Mergers, to Private Altimmune and its subsidiaries, and for periods following the completion of the Mergers, to the combined company and its subsidiaries.

Reverse Stock Split

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. Unless otherwise noted, all share and per share numbers in this Quarterly Report on Form 10-Q are reflected on a Post-Reverse Stock Split basis for all periods presented.

Financing

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 167,700 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 73,530 shares of our common stock upon the default by the Company or at the holder's option on the maturity date and is 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." In addition, the Company agreed to redeem all these holders remaining shares of Series B Preferred Stock, in cash, at the face value of $2,364,044.

On July 11, 2018, we entered into exchange agreements with certain other 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. After receiving the approval of our stockholders at our annual meeting of stockholders held on August 30, 2018, we issued an additional 145,038 shares of common stock in exchange for Existing Warrants to purchase 22,523 shares of common stock. We refer to these transactions as the "Second Exchange."

On September 7, 2019, we entered into exchange agreements with certain other holders of our Existing Warrants pursuant to which we issued 5,929 shares of common stock in exchange for Existing Warrants to purchase 921 shares of common stock. We refer to this transaction as the "Third Exchange" and together with the First Exchange and Second Exchange as the "Exchanges."

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 "First Registered Direct Offering"). The net proceeds of the First Registered Direct Offering were approximately $4.3 million, after deducting placement agent fees and estimated offering expenses payable by us.

On October 2, 2018, we sold a combined total of 2,400,000 common units and pre-funded units in an underwritten public offering (the "Unit Offering"). Each common unit in the Offering was sold at a public offering price of $5.00 and consisted of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of $6.00. Each warrant sold in the Unit Offering is exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Unit Offering was sold at a public offering price of $4.99 and consisted of a pre-funded warrant to purchase one share of our common stock at an exercise price of $0.01 per share and a warrant to purchase one share of our common stock at an exercise price of $6.00. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The net proceeds of the Unit Offering were approximately $10.1 million, after deducting the underwriting discount and estimated offering expenses payable by us.

On October 10, 2018, we sold a combined total of 4,629,630 common units and pre-funded units to certain institutional investors in a registered direct offering (the "Second Registered Direct Offering"). Each common unit in the offering was sold at a price of $5.40 and consisted of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of $5.40. Each warrant sold in the Second Registered Direct Offering is exercisable immediately and expires five years from the date of issuance. Each pre-funded unit in the Second Registered Direct Offering was sold at a public offering price of $5.39 and consisted of a pre-funded warrant to purchase one share of our common stock at an exercise price of $0.01 per share and a warrant to purchase one share of our common stock at an exercise price of $5.40. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The net proceeds of the Second Registered Direct Offering were approximately $22.6 million, after deducting the underwriting discount and estimated offering expenses payable by us.

The Second Registered Direct Offering triggered an adjustment to the exercise price of the warrants issued in the Unit Offering from $6.00 to $4.1798.

Current Resources

As described above, the Company secured net proceeds of $37 million through equity sales that occurred from September 24, 2018 through October 10, 2018. Accordingly, the Company has sufficient capital to fund its plan of operations for at least a twelve-month period from the issuance date of our September 30, 2018 financial statements.

Critical Accounting Policies and Significant Judgment and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. and the rules and regulations of the SEC for interim financial reporting. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses, and the related disclosure of contingent assets and liabilities. We base our estimates and judgments on historical experience, knowledge of current conditions, and expectations of what could occur in the future given available information.

There have been no changes in our critical accounting policies and significant judgment and estimates as disclosed in our annual report on Form 10-K for the year ended December 31, 2017. For more information regarding our critical accounting policies, we encourage you to read the discussion contained in Item 7 under the heading "Critical Accounting Policies and Significant Judgments and Estimates" and Note 4 "Summary of Significant Accounting Policies" included in the notes to the consolidated financial statements contained in our annual report on Form 10-K for the year ended December 31, 2017.

Results of Operations

Comparison of the three months ended September 30, 2018 and 2017

	Three Months Ended September 30,			
	2018	2017	Increase (Decrease)	
Revenue				
Research grants and contracts	$ 2,629,446	4,565,251	$ (1,935,805)	(42)%
License revenue	4,947	26,689	(21,742)	(81)
Total revenue	2,634,393	4,591,940	(1,957,547)	(43)
Operating expenses				
Research and development	4,728,726	5,905,552	(1,176,826)	(20)
General and administrative	1,963,733	3,038,756	(1,075,023)	(35)
Goodwill impairment	—	26,600,000	(26,600,000)	—
Total operating expenses	6,692,459	35,544,308	(28,851,849)	(81)
Loss from operations	(4,058,066)	(30,952,368)	26,894,302	87
Other income (expense):				
Changes in fair value of warrant liability, including gain (loss) on exchange	806,224	(508,316)	1,314,540	259
Changes in fair value of embedded derivative	185,768	(1,157)	186,929	16,156
Interest expense	(166,946)	(2,344)	(164,602)	(7,022)
Interest income	21,100	15,372	5,728	37
Other income (expenses)	31,378	10,786	20,592	191
Total other income (expense)	877,524	(485,659)	1,363,183	281
Net loss before income tax benefit	(3,180,542)	(31,438,027)	28,257,485	90
Income tax benefit	829,393	1,532,790	(703,397)	(46)
Net loss	$(2,351,149)	$(29,905,237)	$ 27,554,088	92%

Comparison of the nine months ended September 30, 2018 and 2017

	Nine Months Ended September 30,			
	2018	2017	Increase (Decrease)	
Revenue				
Research grants and contracts	$ 7,727,681	7,892,919	$ (165,238)	(2)%
License revenue	14,833	36,565	(21,732)	(59)
Total revenue	7,742,514	7,929,484	(186,970)	(2)
Operating expenses				
Research and development	15,394,616	13,946,403	1,448,213	10
General and administrative	7,345,651	6,863,782	481,869	7
Goodwill impairment	490,676	26,600,000	(26,109,324)	(98)
Total operating expenses	23,230,943	47,410,185	(24,179,242)	(51)
Loss from operations	(15,488,429)	(39,480,701)	23,992,272	61
Other income (expense):				
Changes in fair value of warrant liability, including loss on exchange	(2,874,484)	(508,316)	(2,366,168)	(465)
Changes in fair value of embedded derivative	183,638	(1,157)	184,795	15,972
Interest expense	(169,737)	(160,103)	(9,634)	(6)
Interest income	78,306	19,538	58,768	301
Other income (expenses)	289,053	9,839	279,214	2,838
Total other income (expense)	(2,493,224)	(640,199)	(1,853,025)	(289)
Net loss before income tax benefit	(17,981,653)	(40,120,900)	22,139,247	55
Income tax benefit	3,318,124	2,526,499	791,625	31
Net loss	$(14,663,529)	$(37,594,401)	$ 22,930,872	61%

Revenue

Revenue consists primarily of research grants from BARDA and NIAID in the United States for our anthrax vaccine product candidates. These contracts are cost reimbursement, with a fixed fee which is either based on costs or milestones.

Revenue decreased by $1.96 million, or 42%, for the three months ended September 30, 2018 as compared to the same period in 2017. The decrease was primarily the result of a decrease of $1.8 million in BARDA revenue due directly to changes in spending on the NasoShield program described below.

Revenue decreased by $0.19 million, or 2%, for the nine months ended September 30, 2018 as compared to the same period in 2017. The decrease was primarily the result of:

(i) a decrease of $0.9 million in BARDA revenue due directly to changes in spending on NasoShield research and development described below; and

(ii) an increase of $0.7 million in NIAID revenue due directly to changes in spending on the SparVax research and development described below.

Research and development expenses

Research and development operating expense decreased by $1.2 million, or 20%, for the three months ended September 30, 2018 as compared to the same period in 2017. The decrease was primarily the result of:

(i) a decrease of $1.4 million due to timing of manufacturing development activities for NasoShield;

(ii) an increase of $0.7 million due to timing of manufacturing development activities for NasoVAX; and

(iii) a decrease of $0.4 million due to timing of a clinical study and related activities for HepTcell.

Research and development operating expense increased by $1.4 million, or 10%, for the nine months ended September 30, 2018 as compared to the same period in 2017. The increase was primarily the result of:

(iv) a decrease of $0.7 million due to timing of manufacturing development activities for NasoShield;

(v) an increase of $1.2 million due to timing of manufacturing development activities for NasoVAX;

(vi) an increase of $0.4 million due to timing of a clinical study and related activities for SparVax;

(vii) an increase of $0.2 million due to timing of clinical study and related activities for HepTcell; and

(viii) an increase of $0.4 million in non-project specific research and development costs driven by employee compensation and additional allocated facility costs.

General and administrative expenses

General and administrative expense decreased by $1.1 million, or 35%, for the three months ended September 30, 2018 as compared to the same period in 2017. The decrease was primarily the result of the timing of professional services. Substantial nonrecurring effort was incurred in Q3 2017 to integrate the activities of the newly merged entity following the completion of the Mergers.

General and administrative expense increased by $0.5 million, or 7%, for the nine months ended September 30, 2018 as compared to the same periods in 2017. Increases are primarily attributable to an increase in labor costs associated with severance related expenses incurred in 2018.

Goodwill impairment charges

Goodwill impairment charges reported during the nine months ended September 30, 2018 represented an adjustment recorded during the measurement period to reduce the tax refund receivable acquired in connection with the Mergers. The adjustment to reduce the tax refund receivable resulted in a corresponding increase in goodwill which was determined to be fully impaired during the year ended December 31, 2017.

Other income (expense)

Other income (expense) increased by $1.4 million and decreased by $1.9 million during the three and nine months ended September 30, 2018, respectively, as compared to the same periods in 2017. These fluctuations are primarily due to changes in the fair value of warrant liability and embedded derivatives.

Income tax benefit

We recorded an income tax benefit of $0.8 million and $3.3 million for the three and nine months ended September 30, 2018 as compared to an income tax benefit of $1.5 million and $2.5 million for the same respective periods of 2017. The income tax benefit recorded in 2018 represents unlimited lived federal net operating losses (NOLs) generated in 2018 that we have determined to be realizable as well as the ability of the Company to carry forward Maryland state NOLs generated in 2018. The income tax benefit recorded in 2017 reflects estimated tax refunds we expected to receive from carrying back 2017 NOLs to offset the 2016 federal and state income taxes paid by PharmAthene. The Tax Cuts and Jobs Act of 2017 limited our ability to carryback federal tax losses to prior years to only a one-year lookback.

Liquidity and Capital Resources

Overview

Our primary sources of cash during the three and nine months ended September 30, 2018 was the cash on-hand as of January 1, 2018 and the receipt of $4.8 million in US state and federal tax refunds, $1.1 million R&D Tax Credit in the United Kingdom and $4.3 million in proceeds from the sale of our common stock. Our cash and cash equivalents were $8.0 million at September 30, 2018. We believe, based on the operating cash requirements and capital expenditures expected, our cash on hand at September 30, 2018, proceeds of our offerings of common stock units which closed on October 2, 2018 and October 10, 2018, and revenue from our government sponsored contracts, are adequate to fund operations for at least one year from the financial statement filing date.

We have not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales. Our sources of revenue consist of revenues under our contract with BARDA and NIAID for the development of NasoShield and SparVax-L, respectively, and to a lesser degree from other licensing arrangements. We have incurred significant losses since we commenced operations. As of September 30, 2018, we had accumulated losses of $92.3 million since our inception. In addition, we have not generated positive cash flows from operations. We have had to rely on a variety of financing sources, including the issuance of debt and equity securities. As capital resources are consumed to fund our research and development activities, we may not have sufficient capital to fund our plan of operations. In order to address our capital needs, including our planned clinical trials, we may need to pursue additional equity or debt financing.

In July 2016, we signed a five-year contract with BARDA which was amended in March 2017. The contract has a total value of up to $130 million and is used to fund clinical development of NasoShield. Under the contract, BARDA pays us a fixed fee and reimburses certain costs for the development of an Ad5-vectored, protective antigen-based intranasal anthrax vaccine

including manufacturing, nonclinical and clinical studies through Phase 2. The contract consists of an initial base performance period providing approximately $24.1 million in funding for the period July 2016 through November 2019. BARDA has seven options to extend the contract to fund certain continued development and manufacturing activities for the anthrax vaccine, including Phase 2 clinical studies. Each option, if exercised by BARDA, would provide additional funding ranging from approximately $1.1 million to $34.4 million for the period July 2018 through July 2021. Through September 30, 2018, we have received an aggregate of approximately $13.2 million under the current BARDA contract.

As part of the Mergers, we assumed a PharmAthene contract with NIAID. The NIAID contract is incrementally funded. Over the base period of the contract, PharmAthene was awarded initial funding of approximately $5.2 million, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestones. NIAID exercised options under this agreement to provide additional funding of approximately $10.1 million and an extension of the period of performance through September 2019. The contract had a maximum total value of up to approximately $28.1 million if all technical milestones are met and all eight contract options were exercised by NIAID. Work under all exercised options will bring total committed and final funding under the NIAID contract to $15.3 million.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30, 2018	2017
Net cash provided by (used in):		
Operating activities	$ (4,233,521)	$ (15,407,930)
Investing activities	$ (993,007)	$ 13,754,583
Financing activities	$ 971,430	$ 15,841,374

Operating Activities

Net cash used in operating activities was $4.2 million for the nine months ended September 30, 2018 compared to $15.4 million during the nine months ended September 30, 2017.

Our sources of cash provided by operations during the nine months ended September 30, 2018 was primarily tax refunds and cash receipts of revenue generated by our BARDA and NIAID contracts. The primary uses of cash from our operating activities include payments for labor and labor-related costs, professional fees, research and development costs associated with our clinical trials, and other general corporate expenditures.

Cash used in operating activities decreased $11.2 million during the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. The change was driven primarily by changes in working capital attributable to activity within accounts receivable, taxes receivable, accounts payable, other accrued liabilities and reimbursement of leasehold improvements.

Investing Activities

During the nine months ended September 30, 2018, the net cash used in investing activities of $1.0 million was primarily due to an investment of $0.97 million made in leasehold improvements in our new facility at 910 Clopper Road in Gaithersburg Maryland.

During the nine months ended September 30, 2017, net cash provided by investing activities of $13.8 million was primarily the result of cash assumed from the Mergers with PharmAthene that closed in May 2017.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2018 of $0.97 million was primarily the result of a $2.4 million cash redemption by certain holders of our Series B Redeemable Preferred stock (the “Stockholders”) and a $1.1 million cash payment to extinguish warrants to purchase our common stock held by the Stockholders, being offset by the receipt of $4.3 million in proceeds from the sale of our common stock and $0.1 million in proceeds from a Montgomery County, Maryland conditional economic incentive.

Net cash provided by financing activities during the nine months ended September 30, 2017 was primarily the result of $3.0 million net proceeds received from the Notes that closed in May 2017 and $13.0 million net proceeds from the redeemable preferred financing, offset by the repayment of notes payable for $0.2 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2018, we had cash and cash equivalents of $8.0 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Because most of our cash is held in bank deposit accounts without restriction, an immediate 100 basis point change in interest rates would not have a material effect on our financial position or the results of our operations. We are subject to interest rate risk from our outstanding notes and borrowings under our credit facility. Borrowings under our credit facility bear interest at an annual rate equal to the bank's prime rate (5.75% at September 30, 2018) plus 2%.

In addition, we are subject to currency risk for cash held in British pounds and Euros in our UK and French subsidiaries. Fluctuations in the exchange rates for the British pound since January 2017 have been about 19% comparing the high and low during the period. Transactions of our UK subsidiary are predominantly settled in British pounds and transactions of our French subsidiary are settled predominantly in Euros; therefore, we believe that we have minimal exposure to foreign currency exchange risks. We do not hedge against foreign currency risks.

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended ("the "Exchange Act") as of the end of the period covered by this Quarterly Report on Form 10-Q.

Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2018, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2018 identified in connection with the evaluation thereof by our management, including the Chief Executive Officer and Chief Financial Officer, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

In addition to the other information included in this quarterly report on Form 10-Q, the following risk factors should be carefully considered when evaluating an investment in us. These risk factors and other uncertainties may cause our actual future results or performance to differ materially from any future results or performance expressed or implied in the forward-looking statements contained in this report and in other public statements we make. In addition, because of these risks and uncertainties, as well as other variables affecting our operating results, our past financial performance is not necessarily indicative of future performance.

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

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 basis on September 14, 2018 and through November 9, 2018, our stock has traded in a range with a low of $3.55 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

$14.7 million for the nine months ended September 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 September 30, 2018, we have an accumulated deficit of $92.3 million. To date, we have not received regulatory approvals for any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable.

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

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

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

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

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

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

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

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

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

We review our long-lived tangible and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. We 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 September 30, 2018, our cash balance was $8.0 million. Based on our current operating plan, we believe that our existing cash will be sufficient to fund our projected operating expenses and capital expenditure requirements for at least a twelve-month period from the issuance date of our September 30, 2018 financial statements. However, we do not expect that these funds will be sufficient to enable us to complete the clinical trials needed to seek marketing approval or commercialize any of our product candidates. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

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

Our future capital requirements depend on many factors, including:

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, BARDA funding, and license and development agreements through strategic partnerships with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt or preferred stock financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, issuing additional equity, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates, or otherwise grant licenses on terms that are not favorable. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our leading product candidates or our preclinical product candidates, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- delays in obtaining required approvals from the Institutional Revenue Board (“IRB”) or other similar committees or bodies at each clinical trial site;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability or after an inspection of clinical operations or trial sites;
- failure to perform clinical trials in accordance with the FDA’s Good Clinical Practices (“GCP”) or applicable regulatory guidelines in other countries, including the United Kingdom;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or a 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 Investigational New Drug ("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, 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 Biologic License Application (“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 Immune Targeting Systems Limited ("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 headaches, runny noses and sore throats. The most common adverse events observed in clinical trials for product candidates developed using the Densigen platform include injection site reactions, headache, malaise and fatigue.

Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed. In addition, the side effect profile of pharmaceutical drugs cannot be fully established

based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or withdrawal of product marketing authorization.

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

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

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

If we fail to obtain regulatory approval in non-U.S. jurisdictions, we will not be able to market our products in those jurisdictions.

We intend to market certain of our product candidates, if approved, in the United Kingdom and other international markets, in addition to the United States. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, such as certain countries of the European Union, a vaccine must be approved for reimbursement, including the price that can be charged, before it can be approved for sale in that country. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product, and additional clinical research may be required to enable comparison of the cost effectiveness of our product candidate to other available alternatives. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory review, which may result in significant additional expense and other restrictions.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval. We may also be required to conduct post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product potentially over many years. If the FDA or other regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, and compliance with cGMP and GCP for any clinical trials that we conduct post-approval. Any such restrictions may result in significant additional expense or could limit sales of the approved product.

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines or warning letters, or clinical holds on clinical trials involving related product candidates;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by the Company or suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and

- injunctions or the imposition of civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in governmental reimbursement programs, such as Medicare, Medicaid and other federal health care programs and curtailment or restructuring of our operations.

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

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

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

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

We may also be subject to competition from biosimilar products in Europe. To date, 27 biosimilar products have been authorized by the EMA. As in the United States the regulatory approval pathway for biosimilar products in Europe is abbreviated. A biosimilar sponsor must however still provide all of the preclinical and clinical data required to demonstrate the similarity of their product with the reference product. The level of data required is assessed on a case by case basis but it will be less than that required for an original biological product. The pathway is more complex than the abridged procedure that may be followed to obtain authorization of a generic version of a non-biological product but it would still allow the biosimilar product to be brought to market more quickly and less expensively than our original product. That said, in Europe applications for marketing authorizations in relation to biosimilar products are subject to the same data and market exclusivity as apply to generic non-biologic products so no biosimilar product could be approved or placed on the market during the periods such exclusivity applies to our product. Marketing authorization of a biosimilar product in Europe does not guarantee that the biosimilar product may be substituted for the reference product. Interchangeability of a biosimilar product with the reference product is not assessed by the EMA but this determination is left to each of the member states. We cannot know at this stage the extent to which any biosimilar product would be interchangeable with our reference product, and this may vary between member states.

Pediatric exclusivity is another type of regulatory market exclusivity our competitors may pursue. In the United States, the FDA has the authority to award additional exclusivity for approved products where the sponsor conducts specified testing on pediatric or adolescent populations upon the written request of the FDA. If granted, pediatric exclusivity adds nine months to existing exclusivity periods applicable to biological products under the BPCIA — namely, the four-year period during which the FDA will not consider an applicable for a biosimilar product, and the twelve-year period during which the FDA will not approve a biosimilar application. This six-month exclusivity, which runs from the end of these exclusivity protection periods, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "written request" for such trial. In Europe, as well, pediatric studies are incentivized by the reward of additional exclusivity. Pediatric Investigation Plans ("PIPs"), are determined by the Pediatric Committee of the EMA. Where an application for a marketing authorization is submitted in respect of a medicinal product designated as an orphan medicinal product and that application contains the results of the PIP studies, market exclusivity for that orphan

medicinal product is extended by two years if the product is authorized across Europe. We may pursue pediatric exclusivity for one or more of our product candidates but may not succeed in obtaining it. There is also a risk that a competitor may achieve pediatric exclusivity that would delay any potential approvals of our product candidates.

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

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

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

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

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 proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. We may not have identified all U.S. and foreign patents or published patent applications that affect our business either by blocking our ability to commercialize our product candidates or by covering similar technologies that affect our market.

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect trade secrets and proprietary know-how that may not be patentable or that we may elect not to patent, processes for which patents are difficult to enforce and any other elements of our technology and development processes that involve proprietary know-how, information or technology that is not covered by patents. In particular, we seek to protect our proprietary technology and processes, in part, by entering into confidentiality

agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. These agreements require that all confidential information developed by the individual or made known to the individual by the Company during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. We also enter into agreements with our employees that provide that any inventions conceived by the individual in the course of rendering services to the Company shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Although we use reasonable efforts to protect our know-how, our employees, consultants, contractors or outside scientific advisors might intentionally or inadvertently disclose our know-how or other proprietary information to competitors. In addition, competitors may otherwise gain access to our know-how or independently develop substantially equivalent information and techniques.

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

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to those of the Company's, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. For example, we have experienced threatened or actual opposition for two trademarks that we were pursuing. We decided to discontinue our use of one of those trademarks, and the other matter was resolved on favorable terms. Although these matters have been resolved on terms that did not materially harm the Company, we may become subject to other trademark challenges in the future. If we are unable to establish long-term name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Commercialization of the Company's Product Candidates

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

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

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

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

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

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

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

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

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance;
- delays as a result of manufacturing problems or re-prioritization of projects at a third-party manufacturer;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to the Company;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how or infringement of third-party intellectual property rights by our contract manufacturers; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

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

In addition, our product candidates involve technically complex manufacturing processes, and even slight deviations at any point in the production process may lead to production failures, and may cause the production of our products to be disrupted, potentially for extended periods of time. 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.

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 establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

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

A key part of our strategy is to seek strategic partnerships in the future, including potentially with major biotechnology or pharmaceutical companies for late-stage development and commercialization of our product candidates. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time consuming and complex. In order for the Company to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other products available for licensing from other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that 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;
- 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 and project tracking systems implemented and operational, and we may not be able to consistently meet these requirements. Performance under the BARDA contracts requires that we comply with appropriate regulations and operational mandates, which require us to engage internal and external expertise for compliance. Our ability to be regularly and fully reimbursed for our activities depends and will depend on our ability to comply and demonstrate compliance with such requirements. In the past, we have experienced delays in reimbursements under a BARDA contract on account of compliance issues, which we have had to dedicate substantial time and resources to remedy, including through modifications to our statement of work related to the program. In addition, under certain circumstances, BARDA may advise us to delay certain activities and invest additional time and resources before proceeding. If we follow such BARDA advice, overall program delays and costs associated with additional resources for which we have not planned may result. The costs associated with following such advice may or may not be reimbursed by BARDA under the contract. We may decide not to follow the advice provided by BARDA and instead pursue activities that we believe are in the best interest of our anthrax vaccine program and our business as a whole, even if BARDA would not reimburse us under our contract.

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

As part of the Mergers, we assumed PharmAthene's contract with NIAID. The NIAID contract is incrementally funded. Over the base period of the contract, PharmAthene was awarded initial funding of approximately $5.2 million, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestones. NIAID exercised four options under this agreement to provide additional funding of approximately $8.8 million and an extension of the period of performance through December 31, 2017. The contract has a maximum total value of up to approximately $28.1 million if all technical milestones were met and all eight contract options were exercised by NIAID. In April 2017, PharmAthene was notified by NIAID that it will exercise only one of the additional remaining options under the contract to provide funding for a rabbit challenge study. Work under all exercised options will bring total committed and final funding under the NIAID contract to $15.3 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 Special Reserve Fund ("SRF"), available for the procurement of MCMs falls below $1.5 billion and how the amount of funding will impact identified MCM priorities. The Cures Act ensures coordinated and efficient processes for executing MCM development and procurement programs by clarifying that the Director of BARDA carry out the programs funded by the SRF, as well as the procurement contracts, grants, and cooperative agreements under BARDA.

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

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

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

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

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

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

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

Our business is subject to audit by the U.S. government in part because of the funding we receive for our anthrax vaccine program under our BARDA contract. U.S. government agencies such as the Defense Contract Audit Agency (the "DCAA") routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. For example, BARDA audited indirect costs charged with respect to the SparVax® contract for the years 2008 through 2014.

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

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

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

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

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

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

Risks Related to Reimbursement and Government Regulation

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

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

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

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

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal FCA. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs.

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

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, and other health privacy measures, which impose requirements on parties with respect to the use and disclosure of individually-identifiable information, such as medical records information, including requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws that require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts, on any of our product candidates that may be approved for marketing (participation in these programs and compliance with the applicable requirements may also subject us to potentially significant discounts on our products and increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);

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

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

Efforts to help ensure that our business arrangements will comply with applicable health care laws and codes of practice may involve substantial costs. We have adopted policies and practices that are designed to help ensure that the Company, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but it is not always possible to assure compliance with applicable requirements, and the precautions we take to achieve compliance may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to the Company, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

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

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

For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care Reform Law. The Health Care Reform Law increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud and abuse, and to provide access to increased health coverage.

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

of Comparative Effectiveness Research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results.

President Trump is seeking to repeal and replace the Health Care Reform Law. Repeal and replace legislation was passed in the House of Representatives, but did not obtain the necessary votes in the Senate. Subsequently, President Trump affirmed his intention to repeal and replace the Health Care Reform Law and has taken a number of administrative actions to materially weaken the Health Care Reform Law. For example, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Health Care Reform Law to waive, defer, grant exemptions from, or delay the implementation of any provision of the Health Care Reform Law that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on December 22, 2017, President Trump signed the 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 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

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

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

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

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

If our securities are delisted from trading on 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;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

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

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

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

Other than for the PharmAthene board of directors' declaration of a special one-time cash dividend of $873.00 per share of PharmAthene common stock paid on February 3, 2017, neither Private Altimmune nor PharmAthene has ever paid any dividends on our common stock. While subject to periodic review, our current policy is to retain all earnings, if any, primarily to finance our future growth or ability to consummate strategic transactions, such as a merger or other business combination. We make no assurances that we will ever pay future dividends, cash or otherwise. Whether we pay any dividends in the future will depend on our financial condition, results of operations, and other factors that we will consider.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On July 11, 2018, pursuant to separate privately negotiated exchange agreements, we issued 32,124 shares of common stock in exchange for all of the shares of Series B Redeemable Convertible Preferred Stock held by the parties to such exchange agreements. After receiving the approval of the Company's stockholders, we issued an additional 145,038 shares of common stock in exchange for 22,523 warrants to purchase shares of common stock held by the parties to such exchange agreements. The issuance of these securities was exempt from registration under the Securities Act pursuant to Section 3(a)(9) and Section 4(a)(2) thereunder.

On September 7, 2018, pursuant to separate privately negotiated exchange agreements, we issued 5,930 shares of common stock in exchange for warrants to purchase 921 shares of common stock. The issuance of these securities was exempt from registration under the Securities Act pursuant to Section 3(a)(9) and Section 4(a)(2) thereunder.

Item 3. Default upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

No.	Description
3.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding a reverse stock split (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on September 13, 2018)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding an increase in authorized shares (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on September 13, 2018)
4.1	Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.3 to the Registrant's Post-Effective Amendment on Form S-1 filed on September 28, 2018)
4.2	Form of Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Post-Effective Amendment on Form S-1 filed on September 28, 2018)
4.3	Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.5 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed on September 26, 2018)
4.4	Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on October 9, 2018)
4.5	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Form 8-K filed on October 9, 2018)
10.1	Form of Exchange Agreements dated July 11, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on July 16, 2018)
10.2	Amendment No. 1 to the Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Appendix A to the Registrant's definitive proxy statement on Schedule 14A filed on July 26, 2018)
10.3*	Amendment No. 4 to Contract Award issued by the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated September 20, 2018 (incorporated by reference to Exhibit 10.8 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed on September 26, 2018)
10.4	Form of Securities Purchase Agreement among Altimmune, Inc. and certain investors named therein dated September 24, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on September 25, 2018)
10.5	Placement Agency Agreement by and between Altimmune, Inc. and Roth Capital Partners, LLC, dated September 24, 2018 (incorporated by reference to Exhibit 1.1 to the Registrant's Form 8-K filed on September 25, 2018)
10.6	Form of Underwriting Agreement ((incorporated by reference to Exhibit 1.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed on September 26, 2018)
10.7	Placement Agency Agreement by and between Altimmune, Inc. and Roth Capital Partners, LLC, dated October 8, 2018 (incorporated by reference to Exhibit 1.1 to the Registrant's Form 8-K filed on October 9, 2018)
10.8	Form of Securities Purchase Agreement among Altimmune, Inc. and certain investors, dated October 8, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 9, 2018)
31.1	Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
31.2	Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
32.1	Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code
32.2	Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code
101.INS	Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Confidential treatment has been granted as to certain portions of this exhibit.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused the report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALTIMMUNE, INC.

Dated: November 13, 2018

By: /s/ William Enright
Name: William Enright
Title: President and Chief Executive Officer (principal executive officer)

Dated: November 13, 2018

By: /s/ William Brown
Name: William Brown
Title: Interim Chief Financial Officer (principal financial and accounting officer)

Exhibit 31.1

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

I, William J. Enright, certify that:

1. I have reviewed this report on Form 10-Q of Altimmune, Inc. for the period ended September 30, 2018;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2018

/s/ William Enright
Name: William Enright
Title: President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, William Brown, certify that:

1. I have reviewed this report on Form 10-Q of Altimmune, Inc. for the period ended September 30, 2018;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2018

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of Altimmune, Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission (the "Report"), I, William Enright, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934.

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William Enright
William Enright
President and Chief Executive Officer
November 13, 2018

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

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

Exhibit 32.2

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

In connection with the quarterly report on Form 10-Q of Altimmune, Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission (the "Report"), I, William Brown, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934.

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William Brown
William Brown
Interim Chief Financial Officer
November 13, 2018

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

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