

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

**FORM 10-K**

(Mark One)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

**For the fiscal year ended December 31, 2012**

Transition Report under Section 13 or 15(d) of the Securities Exchange Act of 1934

**For the transition period from    to**

Commission File Number: 001-32587

**PHARMATHENE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**20-2726770**

(I.R.S. Employer Identification No.)

**One Park Place, Suite 450, Annapolis, MD**

(Address of principal executive offices)

**21401**

(Zip Code)

Registrant's telephone number, including area code: **(410) 269-2600**

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

Title of Each Class:

**Common Stock, par value \$0.0001 per share**

Name of Each Exchange on Which Registered:

**NYSE MKT**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b—2 of the Exchange Act. (Check one):

Large Accelerated Filer     Accelerated Filer     Non-Accelerated Filer     Smaller Reporting Company

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately \$56.3 million based upon the closing price of the common equity on the NYSE MKT on the last business day of the registrant’s most recently completed second fiscal quarter (June 29, 2012).

The number of shares of the registrant’s Common Stock, par value \$0.0001 per share, outstanding as of February 28, 2013 was 48,365,984.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant’s definitive Proxy Statement for its 2012 Annual Meeting of Stockholders or Annual Report on Form 10-K/A, to be filed on or before April 30, 2013, are incorporated by reference into Part III of this Report.

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## Special Note Regarding Forward-Looking Statements

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This information may involve known and unknown risks, uncertainties and other factors that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risk associated with the following:*

- *the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates,*
- *funding delays, reductions in or elimination of U.S. government funding and/or non-renewal of expiring funding for one or more of our development programs,*
- *the award of government contracts to our competitors or delays caused by third parties challenging government contract awards to us,*
- *unforeseen safety issues,*
- *challenges related to the development, technology transfer, scale-up, and/or process validation of manufacturing processes for our product candidates,*
- *unexpected determinations that these product candidates prove not to be effective and/or capable of being marketed as products,*

*as well as risks detailed under the caption "Risk Factors" in this Report on Form 10-K and in our other reports filed with the U.S. Securities and Exchange Commission (the "SEC") from time to time hereafter. In particular, there can be no assurance that the Company will prevail in any appeal to the Delaware Supreme Court of the ruling of the Delaware Court of Chancery awarding PharmAthene 50% of all net profits (as defined in the court's final judgment) related to the sale of Arestvyr™ (formerly called ST-246®) and related products for 10 years following initial commercial sale of the drug once SIGA Technologies, Inc. ("SIGA") earns \$40 million in net profits from the sale of Arestvyr™ and related products. Further, the timing and amount of any future sales and revenues of Arestvyr™ is uncertain. Significant additional non-clinical animal studies, human clinical trials, and manufacturing development work remain to be completed for all our products candidates, including Valortim®, and with FDA's August 2012 clinical hold of SparVax®, it is unclear when, if ever, we can re-initiate human clinical trials for that product candidate. At this point future government funding to support the development of Valortim® is unlikely and remains uncertain. It is also uncertain whether any of our product candidates will be shown to be safe and effective and approved by regulatory authorities for use in humans. Forward-looking statements describe management's current expectations regarding our future plans, strategies and objectives and are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," "project," "potential" or "plan" or the negative of these words or other variations on these words or comparable terminology. Such statements include, but are not limited to:*

- *statements about potential future government contract or grant awards,*
- *potential payments under government contracts or grants,*
- *potential regulatory approvals,*
- *future product advancements, and*
- *anticipated financial or operational results.*

*Forward-looking statements are based on assumptions that may be incorrect, and we cannot assure you that the projections included in the forward-looking statements will come to pass.*

*We have based the forward-looking statements included in this Annual Report on Form 10-K on information available to us on the date of this Annual Report, 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.*

*All forward-looking statements included herein are expressly qualified in their entirety by the cautionary statements contained or referred to elsewhere in this Annual Report. Unless otherwise indicated, the information in this annual report is as of December 31, 2012.*

## **PART I**

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

#### **Background of PharmAthene, Inc.**

We were formed in April 2005 as Healthcare Acquisition Corp., a special purpose acquisition company, formed solely to acquire a then unidentified business. On August 3, 2005, we consummated our initial public offering. On August 3, 2007, we acquired all the outstanding equity of PharmAthene, Inc., a Delaware Corporation, and changed our name from Healthcare Acquisition Corp. to PharmAthene, Inc. We refer to this transaction as the Merger.

In March 2008, PharmAthene Inc., through its wholly-owned subsidiary PharmAthene UK Limited, acquired substantially all the assets and liabilities related to the biodefense vaccines business (the “Avecia Acquisition”) of Avecia Biologics Limited (along with its affiliates, “Avecia”).

Our executive offices are located at One Park Place, Suite 450, Annapolis, Maryland 21401 and our telephone number is 410-269-2600. Our stock trades on the NYSE MKT (formerly NYSE Amex) under the symbol “PIP.” We maintain a website at <http://www.PharmAthene.com>. We make available for download free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we have electronically filed, or furnished, them to the SEC. Our website and the information contained therein or connected thereto are not incorporated into this annual report on Form 10-K.

*Unless the context otherwise requires, all references in this report to the “Company”, “PharmAthene”, “we”, “us” or “our” refers to the business of the combined company after the Merger and to the business of former PharmAthene prior to the Merger. Unless the context otherwise requires, the information contained in this report gives effect to the consummation of the Merger on August 3, 2007 and the change of our name from “Healthcare Acquisition Corp.” to “PharmAthene, Inc.”*

#### **Overview**

We are a biodefense company engaged in the development and commercialization of next generation medical countermeasures against biological and chemical threats. Our current biodefense portfolio includes the following product candidates:

- SparVax<sup>®</sup>, a next generation recombinant protective antigen (“rPA”) anthrax vaccine,
- rBChE (recombinant butyrylcholinesterase) bioscavanger, a medical countermeasure for nerve agent poisoning by organophosphorous compounds, including nerve gases and pesticides, and
- Valortim<sup>®</sup>, a fully human monoclonal antibody for the prevention and treatment of anthrax infection.

In addition, we were awarded by the Delaware Court of Chancery in September 2011 the right to receive 50% of all net profits (as defined in the court’s final judgment) related to the sale of SIGA Technologies, Inc.’s (SIGA) Arestvyr<sup>™</sup> (formerly known as ST-246<sup>®</sup>) and related products for 10 years following initial commercial sale of the drug once SIGA earns \$40 million in net profits from the sales of Arestvyr<sup>™</sup> and related products. In May 2012, the Court issued its final judgment. SIGA has appealed aspects of the decision to the Delaware Supreme Court. In response, we have cross-appealed other aspects of the decision. In January 2013, the Delaware Supreme Court heard oral argument in the case.

#### **Business Concept and Strategy**

Our goal is to become the premier company worldwide specializing in the development and commercialization of best-in-class prophylactic and therapeutic drugs for defense against biological and chemical threats and emerging

infectious diseases. In assembling our product candidate portfolio we have adhered to a strategy emphasizing specific selection criteria to enhance the likelihood of U.S. government procurement. These selection criteria include:

- Demonstration of technical proof-of-concept in humans and/or appropriate animal models
- Advantages over existing products or technologies
- Demonstrated interest by the U.S. Government in procurement
- A defined development path and regulatory strategy

We seek to acquire and develop leading compounds and technologies targeting the highest priority U.S. Government biodefense requirements. We also look to bring products into our portfolio with dual-use potential that may serve both biodefense and commercial markets.

We have developed and will continue to develop unique biodefense product development and contracting capabilities. Development of these capabilities has required a substantial investment, which we may leverage further through possible acquisitions of additional biodefense product candidates, whether under licensing deals, mergers and acquisitions, or otherwise. We believe that product opportunities will come primarily from companies focused on commercial markets that wish to see their products or technologies exploited in biodefense.

## **Biodefense Industry**

### ***Market Overview***

The worldwide biodefense market can generally be divided into three segments: U.S. civilian, U.S. military, and non-U.S. markets. U.S. government funding represents the vast majority of the worldwide market. According to the University of Pittsburgh Medical Center - Center for Biosecurity, U.S. government biodefense military and civilian spending was over \$5.7 billion in fiscal year 2011 and was estimated at approximately \$5.6 billion in fiscal year 2012.

***U.S. Civilian Market:*** The U.S. civilian market includes funds to protect the U.S. population from biowarfare agents and is largely funded by the Project BioShield Act of 2004. Project BioShield, the U.S. government's largest biodefense initiative, seeks to accelerate the research, development and purchase of medical countermeasures ("MCMs"). At the end of calendar year 2012, approximately \$1.0 billion was in the Project BioShield Special Reserve fund ("SRF") set aside specifically for the procurement of MCMs. Currently, the government is operating under a continuing resolution at the fiscal year 2012 level. As \$415 million was the level of annual funding for BARDA operations in fiscal year 2012, a portion of that amount is being transferred from the SRF to cover fiscal year 2013 operating expenses, and thus will not be available for product purchases for the U.S. Strategic National Stockpile ("SNS"). The continuing resolution will end in late March 2013. It is unclear at this time how Congress will choose to move forward with funding the government for the remainder of fiscal year 2013.

Passage of legislation to reauthorize key biodefense legislation as part of the Pandemic and All Hazards Preparedness Act ("PAHPA") reauthorization did not occur in the last congress. However, both the Senate and House moved the measure quickly at the beginning of the new congress and the bill will be presented to the President for signing.

***U.S. Military Market:*** The Department of Defense ("DoD") is responsible for the development and procurement of countermeasures for the military segment, which focuses on providing biowarfare protection for military personnel and civilians who are on active duty. Under the continuing resolution, DoD is currently operating at the fiscal year 2012 level until a fiscal year 2013 budget is passed or the continuing resolution is extended. It is unclear at this time how the sequester will be implemented and if so, what the full impact would be on defense spending.



***Non-U.S. Markets:*** Non-U.S. markets address protection against biowarfare agents for both civilians and military personnel in foreign countries. We anticipate that foreign countries will procure biodefense products as they are developed and validated by procurement by the U.S. government.

### ***Project BioShield***

Project BioShield, established under the Project BioShield Act of 2004 and the U.S. government's largest biodefense initiative, is focused on acquiring products with low technological risk that will be available for purchase in the near term. The U.S. government has identified the following threats as critical biodefense priorities: anthrax, smallpox, botulinum toxin, radiation, and nerve agent exposure. To evaluate and select the best products for these threats, the Department of Health and Human Services ("DHHS") typically issues Requests for Information followed by Requests for Proposals ("RFP"). RFPs detail product and procurement requirements including treatment types, numbers of doses and delivery timeframes. To qualify for Project BioShield funding, products must demonstrate product efficacy in an animal model and complete advanced development activities, and companies must show that they can provide sufficient manufacturing capability. As of December 31, 2012, nine awards have been made under Project BioShield, including those for the treatment or prevention of anthrax, smallpox, radiation and botulinum toxin.

### **Anthrax**

The three general modes of infection by *Bacillus anthracis* ("*B. anthracis*"), the bacterium which causes anthrax infection, are by inhalation, ingestion or skin contact with anthrax spores. Inhalational anthrax is the most lethal form of infection and occurs when anthrax spores become airborne and enter a person's body through the lungs. Inhalational anthrax is almost always fatal if left untreated; the mortality rate in patients treated aggressively with antibiotics and supportive care is 50% or less. Persons infected by *B. anthracis* that is ingested will suffer from gastrointestinal anthrax; those whose skin comes into contact with anthrax will suffer from cutaneous anthrax. Gastrointestinal anthrax has a mortality rate of more than 40% if left untreated. Cutaneous anthrax generally causes skin infections within a week or two after exposure. Cutaneous anthrax is the least fatal. Without treatment, approximately 20% of all skin infection cases are fatal. Treated cutaneous anthrax is rarely fatal.

The DoD estimates that up to ten countries may possess anthrax weapons and an undetermined number of individuals and terrorist groups could have access to anthrax. Anthrax is an effective bioterrorism agent because the spores are stable for extended periods of time (years), can be milled to a fine powder, and can be widely dispersed with readily available instruments and machinery. The U.S. Congressional Office of Technology Assessment in 1993 analyzed the potential scope of an anthrax attack, calculating that there would be between 130,000 and 3 million deaths following the release of 100 kilograms of anthrax in a highly populated area.

In light of the limited effectiveness of current antibiotics and supportive care, we believe that currently available treatments for inhalational anthrax – antibiotics and vaccines - are suboptimal. Following exposure, but prior to the onset of symptoms, antibiotics like ciprofloxacin, doxycycline or penicillin can be used as post-exposure prophylaxis with the goal of preventing progression of the disease with a recommended antibiotic course of treatment of 60 days, sometimes in combination with the administration of an existing anthrax vaccine. We believe that both compliance and side effects are problematic for anyone asked to take antibiotics for such an extended period of time. Furthermore, antibiotic resistance, whether naturally occurring or genetically engineered, is a concern.

### **Smallpox**

Smallpox virus is classified as a Category 'A' agent by the U.S. Centers for Disease Control and Prevention and is considered one of the most significant threats for use as a biowarfare agent. Although declared eradicated in 1979 by the World Health Organization ("WHO"), there is a threat that a rogue nation or a terrorist group may already possess or have the capability to produce an illegal inventory of the virus that causes smallpox. Inventories of the virus are known to be contained under extremely tight security at the CDC in Atlanta, Georgia and at the Vector laboratory in Russia.

Many scientists agree that with the scientific tools available today smallpox can be created by modifying another orthopox virus available naturally worldwide by a scientist with access to a modern laboratory. Studies conducted prior to the eradication of natural reservoirs of smallpox virus show that the disease has a mortality rate of 30% or higher, and survivors are scarred and can suffer other permanent detriments.

### **Chemical Weapons and Nerve Agents**

Chemical weapons use the toxic properties of chemical substances to produce physiological effects on an enemy or civilian target. Classic chemical weapons, such as chlorine and phosgene, were employed during World War I and consisted primarily of commercial chemicals used as choking and blood agents, to cause respiratory damage and asphyxiation. Organophosphorous agents (nerve agents), one of the most lethal forms of chemical weapons, were developed in the 1930s in the years leading up to World War II.

Nerve agents function by binding to acetylcholinesterase, an enzyme that normally causes termination of the activity of the neurotransmitter acetylcholine. Nerve agents block the activity of acetylcholinesterase, allowing the activity of acetylcholine to continue unchecked. As a result, nerve impulses are continually transmitted, causing muscle contractions that do not stop. This effect is referred to as a “cholinergic crisis” and results in a loss of muscle control, respiratory failure, paralysis and convulsions. Nerve agent exposure that does not cause death after a short period can lead to permanent brain damage.

There is currently only one FDA-approved pre-treatment for nerve agents, pyridostigmine bromide (“PB”). PB is only approved for the pre-treatment of exposure to the nerve agent soman. It confers no protection on its own but enhances the protection conferred by post-exposure treatment. The standard of care for post-exposure treatment involves repeated doses of a cocktail of drugs including atropine, reactivators including the oxime 2-PAM, and anti-convulsants. However, this type of treatment acts primarily on the symptoms of nerve agents, not their underlying cause. We believe available pre-and post-treatment options are inadequate and that there is a need for more efficacious countermeasures, especially as evidence mounts that modified, more toxic forms of nerve agents may be used in future attacks.

### **Product Candidates**

#### ***SparVax<sup>®</sup>: Recombinant Protective Antigen (PA)-based Anthrax Vaccine***

SparVax<sup>®</sup> is a second generation, rPA anthrax vaccine designed to protect against inhalational anthrax, the most lethal form of *B. anthracis* infection in humans. The vaccine has been shown to induce anti-Protective Antigen (“PA”) antibodies in clinical trials in healthy human volunteers and in animal models of inhalational anthrax. These antibodies are believed to function by targeting PA, a protein component necessary for the transportation of bacterial toxins into the cell and the subsequent toxic cascade that leads to morbidity and mortality. Vaccination with SparVax<sup>®</sup> generates high titers of antibodies and up to 100% efficacy in rabbits and non-human primates that are subsequently exposed to lethal inhalation doses of anthrax spores. One Phase I and two Phase II clinical trials have been completed involving approximately 770 individuals. Data from these trials demonstrated that SparVax<sup>®</sup> is generally well tolerated, and immunogenic.

SparVax<sup>®</sup> is being developed for two indications: post-exposure prophylaxis (“PEP”) in conjunction with antibiotics and general use prophylaxis (“GUP”). In a PEP setting, the vaccine would be administered following a suspected exposure to augment the natural immune response and provide protection once antibiotics are discontinued. In the GUP setting, the vaccine is administered in advance of any exposure and is intended to induce an immune response that will be protective should there be an exposure.

#### **Pre-clinical Safety Studies**

Prior to an Investigational New Drug (“IND”) application being filed with the FDA, SparVax<sup>®</sup> underwent safety testing in mice, rats, and rabbits and non-human primates. SparVax<sup>®</sup> was well tolerated with no deaths and no behavioral or clinical signs observed in all species. All of the toxicology studies were compliant with Good

Laboratory Practices (“GLP”) and the data were used to support the IND and allowed for the initiation of clinical trials of SparVax®.

### **Non-clinical Studies**

Clinical trials to demonstrate efficacy of an anthrax vaccine in humans are unethical; therefore, the strategy is to obtain licensure of SparVax® via the FDA’s Animal Rule (21 CFR 601.90) which allows for efficacy testing in appropriate animal models in lieu of human clinical efficacy trials. To date, a majority of our animal model development and efficacy studies in both rabbits and non-human primates for both GUP and PEP indications using SparVax® have been sponsored by the National Institute of Allergy and Infectious Diseases (“NIAID”) and conducted by a contract research organization. Data from these studies have shown that SparVax® is immunogenic and efficacious in both rabbits and non-human primates and that immunogenicity and protection against an aerosol challenge are dependent on vaccine dosage; the vaccine used in these studies was manufactured using drug substance manufactured at Avecia. A rabbit efficacy study was performed following the successful transfer of technology and scale up to a 1,500 liter (bioreactor) commercial scale process. The results of this recent study confirm previous findings that immunogenicity and protection conferred by SparVax® are dependent upon vaccine dosage. Moreover, these results and other studies have demonstrated that the drug product made using drug substance manufactured at Fujifilm Diosynth Biotechnologies USA (“Diosynth”) is comparable to the vaccine based on drug substance manufactured at Avecia.

### **Clinical Studies**

The Phase I trial was a dose escalation study designed to evaluate a range of dosage levels administered with either of two different dosing schedules. There were no vaccine-related serious adverse events or changes in blood chemistries, vital signs or electrocardiograms (“ECGs”) reported. The results demonstrated that the vaccine was generally well tolerated, and immunogenic and that the immunogenic response was dependent on vaccine dosage.

The Phase II program was designed to evaluate the safety and immunogenicity of the two highest dosages tested in Phase I using a three dose regimen in a larger number of subjects. Two Phase II trials were conducted, both of which studied the effect of different vaccine dosage levels and schedules.

In the Phase IIa trial, SparVax® was shown to be immunogenic, and generally well tolerated with no vaccine-related serious adverse events.

The Phase IIb trial compared a longer dosing regimen at two different vaccine dosages with a smaller control group that received the currently licensed anthrax vaccine, BioThrax®. As in the Phase IIa trial, SparVax® was immunogenic, and generally well tolerated with no vaccine-related serious adverse events. The immunogenicity data showed that SparVax® elicited an immune response after the primary immunization series as well as having induced an anamnestic response after a booster dose given at 6 or 12 months after the primary dosing schedule. While both SparVax® and BioThrax® were immunogenic following a 3-dose series with seroconversion rates of approximately 90% (as measured by ELISA titers), an increased proportion of individuals experienced injection site pain in the BioThrax® group (where the vaccine was administered subcutaneously) as compared to the SparVax® groups.

Future studies will seek to confirm the dose and schedule of SparVax® that induces antibody levels in humans which are comparable to those shown to be protective in the animal models, demonstrate the acceptability of using SparVax® in conjunction with antibiotics, and confirm the safety of SparVax® in a sufficient number of human subjects (as required by FDA).

### **Product Stability**

In 2011, we announced that SparVax® product produced from bulk drug substance manufactured at Avecia Biologics Laboratories in the United Kingdom had demonstrated 52 month stability. Moreover we have demonstrated over 36 month stability for our final drug product vaccine formulation based on bulk drug substance manufactured at Avecia. The stability data were prepared utilizing a variety of analytical methods and a mouse

challenge potency assay. Subsequent to the transfer of manufacturing technology to Diosynth, one 1,500 liter engineering lot of bulk drug substance and one 1,500 liter GMP lot of bulk drug substance were manufactured at Diosynth; engineering and GMP lots of final drug product were manufactured from aliquots of the engineering and GMP lots of bulk drug substance, respectively. The GMP bulk drug substance and final drug product lots are currently on formal International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) compliant stability programs. In parallel, the stability of the engineering lots of bulk drug substance and final drug product is also being monitored to support the findings from the formal stability programs. Data obtained to date demonstrate that the bulk drug substance is stable for up to 18 months and the final drug product is stable for up to 12 months.

In August 2012, we received notification from the FDA that our SparVax<sup>®</sup> rPA anthrax vaccine program was placed on clinical hold prior to initiating any patient dosing. The FDA has requested additional stability data and information related to the stability indicating assays. We have provided some supporting data and information to the FDA and have commenced discussions with that agency as well as our customer, Biomedical Advanced Research and Development Authority (BARDA), regarding the clinical hold. We cannot be certain that the FDA will find our current data to be satisfactory and it is unclear at this point whether or when SparVax<sup>®</sup> will be removed from clinical hold or when or if we will be able to commence the planned Phase II human clinical trial with SparVax<sup>®</sup>.

### **Funding**

To date, funding for the development of SparVax<sup>®</sup> has occurred under two contracts from the National Institutes of Health (NIH) originally entered into in 2002 and 2003 which, not including the modification discussed below, provided for aggregate funding of up to approximately \$128 million.

In April 2009, the United States Government transferred the SparVax<sup>®</sup> contract to BARDA. In February 2010, PharmAthene and BARDA entered into negotiations to modify our existing advanced development contract for SparVax<sup>®</sup>. During the base period of performance under the contract modification we have been funded up to approximately \$62 million on a cost-reimbursement-plus-fixed-fee basis, assuming that all milestones are achieved. The contract was subsequently modified to extend the period of performance through February 2014. As of December 31, 2012, approximately \$28 million remains available under base contract funding. In addition, approximately \$17 million in unfunded options remained under the contract. It is unclear when or if BARDA will consider a new funding request.

### ***Recombinant Human Butyrylcholinesterase Nerve Agent Countermeasure***

In 2006 we entered into a contract with the DoD to develop our Protexia<sup>®</sup> medical countermeasure for nerve agent exposure to protect the warfighter. This program utilized the recombinant enzyme butyrylcholinesterase, or “rBChE”, a naturally occurring bioscavenger, as its active ingredient. This first generation program for producing rBChE utilized transgenic goats to produce the enzyme in their milk. This contract expired on December 31, 2010, and we shut down our Protexia<sup>®</sup> related operations and sold our production facilities in December 2011.

We have also been working on a second generation approach, which we refer to as our Advanced Expression System, or “AES”, that utilizes a mammalian-cell-based expression system (i.e. the PER.C6<sup>®</sup> human cell line) for rBChE. In August 2011 DoD awarded us a fixed price contract for up to approximately \$5.7 million to support our on-going research into the production of rBChE using this mammalian-cell based advanced expression system. As of December 31, 2012, approximately \$3.3 million remains available under this contract. While the AES technology is still at an early research stage, if our efforts are successful, we believe this cell-based approach could have significant advantages over the transgenic goat-based approach originally developed to produce Protexia<sup>®</sup>. Specifically, we believe these advantages could include:

- An established manufacturing platform, consistent with those used for other biotechnology products and with the U.S. government’s recent advanced manufacturing system initiative.
- Final product with a pharmacokinetic (PK) profile that more closely resembles naturally occurring butyrylcholinesterase, or BChE, from human blood.

- Higher production yields than a transgenic goat based approach.
- Substantially lower costs of production to yield significant savings to our DoD and, potentially, civilian customers.
- A more traditional regulatory path to FDA licensure.
- Greater ability to scale up production if demand increases.

In December 2012, we exclusively licensed from Percivia the rights for use of the PER.C6<sup>®</sup> human cell line for the manufacture of our rBChE product. This platform offers many advantages over traditional expression systems and should enable the final product to have a pharmacokinetic profile that more closely matches the naturally occurring BChE found in human plasma.

***Valortim<sup>®</sup>: Anthrax Monoclonal Antibody***

Valortim<sup>®</sup> is a fully human monoclonal antibody designed to protect against and treat human inhalational anthrax, as both post-exposure prophylaxis (i.e., before symptoms manifest) and post-exposure therapy (i.e., once symptoms are evident). Valortim<sup>®</sup> is designed to bind to PA and protect the cells from damage by the anthrax toxins. In non-clinical studies, animals were protected against this fatal disease when Valortim<sup>®</sup> was administered following a lethal aerosol challenge of anthrax spores, demonstrating that Valortim<sup>®</sup> induces recovery and survival in animals exposed to inhalational anthrax.

**BMS Collaboration and Development Timeline**

We are developing Valortim<sup>®</sup> in collaboration with Bristol Myers Squibb (“BMS”) pursuant to a collaboration agreement entered into in November 2004. Under the terms of the collaboration agreement, we and BMS will share operating profits according to a formula that establishes our share of the profits at between 20% and 60%, with the final split largely dependent on the amount of funding provided by us prior to sale of product to the U.S. government. Prior to distribution of operating profits, each party is entitled to reimbursement of research and development expenses incurred that were not otherwise covered by government funding. Valortim<sup>®</sup> has received Fast Track designation from the FDA as well as orphan drug status.

**Clinical and Non-clinical Studies**

Valortim<sup>®</sup> is being developed for two indications: (i) post-exposure prophylaxis; and (ii) as a therapeutic.

**Clinical Phase I Studies**

In 2006 PharmAthene and BMS completed an initial Phase I open-label, dose-escalation clinical trial to evaluate the safety, tolerability, immunogenicity, and pharmacokinetics (the study of absorption, metabolism and action of drugs) of a single dose of Valortim<sup>®</sup> administered intravenously or intramuscularly in healthy volunteers. No drug-related serious adverse effects were reported. In August 2009 we began a second Phase I clinical trial of Valortim<sup>®</sup> in combination with the antibiotic ciprofloxacin. During the course of the study, there were two serious adverse events, so we halted the trial and the FDA placed the study on partial clinical hold. Following an investigation, the FDA lifted the partial clinical hold in December 2010, and we then commenced and completed an intravenous (IV) dose-escalation study of Valortim<sup>®</sup>. We submitted the final study report for the trial in January 2012.

**Non-clinical Studies**

We have conducted studies in two animal models to evaluate the use of Valortim<sup>®</sup> as a post-exposure prophylaxis. Treatment in both animal models was initiated within one hour following exposure to the anthrax spores. Eighty-five percent (85%) of rabbits treated intravenously with doses of Valortim<sup>®</sup> survived following inhalation exposure to anthrax spores. One hundred percent (100%) of cynomolgus monkeys treated intramuscularly with doses of Valortim<sup>®</sup> were protected from death following exposure to inhalational anthrax spores.

We have conducted studies in rabbits to evaluate the use of Valortim<sup>®</sup> as a therapeutic intervention for inhalational anthrax. This indication for Valortim<sup>®</sup> would be intended to treat patients who have already developed signs and/or symptoms of inhalational anthrax. In two studies, up to 100% of the animals survived that were treated with Valortim<sup>®</sup> intravenously at the time they tested positive for the presence of PA in the blood or had significant increases in body temperature.

We have also conducted two studies in African green monkeys treated with Valortim<sup>®</sup> at the time they tested positive for the presence of PA in the blood. Up to 70% of animals treated intravenously with Valortim<sup>®</sup> survived. In contrast, the mortality rate for animals exposed to inhalational anthrax that received a saline control at the time they tested positive for the presence of PA in the blood is close to 100%.

### **Funding**

In 2006 and 2008, we received DoD funding for the advancement of Valortim<sup>®</sup> in the aggregate amount of \$4.2 million, all of which was received by December 31, 2012. In September 2007, NIAID awarded us a \$13.9 million contract for the advanced development of Valortim<sup>®</sup> as an anti-toxin therapeutic to treat inhalational anthrax infection. In April 2009 that amount was increased to \$15.9 million (which was reduced to \$15.3 million in August 2010). Funding from NIAID ran through January 31, 2012, when this contract ended.

In August 2012, we responded to BARDA Solicitation RFP-12-100-SOL-00026, an Indefinite-Delivery, Indefinite-Quantity (ID/IQ) contract for the acquisition of anthrax antitoxins. In November 2012, BARDA notified us that our proposal was within the competitive range for award consideration, and in January 2013 we submitted our Final Proposal Revision. While the ID/IQ would not guarantee funding for the Valortim<sup>®</sup> program, if awarded it would provide us with a contract vehicle under which to compete for specific work orders submitted by BARDA on an expedited basis with others included in the ID/IQ contract.

There can be no assurance we will be successful in obtaining additional financial support for this program.

### ***PharmAthene's Interest in ARESTVYR<sup>™</sup>: Smallpox antiviral***

Arestvyr<sup>™</sup>, which is being developed by SIGA (whose common stock is currently traded on the NASDAQ under the symbol "SIGA"), is an orally administered anti-viral drug candidate to treat orthopox virus diseases including smallpox. Arestvyr<sup>™</sup> acts by blocking the ability of the virus to spread to other cells, preventing it from causing disease. The FDA has designated Arestvyr<sup>™</sup> for "fast-track status" enabling potential expedited FDA review and approval. In addition, Arestvyr<sup>™</sup> has been granted Orphan Drug designation for both the treatment and prevention of smallpox.

Pursuant to an opinion issued September 2011 and a final ruling and judgment issued May 2012 by the Delaware Court of Chancery, we were awarded the right to receive 50% of the net profits (as defined in the court's final judgment) over 10 years from all sales of Arestvyr<sup>™</sup> and related products, once SIGA earns the first \$40 million in net profits. The Delaware Court of Chancery also awarded us one-third of our attorneys' fees and expert witness costs of approximately \$2.4 million plus interest. SIGA has appealed aspects of the decision to the Delaware Supreme Court. In response, we cross-appealed other aspects of the decision. The high court heard oral argument in the case in January 2013. While the Delaware Supreme Court generally issues rulings 90-120 days after oral argument, we cannot predict with certainty when it will issue its opinion in this case.

SIGA indicated in its year end 2012 investor conference call held on March 6, 2013 that it expects that approximately 190,000 courses of Arestvyr<sup>™</sup> will be accepted by BARDA in March 2013 and they will surpass the delivery of the first 500,000 courses of treatment before the end of the third quarter 2013. SIGA also stated that it expects to fully deliver 2 million courses of Arestvyr<sup>™</sup> within the next two years. SIGA's ability to deliver product to the SNS, and the timing thereof, is subject to a number of significant risks and uncertainties (certain of which are outlined in SIGA's filings with the SEC), as to which we have limited knowledge and which we have no ability to control, mitigate or fully evaluate. Further, our financial interest in Arestvyr<sup>™</sup> is subject to a number of significant risks and uncertainties, certain of which are set out below under "Risk Factors – Risks Related to Our Financial

Condition - *Our interest in Arestvyr™ and related products is subject to the risk of an appeal of the judgment by SIGA and other risks.*”

## **U.S. Government Regulation of Biological Products**

### ***General***

Regulation by governmental authorities in the United States and other countries will have a significant impact on our research, product development, manufacturing and marketing of any biopharmaceutical products. The nature and the extent to which regulations apply to us will vary depending on the nature of any such products. Our potential biopharmaceutical products will require regulatory approval by governmental agencies prior to commercialization. The products we are developing are subject to federal regulation in the United States, principally by the FDA under the Public Health Service Act and Federal Food, Drug, and Cosmetic Act (“FFDCA”) and by state and local governments, as well as regulatory and other authorities in foreign governments that include rigorous preclinical and clinical testing and other approval procedures. Such regulations govern or influence, among other things, the research, development, testing, manufacture, safety and efficacy requirements, labeling, storage, recordkeeping, licensing, advertising, promotion, distribution and export of products, manufacturing and the manufacturing process. In many foreign countries, such regulations also govern the prices charged for products under their respective national social security systems and availability to consumers.

The Public Health Service Act classifies our current drug candidates which are produced using biological systems, as biological drug products, or biologics (“Biologics”). All drugs intended for human use, including Biologics, are subject to rigorous regulation by the FDA in the United States and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before a biological drug product may be marketed in the United States are similar to steps required in most other countries and include, but are not limited to:

- completion of preclinical laboratory tests, preclinical animal testing and formulation studies;
- submission to the FDA of an Investigational New Drug application (“IND”), which must be in effect before clinical trials may commence;
- submission to the FDA of a Biologics License Application (“BLA”) that includes preclinical data, clinical trial data and manufacturing information;
- FDA review of the BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and
- FDA approval of the BLA, including approval of all product labeling.

The research, development and approval process requires substantial time, effort and financial resources, and approvals may not be granted on a timely or commercially viable basis, if at all.

Preclinical testing includes laboratory evaluations to characterize the product’s composition, impurities, stability, and mechanism of its biologic effect, as well as animal studies to assess the potential safety, purity and potency of each product. Preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices (“GLP”) and the U.S. Department of Agriculture’s Animal Welfare Act. Violations of these laws and regulations can, in some cases, lead to invalidation of the tests, requiring such tests to be repeated and delaying approval of the BLA. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical trials. Unless the FDA objects to an IND by placing the study on clinical hold, the IND will go into effect 30 days following its receipt by the FDA. The FDA may authorize trials only on specified terms and may suspend clinical trials at any time on various grounds, including a finding that patients are being exposed to unacceptable health risks. If the FDA places a study on clinical hold, the sponsor must resolve all of the FDA’s concerns before the study may proceed. The IND application process may become extremely costly

and substantially delay development of products. Similar restrictive requirements also apply in other countries. Additionally, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Clinical trials involve the administration of the investigational product to humans under the supervision of qualified principal investigators. Our clinical trials must be conducted in accordance with Good Clinical Practice (“GCP”) regulations under protocols submitted to the FDA as part of an IND. In addition, each clinical trial is approved and conducted under the auspices of an institutional review board (“IRB”) and requires the patients’ informed consent. The IRB considers, among other things, ethical factors, the safety of human subjects, and the possibility of liability of the institutions conducting the trial. The IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for a variety of reasons, including a belief that the test subjects are being exposed to an unacceptable health risk. Since our products are being developed using funding from the U.S. government, additional review by either the NIH’s IRB or the DoD’s IRB-equivalent will also be required. These reviews take place following approval by the independent IRB. As the sponsor, we can also suspend or terminate a clinical trial at any time.

Clinical trials are typically conducted in three sequential phases, Phases I, II, and III, involving an increasing number of human subjects. These phases may sometimes overlap or be combined. Phase I trials are performed in a small number of healthy human subjects or subjects with the targeted condition, and involve testing for safety, dosage tolerance, absorption, distribution, metabolism and excretion or immunogenicity for vaccine products. Phase II studies, which may involve up to hundreds of subjects, seek to identify possible adverse effects and safety risks, preliminary information related to the efficacy of the product for specific targeted diseases, dosage tolerance, and optimal dosage. Finally, Phase III trials may involve up to thousands of individuals often at geographically dispersed clinical trial sites, and are intended to provide the documentation of effectiveness and important additional safety data required for licensing. Prior to commencing Phase III clinical trials many sponsors elect to meet with FDA officials to discuss the conduct and design of the proposed trial or trials.

In addition, federal law requires the listing, on a publicly-available website, of detailed information on clinical trials for investigational drugs. Some states have similar or supplemental clinical trial reporting laws.

In 2002, the FDA amended its requirements applicable to BLAs to permit the approval of certain Biologics that are intended to reduce or prevent serious or life-threatening conditions based on evidence of safety from trial in healthy subjects and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, also known as the “Animal Rule”, and published in the Code of Federal Regulations (21 CFR 601 Subpart H) authorize the FDA to rely on evidence from animal studies to provide evidence of a product’s effectiveness under circumstances where there is a reasonably well-understood mechanism for the toxicity of the agent. Under these requirements, and with FDA’s prior agreement, Biologics used to reduce or prevent the toxicity of chemical, biological, radiological or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated for effectiveness under this rule are evaluated for safety under preexisting requirements for establishing the safety of new drug and biological products, including Phase I through Phase II 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. Products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We intend to rely on the Animal Rule in seeking marketing approval for our product candidates because we cannot ethically expose humans to anthrax, or nerve agents. Other countries do not, at this time, have established criteria for review and approval of these types of products outside their normal review process, i.e. there is no “Animal Rule” equivalent in countries other than the United States.

Success in early-stage animal studies and clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from animal studies and clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval.



All data obtained from the preclinical studies and clinical trials, in addition to detailed information on the manufacture and composition of the product, would be submitted in a BLA to the FDA for review and approval for the manufacture, marketing and commercial shipments of any of our products. FDA approval of the BLA is required before commercial marketing or non-investigational interstate shipment may begin in the United States. The FDA may also conduct an audit of the clinical trial data used to support the BLA.

However, under the Project BioShield Act of 2004, or Project BioShield, the Secretary of the DHHS may, with the concurrence of the Secretary of the Department of Homeland Security, or DHS, and upon the approval of the President, contract to purchase unapproved 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 DHHS must determine that there are sufficient and satisfactory clinical results or research data, including data, if available, from preclinical 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 DHHS to authorize the emergency use of medical products that have not yet been approved by the FDA. To exercise this authority, the Secretary of DHHS must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- the product may reasonably be believed to 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 alternative to the product that is approved and available.

Although this provision permits the Secretary of DHHS to circumvent the FDA approval process, its use would be limited to rare circumstances.

Our products 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 products will meet the criteria set forth by DHHS or the FDA for procurement and Emergency Use Authorization (“EUA”), respectively.

With regard to a BLA, the FDA may deny or delay approval of an application that does not meet applicable regulatory criteria, e.g. if the FDA determines that the preclinical or clinical data or the manufacturing information does not adequately establish the safety, purity and potency (including efficacy) of the Biologic. The FDA has substantial discretion in the approval process and may disagree with an applicant’s interpretation of the data submitted in its BLA. The FDA can request additional information, seek clarification regarding information already provided in the submission or ask that clinical trials be conducted, all of which can delay approval. The FDA also may, at any time, require the submission of product samples and testing protocols for lot-by-lot confirmatory review or testing, known as lot release, by the FDA prior to commercial distribution. This means a specific lot of Biologic cannot be released for commercial distribution until the FDA has authorized such release. Similar types of regulatory processes will be encountered as efforts are made to market any Biologic internationally. We will be required to assure product performance and manufacturing processes from one country to another.

If the FDA approves a product, it may limit the approved uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk evaluation and mitigation strategy, or REMS, or otherwise limit the scope of any approval or limit labeling. Once it approves a BLA, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to

monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies. The Animal Rule 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. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy civil and criminal penalties, suspend or delay issuance of approvals, seize or recall products and revoke approvals.

The FDA's Fast Track designation program is designed to facilitate the development and review of new drugs, including biological products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug for a specific indication that receives Fast Track designation. The sponsor of a product designated as being in a Fast Track drug development program may engage in early communication with the FDA, including timely meetings and early feedback on clinical trials, and may submit portions of an application on a rolling basis rather than waiting to submit a complete application. Products in Fast Track drug development programs also may receive priority review or accelerated approval, under which an application may be reviewed within six months after a complete NDA or BLA is accepted for filing or sponsors may rely on a surrogate endpoint for approval, respectively. The FDA may notify a sponsor that its program is no longer classified as a Fast Track development program if the Fast Track designation is no longer supported by emerging data or the designated drug development program is no longer being pursued.

Biologics manufacturers, distributors and their subcontractors are required to register their facilities with the FDA and state agencies and are subject to periodic inspection by the FDA and other authorities, where applicable, and must comply with the FDA's current Good Manufacturing Practices ("cGMP") regulations, the FDA's general biological product standards, and the product establishment standards set forth in the approved BLA. The cGMP requirements for biological products in particular are extensive and compliance with them requires considerable time, resources and ongoing investment. The regulations require manufacturers to establish validated systems to ensure that products meet high standards of sterility, purity and potency. The requirements apply to all stages of the manufacturing process, including the synthesis, processing, sterilization, packaging, labeling, storage and shipment of the biological product. For all drugs and biological products, the regulations require investigation and correction of any deviations from cGMP requirements and impose documentation requirements upon us and any third party manufacturers that we may decide to use. Manufacturing establishments are subject to periodic unannounced inspections by the FDA and state agencies for compliance with all cGMP requirements. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner.

We or our present or future suppliers may not be able to comply with cGMP and other FDA regulatory requirements. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as a delay or refusal to approve a BLA, suspension of manufacturing, seizure or recall of a product, or civil or criminal prosecution of the company or individual officers or employees.

### ***Post-Marketing Regulation***

Any products manufactured or distributed by us pursuant to FDA licenses or approvals are subject to pervasive and continuing regulation by the FDA, including:

- recordkeeping requirements;
- periodic reporting requirements;
- cGMP requirements related to all stages of manufacturing, testing, storage, packaging, labeling and distribution of finished dosage forms of the product;
- reporting of adverse experiences with the product; and
- advertising and promotion restrictions.

Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be revoked if compliance with regulatory requirements is not maintained or if problems concerning safety or effectiveness of the product occur following approval. As a condition of NDA or BLA approval, the FDA may require post-approval testing and surveillance to monitor a product's safety or efficacy. The FDA also may impose other conditions, including labeling restrictions which can materially impact the potential market and profitability of a product.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote Biologics, including, among others, standards and restrictions on direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in administrative and judicial enforcement actions, including the issuance of a Warning Letter directing correction of deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions. Foreign regulatory bodies also strictly enforce these and other regulatory requirements and drug marketing may be prohibited in whole or in part in other countries.

We, our collaborators or our third party contract manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements, may result in:

- restrictions on the marketing or manufacturing of a product;
- Warning Letters or Untitled Letters from the FDA asking us, our collaborators or third party contractors to take or refrain from taking certain actions;
- withdrawal of the product from the market;
- FDA's refusal to approve pending applications or supplements to approved applications;
- voluntary or mandatory product recall;
- fines or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusals to permit the import or export of products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

### ***Other Regulations***

In addition to the substantial regulations enforced by the FDA, we are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our various activities. We cannot accurately predict the extent of government regulation that might result from any future legislation or administrative action.

### ***Changing Legal and Regulatory Landscape***

Periodically legislation is introduced in the U.S. Congress that could change the statutory provisions governing the approval, manufacturing and marketing of drugs, including biological products. In addition, FDA regulations and

guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and products. We cannot predict whether or when legislation impacting our business will be enacted, what FDA regulations, guidance or interpretations may change, or what the impact of such changes, if any, may be in the future.

### ***Process and Analytical Development, and Manufacturing***

While we have no drug substance or drug product development, analytical or manufacturing facilities of our own, we believe that acceptable alternatives are available through third-party contract manufacturing organizations (“CMOs”) and contract research organizations (“CROs”). CMOs have experience in developing biological manufacturing processes and operating under cGMPs established by the Code of Federal Regulations and the Food, Drug and Cosmetic Act (Biologics) regulated by the FDA, and we rely on them for clinical and future commercial production of our product candidates. CROs provide cGLP/cGMP-compliant services for product analytical tests.

For SparVax<sup>®</sup>, in June 2011 we announced the successful completion of the technology transfer of the rPA bulk drug substance manufacturing to a new CMO, Diosynth. Subsequently in 2011 we successfully completed a commercial scale 1,500 liter engineering run and a 1,500 liter cGMP run of SparVax<sup>®</sup> bulk drug substance at the Diosynth site. Formulation and filling of the final drug product, adjuvanted rPA, are performed at Baxter Pharmaceutical Solutions LLC, located in the United States. The final dosage presentation is in unit dose syringes. All analytical data generated to date demonstrate that the bulk drug substance manufactured at Diosynth is comparable to bulk drug substance manufactured previously at Avecia in the UK, and in the 4th quarter 2012 FDA confirmed its concurrence that the bulk drug substances manufactured at the two sites are comparable.

For Valortim<sup>®</sup>, the cell culture and purification process was developed by BMS, and results in a commercially feasible and high purity product. We have successfully manufactured bulk drug substance at large scale following technology transfer to a CMO, Laureate Biopharma. The final drug product has been formulated and filled, tested and released for use in clinical trials and non-clinical studies.

Certain raw materials used in producing our product candidates are available from only one source or a limited number of sources. We attempt to mitigate the risk associated with such sole source raw materials by actively managing our inventories. We have not experienced any shortages in supplies of such raw materials. Unavailability of certain materials or the loss of current sources of production could cause an interruption in production on a temporary basis pending establishment of new sources or, in some cases, implementation of alternative processes.

### **Intellectual Property**

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

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

| Patent/Patent Application                          | Patent Number/<br>Application<br>Number | Country of<br>Issue/Filing | Issue Date/File<br>Date | Expiration Date |
|--|---|----------------------------|-------------------------|-----------------|
| Anthrax Vaccine<br>Formulation and Uses<br>Thereof | GB2009/051293                           | WO                         | October 2, 2009         | October 2, 2029 |
|  | 12/998245                               | U.S.                       | October 2, 2009         | October 2, 2029 |
|  | 2011-529634                             | Japan                      | October 2, 2009         | October 2, 2029 |
|  | 09785720.5                              | Europe                     | October 2, 2009         | October 2, 2029 |
|  | 2,738,621                               | Canada                     | October 2, 2009         | October 2, 2029 |
|  | 2009299615                              | Australia                  | October 2, 2009         | October 2, 2029 |
|  | 212118                                  | Israel                     | October 2, 2009         | October 2, 2029 |

|   |                   |           |                   |                   |
|---|-------------------|-----------|-------------------|-------------------|
| Recombinant Butyrylcholinesterase & Truncates thereof | PCT/US10/03225    | WO        | December 21, 2010 | December 21, 2030 |
|   | 13/517,081        | U.S.      | December 21, 2010 | December 21, 2030 |
|   | 2012-545932       | Japan     | June 21, 2012     | December 21, 2030 |
|   | 10842361.7        | Europe    | December 21, 2010 | December 21, 2030 |
|   | 2,784,861         | Canada    | June 18, 2012     | December 21, 2030 |
|   | 2010340358        | Australia | December 21, 2010 | December 21, 2030 |
|   | 220508            | Israel    | June 19, 2012     | December 21, 2030 |
| Method for Assaying Antigens                          | GB07/001353       | WO        | April 12, 2007    | April 13, 2027    |
|   | 12/226101         | U.S.      | October 7, 2008   | April 13, 2027    |
|   | 2009-504819       | Japan     | October 10, 2008  | April 13, 2027    |
|   | 2010914 2,648,850 | Europe    | November 10, 2008 | April 13, 2027    |
|   | 2007242647        | Canada    | October 9, 2008   | April 13, 2027    |
|   | 194459            | Australia | October 24, 2008  | April 13, 2027    |
|   |                   | Israel    | November 1, 2012  | April 13, 2027    |
| Long Half-Life Recombinant Butyrylcholinesterase      | US07/017279       | WO        | August 2, 2007    | August 3, 2027    |
|   | 12/309909         | U.S.      | February 2, 2009  | August 3, 2027    |
|   | 2009-523781       | Japan     | February 4, 2009  | August 3, 2027    |
|   | 07811030.1        | Europe    | August 2, 2007    | August 3, 2027    |
|   | 2659809           | Canada    | February 3, 2009  | August 3, 2027    |
|   | 2007281998        | Australia | February 10, 2009 | August 3, 2027    |
|   | 196,871           | Israel    | February 4, 2009  | August 3, 2027    |

In addition, we are a party to various exclusive and non-exclusive licenses, which provide access to intellectual property and know-how useful for our products. We are a party to license agreements with The Defence Science and Technology Laboratory of the United Kingdom Ministry of Defence (“DSTL”) originally executed May and December 2006, and amended and restated in February 2009. These agreements allow for the licensing of certain patents and technology useful in our rPA program. Upon commercialization of a product covered by a license, the license agreements require that we make royalty payments equal to a specified percentage of future sales of products for both government procurement and commercial markets. No royalty payments on these licenses have been incurred. Some of our licenses, which generally extend for the life of any applicable patent, require us to pay royalties on sales of products that may be derived from or produced using the licensed technology. We derive rights to the patents, patent applications and know-how relating to Valortim<sup>®</sup> through our collaboration arrangement with BMS, which owns such rights. For additional information on our license agreements, please refer to Note 7—Commitments and Contingencies—License Agreements in the Notes to our Consolidated Financial Statements.

The expiration dates for the licenses described above are as follows:

| License      | Expiration Date   |
|--------------|---|
| DSTL Anthrax | No expiration specified   |
| Percivia     | No expiration specified   |
| BMS          | Two years after the earlier of the date that (a) the collaboration product is no longer exploited under the agreement or (b) Unilateral Product (as defined in our collaboration agreement with BMS) is no longer exploited under a unilateral development and commercialization agreement. |

We currently own no material trademarks.

We rely upon certain proprietary trade secrets, know-how and continuing technological advances to develop a competitive position. In efforts to maintain confidentiality and ownership of trade secrets, proprietary information and developments, all of our employees are required to execute agreements regarding confidentiality and assigning to us all rights to any inventions and processes they develop while they are employed by us.

We intend to use license agreements to access external products and technologies, as well as to convey our own intellectual property to others. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

## **Competition**

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. A large number of companies of all sizes engage in activities similar to our activities and many of our competitors have substantially greater financial and other resources available to them.

### ***Anthrax Product Competition***

With respect to the development of a recombinant PA-based vaccine, we are aware of three other companies developing competing vaccines that are in the clinical stage of development: Emergent BioSolutions, Inc., which is the sole supplier to the U.S. government of the only currently FDA-licensed anthrax vaccine - BioThrax<sup>®</sup> Anthrax Vaccine Adsorbed, Green Cross, and Panacea Biotec Ltd. There are a number of companies with anthrax vaccines in preclinical development including Bavarian Nordic, Dynavax, IBio, Immunovaccine, PaxVax, Vaxin, and Pfenex and there may be other companies developing competing vaccines that we are not aware of.

Monoclonal antibodies (“MAbs”) directed against PA are being developed for post-exposure prophylaxis and as symptomatic therapy for anthrax infection. There are a limited number of companies we are aware of with anti-anthrax MAbs and/or polyclonal antibodies in development, including: Cangene Corporation, GlaxoSmithKline plc., Elusys Therapeutics, Inc., Emergent BioSolutions, Inc., and IQ Corporation BV.

There are a number of orally available small molecule and other drugs approved and/or under development for the treatment of anthrax. These include broad spectrum antibiotics as well as anthrax specific products. Bayer AG produces ciprofloxacin, or Cipro<sup>®</sup>, which has been approved for the post-exposure prophylaxis of inhalational anthrax. In late 2004, generic versions of Cipro<sup>®</sup> were also approved by the FDA. In addition, levofloxacin, an antibiotic marketed in the United States by Ortho-McNeil Pharmaceuticals, and the generic antibiotic, doxycycline, are both approved for post-exposure prophylaxis of inhalational anthrax. There may be other companies developing competing therapies that we are not aware of.

### ***Nerve Agent Product Competition***

We are aware of antidotes to nerve agents being developed by pharmaceutical companies, including Countervail Corporation, Meridian Medical Technologies, a subsidiary of Pfizer, Inc., Protalix BioTherapeutics, Inc. and Dynport Vaccine Company, LLC, in collaboration with Baxter Healthcare Corporation.

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

For the foreseeable future, we believe our main customer will continue to be national governments, primarily the U.S. government. Substantially all of our revenues to date have been derived from grants and U.S. government contracts. There can be no assurances that existing government contracts will be renewed or that we can enter into new contracts or receive new grants to supply the U.S. or other governments with our products. The process of obtaining government contracts is lengthy and uncertain.

U.S. government contracts typically contain unilateral termination provisions for the government and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. These risks include the ability of the U.S. government unilaterally to:

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our contracts, including if funds become unavailable or are not provided to the applicable governmental agency;
- reduce the scope and value of our 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;
- claim rights to products, including intellectual property, developed under the contract;
- change certain terms and conditions in our contracts; and
- cancel outstanding RFP solicitations (as was the case with RFP-BARDA-08-15) or BAAs.

The U.S. government will be able to terminate any of its contracts with us 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.

## **Employees**

As of December 31, 2012, we employed 57 persons on a full-time basis, including 37 individuals engaged in research and development activities and 20 individuals engaged in general and administrative functions, such as human resources, finance, accounting, legal and investor relations. At that date, our staff included 13 employees with Ph.D. degrees. None of our employees are party to any collective bargaining agreement, and we believe that our relationship with our employees is good.

Information concerning our directors and executive officers can be found in Part III, Item 10 under the caption “Directors, Executive Officers and Corporate Governance.”

## **Financial Information by Geographic Area**

For the fiscal years ended December 31, 2012, 2011 and 2010 all revenues from external customers were attributed to United States customers. PharmAthene, Inc.’s country of domicile is the United States.

As of December 31, 2012, 2011 and 2010 all long-lived assets, with a net book value, were located in the United States. PharmAthene Canada’s long-lived assets were reclassified as assets held for sale as of December 31, 2010. Canadian long-lived assets had a net book value on January 1, 2010 of approximately \$5.9 million.

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

*Investing in our securities involves risks. In addition to the other information in this annual report on Form 10-K, stockholders and potential investors should carefully consider the risks described below relating to investment in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment.*

## **Risks Related to Our Financial Condition**

*We have a history of losses and negative cash flow, anticipate future losses and negative cash flow, and cannot provide assurances that we will achieve profitability.*

We have incurred significant losses since we commenced operations. We have accumulated losses of \$198.6 million since our inception, and have had net losses of approximately \$4.9 million, \$3.8 million, and \$34.8 million during the last three years, respectively. Our losses to date have resulted principally from research and development costs related to the development of our product candidates and general and administrative costs related to operations. Currently our development efforts are primarily focused on one product candidate, SparVax<sup>®</sup>. At December 31, 2012 we had cash on hand of approximately \$12.7 million.

We expect that we will incur substantial losses for the foreseeable future as a result of increases in our research and development costs, including costs associated with conducting preclinical testing, clinical trials and regulatory compliance activities. If we continue to incur losses and are not able to raise adequate funds to cover those losses, we may be required to curtail significantly our development and commercialization activities. This would have a material adverse effect on our business, financial condition and/or results of operations.

Our likelihood for achieving profitability will depend on numerous factors, including success in:

- prevailing in SIGA's appeal of the September 22, 2011 Delaware Court of Chancery opinion issued;
- the timing, amount and profitability of sales of Arestvyr<sup>™</sup> (including the timing of SIGA's recognition of revenue related thereto), and our ability to receive our allocable portion of "net profits" (as defined in the court's final judgment), if any;
- developing our existing products and developing and testing new product candidates;
- continuing to receive government funding and identifying new government funding opportunities;
- receiving regulatory approvals;
- carrying out our intellectual property strategy;
- establishing our competitive position;
- pursuing third-party collaborations;
- acquiring or in-licensing products; and
- manufacturing and marketing products.

Many of these factors will depend on circumstances beyond our control. We cannot guarantee that we will achieve sufficient revenues for profitability. Even if we do achieve profitability, we cannot guarantee that we can sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than we anticipate, or if operating expenses exceed our expectations or cannot be adjusted accordingly, then our business, results of operations, financial condition and cash flows will be materially and adversely affected. Because our strategy includes potential acquisitions of other businesses, acquisition expenses and any cash used to make these acquisitions will reduce our available cash.

At December 31, 2012, we have \$12.7 million of cash on hand, and \$11.7 million of total equity. While we believe we have sufficient resources to fund our operations at least through December 31, 2013, there can be no assurances that we will be able to do so without significantly curtailing our operations or raising additional debt and/or equity capital. In addition, we have several contingent liabilities and commitments that may require additional resources.



Under the terms of our agreements with Avecia, we are required to pay Avecia (now a subsidiary of Fujifilm) \$5 million within 90 days of entering into a multi-year funded development contract that was to be issued by BARDA under solicitation number RFP-BARDA-08-15 (or any substitution or replacement thereof) for the further development of SparVax<sup>®</sup>. RFP-BARDA-08-15 was cancelled by BARDA in December 2009. We have received funds from BARDA and other U.S. government agencies under various development agreements between us and BARDA. Any development contract deemed to be a substitute or replacement of RFP-BARDA-08-15 could trigger our obligation to make the \$5 million payment.

Global economic uncertainty continues to make capital markets more volatile and is threatening to once again tighten the credit markets. As a result, there can be no assurances that we would be successful in obtaining sufficient financing on commercially reasonable terms or at all. Our requirements for additional capital may be substantial and will be dependent on many factors, including the success of our research and development efforts, our ability to commercialize and market products, our ability to successfully pursue our licensing and collaboration strategy, the receipt of continued government funding, competing technological and marketing developments, costs associated with the protection of our intellectual property and any future change in our business strategy.

To the extent that we raise additional capital through the sale of securities, the issuance of those securities or shares underlying such securities would result in dilution that could be substantial to our stockholders. In addition, if we incur additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities.

If adequate funds are not available, we may be required to curtail significantly our development and commercialization activities. This would have a material adverse effect on our business, financial condition and/or results of operations.

*Our interest in Arestvyr<sup>™</sup> and related products is subject to the risk of an appeal of the judgment by SIGA and other risks.*

We may never receive any proceeds from our court-ordered financial interest in a portion of net profits related to SIGA's future sales of Arestvyr<sup>™</sup>.

In addition to the risks that ordinarily accompany the development and commercialization of biodefense products, including with respect to government contracting activities (including protests filed by third parties), competition (which with respect to Arestvyr<sup>™</sup> includes potential competing products being developed by Chimerix, Inc.), FDA and other regulatory approval and commercialization efforts, which are described elsewhere in these risk factors, our interest in future sales of SIGA's product Arestvyr<sup>™</sup> and related products is subject to additional risks, including, but not limited to the following.

We can provide no assurances that SIGA will not prevail on its appeal of the decision of the Chancery Court and that the Delaware Supreme Court will not overturn or modify the trial court's decision awarding us a 10 year 50% net profit interest in sales of Arestvyr<sup>™</sup> and related products or that sales of Arestvyr<sup>™</sup> (if any) in the future will result in our receiving any payments from SIGA. If the Delaware Supreme Court rules in favor of SIGA, our award can be modified, reduced or reversed completely. As a result, we may lose all of our rights, we may incur additional expense or our ability to recover any amounts could be delayed further.

In addition, SIGA's ability to deliver product to the SNS (and potential foreign government purchasers), and the timing and profitability thereof (including the timing of SIGA's recognition of revenue related thereto), is subject to a number of significant risks and uncertainties (certain of which are outlined in SIGA's filings with the SEC) as to which we have limited knowledge and no ability to control, mitigate or fully evaluate. We have no first-hand knowledge of, and SIGA has not publicly disclosed, any information related to the potential margins or profitability of Arestvyr<sup>™</sup> and related products.

## **Risks Related to Product Development and Commercialization**

*We have not commercialized any products or recognized any revenues from sales. SparVax<sup>®</sup> has been placed on clinical hold. All of our product candidates are still under development, and there can be no assurance of successful commercialization of any of our products.*

We have not commercialized any products or recognized any revenues from product sales. In general, our research and development programs are in development stages. There can be no assurances that one or more of our future product candidates will not fail to meet safety standards in human testing, even if those product candidates are found to be effective in animal studies. To develop and commercialize biodefense treatment and prophylactic product candidates, we must provide the FDA and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate adequate safety and effectiveness. To generate these data, we will have to subject our product candidates to significant additional research and development efforts, including extensive non-clinical studies and clinical testing. We cannot be sure that our approach to drug discovery will be effective or will result in the development of any drug. Currently our development efforts are primarily focused on one product candidate, SparVax<sup>®</sup>. Even if our product candidates are successful when tested in animals, such success would not be a guarantee of the safety or effectiveness of such product candidates in humans.

In August 2012 we received notification from the FDA that our SparVax<sup>®</sup> rPA anthrax vaccine program was placed on clinical hold. The FDA requested additional stability data and information related to the stability indicating assays. We have provided some supporting data and information to the FDA and commenced discussions with that agency as well as our customer, BARDA, regarding the clinical hold. We cannot be certain that the FDA will find our current data to be satisfactory and it is unclear at this point when or if we will be able to commence the planned Phase II human clinical trial with SparVax<sup>®</sup>. Consequently, revenues we recognize in future periods under our SparVax<sup>®</sup> contract will not include those related to this clinical trial until such time, if ever, as we are able to move forward with the clinical trial and overall SparVax<sup>®</sup> revenues until such time will be substantially less than they otherwise would have been had we commenced the clinical trial as planned. It is also unclear whether or to what extent the clinical hold will affect future government funding for our SparVax<sup>®</sup> program. The clinical hold has the effect of delaying the commercialization, if any, of SparVax<sup>®</sup> and we cannot offer any assurance that we will ever be able to continue or complete product development for SparVax<sup>®</sup>.

Research and development efforts in the biodefense industry are time-consuming and subject to delays. Even if we initially receive positive early-stage pre-clinical or clinical results, such results may not be indicative of results that could be anticipated in the later stages of drug development. Delays in obtaining results in our non-clinical studies and clinical testing can occur for a variety of reasons, such as slower than anticipated enrollment by volunteers in the trials, adverse events related to the products, failure to comply with Good Clinical Practices, unforeseen safety issues, unsatisfactory results in trials, perceived defects in the design of clinical trials, changes in regulatory policy as well as for reasons detailed in “—Necessary Reliance on the Animal Rule in Conducting Trials is Time-Consuming and Expensive.”

Any delay or adverse clinical event arising during any of our clinical trials could force us to conduct additional clinical trials in order to obtain approval from the FDA and other regulatory bodies. Our development costs will increase substantially if we experience material delays in any clinical trials or if we need to conduct more or larger trials than planned.

If delays are significant, or if any of our products do not prove to be safe, pure, and potent (including efficacy) or do not receive required regulatory approvals, we may have to abandon the product altogether and will be unable to recognize revenues from the sale of that product. In addition, our collaborative partners may not be able to conduct clinical testing or obtain necessary approvals from the FDA or other regulatory authorities for any product candidates jointly developed by us and our partners. If we fail to obtain required governmental approvals, we and our collaborative partners will experience delays in, or be precluded from, marketing products developed through them or, as applicable, their research.

*If we cannot maintain successful licensing arrangements and collaborations, enter into new licensing arrangements and collaborations, or effectively accomplish strategic acquisitions, our ability to develop and commercialize a diverse product portfolio could be limited and our ability to compete may be harmed.*

A key component of our business strategy is the in-licensing of compounds and products developed by other pharmaceutical and biotechnology companies or academic research laboratories. In addition, we have entered into licensing and research and development agreements with a number of other parties and collaborators. There can be no assurances that the research and development conducted pursuant to these agreements will result in revenue generating product candidates. If our suppliers, vendors, licensors, or other collaboration partners experience financial difficulties as a result of the weak economy, change in strategic direction (like the decision of our main CRO vendor on our rBChE program to suddenly cease its research and development operations), or if they are acquired as part of the current wave of consolidations in the pharmaceutical industry (such as, for example, with the acquisitions of Medarex by Bristol-Myers Squibb and Diosynth Biotechnologies, Inc.'s parent company by Merck & Co., Inc. in 2009 and of Avecia's CMO subsidiary (Avecia Biologics) by Merck in 2010 and the subsequent acquisition of these two entities by Fujifilm in 2011), their priorities or our working relationship with them might change. As a result, they might shift resources away from the research, development and/or manufacturing efforts intended to benefit our products, which could lead to significant delays in our development programs and potential future sales. Our current licensing, research and development, and supply agreements may expire and may not be renewable or could be terminated if we do not meet our obligations.

If we are not able to identify new licensing opportunities or enter into other licensing arrangements on acceptable terms, we may be unable to develop a diverse portfolio of products. For our future collaboration efforts to be successful, we must first identify partners whose capabilities complement and integrate well with ours. We face, and will continue to face, significant competition in seeking appropriate collaborators. Collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other similar arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us. Furthermore, technologies to which we gain access may prove ineffective, become obsolete, or unsafe or our partners may prove difficult to work with or less skilled than we originally expected. In addition, any past collaborative successes are no indication of potential future success.

*If we cannot effectively accomplish strategic acquisitions, our ability to develop and commercialize a diverse product portfolio could be limited and our ability to compete may be harmed.*

We may pursue strategic acquisitions to further our development and commercialization efforts, which could result in our incurring significant out of pocket costs as well as expending management time and those of other employees. To achieve the anticipated benefits of an acquisition, we must integrate the acquired company's business, technology and employees in an efficient and effective manner. The successful combination of companies in a rapidly changing biodefense industry may be more difficult to accomplish than in other industries. The combination of two companies requires, among other things, integration of the companies' respective technologies and research and development efforts. We cannot assure you that any integration will be accomplished smoothly or successfully. The difficulties of integration are increased by the need to coordinate geographically separated organizations and address possible differences in corporate cultures and management philosophies. The integration of certain operations will require the dedication of management resources that may temporarily distract attention from the day-to-day operations of the combined companies. The business of the combined companies may also be disrupted by employee retention uncertainty and lack of focus during integration. The inability of management to integrate successfully the operations of the two companies, in particular, to integrate and retain key scientific personnel, or the inability to integrate successfully two technology platforms, could have a material adverse effect on our business, results of operations and financial condition.

*Necessary Reliance on the Animal Rule in Conducting Trials is Time-Consuming and Expensive.*

As further described above under "Business—U.S. Government Regulatory Pathway—General", to obtain FDA approval for our biological warfare defense products under current FDA regulations, we are required to utilize animal model studies for efficacy and provide animal and human safety data under the "Animal Rule." For many of the biological and chemical threats, animal models are not yet available, and as such we are developing, or will have to develop, appropriate animal models, which is a time-consuming and expensive research effort. Further, we may

not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these corollaries are difficult to establish and are often unclear. The FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. 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 U.S. and internationally have the capability to test animals with anthrax, nerve agents, or other lethal biotoxins or chemical agents or otherwise assist us in qualifying the requisite animal models. We have to 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 the testing in a predictable timeframe or at all.

*Even if we succeed in commercializing our product candidates, they may not become profitable and manufacturing problems or side effects discovered at later stages can further increase costs of commercialization.*

We cannot assure you that any drugs resulting from our research and development efforts will become commercially available. Even if we succeed in developing and commercializing our product candidates, we may never generate sufficient or sustainable revenues to enable us to be profitable. Even if effective, a product that reaches market may be subject to additional clinical trials, changes to or re-approvals of our manufacturing facilities or a change in labeling if we or others identify side effects or manufacturing problems after a product is on the market. This could harm sales of the affected products and could increase the cost and expenses of commercializing and marketing them. It could also lead to the suspension or revocation of regulatory approval for the products.

We and our CMOs will also be required to comply with the applicable FDA current Good Manufacturing Practice, or cGMP, regulations. These regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved to supply licensed products to the commercial marketplace. We and our contract manufacturers may not be able to comply with the applicable cGMP requirements and other FDA regulatory requirements. Should we or our contract manufacturers fail to comply, we could be subject to fines or other sanctions or could be precluded from marketing our products.

*We may become subject to product liability claims, which could reduce demand for our product candidates or result in damages that exceed our insurance coverage.*

We face an inherent risk of exposure to product liability suits in connection with our product candidates being tested in human clinical trials or sold commercially. We may become subject to a product liability suit if any product we develop causes injury, or if treated individuals subsequently become infected or suffer adverse effects from our products. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to our reputation, withdrawal of clinical trial volunteers, and loss of revenues.

In addition, if a product liability claim is brought against us, the cost of defending the claim could be significant and any adverse determination may result in liabilities in excess of our insurance coverage. Although our anthrax countermeasures are covered under the general immunity provisions of the U.S. Public Readiness and Emergency Preparedness Act (the “Public Readiness Act”), there can be no assurance that the U.S. Secretary of Health and Human Services 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. For further discussion of that act, see “—Legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and we cannot be certain that any such protection will apply to our products or if applied what the scope of any such coverage will be.” Additionally, we are considering applying for indemnification under the U.S. Support Anti-terrorism by Fostering Effective Technologies (SAFETY) Act of 2002 which preempts and modifies tort laws so as to 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 or adequate insurance coverage on acceptable terms, if at all.

## **Risks Related to Our Dependence on U.S. Government Contracts**

*All of our immediately foreseeable future revenues are contingent upon grants and contracts from the U.S. government and we may not achieve sufficient revenues from these agreements to attain profitability.*

For the foreseeable future, we believe our main customer will be national governments, primarily the U.S. government. Substantially all of our revenues to date have been derived from grants and U.S. government contracts. There can be no assurances that existing government contracts will be renewed or that we can enter into new contracts or receive new grants to supply the U.S. or other governments with our products. The process of obtaining government contracts is lengthy and uncertain.

If the U.S. government makes significant contract awards to our competitors, rather than to us, for the supply to the U.S. emergency stockpile, our business will be harmed and it is unlikely that we will ultimately be able to supply that particular treatment or product 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 products we are developing. For example, while RFP-BARDA-08-15 for an rPA-based anthrax vaccine for the SNS initially indicated that the government would make an award by September 26, 2008, the award was delayed multiple times and ultimately canceled in December 2009.

Funding is subject to Congressional appropriations generally made on an annual basis even for multi-year contracts. More generally, due to the ongoing economic 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 us. Future funding levels for two of our key government customers, BARDA and DoD, for the advanced development and procurement of medical countermeasures are uncertain, and may be subject to budget cuts as the U.S. Congress and the President look to reduce the nation's budget deficit.

For example, due to DoD budget constraints and concerns about potential duration of protection with the current route of Protexia<sup>®</sup> administration, the DoD did not extend our September 2006 contract for Protexia<sup>®</sup>, which contract expired on December 31, 2010. As a result of DoD's decision not to continue funding Protexia<sup>®</sup> development, we closed down our Protexia<sup>®</sup>-related operations. We incurred wind-down costs in the fourth quarter of 2010 and approximately \$0.5 million in 2011, for which we did not get reimbursed by the government. We also wrote down the net book value of our Protexia<sup>®</sup> related assets recognizing approximately \$4.6 million of impairment charges for the year ended December 31, 2010.

The U.S. government deficit and budget crisis has created increasing pressure to reduce government spending. In August 2011, President Obama signed into law the Budget Control Act of 2011 (the "Budget Control Act"), which increased the U.S. government's debt ceiling and enacted 10-year discretionary spending caps expected to generate substantial savings for the U.S. government. The Budget Control Act also established a joint bipartisan committee of Congress responsible for identifying at least \$1.2 trillion in additional savings by November 2011. The joint committee did not meet the deadline for proposing recommended legislation and Congress missed a related deadline in January 2013. Under the Budget Control Act, additional automatic spending cuts (referred to as "sequestration") totaling \$1.2 trillion (subsequently adjusted downward to approximately \$1.0 trillion) over nine years would be triggered. These discretionary spending cuts are expected to be evenly split between defense and non-defense areas.

On March 1, 2013, the sequestration became effective and the law required the President to issue a sequestration order cancelling \$85 billion in budgetary resources across the federal government for the government fiscal year, which ends on September 30, 2013. The Office of Management and Budget calculated that, over the course of the government fiscal year, the sequestration requires a 7.8 percent reduction in non-exempt defense discretionary spending and a 5.0 percent reduction in non-exempt nondefense discretionary spending. The sequestration also requires reductions of 2.0 percent to Medicare, 5.1 percent to other non-exempt nondefense mandatory programs, and 7.9 percent to non-exempt defense mandatory programs. Because these cuts must be achieved over only 7 months instead of 12, the effective percentage reductions will be approximately 13 percent for non-exempt defense programs and 9 percent for non-exempt nondefense programs.

At the end of calendar year 2012, of the total \$5.6 billion allotted under Project BioShield in 2004, over \$2.5 billion in procurement contracts had been awarded and approximately \$2.0 billion had been transferred out of the Project BioShield Special Reserve fund (“SRF”) for non-procurement related activities. Remaining funds in the SRF are now approximately \$1.0 billion. Currently, the government is operating under a continuing resolution at the fiscal year 2012 level. As \$415 million was the level of funding for BARDA in fiscal year 2012, a portion of that amount is being transferred from the SRF to cover fiscal year 2013 expenses. The continuing resolution expires on March 27, 2013. It is unclear at this time how Congress will choose to move forward with funding the government for the remainder of fiscal year 2013. The amount and nature of federal budget spending reductions in general could severely limit our ability to maintain, renew or enter into new contracts and therefore materially adversely impact our business.

Further, at times BARDA has expressed concerns regarding our past performance under our SparVax<sup>®</sup> development contract, and if we are unable to perform adequately under this contract, we may be at increased risk that BARDA will curtail our activities under, or terminate, that contract. As of December 31, 2012, approximately \$28 million remains available under base contract funding.

Our current development contract for Valortim<sup>®</sup> with NIAID expired January 31, 2012. There can be no assurance we will be successful in obtaining additional financial support for this program.

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

U.S. government contracts 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 us to additional risks. These risks include the ability of the U.S. government unilaterally to:

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our contracts, including if funds become unavailable or are not provided to the applicable governmental agency;
- reduce the scope and value of our 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;
- claim rights to products, including intellectual property, developed under the contract;
- change certain terms and conditions in our contracts; and
- cancel outstanding RFP solicitations (as was the case with RFP-BARDA-08-15) or BAAs.

The U.S. government will be able to terminate any of its contracts with us 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 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, the likelihood that the government will exercise its right to extend any of its existing contracts with us and/or the likelihood that the government would procure products from us.

*The U.S. government's determination to award any contracts may be challenged by an interested party, such as another bidder, at 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. If we are awarded a government contract, such challenges or protests could be filed 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.

For example, in March 2010, a third-party filed a bid protest with the GAO challenging the February 2010 decision of the DHHS to modify its existing research and development contract with us for the development of SparVax<sup>®</sup>. In March 2010 DHHS suspended performance under the modification pursuant to the automatic stay provisions of the FAR, pending a decision by the GAO on the protest. While the bid protest was ultimately denied, and the related DHHS "stop work" order canceled in June 2010, the protest contributed to a reduction in revenues and cash and cash equivalents over the period that work could not be performed under the modification. In addition, we incurred unexpected general and administrative expenses to intervene in the protest. In October 2010 a losing bidder filed a successful protest with the small business administration claiming that SIGA did not qualify as a small business entitled to a contract award under RFP-BARDA-09-35 for a smallpox antiviral. When the government subsequently issued a contract to SIGA in May 2011 without the small business requirement, this same losing bidder filed a second protest, this time with the GAO. While this protest was withdrawn, in exchange for dropping the protest, the government agreed to remove an option from the contract permitting the government to purchase up to 12 million additional courses of therapy of Arestvyr<sup>™</sup> beyond the base purchase of 1.7 million courses of therapy.

*Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.*

U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we 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, we could suffer serious reputational harm if allegations of impropriety were made against us.

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

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, or FAR, and agency-specific regulations supplemental to the Federal Acquisition Regulation, 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 False Claims Act and Foreign Corrupt Practices Act;
- 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 adversely affect our revenues and results of operations.

### **Risks Related to Dependence on or Competition From Third Parties**

*The amount of revenue, if any, we realize from our profit split interest in Arestvyr™ and related products is among other things, dependent on SIGA's ability to finish development and deliver Arestvyr™ and related products to the U.S. and foreign governments.*

SIGA's ability to deliver product to the SNS (and potential foreign government purchasers), and the timing and profitability thereof (including the timing of SIGA's recognition of revenue related thereto), is subject to a number of significant risks and uncertainties (certain of which are outlined in SIGA's filings with the SEC) as to which we have limited knowledge and no ability to control, mitigate or fully evaluate along with many of the risks related to drug development and commercialization set forth elsewhere in this "Risk Factors" Section. We have no first-hand knowledge of, and SIGA has not publicly disclosed, any information related to the potential margins or profitability of Arestvyr™ and related products.

*Because we depend on clinical research centers and other contractors for clinical and non-clinical testing, including testing under the Animal Rule, and for certain research and development activities, the results of our clinical trial, non-clinical animal efficacy studies, and research and development activities are largely beyond our control.*

The nature of clinical trials and our business strategy of outsourcing substantially all of our research and development and manufacturing work require that we rely on clinical research centers and other contractors to assist us with research and development, clinical and non-clinical testing (including animal efficacy studies under the Animal Rule), patient enrollment, manufacturing and other activities. As a result, our success depends largely on the success of these third parties in performing their responsibilities. Although we prequalify our contractors and believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Furthermore, we have to compete with other biodefense and biopharmaceutical companies for access to this limited pool of highly specialized



resources. If our contractors do not perform their obligations in an adequate and timely manner or we are unable to enter into contracts with them because of prior commitments to our competitors, the pace of clinical or non-clinical development, regulatory approval and commercialization of our product candidates could be significantly delayed and our prospects could be adversely affected.

*We depend on third parties to manufacture, package and distribute compounds for our product candidates and key components for our product candidates. The failure of these third parties to provide their services or to perform them successfully could harm our business.*

We do not have any of our own manufacturing facilities. We have therefore utilized, and intend to continue utilizing, third parties to manufacture, package and distribute our product candidates and key components of our product candidates. Any material disruption in manufacturing (i.e. due to third party capacity or availability limitations) could cause a delay in our development programs and potential future sales. Furthermore, certain compounds, media, or other raw materials used to manufacture our drug candidates are available from any one or a limited number of sources. Any delays or difficulties in obtaining key components for our product candidates or in manufacturing, packaging or distributing our product candidates could delay clinical trials and further development of these potential products. Additionally, the third parties we rely on for manufacturing and packaging are subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities.

Finally, third-party manufacturers, suppliers and distributors, like most companies, have been adversely affected by the credit crisis and weakening of the global economy and as such may be more susceptible to being acquired as part of the current wave of consolidations in the pharmaceutical industry. It has, for example, become challenging for companies to secure debt capital to fund their operations as financial institutions have significantly curtailed their lending activities. If our third-party suppliers continue to experience financial difficulties as a result of weak demand for their products or for other reasons and are unable to obtain the capital necessary to continue their present level of operations or are acquired by others, they may have to reduce their activities and/or their priorities or our working relationship with them might change. A material deterioration in their ability or willingness to meet their obligations to us could cause a delay in our development programs and potential future sales and jeopardize our ability to meet our obligations under our contracts with the government or other third parties.

*We face, and likely will continue to face, competition from companies with greater financial, personnel and research and development resources. Our commercial opportunities will be reduced or eliminated if our competitors are more successful in the development and marketing of their products.*

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. There are many organizations, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these organizations have substantially greater financial, technical, intellectual property, research and development, and human resources than we have. Competitors may develop products or other technologies that are more effective than any that we are developing or may obtain FDA approval for products more rapidly. For example, the U.S. government selected a plague vaccine product candidate from a competitor for advanced development funding, causing us to wind down activities related to the development of our RypVax™ product candidate in 2010.

If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have limited experience. Many of these organizations also have manufacturing facilities and established marketing capabilities that would enable such companies to market competing products through existing channels of distribution. Our commercial opportunities will be reduced or eliminated if our competitors develop and market products that:

- are more effective;

- have fewer or less severe adverse side effects;
- are more adaptable to various modes of dosing;
- obtain orphan drug exclusivity that blocks the approval of our application for seven years;
- are easier to administer; or
- are less expensive than the products or product candidates that we are, or in the future will be, developing.

While the regulatory climate for generic versions of biological products approved under a Biologics License Application (or a BLA) in the United States remains uncertain, and currently there is no formalized mechanism by which the FDA can approve a generic version of an approved biological product, Federal legislation has been introduced to establish a legal pathway for the approval of generic versions of approved biological products. If enacted, the legislation may impact the revenue projections for our products.

Even if we are successful in developing effective products, and obtain FDA and other regulatory approvals necessary for commercializing them, our products may not compete effectively with other successful products. Our competitors may succeed in developing and marketing products either that are more effective than those that we may develop, alone or with our collaborators, making our products obsolete, or that are marketed before any products that we develop are marketed.

#### **Risks Related to Political and Social Factors**

*Political or social factors may delay or impair our ability to market our products and our business may be materially adversely affected.*

Products developed to treat diseases caused by, or to combat the threat of, bioterrorism will be subject to changing political and social environments. The political and social responses to bioterrorism have been unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business.

#### **Risks Related to Intellectual Property**

*Our commercial success will be affected significantly by our ability (i) to obtain and maintain protection for our proprietary technology and that of our licensors and collaborators and (ii) not to infringe on patents and proprietary rights of third parties.*

Issues surrounding patents of biotechnology firms often involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. We currently have five pending U.S. patent applications, and have a limited number of foreign patents and pending international and foreign patents applications. In addition, we have rights under numerous other patents and patent applications pursuant to exclusive and non-exclusive license arrangements with licensors and collaborators. However, there can be no assurance that patent applications owned or licensed by us will result in patents being issued or that the patents, whether existing or issued in the future, will afford protection against competitors with similar technology. Any conflicts resulting from third-party patent applications and patents could significantly reduce the coverage of the patents owned, optioned by or licensed to us or our collaborators and limit our ability or that of our collaborators to obtain meaningful patent protection.

Further, our commercial success will depend significantly on our ability to operate without infringing the patents and proprietary rights of third parties. We are aware of one U.S. patent covering recombinant production of an antibody and a license may be required under such patent with respect to Valortim<sup>®</sup>, which is a monoclonal antibody and uses recombinant production technologies. Although the patent owner has granted licenses under such patent, we cannot provide any assurances that we will be able to obtain such a license or that the terms thereof will be reasonable. If we do not obtain such a license and if a legal action based on such patent was to be brought against us

or our distributors, licensees or collaborators, we cannot provide any assurances that we or our distributors, licensees or collaborators would prevail or that we have sufficient funds or resources to defend such claims.

The costs associated with establishing the validity of patents, of defending against patent infringement claims of others and of asserting infringement claims against others is expensive and time consuming, even if the ultimate outcome is favorable. An outcome of any patent prosecution or litigation that is unfavorable to us or one of our licensors or collaborators may have a material adverse effect on us. The expense of a protracted infringement suit, even if ultimately favorable, would also have a material adverse effect on us.

We furthermore rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information; however, these measures may not provide adequate protection to us. We have sought to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

### **Risks Related to Regulatory Approvals and Legislation**

*Our use of hazardous materials and chemicals requires us to comply with regulatory requirements which may result in significant costs and expose us to potential liabilities.*

Our research and development involves the controlled use of hazardous materials and chemicals. We are subject to federal, state, local and foreign laws governing the use, manufacture, storage, handling and disposal of such materials. We will not be able to eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be forced to pay significant damages or fines, and these damages could exceed our resources and any applicable insurance coverage. In addition, we may be required to incur significant costs to comply with regulatory requirements in the future.

*Legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and we cannot be certain that any such protection will apply to our products or if applied what the scope of any such coverage will be.*

The U.S. Public Readiness Act was signed into law in December 2005 and creates general immunity for manufacturers of countermeasures, including security countermeasures (as defined in Section 319F-2(c)(1)(B) of that act), when the U.S. Secretary of Health and Human Services 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 countermeasure. Manufacturers are excluded from this protection in cases of willful misconduct. Although our anthrax countermeasures have been covered under the general immunity provisions of the Public Readiness Act since October 1, 2008, there can be no assurance that the Secretary of Health and Human Services 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.

Upon a declaration by the Secretary of Health and Human Services, 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 only after they have exhausted their remedies under the compensation program. A willful misconduct action could be brought against us if an individual(s) has exhausted their remedies under the compensation program which thereby could expose us to liability. Furthermore, there is no assurance that the Secretary of Health and Human Services will issue under this act a declaration to establish a compensation fund. We may also become subject to standard product liability suits and other third party claims if products we develop which fall outside of the Public Readiness Act cause injury or if treated individuals subsequently become infected or otherwise suffer adverse effects from such products.

*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, or EAR, administered by the U.S. Department of Commerce and are, in certain instances (such as aspects of our nerve agent countermeasure product candidates) subject to the International Traffic in Arms Regulations, or 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. 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.

### **Risks Related to Personnel**

*We depend on our key technical and management personnel, and the loss of these personnel could impair the development of our products.*

We rely, and will continue to rely, on our key management and scientific staff, all of whom are employed at-will. The loss of key personnel or the failure to recruit necessary additional qualified personnel could have a material adverse effect on our business and results of operations. There is intense competition from other companies, research and academic institutions and other organizations for qualified personnel. We may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. If we do not succeed in retaining and recruiting necessary personnel or developing this expertise, our business could suffer significantly.

*Biotechnology companies often become subject to claims that they or their employees wrongfully used or disclosed alleged trade secrets of the employees' former employers. Such litigation could result in substantial costs and be a distraction to our management.*

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including at competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management.

### **Risks Related to Our Common Stock and Under our GE Loan Agreement**

*If we do not meet the continued listing standards of the NYSE MKT 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 NYSE MKT, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If, however, we fail to satisfy the continued listing standards, such as, for example, the requirement that our shares not trade “for a substantial period of time at a low price per share” or that we not dispose of our principal operating assets or discontinue a substantial portion of our operations, among other requirements, the NYSE MKT may issue another non-compliance letter or initiate delisting proceedings.

If our securities are delisted from trading on the NYSE MKT and we are not able to list our securities on another exchange or to have them quoted on NASDAQ, our securities could be quoted on the OTC Bulletin Board or on the “pink sheets.” 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).

*Our stock price is volatile.*

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

- our perceived prospects;
- variations in our operating results and whether we have achieved key business targets;
- changes in, or our failure to meet, revenue estimates;
- changes in securities analysts’ buy/sell recommendations;
- differences between our reported results and those expected by investors and securities analysts;
- announcements of new contracts by us or our competitors;
- reaction to any acquisitions, joint ventures or strategic investments announced by us or our competitors; and
- general economic, political or stock market conditions.

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

The issuance of our securities in the future may depress the market price of our stock, and any such financing(s) will dilute our existing shareholders.

In addition, as of December 31, 2012 we had outstanding options to purchase approximately 6.2 million shares of common stock (not including restricted shares). Additional shares are reserved for issuance under our 2007 Long-Term Incentive Compensation Plan. Our stock options are generally exercisable for ten years, with a significant portion exercisable either immediately or beginning one year after the date of the grant.

We filed two registration statements on Form S-3 (File No. 333-161587 and 333-176607) covering the resale of shares issued upon conversion of our 10% convertible notes and issuable upon exercise of related warrants by certain of our affiliates, among other security holders. Both registration statements have been declared effective. We are obligated under the terms of the related registration rights agreement to keep these registration statements effective. The sale by these security holders of their shares pursuant to the registration statement or otherwise could depress the market price of our common stock.

Finally, as of December 31, 2012, we had issued and outstanding additional warrants to purchase up to approximately 5.6 million shares of common stock.

The issuance or even the expected issuance of a large number of shares of our common stock upon 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 shareholders. 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 shareholders and depress the market price of our common stock.

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

We have not paid any dividends on our common stock in 2012, 2011, or 2010 and do not intend to declare any dividends in the foreseeable future. While subject to periodic review, our current policy is to retain all earnings, if any, primarily to finance our future growth. The current GE Loan Agreement specifically restricts the declaration or payment of any dividends. We make no assurances that we will ever pay 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.

*Our fully-secured loan agreement with GE Capital is subject to acceleration in specified circumstances, which may result in GE Capital taking possession and disposing of any collateral.*

In the first quarter 2012, we closed on a senior fully-secured debt facility with GE Capital providing for a \$2.5 million term loan and a revolving line of credit of up to \$5 million based on a percentage of our outstanding qualified accounts receivable. The Company's obligations under the loan and security agreement with GE Capital ("Loan Agreement") are secured by a security interest in substantially all of the Company's assets. While the security interest does not, except in limited circumstances, cover the Company's intellectual property, it does cover any proceeds to the Company from the use of intellectual property. The Loan Agreement contains customary representations, warranties and covenants, including limitations on acquisitions, dispositions, incurrence of indebtedness and the granting of security interests. Upon the occurrence and during the continuance of any event of default, GE Capital may, and at the written request of the requisite lenders shall, terminate the commitments under the facilities and declare any or all of the obligations to be immediately due and payable, without demand or notice to the Company. However, any event of default relating to timely payment of debts, insolvency, liquidation, bankruptcy or similar events will result in automatic acceleration. Among the remedies available to GE Capital in case of an event of default are the taking possession and disposition of any collateral under the Loan Agreement.

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

Not applicable.

**Item 2. Properties.**

Our principal executive offices are located at One Park Place, Annapolis, MD 21401 and are comprised of approximately 21,900 square feet. The lease expires in 2017. We have also leased approximately 2,300 square feet of office space in Durham, North Carolina. This lease expires on September 30, 2013.

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

**Item 3. Legal Proceedings.**

Except as noted below, we are not a defendant in any legal proceedings.

In December 2006, we filed a complaint against SIGA in the Delaware Court of Chancery. The complaint alleges, among other things, that we have the right to license exclusively development and marketing rights for SIGA's drug candidate, Arestvyr™, pursuant to a merger agreement between the parties that was terminated in October 2006. The complaint also alleges that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement.

In September 2011, the Delaware Court of Chancery issued an opinion in the case finding that SIGA had breached certain contractual obligations to us and upholding our claims of promissory estoppel. The Court awarded us the right to receive 50% of all net profits (as defined in the court's final judgment) related to the sale of Arestvyr™ and related products for 10 years following initial commercial sale of the drug once SIGA earns \$40 million in net profits from the sale of Arestvyr™ and related products. The Court also awarded us one-third of our reasonable attorney's fees and expert witness fees, which amounts to approximately \$2.4 million plus interest. In May 2012, the Delaware Court of Chancery issued its final judgment. SIGA has appealed aspects of the decision to the Delaware Supreme Court. In response, we have cross-appealed other aspects of the decision. The Delaware Supreme Court heard oral argument in the case in January 2013.

We can provide no assurances that SIGA will not prevail on its appeal, that we will be successful in our appeal, or that the Delaware Supreme Court will not overturn or modify the trial court's decision.

One of our vendors mishandled the storage of certain biological materials. While we have recently been engaged in discussions with the vendor to address our concerns, so far we have not come to agreement. The vendor recently filed suit against us in Delaware state court seeking a declaration that they are not liable for damages and seeking damages from us for allegedly not maintaining the required amount and type of insurance. We filed suit against the vendor in Maryland state court seeking damages related to the loss of the property. We believe we did maintain the appropriate amount and type of insurance, that in no event did we harm the vendor, and thus their damages claim is without merit. We plan to vigorously defend against their claims while pursuing our own.

**Item 4. Mine Safety Disclosures**

Not applicable.

**PART II**

**Item 5. Market for Registrant's Common Equity and Related Stockholder Matters**

**Market**

Our common stock trades on the NYSE MKT (formerly NYSE Amex) under the symbol "PIP". The following table sets forth the range of high and low sales prices per share of our common stock on the NYSE MKT for the past two years during the fiscal periods shown.

| <b>Fiscal Year 2012</b>        | <b>High</b> | <b>Low</b> |
|--------------------------------|-------------|------------|
| 4th Quarter Ended December 31  | \$ 1.47     | \$ .98     |
| 3rd Quarter Ended September 30 | \$ 1.70     | \$ 1.13    |
| 2nd Quarter Ended June 30      | \$ 1.89     | \$ 1.18    |
| 1st Quarter Ended March 31     | \$ 2.10     | \$ 1.20    |
| <b>Fiscal Year 2011</b>        | <b>High</b> | <b>Low</b> |
| 4th Quarter Ended December 31  | \$ 1.88     | \$ 1.07    |
| 3rd Quarter Ended September 30 | \$ 3.35     | \$ 1.74    |
| 2nd Quarter Ended June 30      | \$ 4.08     | \$ 2.41    |
| 1st Quarter Ended March 31     | \$ 4.58     | \$ 3.01    |

## Holders

As of February 28, 2013 in accordance with our transfer agent records, we had 72 record holders of our common stock. The number of record holders is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in “street name” or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

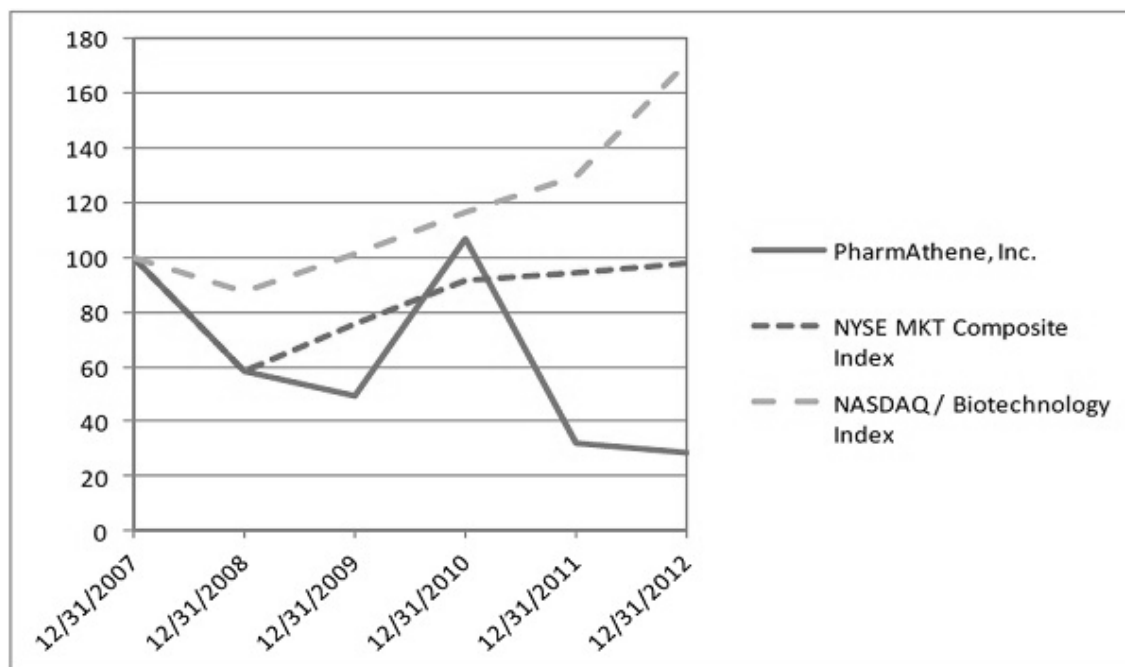
## Dividends

We have not paid any dividends on our common stock in 2012 and 2011 and do not intend to declare any dividends in the foreseeable future. While subject to periodic review, the current policy of our Board of Directors is to retain all earnings, if any, primarily to finance our future growth. The GE Loan Agreement entered into in March 2012 specifically restricts the declaration or payment of any dividends. We make no assurances that we will ever pay 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 the Board of Directors will consider.

## Performance Graph

The following line graph compares the cumulative total stockholder return through December 31, 2012, assuming reinvestment of dividends, by an investor who invested \$100 on December 31, 2007 in each of (i) our common stock, (ii) the NYSE MKT Composite Index; and (iii) the Nasdaq Biotech Composite Index.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*  
Among PharmAthene, Inc., NYSE MKT Composite Index, and the NASDAQ Biotechnology Index



\* \$100 invested on 12/31/2007 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.



|                                | December 31, |          |           |           |           |           |
|--------------------------------|--------------|----------|-----------|-----------|-----------|-----------|
|                                | 2007         | 2008     | 2009      | 2010      | 2011      | 2012      |
| PharmAthene, Inc.              | \$ 100       | \$ 58.23 | \$ 49.62  | \$ 107.09 | \$ 32.15  | \$ 28.35  |
| NYSE MKT Composite Index       | \$ 100       | \$ 58.00 | \$ 75.74  | \$ 91.65  | \$ 94.55  | \$ 97.76  |
| NASDAQ Biotech Composite Index | \$ 100       | \$ 87.37 | \$ 101.03 | \$ 116.19 | \$ 129.91 | \$ 171.36 |

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

### **Securities Authorized for Issuance Under Equity Compensation Plans**

The information required by this Item concerning securities authorized for issuance under equity compensation plans is set forth in Item 12, “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters,” which Item is incorporated herein by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

### **Recent Sales of Unregistered Securities**

None.

### **Use of Proceeds**

Not applicable.

### **Purchases of Equity Securities**

Not applicable.

### **Item 6. Selected Financial Data**

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

We have derived the consolidated statement of operations data for the years ended December 31, 2012, 2011, and 2010 and the consolidated balance sheet data as of December 31, 2012 and 2011 from our audited consolidated financial statements, which are included in this annual report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2009 and 2008 and the consolidated balance sheet data as of December 31, 2010, 2009 and 2008 from our audited consolidated financial statements, which are not included in this annual report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

**Selected Financial Data**

|   | <b>Year Ended December 31,</b> |                             |                              |                              |                              |
|---|--------------------------------|-----------------------------|------------------------------|------------------------------|------------------------------|
|   | <b>2012</b>                    | <b>2011</b>                 | <b>2010</b>                  | <b>2009</b>                  | <b>2008</b>                  |
| Statements of operations data:  |                                |                             |                              |                              |                              |
| Revenue   | \$ 25,175,887                  | \$ 24,266,274               | \$ 20,993,605                | \$ 27,549,978                | \$ 34,179,363                |
| Operating expenses:   |                                |                             |                              |                              |                              |
| Research and development  | 19,509,629                     | 21,219,853                  | 20,875,536                   | 30,219,758                   | 31,812,431                   |
| General and administrative  | 11,628,732                     | 14,311,079                  | 18,015,761                   | 22,432,585                   | 19,397,532                   |
| Acquired in-process research and development  | -                              | -                           | -                            | -                            | 16,131,002                   |
| Depreciation and amortization (including \$4,635,489 impairment charges in 2010)    | 303,916                        | 461,073                     | 5,655,865                    | 872,304                      | 813,891                      |
| Total operating expenses  | <u>31,442,277</u>              | <u>35,992,005</u>           | <u>44,547,162</u>            | <u>53,524,647</u>            | <u>68,154,856</u>            |
| Loss from operations  | (6,266,390)                    | (11,725,731)                | (23,553,557)                 | (25,974,669)                 | (33,975,493)                 |
| Other income (expense):   |                                |                             |                              |                              |                              |
| Interest income   | 17,808                         | 16,660                      | 6,955                        | 269,133                      | 1,225,471                    |
| Interest expense  | (342,561)                      | (54,573)                    | (5,936,480)                  | (2,837,302)                  | (2,573,406)                  |
| Change in fair value of derivative instruments                                      | 591,039                        | 7,144,983                   | (5,457,550)                  | 1,043,782                    | 118,244                      |
| Other income (expense)  | 47,862                         | 39,328                      | 91,355                       | (90,655)                     | 58,106                       |
| Realization of cumulative translation adjustment                                    | 1,227,656                      | -                           | -                            | -                            | -                            |
| Gain on the sale of assets held for sale  | -                              | 781,760                     | -                            | -                            | -                            |
| Loss on the early extinguishment of debt  | -                              | -                           | -                            | (4,690,049)                  | -                            |
| Total other income (expense)  | <u>1,541,804</u>               | <u>7,928,158</u>            | <u>(11,295,720)</u>          | <u>(6,305,091)</u>           | <u>(1,171,585)</u>           |
| Net loss before income taxes  | (4,724,586)                    | (3,797,573)                 | (34,849,277)                 | (32,279,760)                 | (35,147,078)                 |
| Provision for income taxes  | (195,529)                      | -                           | -                            | -                            | -                            |
| Net loss  | <u><u>\$(4,920,115)</u></u>    | <u><u>\$(3,797,573)</u></u> | <u><u>\$(34,849,277)</u></u> | <u><u>\$(32,279,760)</u></u> | <u><u>\$(35,147,078)</u></u> |
| Basic and diluted net loss per share  | \$ (0.10)                      | \$ (0.08)                   | \$ (1.08)                    | \$ (1.17)                    | \$ (1.53)                    |
| Weighted average shares used in calculation of basic and diluted net loss per share | 48,323,067                     | 47,331,763                  | 32,309,621                   | 27,575,332                   | 22,944,066                   |

|                             | <b>As of December 31,</b> |               |               |              |               |
|-----------------------------|---------------------------|---------------|---------------|--------------|---------------|
|                             | <b>2012</b>               | <b>2011</b>   | <b>2010</b>   | <b>2009</b>  | <b>2008</b>   |
| Balance Sheet Data:         |                           |               |               |              |               |
| Cash and cash equivalents   | \$ 12,701,517             | \$ 11,236,771 | \$ 11,785,327 | \$ 2,673,567 | \$ 19,752,404 |
| Working capital             | 12,307,429                | 14,997,664    | 17,420,242    | 12,018,438   | 11,536,932    |
| Total assets                | 22,741,404                | 22,803,509    | 27,199,045    | 35,333,049   | 57,659,305    |
| Total long-term liabilities | 3,579,148                 | 2,336,361     | 8,824,853     | 18,714,430   | 1,554,698     |
| Total stockholders' equity  | 11,673,840                | 15,851,806    | 12,210,705    | 3,152,399    | 20,231,474    |

## **Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion should be read in conjunction with our consolidated financial statements, which present our results of operations for the years ended December 31, 2012 and 2011 as well as our financial positions at December 31, 2011 and 2010, contained elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the “Special Note Regarding Forward Looking Statements” and “Risk Factors” sections of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### **Overview**

We are a biodefense company engaged in the development and commercialization of next generation medical countermeasures against biological and chemical threats. Our current biodefense portfolio includes the following product candidates:

- SparVax<sup>®</sup>, a next generation recombinant protective antigen (“rPA”) anthrax vaccine,
- rBChE (recombinant butyrylcholinesterase) bioscavanger, a medical countermeasure for nerve agent poisoning by organophosphorous compounds, including nerve gases and pesticides, and
- Valortim<sup>®</sup>, a fully human monoclonal antibody for the prevention and treatment of anthrax infection.

In addition, we were awarded by the Delaware Court of Chancery in September 2011 the right to receive 50% of all net profits (as defined in the court’s final judgment) related to the sale of SIGA Technologies, Inc.’s (“SIGA”) Arestvyr<sup>™</sup> and related products for 10 years following initial commercial sale of the drug once SIGA earns \$40 million in net profits from sales of Arestvyr<sup>™</sup> and related products. In May 2012, the Court issued its final judgment. SIGA has appealed aspects of the decision to the Delaware Supreme Court. In response, we have cross-appealed other aspects of the decision. In January 2013, the Delaware Supreme Court heard oral argument in the case.

We can provide no assurances that SIGA will not prevail on its appeal, that we will be successful in our appeal, or that the Delaware Supreme Court will not overturn the trial court’s decision. If the Delaware Supreme Court rules in favor of SIGA, our award can be modified, reduced or reversed completely. As a result, we may lose all of our rights, we may incur additional expense or our ability to recover any amounts could be delayed further.

### **Critical Accounting Policies**

A summary of our critical accounting policies, including those that require the use of significant estimates and judgment, follows. A more comprehensive description of all of our significant accounting policies is contained in Note 2 to our consolidated financial statements.

### **Revenue Recognition**

We generate our revenue from different types of contractual arrangements: cost-plus-fee contracts, cost reimbursable grants and fixed price contracts.

Revenues on cost-plus-fee contracts are recognized in an amount equal to the costs incurred during the period plus an estimate of the applicable fee earned. The estimate of the applicable fee earned is determined by reference to the contract: if the contract defines the fee in terms of risk-based milestones and specifies the fees to be earned upon the completion of each milestone, then the fee is recognized when the related milestones are earned, as further described below; otherwise, we estimate the fee earned in a given period by using a proportional performance method based

on costs incurred during the period as compared to total estimated project costs and application of the resulting fraction to the total project fee specified in the contract.

When we use the milestone method of revenue recognition, milestone payments (including milestone payments for fees) contained in research and development arrangements are recognized as revenue when: (i) the milestones are achieved; (ii) no further performance obligations with respect to the milestone exist; (iii) collection is reasonably assured; and (iv) substantive effort was necessary to achieve the milestone.

Milestones are considered substantive if all of the following conditions are met:

- it is commensurate with either our performance to meet the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone,
- it relates solely to past performance,
- the value of the milestone is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

If a milestone is deemed not to be substantive, the Company recognizes the portion of the milestone payment as revenue that correlates to work already performed; the remaining portion of the milestone payment is deferred and recognized as revenue as the Company completes its performance obligations.

Revenue on fixed price contracts (without substantive milestones as described above) is recognized on the percentage-of-completion method. The percentage-of-completion method recognizes income as the contract progresses (generally related to the costs incurred in providing the services required under the contract). The use of the percentage-of-completion method depends on the ability to make reasonable dependable estimates and the fact that circumstances may necessitate frequent revision of estimates does not indicate that the estimates are unreliable for the purpose for which they are used.

As a result of our revenue recognition policies and the billing provisions contained in our contracts, the timing of customer billings may differ from the timing of recognizing revenue. Amounts invoiced to customers in excess of revenue recognized are reflected on the balance sheet as deferred revenue. We recorded approximately \$1.4 million and \$0.5 million as deferred revenue as of December 31, 2012 and 2011, respectively. Amounts recognized as revenue in excess of amounts billed to customers are reflected on the balance sheet as unbilled accounts receivable.

We analyze each cost reimbursable grant to determine whether we should report such reimbursements as revenue or as an offset to our expenses incurred. For the years ended December 31, 2012, 2011 and 2010, we recorded approximately \$1.1 million, \$0.7 million and \$2.9 million, respectively, of costs reimbursed by the government as an offset to research and development expenses. Included in the 2010 grants was approximately \$0.9 million in therapeutic discovery tax grants which was offset against research and development expense in 2010.

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

Research and development costs are expensed as incurred; advance payments are deferred and expensed as performance occurs. Research and development costs include salaries, facilities expense, overhead expenses, material and supplies, pre-clinical expense, clinical trials and related clinical manufacturing expenses, share-based compensation expense, contract services and other outside services.

### ***Share-Based Payments***

We have a long-term incentive compensation plan (the "LTIP") under which options to purchase shares of our common stock may be granted to employees, consultants and directors at a price no less than the quoted market value on the date of grant. The LTIP also provides for awards in the form of stock appreciation rights, restricted or unrestricted stock awards, stock-equivalent units or performance-based stock awards.

We account for share-based awards to employees and non-employee directors at fair value. The amount of compensation expense recognized using the fair value method requires us to exercise judgment and make assumptions relating to the factors that determine the fair value of our stock option grants. We use the Black-Scholes model to estimate the fair value of our option grants. The fair value calculated by this model is a function of several factors, including grant price, the risk-free interest rate, the expected term of the option and the anticipated volatility of the option.

### ***Intangible Assets and Goodwill***

We continually assess the realizability and recoverability of our intangible assets and goodwill. These assessments contain substantial judgment in determining the fair value of such assets and with respect to future usage of the assets and potential cash flows associated with them.

### ***Financial Instruments***

Our financial instruments, and/or embedded features contained in those instruments, often are classified as derivative liabilities and are recorded at their fair values. The determination of fair value of these instrument and features requires estimates and judgments. Some of our stock purchase warrants are considered to be derivative liabilities due to the presence of net settlement features; the fair value of our warrants is determined based on the Black-Scholes option pricing model. Use of the Black-Scholes option-pricing model requires the use of unobservable inputs such as the expected term, anticipated volatility and expected dividends.

## Results of Operations

### *Year Ended December 31, 2012 Compared to December 31, 2011*

#### *Revenue*

We recognized revenue of \$25.2 million and \$24.3 million during the years ended December 31, 2012 and 2011, respectively. Our revenue in 2012 was derived from contracts with the U.S. government for the development of our product candidates.

| Revenue (\$ in millions) | Year ended December 31, |                |             |
|--------------------------|-------------------------|----------------|-------------|
|                          | 2012                    | 2011           | % Change    |
| SparVax                  | \$ 22.9                 | \$ 19.3        | 18.7%       |
| rBChE - AES              | 1.8                     | 0.7            | 157.1%      |
| rBChE - Protexia         | -                       | 0.6            | -100.0%     |
| Valortim                 | 0.5                     | 3.7            | -86.5%      |
| Total Revenue            | <u>\$ 25.2</u>          | <u>\$ 24.3</u> | <u>3.7%</u> |

Our revenue changed in 2012 from 2011 primarily due to the following:

Under our contract for the development of SparVax<sup>®</sup>, we recognized approximately \$22.9 million of revenue in 2012, an increase of \$3.6 million (or 18.7%) from 2011. During 2012, revenue for the Company's SparVax<sup>®</sup> program was primarily attributable to completion of Final Drug Product (FDP) manufacture, the initiation of Bulk Drug Substance (BDS) Process Characterization, progression in the development of bioanalytical and analytical assays, the execution of non-clinical activities and the achievement of several contract milestones. During 2011, revenue was primarily attributable to activities related to the manufacturing platform for SparVax<sup>®</sup> and additional work performed to develop and qualify analytical and stability-indicating assays for characterization of the product. Milestone revenue for the achievement of key technical milestones was approximately \$2.2 million and \$3.5 million for the years ended December 31, 2012 and 2011, respectively.

In August 2012, we received notification from the FDA that our SparVax<sup>®</sup> rPA anthrax vaccine program was placed on clinical hold. The FDA has requested additional stability data and information related to the stability indicating assays. We have provided some supporting data and information to the FDA and have commenced discussions with that agency as well as our customer, BARDA, regarding the clinical hold. We cannot be certain that the FDA will find our current data to be satisfactory and it is unclear at this point when or if we will be able to commence the planned Phase II human clinical trial with SparVax<sup>®</sup>. Consequently, revenues we recognize in future periods under our SparVax<sup>®</sup> contract will not include those related to this clinical trial until such time, if ever, as we are able to move forward with the clinical trial and overall SparVax<sup>®</sup> revenues until such time will be substantially less than they otherwise would have been had we commenced the clinical trial as planned. It is also unclear whether or to what extent the clinical hold will affect future government funding for our SparVax<sup>®</sup> program.

Under our contract with the Department of Defense (DoD) for the development of an advanced expression system (AES) for rBChE, our second generation rBChE bioscavanger, we recognized approximately \$1.8 million, representing an increase of approximately \$1.1 million (or 157.1%) from 2011. Significant technical progress was made in the development of our second generation rBChE bioscavanger in 2012, including the establishment of final clones, genetic stability and fed batch evaluation to establish the bioreactor conditions for manufacturing. On July 31, 2012, the DoD exercised a \$2.5 million option to continue to fund work under this contract in 2013.

Under our NIAID contracts for the advanced development of Valortim<sup>®</sup>, we recognized \$0.5 million of revenue in 2012, a substantial decrease of \$3.2 million (or 86.5%) from 2011 levels as a result of our 2007 contract with NIAID for Valortim<sup>®</sup> ending (in accordance with its terms) in the first quarter 2012. Additional government funding has not been awarded for Valortim<sup>®</sup>. There can be no assurance we will be successful in obtaining additional financial support for this program.

### *Research and Development Expenses*

Our research and development expenses were \$19.5 million and \$21.2 million for the years ended December 31, 2012 and 2011, respectively. These expenses resulted from research and development activities related to SparVax<sup>®</sup>, rBChE bioscavenger and Valortim<sup>®</sup>. Research and development expenses include direct expenses (salaries and other costs of personnel, raw materials and supplies, contract research, consulting and clinical development costs) and an allocation of indirect expenses.

Research and development expenses for the years ended December 31, 2012 and 2011 were attributable to research programs as follows:

| (\$ in millions)                        | Year ended December 31, |         |          |
|---|-------------------------|---------|----------|
|   | 2012                    | 2011    | % Change |
| Anthrax therapeutic and vaccines        | \$ 18.3                 | \$ 18.8 | -2.7%    |
| Chemical nerve agent bioscavenger       | 1.1                     | 0.6     | 83.3%    |
| Internal research and development       | 0.1                     | 1.8     | -94.4%   |
| Total research and development expenses | \$ 19.5                 | \$ 21.2 | -8.0%    |

Research and development expenses for both 2012 and 2011 were net of cost reimbursements under certain of our government grants of \$1.1 million and \$0.7 million, respectively.

In 2012, research and development expenses decreased approximately \$1.7 million from 2011, primarily due to a reduction in (i) indirect operating expenses including overhead and internal research and development, and (ii) direct costs related to our Valortim<sup>®</sup> program as a result of the completion in the first quarter of 2012 of work under our 2007 contract with NIAID, offset by higher direct SparVax<sup>®</sup> program expenses. As a result of the FDA clinical hold related to SparVax<sup>®</sup>, costs we recognize in future periods under our SparVax<sup>®</sup> contract related to the SparVax<sup>®</sup> clinical trial, may be substantially less than they otherwise would have been until such time, if ever, as we are able to move forward with the clinical trial.

### *General and Administrative Expenses*

General and administrative functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal, and compliance. For each function, we may incur expenses such as salaries, supplies and third-party consulting and other external costs and non-cash expenditures such as expense related to stock option and restricted share awards. An allocation of indirect costs such as facilities, utilities and other administrative overhead is also included in general and administrative expenses.

Expenses associated with general and administrative functions were \$11.6 million for 2012 and \$14.3 million for 2011, an approximate 19% decrease. The decrease in general and administrative expenses from 2011 to 2012 was largely due to (i) a \$2.3 million reduction in legal and professional expenses primarily related to the SIGA litigation and trial activities and (ii) a planned reduction in headcount, offset in part by a \$1.4 million insurance recovery that was received in 2011.

### *Depreciation Expense*

Depreciation expenses were approximately \$0.3 million and \$0.5 million for the years ended December 31, 2012 and 2011, respectively. The decrease was related to previously purchased assets being fully depreciated during the year ended December 31, 2012.

### *Other Income (Expense)*

Other income in 2012 was \$1.5 million, compared to \$7.9 million in 2011, a decrease of \$6.4 million. The decrease was primarily the result of (i) a \$6.5 million difference in gains related to the changes in fair value of our derivative instruments, (ii) a \$0.8 million gain in 2011 from the sale of Canadian assets held for sale, and (iii) approximately \$0.3 million of additional interest expense in 2012 generated from our loans with GE Capital, offset by \$1.2 million

of income related to the realization of the cumulative translation adjustment upon the substantial liquidation of PharmAthene Canada, Inc. in July 2012.

#### *Income Taxes*

The provision for income taxes was approximately \$0.2 million for the year ended December 31, 2012, compared to no provision in 2011. The provision for income taxes in 2012 resulted from the difference between the treatment of goodwill for income tax purposes and for U.S. GAAP.

#### ***Year Ended December 31, 2011 Compared to December 31, 2010***

#### *Revenue*

We recognized revenue of \$24.3 million and \$21.0 million during the years ended December 31, 2011 and 2010, respectively. Our revenue was derived primarily from contracts with the U.S. government for the development of our product candidates.

| Revenue (\$ in millions) | Year ended December 31, |         |          |
|--------------------------|-------------------------|---------|----------|
|                          | 2011                    | 2010    | % Change |
| SparVax                  | \$ 19.3                 | \$ 11.7 | 65.0%    |
| rBChE - AES              | 0.7                     | -       | 100.0%   |
| rBChE - Protexia         | 0.6                     | 5.8     | -89.7%   |
| Valortim                 | 3.7                     | 3.0     | 23.3%    |
| Other                    | -                       | 0.5     | -100.0%  |
| Total Revenue            | \$ 24.3                 | \$ 21.0 | 15.7%    |

Our revenue for the year ended December 31, 2011 changed from 2010 primarily due to the following:

Under our contract for the development of SparVax<sup>®</sup>, we recognized approximately \$19.3 million in 2011, an increase of 65.0% from 2010 levels. The increase in revenue for the SparVax<sup>®</sup> program during 2011 is attributable to additional work in preparation and execution of the scale up campaign at our U.S.-based SparVax<sup>®</sup> bulk drug substance manufacturer as well as an increase in our billing rate under the contract. Additional activities related to the establishment of analytical and stability-indicating assays for characterization of the product. Of the revenue amounts set forth above, \$3.5 million in 2011 and \$1.8 million in 2010 represent substantive milestone payments that were tied to our successful achievement of certain technical activities.

Under the September 2007 contract for the advanced development of Valortim<sup>®</sup>, we recognized approximately \$3.7 million in 2011 a 23.3% increase from 2010 levels. Revenue in 2011 reflects both clinical and non clinical work following the release of the FDA partial clinical hold in December 2010. Final patient dosing in clinical trial was completed in April 2011 and the in-life portion of the trial ended in the third quarter 2011. Revenue in 2010 was largely attributable to reimbursement of costs related to clinical and non-clinical studies, including work in connection with the investigation related to the partial clinical hold and certain manufacturing-related activities.

Under the September 2006 contract for the advanced development of Protexia<sup>®</sup>, we recognized approximately \$5.8 million in the year ended December 31, 2010, of which \$0.7 million in 2010 represent substantive milestone payments that were tied to our successful achievement of certain technical activities. The decline in revenue is attributed to completion of major development activities for this program in past years. In 2011, we generated additional revenue of \$0.7 million under the fixed price contract with the DoD for the development of the AES for rBChE, our nerve agent medical countermeasure, which was awarded in August 2011.



### *Research and Development Expenses*

Our research and development expenses were approximately \$21.2 million and \$20.9 million for the years ended December 31, 2011 and 2010, respectively. Research and development expenses for the years ended December 31, 2011 and 2010 were attributable to research programs as follows:

| (\$ in millions)                        | Year ended December 31, |         |          |
|---|-------------------------|---------|----------|
|   | 2011                    | 2010    | % Change |
| Anthrax therapeutic and vaccines        | \$ 18.8                 | \$ 15.2 | 23.7%    |
| Chemical nerve agent protectants        | 0.6                     | 4.7     | -87.2%   |
| Recombinant dual antigen plague vaccine | -                       | 0.1     | -100.0%  |
| Internal research and development       | 1.8                     | 0.9     | 100.0%   |
| Total research and development expenses | \$ 21.2                 | \$ 20.9 | 1.4%     |

For the year ended December 31, 2011, research and development expenses increased \$0.3 million from the prior year. This change was primarily due to the increased technical activity and the achievement of key technical milestones on our SparVax<sup>®</sup> program and the completion of the Phase I Valortim<sup>®</sup> dose escalation clinical trial partially offset by a decrease in development expenses related to the clinical nerve agent protectants program as a result of the December 31, 2010 shut down of the Protexia<sup>®</sup> program.

Research and development expenses for the years ended December 31, 2011 and 2010 were net of cost reimbursements under certain of our government grants of \$0.7 million and \$2.9 million, respectively. Included in the 2010 grants were \$0.9 million in therapeutic discovery tax grants.

### *General and Administrative Expenses*

General and administrative expenses were approximately \$14.3 million and \$18.0 million for the years ended December 31, 2011 and 2010, respectively. The decrease in 2011 primarily resulted from a \$3.0 million reduction in bad debt expense and a property loss insurance recovery of \$1.4 million in 2011, partially offset by an increase in non-cash stock compensation expenses as well as taxes and other expenses. The bad debt expenses in 2010 consisted primarily of provisions associated with an invoice to our U.S. government customer for the work at Avecia as well as the wind down of the third generation anthrax vaccine program.

### *Depreciation and Intangible Amortization (including impairment charges)*

Depreciation and amortization expenses were approximately \$0.5 million and \$5.7 million for the years ended December 31, 2011 and 2010, respectively. The decrease in 2011 is primarily a result of the impairment charge taken in December 2010 of approximately \$4.6 million with the closing of our Canadian operations.

### *Other Income (Expense)*

Other income (expense) in 2011 was a net income of \$7.9 million, compared to a net expense of \$11.3 million in 2010. Most of the change was due to (i) a significant reduction in interest expense of \$5.9 million resulting from the conversion of our convertible notes in the fourth quarter of 2010, (ii) a significant change in the fair value of our derivatives instruments (a \$5.5 million loss in 2010 compared to a \$7.1 million gain in 2011) primarily as a result of the change in our stock price, and (iii) a \$0.8 million gain on the sale of Canadian assets held for sale in 2011.

## **Liquidity and Capital Resources**

### *Overview*

Our primary use of cash during 2012 was to fund our operations (including our research and development programs) and support our general and administrative activities. Our future capital requirements will depend on many factors, including, the progress of our research and development programs; the progress of pre-clinical and clinical testing; the time and cost involved in obtaining regulatory approval; the cost of filing, prosecuting, defending and enforcing

any patent claims and other intellectual property rights; changes in our existing research relationships; competing technological and marketing developments; our ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and any future change in our business strategy. These cash requirements could change materially as a result of shifts in our business and strategy. The need to raise additional capital will depend on many factors, including but not limited to, our future cash requirements, future contract funding, whether SIGA prevails in its appeal challenging the trial court ruling awarding us an interest in a portion of the net profits of Arestvyr™, the timing, amount, and profitability of sales of Arestvyr™, if any (including the timing of SIGA's recognition of revenue related thereto), and if the trial court ruling is upheld, our ability to collect our portion of net profits related to Arestvyr™.

Historically, we have not generated positive cash flows from operations. To bridge the gap between payments made to us under our government contracts and grants and our operating and capital needs, we have had to rely on a variety of financing sources, including the issuance of equity securities and equity-linked securities and proceeds from loans and other borrowings. For the foreseeable future, we will continue to need these types of financing vehicles and potentially others to help fund our future operating and capital requirements.

Global economic uncertainty continues to make capital markets more volatile and is threatening to once again tighten the credit markets. As a result, there can be no assurances that we would be successful in obtaining sufficient financing on commercially reasonable terms or at all. In addition, due to the U.S. government's continuing substantial efforts to stabilize the economy, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government contract awards, the likelihood that the government will exercise its right to extend any of its existing contracts with us and/or the likelihood that the government would procure products from us.

We have \$12.7 million of cash on hand at December 31, 2012. We also had approximately \$1.6 million in additional funding available to borrow on our revolving line of credit with GE Capital. As a result of the clinical hold placed on our SparVax® program in 2012, it is unclear when or if we will be able to commence the planned Phase II human clinical trial. Consequently we expect SparVax® related revenues and corresponding research and development expenses until such time, if ever, as we are able to move forward with the clinical trial to be substantially less than they otherwise would have been had we commenced the clinical trial as planned. Nevertheless, we still currently anticipate that our cash on hand, amounts available under the line of credit, and cash to be collected from our various contracts currently in place, will be sufficient to meet the Company's ongoing expenses and capital requirements through at least December 31, 2013.

### *Cash Flows*

The following table provides information regarding our cash flows for the years ended December 31, 2012, 2011 and 2010.

|                                       | <b>Year ended December 31,</b> |                     |                     |
|---------------------------------------|--------------------------------|---------------------|---------------------|
|                                       | <b>2012</b>                    | <b>2011</b>         | <b>2010</b>         |
| Net cash provided by (used in):       |                                |                     |                     |
| Operating activities                  | \$ (2,322,906)                 | \$ (7,808,553)      | \$ (14,864,577)     |
| Investing activities                  | 67,400                         | 1,687,521           | 2,756,007           |
| Financing activities                  | 3,720,071                      | 5,781,328           | 21,460,452          |
| Effects of exchange rates on cash     | 181                            | (208,852)           | (240,122)           |
| Total increase (decrease) in net cash | <u>\$ 1,464,746</u>            | <u>\$ (548,556)</u> | <u>\$ 9,111,760</u> |

### *Sources and Uses of Cash*

Cash and cash equivalents were \$12.7 million, \$11.2 million and \$11.8 million at December 31, 2012, 2011 and 2010, respectively. The \$1.5 million increase at December 31, 2012 compared to December 31, 2011 was primarily attributable to the \$2.5 million term loan, which we closed in the first quarter 2012, and the \$1.3 million borrowed under the revolving line of credit, partially offset by \$2.3 million of cash used in operations. The \$0.6 million decrease at December 31, 2011 as compared to December 31, 2010 was primarily due to the receipt of net proceeds

of \$5.8 million from a registered direct public offering of common stock and warrants, as well as \$1.8 million related to the sale of assets in Canada, offset by \$7.8 million of cash used in operations.

#### *Operating Activities*

Net cash used in operating activities was approximately \$2.3 million, \$7.8 million and \$14.9 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Net cash used in operations during the year ended December 31, 2012 reflects our net loss of \$4.9 million, adjusted for non-cash share-based compensation expense of \$1.9 million, the \$1.2 million gain on the realization of the cumulative translation adjustment related to PharmAthene Canada, Inc., the decrease in the fair value of derivative instruments of \$0.6 million and other noncash expenses of \$0.6 million. The decrease in accounts receivable of approximately \$2.0 million and increase in deferred revenue of approximately \$0.9 million was partially offset by an increase in unbilled accounts receivable of approximately \$1.1 million.

Net cash used in operations during the year ended December 31, 2011 reflects our net loss of \$3.8 million, adjusted for the change in market value of non-cash derivative instruments of \$7.1 million, the sale of the assets held for sale for a net gain of \$0.8 million and depreciation of \$0.5 million. Net cash used in operations was also impacted by non-cash share-based compensation expense of \$2.6 million, a decrease in unbilled accounts receivable of \$1.0 million, prepaid expenses and other current assets of \$1.5 million, and accounts payable of \$1.7 million.

Net cash used in operations during the year ended December 31, 2010 reflects our net loss of \$34.8 million, adjusted for the change in market value of derivative instruments of \$5.5 million, non-cash interest of \$4.7 million, bad debt expense of \$2.9 million, and non-cash share-based compensation expenses of \$2.5 million, decreases in unbilled accounts receivable of \$5.4 million and in accounts receivable of \$1.3 million, increases in depreciation and amortization of \$5.7 million (including an impairment charge of \$4.6 million) primarily associated with the write down of Canadian assets, and an increase in accounts payable of \$1.2 million, and adjusted upward by a decrease in accrued expenses and other liabilities of \$8.5 million.

#### *Investing Activities*

There were no significant investing activities for the year ended December 31, 2012. The net cash provided by investing activities was approximately \$1.7 million for the year ended December 31, 2011 as compared to net cash provided of approximately \$2.8 million for the year ended December 31, 2010. Investing activities in 2011 consisted primarily of the sale of the Canadian farm operations.

Investing activities for 2010 related primarily to liquidating available for sale investments to meet working capital requirements.

#### *Financing Activities*

Net cash provided by financing activities was \$3.7 million for the year ended December 31, 2012 as compared to \$5.8 million for the year ended December 31, 2011 and \$21.5 million provided by financing activities for the year ended December 31, 2010.

The majority of our cash provided by financing for the year ended December 31, 2012, related to our debt arrangements with GE Capital, as described in Note 6 to the consolidated financial statements. The term loan of \$2.5 million and approximately \$1.3 million under the revolving line of credit were outstanding as of December 31, 2012.

In 2011, we raised net proceeds of approximately \$5.8 million primarily from the issuance and sale of 1,857,143 shares of common stock and warrants to purchase up to an additional 371,423 shares of common stock at an exercise price of \$3.50 per share.

Net cash provided from financing activities for the year ended December 31, 2010 was primarily the result of the proceeds from the issuance of common stock and warrants.

In April 2010, we completed a public offering of 1,666,668 shares of our common stock at \$1.50 per share and warrants to purchase an aggregate of 500,000 shares of our common stock at an exercise price of \$1.89 per share, generating net proceeds of approximately \$2.2 million.

In July 2010, we completed a public offering of 2,785,714 shares of our common stock at \$1.40 per share and warrants to purchase an aggregate of 1,323,214 shares of our common stock at an exercise price of \$1.63 per share, generating net proceeds of approximately \$3.5 million.

In November 2010, we completed an underwritten public offering of 4,945,000 shares of our common stock at a price to the public of \$3.50 per share, generating net proceeds of approximately \$15.9 million.

As discussed in Note 8 to the consolidated financial statements, we have issued and sold certain stock purchase warrants for fixed exercise prices that range from \$1.61 to \$3.97. Since these warrants are classified in stockholders' equity, any loss in value upon exercise as a result of the warrant being "in the money" will result in dilution to existing shareholders and such dilution will not be reflected in our consolidated statements of operations or consolidated statements of comprehensive loss.

#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

#### Contractual Obligations

The following are contractual commitments at December 31, 2012:

| Contractual Obligations <sup>(1)</sup> | Total        | Less than 1<br>Year | 1-3 Years    | 3-5 Years    | More than 5<br>Years |
|--|--------------|---------------------|--------------|--------------|----------------------|
| Operating facility leases              | \$ 3,631,800 | \$ 809,400          | \$ 1,619,300 | \$ 1,203,100 | \$ -                 |
| Research and development agreements    | 7,252,600    | 7,252,600           | -            | -            | -                    |
| Term loan                              | 2,500,000    | 749,997             | 1,750,003    | -            | -                    |
| Total contractual obligations          | \$13,384,400 | \$ 8,811,997        | \$3,369,303  | \$ 1,203,100 | \$ -                 |

(1) This table does not include any royalty payments relating to future sales of products subject to license agreements the Company has entered into in relation to its in-licensed technology, as the timing and likelihood of such payments are not known. In addition, the table does not include the final payment fee of \$75,000 on the term loan, which is being accrued and expensed over the term of the agreement, using the effective interest method or the debt discount, which is being amortized over the term of the agreement. The debt discount and final payment accrual at December 31, 2012 were \$45,895 and \$25,278 respectively.

#### Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Our exposure to market risk is currently confined to our cash and cash equivalents and our revolving line of credit. We currently do not hedge interest rate exposure or foreign currency exchange exposure. We have not used derivative financial instruments for speculation or trading purposes.

The Company's current operations in foreign countries are minimal. We have closed our active operations in Canada and maintain only nominal operations in the United Kingdom. A 10% change in exchange rates (against the U.S. dollar) would not have a material impact on earnings, fair values or cash flow.

Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market interest rates would have a significant impact on their realized value. Our term loan with GE Capital is at a fixed 10.14% rate. Because of the fixed rate, a change in market interest rates would not have a material impact on interest expense associated with the loan. The interest rate on the revolving line of credit is variable; therefore, a 1% increase in market interest rates above the interest rate floor of 1.5%, would increase interest expense associated with the line by \$50,000 if the maximum amount of the line (\$5.0 million) was drawn for a full year.

The change in fair value of our derivative instruments is calculated utilizing the Black-Scholes model; therefore, a 10% increase/decrease in the closing price of PharmAthene's common stock at December 31, 2012, would have resulted in a change in fair value of derivative instruments and our earnings of approximately \$0.2 million.

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

Our financial statements and supplementary data required to be filed pursuant to this Item 8 appear in a separate section of this report beginning on page F-1.

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

None.

**Item 9A. Controls and Procedures**

**Disclosure Controls and Procedures**

Our management has evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of December 31, 2012. Based upon this evaluation, our management has concluded that our disclosure controls and procedures were effective as of December 31, 2012.

**Management's Annual Report on Internal Control Over Financial Reporting**

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsored Organization of the Treadway Commission ("COSO") in "Internal Control-Integrated Framework." Based on this assessment, management concluded that as of December 31, 2012, the Company's internal control over financial reporting is effective at the reasonable assurance level.

The Company's independent registered public accounting firm has issued a report on the effectiveness of internal control over financial reporting. This report dated March 13, 2013 appears on page F-2 of this Form 10-K.

**Changes in Internal Control Over Financial Reporting**

There was no change in the Company's internal control over financial reporting during the most recently completed quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information.**

None.

### **Part III**

#### **Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this Item 10 is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

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

The information required by this Item 11 is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

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

The information required by this Item 12 is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

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

The information required by this Item 13 is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

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

The information required by this Item 14 is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

### **Part IV**

#### **Item 15. Exhibits and Financial Statement Schedules.**

##### **Financial Statements**

Reference is made to the Index to the Consolidated Financial Statements beginning on page F-1 of this report.

##### **Financial Statement Schedules**

Required information is included in the footnotes to the financial statements.

##### **Exhibit Index**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 2.1                | Agreement and Plan of Merger, dated January 19, 2007, by and among Healthcare Acquisition Corp., PAI Acquisition Corp., and PharmAthene, Inc. (2)  |
| 2.2                | Sale and Purchase Agreement, dated March 20, 2008, by and among the Registrant and Avecia Investments Limited, Avecia Biologics Limited and Avecia Biologics, Inc. (5)   |
| 2.3                | Amendment Agreement, dated April 2, 2008, by and among, PharmAthene, Inc., PharmAthene UK Limited and PharmAthene US Corporation and Avecia Investments Limited, Avecia Biologics Limited and Avecia Biologics, Inc. (6) |

- 3.1 Amended and Restated Certificate of Incorporation of the Company, as amended. (17)
- 3.2 By-laws, as amended. (7)
- 4.1 Specimen Unit Certificate. (1)
- 4.2 Specimen Common Stock Certificate. (4)
- 4.3 Amendment to Unit Purchase Option by and between the Registrant and Maxim Partners, LLC dated January 28, 2007. (3)
- 4.4 Form of Warrant in connection with Securities Purchase Agreement dated as of March 23, 2009. (15)
- 4.5 Form of Warrant in connection with Note and Warrant Purchase Agreement, as amended as of July 28, 2009. (14)
- 4.6 Form of Warrant in connection with Securities Purchase Agreement dated as of April 7, 2010. (21)
- 4.7 Form of Warrant in connection with Securities Purchase Agreement dated as of July 20, 2010. (22)
- 4.8 Form of Warrant in connection with Subscription Agreement dated as of June 10, 2011. (30)
- 4.9 Form of Warrant in connection with Loan and Security Agreement, dated March 30, 2012. (31)
- 10.4 Form of Registration Rights Agreement among the Registrant and the Initial Stockholders. (1)
- 10.9 Form of Registration Rights Agreement by and among Healthcare Acquisition Corp. and the former stockholders and note holders of PharmAthene, Inc. (2)
- 10.12 Amended and Restated 2007 Long-Term Incentive Compensation Plan. (8)
- 10.23 Collaboration Agreement, dated November 29, 2004, by and between the Company and Medarex, Inc. (4) +
- 10.28 Office Lease, dated September 14, 2006, by and between the Company and Park Place Trust, as amended by First Amendment to Office Lease, dated January 22, 2007. (4) +
- 10.28.2 Second Amendment to Office Lease, by and between the Company and Park Place Trust, dated September 16, 2008. (28)
- 10.30 Form of PharmAthene Inc. Executive Employment Agreement. (9) ++
- 10.30.1 Employment Agreement, dated April 18, 2008, by and between Eric Richman and the Company ++ (26)
- 10.30.3 Amendment, dated as of May 18, 2010, to Employment Agreement, dated as of April 18, 2008, by and between Eric I. Richman and the Company. ++ (25)
- 10.30.5 Employment Agreement, dated April 5, 2010, by and between Thomas Fuerst and the Company. ++ (28)
- 10.30.6 Form of Executive Restricted Stock Award Agreement. ++ (29)
- 10.30.7 Form of Executive Stock Option Agreement. ++ (29)

- 10.30.8 Form of Director Stock Option Agreement. ++ (29)
- 10.30.9 Employment Agreement, dated June 30, 2008, by and between Jordan P. Karp and the Company. ++
- 10.30.10 Employment Agreement, dated February 7, 2012, by and between Linda Chang and the Company. ++
- 10.31 Form of PharmAthene Inc. Confidentiality and Non-Solicitation Agreement. (9)
- 10.33 Master Service Agreement, dated December 15, 2004, between Avecia Limited and the Secretary of State for Defence, acting through the Defence Science and Technology Laboratory (DSTL). (10)+
- 10.34 Master Service Agreement, dated August 18, 2005, between Avecia Limited and DSTL. (10) +
- 10.35 Manufacturing Licence Agreement, dated June 20, 2006, between Avecia Limited and DSTL. (10) +
- 10.36.1 Amended and Restated Manufacturing and Marketing Licence Agreement between the Secretary of State for Defence as represented by the Defence Science and Technology Laboratory (Dstl) and PharmAthene UK Ltd. in respect of Recombinant [\*\*\*] Vaccine, dated February 11, 2009. (13) +
- 10.37 Letter Agreement, dated March 20, 2008, between Avecia Biologics Limited and DSTL. (10)+
- 10.37.1 Amended and Restated Licence Agreement between the Secretary of State for Defence as represented by the Defence Science and Technology Laboratory (Dstl) and PharmAthene UK Ltd. in respect of Recombinant [\*\*\*] Vaccine, dated February 5, 2009. (13) +
- 10.44 Contract with the National Institutes of Health for the Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine (#N01-AI-30052) (“NIH Prime Contract-Anthrax”), dated September 29, 2003. (19) +
- 10.45 Amendments 1 through 13 to the NIH Prime Contract-Anthrax. (19) + , \*\*
- 10.45.1 Modification (Amendment) 16 to the Contract with the National Institutes of Health for the Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine (#N01-AI-30052). (18) +
- 10.45.2 Modification (Amendment) 18 to the Contract with the National Institutes of Health for the Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine (HHSO100200900203C). (27) +
- 10.48 Form of Indemnification Agreement (12)
- 10.49 Form of Securities Purchase Agreement dated as of March 23, 2009 between the Company and the Purchasers party thereto. (15)
- 10.51 Form of Note and Warrant Purchase Agreement, dated as of July 24, 2009, by and among PharmAthene, Inc. and the investors signatories thereto, as amended by Amendment No. 1 to Note and Warrant Purchase Agreement, dated as of July 26, 2009 and Amendment No. 2 to Note and Warrant Purchase Agreement, dated as of July 28, 2009. (14)
- 10.52 Form of Registration Rights Agreement, dated as of July 28, 2009 by and among PharmAthene, Inc. and the investors signatories thereto. (14)
- 10.53 Technology Transfer and Development Services Subcontract, dated as of September 17, 2009, by and between Diosynth Biotechnologies Inc. and PharmAthene, Inc. (18) +



- 10.55 Form of Securities Purchase Agreement, dated as of April 7, 2010, between PharmAthene and the Purchasers party thereto.(23)
- 10.56 Form of Securities Purchase Agreement, dated as of July 20, 2010, between PharmAthene and the Purchasers party thereto.(24)
- 10.57 Form of Subscription Agreement, dated as of June 10, 2011, between PharmAthene and the Investors party thereto. (30)
- 10.58 Loan and Security Agreement, dated March 30, 2012. (31)
- 10.59 Agreement, dated December 5, 2011, between PharmAthene Canada, Inc. and Ferme Pillar Hill Enr., regarding the sale of real estate.\*
- 21 Subsidiaries. (28)
- 23 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm \*
- 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 of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350.\*
- 32.2 Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.\*
- (101) The following consolidated financial statements from the PharmAthene, Inc. Annual Report on Form 10-K for the year ended December 31, 2012, formatted in Extensive Business Reporting Language (“XBRL”): (i) Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011, (ii) Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders’ Equity for the years ended December 31, 2012, 2011 and 2010, (v) Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010, and (v) Notes to consolidated financial statements.\*
- 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\*
- (1) Incorporated by reference to the Registration Statement on Form S-1 of the Registrant filed on May 6, 2005.
- (2) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on January 22, 2007.
- (3) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on

January 25, 2007.

- (4) Incorporated by reference to the Current Report on Form 8-K/A filed by the Registrant on September 24, 2007.
- (5) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on March 26, 2008.
- (6) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on April 8, 2008.
- (7) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on May 2, 2008.
- (8) Incorporated by reference to Appendix B to the Proxy Statement on Schedule 14A filed by the Registrant on May 15, 2008.
- (9) Incorporated by reference to the corresponding exhibit to the Quarterly Report on Form 10-Q filed by the Registrant on August 14, 2008.
- (10) Incorporated by reference to the corresponding exhibit to the Amendment to the Quarterly Report on Form 10-Q/A filed by the Registrant on August 19, 2008.
- (11) Incorporated by reference to the corresponding exhibit to the Quarterly Report on Form 10-Q filed by the Registrant on November 14, 2008.
- (12) Incorporated by reference to Exhibit 10.45 to the Current Report on Form 8-K filed by the Registrant on January 27, 2009.
- (13) Incorporated by reference to the corresponding exhibit to the Quarterly Report on Form 10-Q filed by the Registrant on May 15, 2009.
- (14) Incorporated by reference to Amendment No. 1 to the Company's current report on Form 8-K filed on August 3, 2009.
- (15) Incorporated by reference to Exhibits 10.1 and 10.2, respectively, to the Current Report on Form 8-K filed by the Registrant on March 27, 2009 (File No. 001-32587).
- (16) Intentionally omitted.
- (17) Incorporated by reference to the Company's current report on Form 8-K filed on November 4, 2009.
- (18) Incorporated by reference to the Exhibits 10.45.1 and 10.52, respectively, to the Company's quarterly report on Form 10-Q filed on November 13, 2009.
- (19) Incorporated by reference to the corresponding exhibit to the Company's annual report on Form 10-K for the year ended December 31, 2008.
- (20) Incorporated by reference to Exhibit 10.44 to the Quarterly Report on Form 10-Q filed by the Registrant on November 14, 2008.
- (21) Incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed on April 8, 2010.
- (22) Incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed on July 20, 2010.

- (23) Incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed on April 8, 2010.
- (24) Incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed on July 20, 2010.
- (25) Incorporated by reference to Exhibit 10.30.3 to the Company's current report on Form 8-K filed on May 24, 2010.
- (26) Incorporated by reference to the Company's annual report on Form 10-K for the year ended December 31, 2009.
- (27) Incorporated by reference to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2010.
- (28) Incorporated by reference to the Company's annual report on Form 10-K for the year ended December 31, 2010.
- (29) Incorporated by reference to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2011.
- (30) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on June 10, 2011.
- (31) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on April 3, 2012.
- \* Filed herewith.
- \*\* Amendments No. 2 and 5 to the NIH Prime Contract-Anthrax have been superseded in full by subsequent amendments filed herewith and are therefore omitted. Amendment No. 12 to the NIH Prime Contract-Anthrax and Amendment No. 8 to the NIH Prime Contract-Plague were never executed and are therefore omitted.
- + Certain confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.
- + Management Compensation Arrangement.

**Financial Statements and Schedules of Subsidiaries and Affiliates**

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the city of Annapolis, State of Maryland, on the 13th day of March, 2013.

### PHARMATHENE, INC.

By: /s/ Eric I. Richman  
Eric I. Richman  
*President & Chief Executive Officer*

## POWER OF ATTORNEY

BY THESE PRESENTS, each person whose signature appears below constitutes and appoints Eric I. Richman, Linda L. Chang, and Jordan P. Karp his true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

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

| <b>Signature</b>                                      | <b>Title</b>  | <b>Date</b>    |
|---|---|----------------|
| <u>/s/ Eric I. Richman</u><br>Eric I. Richman         | Chief Executive Officer and Director<br>(Principal Executive Officer)                     | March 13, 2013 |
| <u>/s/ Linda L. Chang</u><br>Linda L. Chang           | Chief Financial Officer<br>(Principal Financial Officer and Principal Accounting Officer) | March 13, 2013 |
| <u>/s/ Mitchel Sayare</u><br>Mitchel Sayare, Ph.D.    | Chairman of the Board   | March 13, 2013 |
| <u>/s/ John Gill</u><br>John Gill                     | Director  | March 13, 2013 |
| <u>/s/ Brian Markison</u><br>Brian Markison           | Director  | March 13, 2013 |
| <u>/s/ Derace Schaffer</u><br>Derace Schaffer, M.D.   | Director  | March 13, 2013 |
| <u>/s/ Joel McCleary</u><br>Joel McCleary             | Director  | March 13, 2013 |
| <u>/s/ Jeffrey W. Runge</u><br>Jeffrey W. Runge, M.D. | Director  | March 13, 2013 |
| <u>/s/ Steven St. Peter</u><br>Steven St. Peter, M.D. | Director  | March 13, 2013 |

**PHARMATHENE, INC.**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

### INTERNAL CONTROL OVER FINANCIAL REPORTING

Board of Directors and Stockholders of  
PharmAthene, Inc.

We have audited PharmAthene, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). PharmAthene, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management Report on Internal Control over Financial Reporting." Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, PharmAthene, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of PharmAthene, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 and our report dated March 13, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, Maryland  
March 13, 2013

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**CONSOLIDATED FINANCIAL STATEMENTS**

Board of Directors and Stockholders of  
PharmAthene, Inc.

We have audited the accompanying consolidated balance sheets of PharmAthene, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of PharmAthene, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), PharmAthene, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, Maryland  
March 13, 2013

**PHARMATHENE, INC.  
CONSOLIDATED BALANCE SHEETS**

|  | <b>December 31,</b> |               |
|--|---------------------|---------------|
|  | <b>2012</b>         | <b>2011</b>   |
| <b><u>ASSETS</u></b>   |                     |               |
| Current assets:  |                     |               |
| Cash and cash equivalents  | \$ 12,701,517       | \$ 11,236,771 |
| Accounts receivable (billed)   | 2,432,641           | 4,424,442     |
| Unbilled accounts receivable   | 4,114,442           | 3,021,208     |
| Prepaid expenses and other current assets  | 547,245             | 830,585       |
| Restricted cash  | -                   | 100,000       |
| Total current assets   | 19,795,845          | 19,613,006    |
| Property and equipment, net  | 483,976             | 788,666       |
| Other long-term assets and deferred costs  | 113,130             | 53,384        |
| Goodwill   | 2,348,453           | 2,348,453     |
| Total assets   | \$22,741,404        | \$22,803,509  |
| <b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>   |                     |               |
| Current liabilities:   |                     |               |
| Accounts payable   | \$1,697,280         | \$1,445,700   |
| Accrued expenses and other liabilities   | 2,328,877           | 2,655,330     |
| Deferred revenue   | 1,381,755           | 514,312       |
| Current portion of long-term debt  | 749,997             | -             |
| Short-term debt  | 1,330,507           | -             |
| Total current liabilities  | 7,488,416           | 4,615,342     |
| Other long-term liabilities  | 579,427             | 449,709       |
| Long-term debt, less current portion   | 1,704,108           | -             |
| Derivative instruments   | 1,295,613           | 1,886,652     |
| Total liabilities  | 11,067,564          | 6,951,703     |
| Stockholders' equity:  |                     |               |
| Common stock, \$0.0001 par value; 100,000,000 shares<br>authorized; 48,352,651 and 48,236,172 shares issued and<br>outstanding at December 31, 2012 and 2011, respectively | 4,835               | 4,824         |
| Additional paid-in-capital   | 210,495,905         | 208,525,917   |
| Accumulated other comprehensive (loss) income  | (217,328)           | 1,010,522     |
| Accumulated deficit  | (198,609,572)       | (193,689,457) |
| Total stockholders' equity   | 11,673,840          | 15,851,806    |
| Total liabilities and stockholders' equity   | \$22,741,404        | \$22,803,509  |

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



**PHARMATHENE, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

|  | <b>Year Ended December 31,</b> |                       |                        |
|--|--------------------------------|-----------------------|------------------------|
|  | <b>2012</b>                    | <b>2011</b>           | <b>2010</b>            |
| Revenue  | \$ 25,175,887                  | \$ 24,266,274         | \$ 20,993,605          |
| Operating expenses:  |                                |                       |                        |
| Research and development   | 19,509,629                     | 21,219,853            | 20,875,536             |
| General and administrative   | 11,628,732                     | 14,311,079            | 18,015,761             |
| Depreciation and amortization (including<br>\$4,635,489 of impairment charges in 2010) | 303,916                        | 461,073               | 5,655,865              |
| Total operating expenses   | <u>31,442,277</u>              | <u>35,992,005</u>     | <u>44,547,162</u>      |
| Loss from operations   | \$ (6,266,390)                 | \$ (11,725,731)       | \$ (23,553,557)        |
| Other income (expense):  |                                |                       |                        |
| Interest income  | 17,808                         | 16,660                | 6,955                  |
| Interest expense   | (342,561)                      | (54,573)              | (5,936,480)            |
| Gain on the sale of assets held for sale   | -                              | 781,760               | -                      |
| Realization of cumulative translation adjustment                                       | 1,227,656                      | -                     | -                      |
| Change in fair value of derivative instruments   | 591,039                        | 7,144,983             | (5,457,550)            |
| Other income, net  | 47,862                         | 39,328                | 91,355                 |
| Total other income (expense)   | <u>1,541,804</u>               | <u>7,928,158</u>      | <u>(11,295,720)</u>    |
| Net loss before income taxes   | (4,724,586)                    | (3,797,573)           | (34,849,277)           |
| Provision for income taxes   | (195,529)                      | -                     | -                      |
| Net loss   | <u>\$ (4,920,115)</u>          | <u>\$ (3,797,573)</u> | <u>\$ (34,849,277)</u> |
| Basic and diluted net loss per share   | \$ (0.10)                      | \$ (0.08)             | \$ (1.08)              |
| Weighted average shares used in calculation of basic<br>and diluted net loss per share | 48,323,067                     | 47,331,763            | 32,309,621             |

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

**PHARMATHENE, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

|   | Year ended December 31, |                |                 |
|---|-------------------------|----------------|-----------------|
|   | 2012                    | 2011           | 2010            |
| Net loss  | \$ (4,920,115)          | \$ (3,797,573) | \$ (34,849,277) |
| Other comprehensive (loss) income:                                    |                         |                |                 |
| Realization of cumulative translation adjustment included in net loss | (1,227,656)             | -              | -               |
| Foreign currency translation adjustments                              | (194)                   | (239,975)      | 68,824          |
| Net unrealized losses on investments                                  | -                       | -              | (6,483)         |
| Comprehensive loss  | \$ (6,147,965)          | \$ (4,037,548) | \$ (34,786,936) |

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

**PHARMATHENE, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

|   | <b>Common Stock</b> |                | <b>Additional Paid-In Capital</b> | <b>Accumulated and Other Comprehensive Income (Loss)</b> | <b>Accumulated Deficit</b> | <b>Stockholders' Equity</b> |
|---|---------------------|----------------|-----------------------------------|--|----------------------------|-----------------------------|
|   | <b>Shares</b>       | <b>Amount</b>  |                                   |  |                            |                             |
| <b>Balance as of 12/31/2009</b>                   | 28,130,284          | \$2,813        | \$157,004,037                     | \$1,188,156  | \$(155,042,607)            | \$3,152,399                 |
| Net loss  | -                   | -              | -                                 | -  | (34,849,277)               | (34,849,277)                |
| Net unrealized (losses) on short-term investments | -                   | -              | -                                 | (6,483)  | -                          | (6,483)                     |
| Foreign currency translation adjustments          | -                   | -              | -                                 | 68,824   | -                          | 68,824                      |
| Issuance of common stock, net issuance costs      | 9,397,382           | 940            | 19,471,084                        | -  | -                          | 19,472,024                  |
| Exercise of stock purchase warrants               | 14,537              | 1              | 2,698                             | -  | -                          | 2,699                       |
| Share-based compensation - stock options          | -                   | -              | 2,292,479                         | -  | -                          | 2,292,479                   |
| Shares issued upon exercise of stock options      | 22,316              | 2              | 56,206                            | -  | -                          | 56,208                      |
| Employee vesting of restricted shares, net        | 84,742              | 9              | 191,486                           | -  | -                          | 191,495                     |
| Conversion of July 2009 Convertible Debt          | 8,588,983           | 859            | 21,829,478                        | -  | -                          | 21,830,337                  |
| <b>Balance as of 12/31/2010</b>                   | <b>46,238,244</b>   | <b>\$4,624</b> | <b>\$200,847,468</b>              | <b>\$1,250,497</b>                                       | <b>\$(189,891,884)</b>     | <b>\$12,210,705</b>         |
| Net loss  | -                   | -              | -                                 | -  | (3,797,573)                | (3,797,573)                 |
| Foreign currency translation adjustments          | -                   | -              | -                                 | (239,975)  | -                          | (239,975)                   |
| Issuance of common stock, net issuance costs      | 1,857,143           | 186            | 5,068,542                         | -  | -                          | 5,068,728                   |
| Share-based compensation - stock options          | -                   | -              | 2,251,501                         | -  | -                          | 2,251,501                   |
| Shares issued upon exercise of stock options      | 44,464              | 4              | 118,305                           | -  | -                          | 118,309                     |
| Employee vesting of restricted shares, net        | 96,321              | 10             | 240,101                           | -  | -                          | 240,111                     |
| <b>Balance as of</b>                              | <b>48,236,172</b>   | <b>\$4,824</b> | <b>\$208,525,917</b>              | <b>\$1,010,522</b>                                       | <b>\$(193,689,457)</b>     | <b>\$15,851,806</b>         |

|  |                   |                |                      |                    |                        |                     |
|--|-------------------|----------------|----------------------|--------------------|------------------------|---------------------|
| <b>12/31/2011</b>  |                   |                |                      |                    |                        |                     |
| Net loss   | -                 | -              | -                    | -                  | (4,920,115)            | (4,920,115)         |
| Reclassification of the cumulative translation adjustment on substantial liquidation of PharmAthene Canada | -                 | -              | -                    | (1,227,656)        | -                      | (1,227,656)         |
| Foreign currency translation adjustments   | -                 | -              | -                    | (194)              | -                      | (194)               |
| Share-based compensation - stock options   | -                 | -              | 1,803,427            | -                  | -                      | 1,803,427           |
| Shares issued upon exercise of stock options   | 31,474            | 3              | 38,981               | -                  | -                      | 38,984              |
| Employee vesting of restricted shares, net   | 85,005            | 8              | 57,704               | -                  | -                      | 57,712              |
| Warrants to purchase common stock issued in connection with issuance of long-term debt                     | -                 | -              | 69,876               | -                  | -                      | 69,876              |
| <b>Balance as of 12/31/2012</b>  | <u>48,352,651</u> | <u>\$4,835</u> | <u>\$210,495,905</u> | <u>\$(217,328)</u> | <u>\$(198,609,572)</u> | <u>\$11,673,840</u> |

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

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

|   | <b>Year ended December 31,</b> |                |                 |
|---|--------------------------------|----------------|-----------------|
|   | <b>2012</b>                    | <b>2011</b>    | <b>2010</b>     |
| <b>Operating activities</b>   |                                |                |                 |
| Net loss  | \$ (4,920,115)                 | \$ (3,797,573) | \$ (34,849,277) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                |                |                 |
| Realization of cumulative translation adjustment                            | (1,227,656)                    | -              | -               |
| Bad debt (recovery) expense   | -                              | (40,524)       | 2,935,063       |
| Change in fair value of derivative instruments                              | (591,039)                      | (7,144,983)    | 5,457,550       |
| Depreciation and amortization expense                                       | 303,916                        | 461,073        | 1,020,376       |
| Impairment of assets held for sale  | -                              | -              | 4,635,489       |
| Gain on the disposal of assets held for sale                                | -                              | (781,760)      | -               |
| Gain of the disposal of property and equipment                              | (66,626)                       | -              | -               |
| Share-based compensation expense  | 1,894,099                      | 2,565,961      | 2,513,159       |
| Deferred income taxes   | 195,529                        | -              | -               |
| Non-cash interest expense   | 122,342                        | -              | 4,653,633       |
| Changes in operating assets and liabilities:                                |                                |                |                 |
| Accounts receivable   | 1,991,801                      | 20,748         | 1,279,875       |
| Unbilled accounts receivable  | (1,093,234)                    | 987,408        | 5,408,216       |
| Prepaid expenses and other current assets                                   | 367,149                        | 1,481,150      | (650,722)       |
| Accounts payable  | 251,561                        | (1,682,461)    | 1,245,975       |
| Accrued expenses and other liabilities                                      | (418,076)                      | (391,904)      | (8,513,914)     |
| Deferred revenue  | 867,443                        | 514,312        | -               |
| Net cash used in operating activities                                       | (2,322,906)                    | (7,808,553)    | (14,864,577)    |
| <b>Investing activities</b>   |                                |                |                 |
| Purchases of property and equipment   | -                              | (71,439)       | (374,581)       |
| Proceeds from the disposal of assets held for sale                          | -                              | 1,758,960      | -               |
| Proceeds from the sale of property and equipment                            | 67,400                         | -              | -               |
| Proceeds from sales of short-term investments                               | -                              | -              | 3,130,588       |
| Net cash provided by investing activities                                   | 67,400                         | 1,687,521      | 2,756,007       |
| <b>Financing activities</b>   |                                |                |                 |
| Proceeds from issuance (repayment) of debt                                  | 2,500,000                      | -              | (11,439)        |
| Proceeds from revolving credit agreement                                    | 1,330,507                      | -              | -               |
| Deferred financing costs  | (216,460)                      | -              | -               |
| Change in restricted cash requirements                                      | 100,000                        | -              | (100,000)       |
| Proceeds from issuance of common stock and warrants                         | 38,984                         | 5,855,689      | 21,601,075      |
| Other   | (32,960)                       | (74,361)       | (29,184)        |
| Net cash provided by financing activities                                   | 3,720,071                      | 5,781,328      | 21,460,452      |
| Effects of exchange rates on cash   | 181                            | (208,852)      | (240,122)       |
| Increases (decreases) in cash and cash equivalents                          | 1,464,746                      | (548,556)      | 9,111,760       |
| Cash and cash equivalents, at beginning of period                           | 11,236,771                     | 11,785,327     | 2,673,567       |
| Cash and cash equivalents, at end of period                                 | \$ 12,701,517                  | \$ 11,236,771  | \$ 11,785,327   |
| <b>Supplemental disclosure of cash flow information</b>                     |                                |                |                 |
| Cash paid for interest  | \$ 220,219                     | \$ 54,573      | \$ 1,234,142    |
| Cash paid for income taxes  | \$ -                           | \$ 10,630      | \$ -            |
| <b>Financing activity</b>   |                                |                |                 |
| Value of warrants issued to lender in connection with loan                  | \$ 69,876                      | \$ -           | \$ -            |
| Value of warrants issued in connection with the issuance of common stock    | -                              | \$ 668,640     | \$ 2,070,146    |

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

**PharmAthene, Inc.**  
**Notes to Consolidated Financial Statements**  
**As of and For the Year Ended December 31, 2012**

**Note 1 - Organization and Business**

We were formed in April 2005 as Healthcare Acquisition Corp. (“HAQ”), a special purpose acquisition company, formed solely to acquire a then unidentified business. On August 3, 2005, we consummated our initial public offering. On August 3, 2007, we acquired all the outstanding equity of PharmAthene, Inc., a Delaware Corporation, and changed our name from Healthcare Acquisition Corp. to PharmAthene, Inc. In March 2008, PharmAthene Inc., through its wholly-owned subsidiary PharmAthene UK Limited, acquired substantially all the assets and liabilities related to the biodefense vaccines business of Avecia Biologics Limited.

We are incorporated under the laws of the State of Delaware and are a biopharmaceutical company focused on developing biodefense countermeasure applications. We are subject to those risks associated with any biopharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change and are largely dependent on the services and expertise of our employees, consultants and other third parties.

Historically, we have performed under government contracts and grants and raised funds from investors (including additional debt and equity issued in 2012, 2011 and 2010) to sustain our operations. The Company has spent and will continue to spend substantial funds in the research, development, clinical and pre-clinical testing of the Company’s product candidates with the goal of ultimately obtaining approval from the FDA, to market and sell our products. We may elect to raise additional capital through debt and or equity to strengthen our financial position.

**Note 2 - Summary of Significant Accounting Policies**

***Basis of Presentation***

Our consolidated financial statements include the accounts of PharmAthene, Inc. and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation. Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. We currently operate in one business segment. Certain receivables, primarily related to tax credits or grants, of approximately \$0.5 million and \$0.6 million as of December 31, 2011 and 2010 respectively, previously classified in our consolidated balance sheets as “accounts receivable,” have been reclassified as “prepaid expenses and other current assets” to conform with current period presentation.

***Use of Estimates***

The preparation of financial statements in conformity with generally accepted accounting principles in the United States (“U.S. GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Our consolidated financial statements include significant estimates for the expected economic life and value of our intangible assets, and the amount of our net operating losses, our share-based compensation, our financial instruments, among other things. Because of the use of estimates inherent in the financial reporting process, actual results could differ significantly from those estimates.

***Foreign Currency Translation***

The functional currency of our wholly owned foreign subsidiaries is their local currency. Assets and liabilities of our foreign subsidiaries are translated into United States dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the weighted average exchange rates prevailing during the

reporting period. Translation adjustments for subsidiaries that have not been sold, substantially liquidated or otherwise disposed of, are accumulated in other comprehensive income (loss), a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive income (loss) at December 31, 2012 and 2011. Transaction gains or (losses) are included in the determination of net income or loss, and were approximately (\$0.01) million, (\$0.1) million and \$0.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

In July 2012, we substantially liquidated our Canadian subsidiary, which we acquired in 2005. As a result, we realized approximately \$1.2 million of income in our consolidated statement of operations, which represents the amount of previously recorded foreign currency translation adjustments related to our Canadian subsidiary.

### ***Comprehensive Loss and Accumulated Other Comprehensive Income***

Comprehensive loss includes the total of our net loss and all other changes in equity other than transactions with owners, including (i) changes in equity for cumulative translation adjustments resulting from the consolidation of foreign subsidiaries as the financial statements of the subsidiaries located outside of the United States are accounted for using the local currency as the functional currency, and (ii) unrealized gains and losses on short term available-for-sale investments.

Effective January 1, 2012, the Company adopted ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). As a result, the Company now presents comprehensive income (loss) in its consolidated financial statements as a single financial statement. The adoption of ASU 2011-05 did not affect the Company's consolidated results of operations, financial position, or liquidity.

### ***Cash and Cash Equivalents and Restricted Cash***

Cash and cash equivalents are stated at market value. We consider all highly liquid investments with original maturities of three months or less to be cash equivalents. Interest income earned on cash and cash equivalents and short-term investments was approximately \$0.02 million, \$0.02 million and \$0.01 million in 2012, 2011 and 2010, respectively.

As of December 31, 2011 and 2010 we had \$0.1 million in restricted cash associated with a letter of credit to support our corporate credit card program. As of December 31, 2012, none of our cash was restricted.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash, restricted cash and cash equivalents, and billed and unbilled accounts receivable. We maintain our cash, restricted cash and cash equivalents in the form of money market accounts and overnight deposits with financial institutions that we believe are credit worthy. Because our billed and unbilled accounts receivable consist of amounts due from the U.S. federal government, management deems there to be minimal credit risk.

### ***Revolving Line of Credit and Term Loan***

As discussed further in Note 6, we entered into a loan agreement with General Electric Capital Corporation ("GE Capital") in March 2012. As part of that agreement, we issued stock purchase warrants to GE Capital that expire in March 2022. The fair value of the warrants was charged to additional paid-in-capital, resulting in a debt discount at the date of issuance. The debt discount is being amortized over the term of the loan agreement using the effective interest method. Financing costs incurred in connection with this agreement are being amortized over the term of the agreement using the effective interest method. The amortization of both the debt discount and deferred financing costs are included in interest expense in the consolidated statement of operations.

### ***Significant Customers and Accounts Receivable***

Our primary customers are the U.S. Department of Defense (the “DoD”), Chemical Biological Medical Systems (“CBMS”), the National Institute of Allergy and Infectious Diseases (“NIAID”), the Biomedical Advanced Research and Development Authority (“BARDA”), and the National Institute of Health (“NIH”).

As of December 31, 2012 and 2011, the Company’s trade receivable balances were comprised solely of receivables from these customers. Unbilled accounts receivable totaling \$4.1 million and \$3.0 million as of December 31, 2012 and 2011, respectively, relate to the contracts with these same customers.

### ***Property and Equipment***

Property and equipment consist of leasehold improvements, furniture and office equipment and computer and other equipment and are recorded at cost. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

| <b>Asset Category</b>          | <b>Estimated Useful Life<br/>(in Years)</b> |
|--------------------------------|---|
| Leasehold improvements         | 8– 10                                       |
| Furniture and office equipment | 5   |
| Computer and other equipment   | 3– 5  |

### ***Impairment of Long-Lived Assets***

Long-lived assets consist primarily of property and equipment. We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of assets exceeds the fair value of the assets.

In the fourth quarter of 2010, we realized an impairment of certain assets associated with the closing of our Canadian operations upon the expiration of the Protexia<sup>®</sup> contract with the DoD. As a result we recognized an impairment charge of approximately \$4.6 million which is included in depreciation and amortization expense in the accompanying 2010 consolidated statement of operations. The remaining assets consisting of land and buildings of approximately \$1.0 million were reclassified as assets held for sale as of December 31, 2010, and subsequently sold in 2011.

### ***Exit Activities***

In the fourth quarter 2011, we recognized a gain on the sale of assets of PharmAthene Canada of approximately \$0.8 million, which is included in 2011 in the consolidated statement of operations. We substantially completed the liquidation of our Canadian subsidiary in July 2012 and at that time realized approximately \$1.2 million of accumulated foreign currency translation adjustments, which is included in 2012, in the consolidated statement of operations and the consolidated statement of comprehensive loss.

### ***Fair Value of Financial Instruments***

The carrying amounts of our short term financial instruments, which primarily include cash and cash equivalents, restricted cash, accounts receivable (billed and unbilled), other current assets, accounts payable, accrued and other liabilities, and short term debt, approximate their fair values due to their short maturities. The fair value of our



long-term indebtedness is estimated based on the current rates offered to the Company for debt of the same remaining maturities. See Note 3 for further details.

### ***Goodwill and Intangible Assets***

Goodwill represents the excess of purchase price over the fair value of net identifiable assets associated with acquisitions. We review the recoverability of goodwill by comparing our market value (as measured by our stock price multiplied by the number of outstanding shares as of the end of the year) to the net book value of our equity. If our market value exceeds our net book value, no further analysis is required. Changes in our business strategy or adverse changes in market conditions could impact the impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value over its estimated fair value. We completed our annual impairment assessment of goodwill on December 31, 2012 and determined that there was no impairment as of that date.

In 2010 we recognized an impairment charge of \$0.8 million associated with our patents related to Protexia<sup>®</sup> as a result of our decision to shut down the Canadian operation upon the expiration of the Protexia<sup>®</sup> contract with the DoD. The impairment charge is included within depreciation and amortization in 2010, in our consolidated statement of operations.

### ***Revenue Recognition***

We generate our revenue from different types of contractual arrangements: cost-plus-fee contracts, cost reimbursable grants and fixed price contracts.

Revenues on cost-plus-fee contracts are recognized in an amount equal to the costs incurred during the period plus an estimate of the applicable fee earned. The estimate of the applicable fee earned is determined by reference to the contract: if the contract defines the fee in terms of risk-based milestones and specifies the fees to be earned upon the completion of each milestone, then the fee is recognized when the related milestones are earned, as further described below; otherwise, we estimate the fee earned in a given period by using a proportional performance method based on costs incurred during the period as compared to total estimated project costs and application of the resulting fraction to the total project fee specified in the contract.

Under the milestone method of revenue recognition, milestone payments (including milestone payments for fees) contained in research and development arrangements are recognized as revenue when: (i) the milestones are achieved; (ii) no further performance obligations with respect to the milestone exist; (iii) collection is reasonably assured; and (iv) substantive effort was necessary to achieve the milestone.

Milestones are considered substantive if all of the following conditions are met:

- it is commensurate with either our performance to meet the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone,
- it relates solely to past performance,
- the value of the milestone is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

If a milestone is deemed not to be substantive, the Company recognizes the portion of the milestone payment as revenue that correlates to work already performed; the remaining portion of the milestone payment is deferred and recognized as revenue as the Company completes its performance obligations.

Revenue on fixed price contracts (without substantive milestones as described above) is recognized on the percentage-of-completion method. The percentage-of-completion method recognizes income as the contract progresses (generally related to the costs incurred in providing the services required under the contract). The use of

the percentage-of-completion method depends on the ability to make reasonable dependable estimates and the fact that circumstances may necessitate frequent revision of estimates does not indicate that the estimates are unreliable for the purpose for which they are used.

As a result of our revenue recognition policies and the billing provisions contained in our contracts, the timing of customer billings may differ from the timing of recognizing revenue. Amounts invoiced to customers in excess of revenue recognized are reflected on the balance sheet as deferred revenue. We recorded approximately \$1.4 million and \$0.5 million as deferred revenue as of December 31, 2012 and 2011. Amounts recognized as revenue in excess of amounts billed to customers are reflected on the balance sheet as unbilled accounts receivable.

We analyze each cost reimbursable grant to determine whether we should report such reimbursements as revenue or as an offset to our expenses incurred. For the years ended December 31, 2012, 2011 and 2010, we recorded approximately \$1.1 million, \$0.7 million and \$2.9 million, respectively, of costs reimbursed by the government as a reduction of research and development expenses. Included in the 2010 grants was approximately \$0.9 million in therapeutic discovery tax grants, which was offset against research and development expense in 2010.

### ***Collaborative Arrangements***

Even though most of our products are being developed in conjunction with support by the U.S. Government, we are an active participant in that development, with exposure to significant risks and rewards of commercialization relating to the development of these pipeline products. In collaborations where we are deemed to be the principal participant of the collaboration, we recognize costs and revenues generated from third parties using the gross basis of accounting; otherwise, we use the net basis of accounting.

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

Research and development costs are expensed as incurred; advance payments are deferred and expensed as performance occurs. Research and development costs include salaries, facilities expense, overhead expenses, material and supplies, pre-clinical expense, clinical trials and related clinical manufacturing expenses, share-based compensation expense, contract services and other outside services.

### ***Share-Based Compensation***

We expense the estimated fair value of share-based awards granted to employees under our stock compensation plans. The fair value of stock options is determined at the grant date using an option pricing model. We have estimated the fair value of each stock option award using the Black-Scholes option pricing model. The Black-Scholes model considers, among other factors, the expected life of the award and the expected volatility of our stock price. The value of the award that is ultimately expected to vest is recognized as expense on a straight line basis over the employee's requisite service period.

The fair value of restricted stock grants is determined based on the closing price of our common stock on the award date and is recognized as expense ratably over the requisite service period.

Employee share-based compensation expense in 2012, 2011 and 2010 is calculated based on awards ultimately expected to vest and is reduced for estimated forfeitures at a rate of 12%.

Share-based compensation expense for 2012, 2011 and 2010 is as follows:

|  | <b>Year ended December 31,</b> |                     |                     |
|--|--------------------------------|---------------------|---------------------|
|  | <b>2012</b>                    | <b>2011</b>         | <b>2010</b>         |
| Research and development               | \$ 518,375                     | \$ 754,554          | \$ 1,008,368        |
| General and administrative             | 1,375,724                      | 1,811,407           | 1,504,791           |
| Total share-based compensation expense | <u>\$ 1,894,099</u>            | <u>\$ 2,565,961</u> | <u>\$ 2,513,159</u> |

During 2012, we granted 852,139 options to employees and non-employee directors and made no restricted stock grants. At December 31, 2012, we had total unrecognized share-based compensation expense related to unvested awards of options and restricted shares of approximately \$2.3 million, net of estimated forfeitures, which we expect to recognize as expense over a weighted-average period of 2.36 years.

During the years ended December 31, 2012, 2011 and 2010, we received \$38,984, \$118,309 and \$56,208 from stock options exercised, respectively.

### ***Income Taxes***

We account for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. We also recognize a tax benefit from uncertain tax positions only if it is “more likely than not” that the position is sustainable based on its technical merits. Our policy is to recognize interest and penalties on uncertain tax positions as a component of income tax expense. As of December 31, 2012 and 2011, we had recognized a full valuation allowance since the likelihood of realization of our tax deferred assets does not meet the more likely than not threshold.

For the year ended December 31, 2012, we incurred income tax expense of approximately \$0.2 million relating exclusively to the generation of a deferred tax liability associated with the amortization of goodwill, which is included as a component of other long-term liabilities on our consolidated balance sheets. There was no income tax expense for the periods ended December 31, 2011 or 2010.

We file a U.S. federal income tax return as well as returns for various state and foreign jurisdictions. Our income taxes have not been examined by any tax jurisdiction since our inception. Uncertain tax positions taken on our tax returns are accounted for as liabilities for unrecognized tax benefits. We recognize interest and penalties, if any, related to unrecognized tax benefits in other income (expense) in the consolidated statements of operations.

### ***Basic and Diluted Net Loss Per Share***

*Income (loss) per share:* Basic income (loss) per share is computed by dividing consolidated net income (loss) by the weighted average number of common shares outstanding during the period, excluding unvested restricted stock.

For periods of net income when the effects are not anti-dilutive, diluted earnings per share is computed by dividing our net income by the weighted average number of shares outstanding and the impact of all potential dilutive common shares, consisting primarily of stock options, unvested restricted stock and stock purchase warrants. The dilutive impact of our dilutive potential common shares resulting from stock options and stock purchase warrants is determined by applying the treasury stock method.

For the periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses. Approximately 11.9 million, 12.0 million and 10.7 million potential dilutive shares have been excluded in the calculation of diluted net loss per share in 2012, 2011 and 2010, respectively, because their inclusion would be anti-dilutive.

### ***Recent Accounting Pronouncements***

Effective January 1, 2012, the Company adopted ASU 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05). As a result, the Company now presents comprehensive income (loss) in its consolidated financial statements as a single financial statement. The adoption of ASU 2011-05 did not affect the Company’s consolidated results of operations, financial position, or liquidity.

Effective January 1, 2012, the Company adopted ASU 2011-04, *Fair Value Measurement (Topic 820)* (“ASU 2011-04”), which contains amendments to achieve common fair value measurement and disclosures in U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 explains how to measure fair value for financial

reporting. The guidance does not require fair value measurements in addition to those already required or permitted by other Topics. The adoption of ASU 2011-04 did not have any effect on the Company's condensed consolidated results of operations, financial position or liquidity.

Effective January 1, 2012, the Company adopted ASU 2011-08, *Intangibles-Goodwill and Other (Topic 350)* (ASU 2011-08). Previous guidance required an entity to test goodwill for impairment, on at least an annual basis, by comparing the fair value of a reporting unit with its carrying amount, including goodwill. If the fair value of a reporting unit is less than its carrying amount, then a second step of the test must be performed to measure the amount of the impairment loss, if any. Under the amendments in ASU 2011-08, an entity is not required to calculate the fair value of a reporting unit unless the entity determines that it is more likely than not that its fair value is less than its carrying amount. The adoption of ASU 2011-08 did not have a material effect on our results of operations, financial position or cash flows.

In February 2013, the FASB issued ASU 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. The objective of this update is to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments in this Update seek to attain that objective by requiring an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. GAAP to be reclassified in its entirety to net income. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under U.S. GAAP that provide additional detail about those amounts. This would be the case when a portion of the amount reclassified out of accumulated other comprehensive income is reclassified to a balance sheet account (for example, inventory) instead of directly to income or expense in the same reporting period. ASU 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. Early adoption is permitted. The adoptions of ASU 2013-02 will not have a material effect on the Company's results of operation, financial position or cash flows.

### **Note 3 - Fair Value Measurements**

We define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. We report assets and liabilities that are measured at fair value using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

An asset's or liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, we perform a detailed analysis of our assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

We have segregated our financial assets and liabilities that are measured at fair value into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the

table below. We have no non-financial assets and liabilities that are measured at fair value at December 31, 2012 and 2011.

|                         | As of December 31, 2012 |         |              | Balance      |
|-------------------------|-------------------------|---------|--------------|--------------|
|                         | Level 1                 | Level 2 | Level 3      |              |
| <b>Liabilities</b>      |                         |         |              |              |
| Derivatives instruments | \$ -                    | \$ -    | \$ 1,295,613 | \$ 1,295,613 |

|                         | As of December 31, 2011 |         |              | Balance      |
|-------------------------|-------------------------|---------|--------------|--------------|
|                         | Level 1                 | Level 2 | Level 3      |              |
| <b>Liabilities</b>      |                         |         |              |              |
| Derivatives instruments | \$ -                    | \$ -    | \$ 1,886,652 | \$ 1,886,652 |

The following table sets forth a summary of changes in the fair value of our Level 3 liabilities for the years ended December 31, 2012, 2011 and 2010:

| Description             | Balance as of December 31, 2011 | New Liabilities | Unrealized (Gains) | Balance as of December 31, 2012 |
|-------------------------|---------------------------------|-----------------|--------------------|---------------------------------|
| Stock purchase warrants | \$ 1,886,652                    | -               | \$ (591,039)       | \$ 1,295,613                    |

| Description             | Balance as of December 31, 2010 | New Liabilities 2011 | Unrealized (Gains) | Balance as of December 31, 2011 |
|-------------------------|---------------------------------|----------------------|--------------------|---------------------------------|
| Stock purchase warrants | \$ 8,362,995                    | \$ 668,640           | \$ (7,144,983)     | \$ 1,886,652                    |

| Description             | Balance as of December 31, 2009 | New Liabilities 2010 | Unrealized Losses | Balance as of December 31, 2010 |
|-------------------------|---------------------------------|----------------------|-------------------|---------------------------------|
| Stock purchase warrants | \$ 835,299                      | \$ 2,070,146         | \$ 5,457,550      | \$ 8,362,995                    |

At December 31, 2012 and 2011 derivative liabilities are comprised of 2,899,991 warrants to purchase common stock. The warrants are considered to be derivative liabilities due to the presence of net settlement features and, as a result, are recorded at fair value at each balance sheet date. The fair value of our warrants is determined based on the Black-Scholes option pricing model. Use of the Black-Scholes option-pricing model requires the use of unobservable inputs such as the expected term, anticipated volatility and expected dividends. Changes in any of the assumptions related to the unobservable inputs identified above may change the stock purchase warrants' fair value; increases in expected term, anticipated volatility and expected dividends generally result in increases in fair value, while decreases in the unobservable inputs generally result in decreases in fair value. Gains and losses on the fair value adjustments for these derivative instruments are classified in other income (expense) as the change in fair value of derivative instruments in our consolidated statements of operations. The \$0.6 million unrealized gains on the change in the market value of derivative instruments during the year ended December 31, 2012 is due primarily to the change in the closing price of our stock, which was \$1.27 per share as of December 30, 2011 and \$1.12 per share as of December 31, 2012. The \$7.1 million unrealized gains on the change in the market value of derivative instruments during the year ended December 31, 2011 is due primarily to the change in the closing price of our stock, which was \$4.23 per share as of December 31, 2010 and \$1.27 per share as of December 31, 2011. The \$5.5 million unrealized loss on the change in the market value of derivative instruments during the year ended December

31, 2010 is due primarily to the unrecognized losses on the new derivative liabilities issued during 2010 and the change in the closing price of our stock from their date of issuance to \$4.23 per share as of December 31, 2010.

| Quantitative Information about Level 3 Fair Value Measurements |                                    |   |
|--|------------------------------------|---|
| Fair Value at 12/31/2012                                       | Valuation Technique                | Unobservable Inputs   |
| \$ 1,295,613   | Black-Scholes option pricing model | Expected term<br>Expected dividends<br>Anticipated volatility |

As of December 31, 2012 and 2011 the Company had no assets or liabilities that were measured at fair value on a non-recurring basis.

The fair value of long-term debt approximates its face value at December 31, 2012, which was \$2.5 million.

#### Note 4 - Property and Equipment

Property and equipment consisted of the following:

|                                | December 31, |             |
|--------------------------------|--------------|-------------|
|                                | 2012         | 2011        |
| Leasehold improvements         | \$ 758,126   | \$ 758,126  |
| Furniture and office equipment | 234,018      | 234,018     |
| Computer and other equipment   | 1,397,012    | 1,409,580   |
|                                | 2,389,156    | 2,401,724   |
| Less accumulated depreciation  | (1,905,180)  | (1,613,058) |
| Property and equipment, net    | \$ 483,976   | \$ 788,666  |

Depreciation expense for the years ended December 31, 2012 and 2011 was \$0.3 million, \$0.5 million, respectively. Depreciation and amortization expense for the year ended December 31, 2010 was \$5.7 million. The Company recorded an impairment charge in 2010 of approximately \$3.8 million associated with the closing of the Canadian operation upon the expiration of the Protexia<sup>®</sup> contract and of certain patents of approximately \$0.8 million. These charges are included in depreciation and amortization in the accompanying 2010 consolidated statement of operations.

#### Note 5 - Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following:

|   | December 31, |              |
|---|--------------|--------------|
|   | 2012         | 2011         |
| Accrued development expenses                  | \$ 1,716,557 | \$ 1,479,105 |
| Accrued professional services                 | 365,680      | 423,756      |
| Accrued employee payroll and related expenses | 189,746      | 752,469      |
| Other   | 56,894       | -            |
| Accrued expenses and other liabilities        | \$ 2,328,877 | \$ 2,655,330 |

#### Note 6 – Debt

##### *Term Loan and Revolving Line of Credit*

On March 30, 2012, we entered into a Loan Agreement with GE Capital. The Loan Agreement provides for a senior secured debt facility including a \$2.5 million term loan and a revolving line of credit of up to \$5 million based on

our outstanding qualified accounts receivable. On March 30, 2012, the term loan was funded for an aggregate amount of \$2.5 million.

Under the terms of the revolving line of credit, the Company may draw down from the revolving line of credit up to 85% of qualified billed accounts receivable and 80% of qualified unbilled accounts receivable. As of December 31, 2012, the total amount available to draw was approximately \$2.9 million, of which \$1.3 million was drawn and outstanding.

The fixed interest rate on the term loan is 10.14% per annum. The revolving line of credit has an adjustable interest rate based upon the 3-month London Interbank Offered Rate (LIBOR), with a floor of 1.5%, plus 5%. As of December 31, 2012, the interest rate was 6.5%. Both the term loan and the revolving line of credit mature in September 2015. Payments on the term loan were originally interest-only for the first 10 months, which has since been extended to 12 months pursuant to terms of the agreement. Subsequently, the term loan will fully amortize over its remaining term as of December 31, 2012. Principal payments on the term loan are scheduled as follows:

| Year | Principal<br>Payments |
|------|-----------------------|
| 2013 | \$ 749,997            |
| 2014 | 999,996               |
| 2015 | 750,007               |
|      | \$ 2,500,000          |

The term loan is recorded on the 2012 consolidated balance sheet, net of debt discount, as follows:

|                                      |              |
|--------------------------------------|--------------|
| Current portion of long-term debt    | \$ 749,997   |
| Long-term debt, less current portion | \$ 1,704,108 |

If we prepay the term loan and terminate the revolving line of credit prior to the scheduled maturity date, we are obligated to pay a prepayment premium equal to 3% of the then outstanding principal amount of the term loan if prepaid during the first two years of the loan and 2% if prepaid during the third year or thereafter. In addition, we are obligated to pay a final payment fee of 3% of the term loan balance. The final payment fee is being accrued and expensed over the term of the agreement, using the effective interest method and is included in other long-term liabilities on the consolidated balance sheet.

Our obligations under the Loan Agreement are collateralized by a security interest in substantially all of our assets. While the security interest does not, except in limited circumstances, cover our intellectual property, it does cover any proceeds received by us from the use or sale of our intellectual property.

The Loan Agreement contains customary representations, warranties and covenants, including limitations on acquisitions, dispositions, incurrence of indebtedness and the granting of security interests. The representations, warranties and covenants contained in the Loan Agreement were made only for purposes of such agreement and as of a specific date or specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the Loan Agreement.

The Loan Agreement contains certain financial and non-financial covenants. Upon the occurrence and during the continuance of any event of default, GE Capital may, and at the written request of the requisite lenders shall, terminate the commitments under the facilities and declare any or all of the obligations to be immediately due and payable, without demand or notice to us; however, any event of default relating to timely payment of debts, insolvency, liquidation, bankruptcy or similar events will result in automatic acceleration. Among the remedies available to GE Capital in case of an event of default are the taking possession and disposition of any collateral under the Loan Agreement.

In connection with the Loan Agreement, we issued GE Capital warrants to purchase 46,584 shares of the Company's common stock at an exercise price of \$1.61 per share. The warrants are exercisable immediately and subject to customary and standard anti-dilution adjustments. The warrants are classified in equity and, as a result, the fair value of the warrants was charged to additional paid-in capital resulting in a debt discount at the date of issuance. The debt discount is being amortized over the term of the loan agreement using the effective interest method. Financing costs incurred in connection with this agreement are also being amortized over the term of the agreement using the effective interest method.

The fair value of the long-term term loan approximates its face value at December 31, 2012, which was approximately \$2.5 million.

### ***Convertible Notes***

In July 2009, we issued approximately \$19.3 million of convertible notes ("Convertible Notes") and stock purchase warrants to investors in a private placement.

In November 2010, holders of Convertible Notes in the aggregate principal amount (plus accrued interest) of approximately \$17.0 million converted their notes into approximately 6.7 million shares of common stock (at the stated conversion price of \$2.54 per share) pursuant to an early conversion offer we made to all holders. During the fourth quarter of 2010, we expensed approximately \$1.1 million related to the early conversion offer. After we issued a redemption (call) notice in November 2010, holders of additional Convertible Notes in the aggregate principal amount (plus accrued interest) of approximately \$4.8 million converted their notes into approximately 1.9 million shares. Convertible Notes with principal plus accrued interest of approximately \$11,000 were not converted, and as a result of the redemption notice, we paid the holder in cash to satisfy our obligations under such note on the redemption date.

We incurred approximately \$5.8 million of interest expense related to the Convertible Notes in 2010.

### **Note 7 - Commitments and Contingencies**

#### ***Leases***

We lease our offices in Maryland under a 10 year operating lease, which commenced on May 1, 2007. We also lease offices in North Carolina with the lease term expiring in September 2013. Remaining annual minimum payments for these two leases are as follows:

| Year | Lease Payments |
|------|----------------|
| 2013 | \$ 809,400     |
| 2014 | \$ 797,700     |
| 2015 | \$ 821,600     |
| 2016 | \$ 846,200     |
| 2017 | \$ 356,900     |

For each of the years ended December 31, 2012, 2011 and 2010 total rent expense under operating lease agreements approximated \$0.8 million, \$0.8 million and \$1.0 million, respectively.

#### ***License Agreements***

In connection with an acquisition in 2008, we acquired license agreements with The Defence Science and Technology Laboratory of the United Kingdom Ministry of Defence ("DSTL") for the rights to certain technologies. These agreements allow for the licensing of certain patents and technology necessary to perform development of the rPA vaccine program as required under the Company's government contracts. Upon commercialization, the license agreements require that PharmAthene make royalty payments equal to a specified percentage of future sales of products for both government procurement and commercial markets. No royalty payments on these licenses have been incurred.



In 2012 we entered into a commercial licensing agreement allowing for the licensing of certain patent and other intellectual property rights from a research company related to BChE. The agreement includes certain annual maintenance and other development milestone payments. Upon commercialization, the license agreement requires royalty payments equal to a specified percentage of future sales of products for both government procurement and commercial market sales subject to the license through the expiration of the licensed patents. No maintenance or milestone payments were incurred in 2012.

### ***SIGA Litigation***

In December 2006, we filed a complaint against SIGA Technologies, Inc. (“SIGA”) in the Delaware Court of Chancery. The complaint alleged, among other things, that we have the right to license exclusively development and marketing rights for SIGA’s drug candidate, Arestvyr™(Tecovirimat), pursuant to a merger agreement between the parties that was terminated in 2006. The complaint also alleged that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement.

In September 2011, the Court issued an opinion in the case finding that SIGA had breached certain contractual obligations to us and upholding our claims of promissory estoppel. The Court awarded us the right to receive 50% of all net profits (as defined in the court’s final judgment) related to the sale of Arestvyr™ and related products for 10 years following initial commercial sale of the drug once SIGA earns \$40 million in net profits from the sale of Arestvyr™ and related products. The Court also awarded us one-third of our reasonable attorney’s fees and expert witness fees, which amounts to approximately \$2.4 million plus interest. In May 2012, the Court issued its final judgment. SIGA has appealed aspects of the decision to the Delaware Supreme Court. In response, we cross-appealed other aspects of the decision. In January 2013, the Delaware Supreme Court heard oral argument in the case.

We can provide no assurances that SIGA will not prevail on its appeal, that we will be successful in our appeal, and that the Delaware Supreme Court will not overturn the trial court’s decision awarding us a 10 year 50% net profit of the sales of Arestvyr™ and related products (once SIGA retains the first \$40 million in net profit). We have not yet recorded any amount due from SIGA in relation to this case.

### ***Vendor litigation***

One of our vendors mishandled the storage of certain biological materials. While we have recently been engaged in discussions with the vendor to address our concerns, so far we have not come to agreement. The vendor recently filed suit against us in Delaware state court seeking a declaration that they are not liable for damages and seeking damages from us for allegedly not maintaining the required amount and type of insurance. We filed suit against the vendor in Maryland state court seeking damages related to the loss of the property. We believe we did maintain the appropriate amount and type of insurance, that in no event did we harm the vendor, and thus their damages claim is without merit. We plan to vigorously defend against their claims while pursuing our own.

### ***Government Contracting***

Payments to the Company on cost-plus-fee contracts are provisional and are subject to adjustment upon audit by the Defense Contract Audit Agency and BARDA. In our opinion, adjustments that may result from audits are not expected to have a material effect on our financial position, results of operations, or cash flows.

### ***Registration Rights Agreements***

We entered into a Registration Rights Agreement with the investors who participated in the July 2009 private placement of convertible notes and related warrants. We subsequently filed two registration statements on Form S-3 with the Securities and Exchange Commission to register the shares underlying the convertible notes and related warrants, which registration statements have been declared effective. We are obligated to maintain the registration statements effective until the date when all shares underlying the convertible notes and related warrants (and any other securities issued or issuable with respect to in exchange for such shares) have been sold. The convertible notes

were converted or extinguished in 2010, although the related warrants remain outstanding. The warrants will expire on January 28, 2015.

We have separate registration rights agreements with investors, under which we have obligations to keep the corresponding registration statements effective until the registrable securities (as defined in each agreement) have been sold, and under which we may have separate obligations to file registration statements in the future on either a demand or “piggy-back” basis or both.

Under the terms of the convertible notes, which were converted or extinguished in 2010, if after the 2nd consecutive business day (other than during an allowable blackout period) on which sales of all of the securities required to be included on the registration statement cannot be made pursuant to the registration statement (a “Maintenance Failure”), we will be required to pay to each selling stockholder a one-time payment of 1.0% of the aggregate principal amount of the convertible notes relating to the affected shares on the initial day of a Maintenance Failure. Our total maximum obligation under this provision at December 31, 2012, would be approximately \$0.2 million.

Following a Maintenance Failure, we will also be required to make to each selling stockholder monthly payments of 1.0% of the aggregate principal amount of the convertible notes relating to the affected shares on every 30th day after the initial day of a Maintenance Failure, in each case prorated for shorter periods and until the failure is cured. Our total maximum obligation under this provision would be approximate \$0.2 million for each month until the failure, if it occurs, is cured.

## **Note 8 - Stockholders' Equity**

### ***Common Stock***

In April 2010, we completed a public offering of 1,666,668 shares of our common stock at \$1.50 per share and warrants to purchase an aggregate of 500,000 shares of our common stock at an exercise price of \$1.89 per share, generating gross proceeds of approximately \$2.5 million. The warrants became exercisable on October 13, 2010 and expire on October 13, 2015 and are classified as derivative instruments. Placement fees of approximately \$175,000 and legal and other fees of approximately \$140,000 were incurred in connection with this transaction.

In July 2010, we completed a public offering of 2,785,714 shares of our common stock at \$1.40 per share and warrants to purchase an aggregate of 1,323,214 shares of our common stock at an exercise price of \$1.63 per share, generating gross proceeds of approximately \$3.9 million. The warrants became exercisable on January 23, 2011 and expire on January 23, 2017 and are classified as derivative instruments. Placement fees of approximately \$260,000 and legal and other fees of approximately \$145,000 were incurred in connection with this transaction.

In November 2010, we completed an underwritten public offering of 4,945,000 shares of our common stock at a price to the public of \$3.50 per share, generating gross proceeds of approximately \$17.3 million. We incurred offering expenses of approximately \$1.0 million and legal and other fees of approximately \$0.4 million in connection with this transaction.

In June 2011, we completed a public offering of 1,857,143 shares of common stock at \$3.50 per share inclusive of warrants to purchase up to an additional 371,423 shares of common stock. The warrants are exercisable immediately at an exercise price of \$3.50 per share until the fifth anniversary of the date of issuance which is June 15, 2016. The warrants are classified as derivative instruments because they include net settlement provisions. We received gross proceeds of approximately \$6.5 million and net proceeds of approximately \$5.1 million for stock and \$0.7 million for derivative instruments.

### ***Long-Term Incentive Compensation Plan***

In 2007, the Company's stockholders approved the 2007 Long-Term Incentive Compensation Plan (the “2007 Plan”) which provides for the granting of incentive and non-qualified stock options, stock appreciation rights, performance units, restricted common awards and performance bonuses (collectively “awards”) to Company

officers and employees. Additionally, the 2007 Plan authorizes the granting of non-qualified stock options and restricted stock awards to Company directors and to independent consultants.

In 2008, the Company's shareholders approved amendments to the 2007 Plan, increasing from 3.5 million shares to 4.6 million shares the maximum number of shares authorized for issuance under the plan and adding an evergreen provision pursuant to which the number of shares authorized for issuance under the plan will increase automatically in each year, beginning in 2009 and continuing through 2015, according to certain limits set forth in the 2007 Plan. At December 31, 2012, there are approximately 8.2 million shares approved for issuance under the 2007 plan, of which approximately 1.3 million shares are available to be issued. The Board of Directors in conjunction with management determines who receives awards, the vesting conditions and the exercise price. Options may have a maximum term of ten years.

The following tables summarize the activity of the 2007 Plan for options:

|  | Shares      | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term |
|--|-------------|---------------------------------|---|
| <b>Options</b>                                 |             |                                 |   |
| Outstanding January 1, 2010                    | 4,913,366   | \$ 3.88                         | 8.1   |
| Granted  | 2,722,131   | 2.50                            |   |
| Exercised                                      | (22,316)    | 2.56                            |   |
| Forfeited                                      | (2,273,768) | 3.89                            |   |
| Outstanding, December 31, 2010                 | 5,339,413   | \$ 3.18                         | 8.3   |
| Granted  | 1,934,566   | 1.71                            |   |
| Exercised                                      | (44,464)    | 2.66                            |   |
| Forfeited                                      | (936,533)   | 3.07                            |   |
| Outstanding, December 31, 2011                 | 6,292,982   | \$ 2.74                         | 8.0   |
| Granted  | 852,139     | 1.22                            |   |
| Exercised                                      | (31,474)    | 1.24                            |   |
| Forfeited                                      | (888,035)   | 2.91                            |   |
| Outstanding, December 31, 2012                 | 6,225,612   | \$ 2.52                         | 7.4   |
|  |             |                                 |   |
|  | Shares      | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term |
| Exercisable, December 31, 2012                 | 4,044,636   | \$ 2.86                         | 6.6   |
| Vested and expected to vest, December 31, 2012 | 5,963,894   | \$ 2.55                         | 7.3   |

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2012 and (ii) the exercise price of the underlying awards, multiplied by the number of options that had an exercise price less than the closing price on the last trading day. Our outstanding and exercisable options had no aggregate intrinsic value as of December 31, 2012, as the exercise price of all outstanding and exercisable options was below the closing price of the common stock at December 31, 2012.

At December 31, 2012, total compensation costs for unvested stock option awards outstanding approximated \$2.2 million, net of estimated forfeitures, which we expect to recognize as stock compensation expense over a weighted average period of 2.37 years.

***Valuation assumptions used to determine fair value of share-based compensation***

The weighted-average grant date fair value for options granted in 2012, 2011 and 2010 approximated \$0.86, \$1.17 and \$1.88, respectively. The aggregate intrinsic value of options exercised during the years ended December 31,

2012, 2011 and 2010 was \$9,067, \$34,935 and \$29,319, respectively. The total fair value of awards vested during 2012, 2011 and 2010 was \$2,071,649, \$2,259,625 and \$2,300,053, respectively. The fair value for the 2012, 2011 and 2010 awards were estimated at the date of grant using the Black-Scholes option-pricing model using the following assumptions:

|  | <b>December 31,</b> |               |              |
|--|---------------------|---------------|--------------|
|  | <b>2012</b>         | <b>2011</b>   | <b>2010</b>  |
| Weighted-average volatility              | 86%                 | 83%           | 87%          |
| Risk-free rate                           | 0.79% - 1.18%       | 0.79% - 2.79% | 0.28% - 3.2% |
| Expected annual dividend yield           | -                   | -             | -            |
| Expected weighted-average life, in years | 5.9                 | 5.9           | 6.0          |

The valuation assumptions were determined as follows:

- **Weighted average volatility:** We determine expected volatility by using our historical volatility weighted 50% and the average historical volatility from comparable public companies with an expected term consistent with the expected term of our options weighted 50%.
- **Risk-free interest rate:** The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term of the award.
- **Expected annual dividend yield:** The estimate for annual dividends is zero because we have not historically paid a dividend and do not intend to do so in the foreseeable future.
- **Expected life:** The expected term of the awards represents the period of time that the awards are expected to be outstanding. The Company estimated the expected term using the “simplified-method” as it does not have sufficient historical exercise data to provide a reasonable estimate.

The following table summarizes the activity of the 2007 plan for restricted shares:

|                                | <b>Shares</b> | <b>Weighted-Average Grant Date Fair Value</b> | <b>Aggregate Intrinsic Value</b> |
|--------------------------------|---------------|---|----------------------------------|
| <b>Restricted Shares</b>       |               |   |                                  |
| Outstanding January 1, 2010    | 305,316       | \$ 3.36                                       | \$ 598,419                       |
| Granted                        | 35,000        | 2.67  |                                  |
| Vested                         | (101,899)     | 3.29  |                                  |
| Forfeited                      | (127,286)     | 3.95  |                                  |
| Outstanding, December 31, 2010 | 111,131       | \$ 2.92                                       | \$ 470,084                       |
| Granted                        | 145,000       | 1.43  |                                  |
| Vested                         | (123,066)     | 2.59  |                                  |
| Forfeited                      | (9,168)       | 2.46  |                                  |
| Outstanding, December 31, 2011 | 123,897       | \$ 1.53                                       | \$ 157,349                       |
| Granted                        | -             | -   |                                  |
| Vested                         | (110,564)     | 1.53  |                                  |
| Forfeited                      | -             | -   |                                  |
| Outstanding, December 31, 2012 | 13,333        | \$ 1.59                                       | \$ 14,933                        |

### ***Warrants***

At December 31, 2012 and 2011 there were warrants outstanding to purchase 5,620,128 and 5,573,544 shares of our common stock, respectively. At December 31, 2010, there were warrants outstanding to purchase 5,202,121 shares of our common stock (of which 1,323,214 were not exercisable until January 2011). The warrants outstanding as of December 31, 2012 were as follows:

| Number of Common<br>Shares Underlying<br>Warrants | Issue Date/Exercisable<br>Date | Exercise Price | Expiration Date |
|---|--------------------------------|----------------|-----------------|
| 100,778(1)  | Mar-07 / Mar-07                | \$ 3.97        | Mar-17          |
| 705,354(2)  | Mar-09 / Sep-09                | \$ 3.00        | Sep-14          |
| 2,572,775(1)                                      | Jul-09 / Jan-10                | \$ 2.50        | Jan-15          |
| 500,000(2)  | Apr-10 / Oct-10                | \$ 1.89        | Oct-15          |
| 1,323,214(2)                                      | Jul-10 / Jan-11                | \$ 1.63        | Jan-17          |
| 371,423(2)  | Jun-11 / Jun-11                | \$ 3.50        | Jun-16          |
| 46,584(1)   | Mar-12 / Mar-12                | \$ 1.61        | Mar-22          |
| <u>5,620,128</u>                                  |                                |                |                 |

- (1) These warrants to purchase common stock are classified as equity.
- (2) These warrants to purchase common stock are classified as derivative liabilities. The fair value of these liabilities (see note 4) is remeasured at the end of every reporting period and the change in fair value is reported in the consolidated statements of operations as other income (expense).

### Note 9 - Income Taxes

The actual income tax provision differs from the expected income tax provision computed at the federal statutory rate as follows:

|  | December 31,      |                     |                    |
|--|-------------------|---------------------|--------------------|
|  | 2012              | 2011                | 2010               |
| Statutory federal tax benefit                                  | \$ (1,604,648)    | \$ (1,291,175)      | \$ (11,848,754)    |
| State income tax, net of federal benefit                       | (19,918)          | (232,489)           | (1,284,265)        |
| Other permanent differences                                    | 4,975             | 22,101              | 607,981            |
| Foreign rate differential                                      | (80,292)          | (50,173)            | 2,492,478          |
| Rate change  | 388,656           | -                   | -                  |
| Lobbying costs   | 122,204           | -                   | -                  |
| Write-off of expired/forfeited options and conversion of notes | 193,605           | 391,826             | 3,071,189          |
| Canada transfer pricing and expiring attributes                | -                 | (8,965,832)         | -                  |
| Expiration (reversal of expiration) of net operating losses    | -                 | (4,745,271)         | 5,053,927          |
| Other  | 1,393,366         | 732,322             | 309,840            |
| Subtotal   | <u>397,948</u>    | <u>(14,138,691)</u> | <u>(1,597,604)</u> |
| Decrease (increase) in valuation allowance                     | (202,451)         | 14,138,691          | 1,597,604          |
| Income tax expense   | <u>\$ 195,497</u> | <u>\$ -</u>         | <u>\$ -</u>        |

Our net deferred tax assets consisted of the following:

|  | December 31,       |                    |
|--|--------------------|--------------------|
|  | 2012               | 2011               |
| Net operating loss carry forwards                    | \$ 58,334,073      | \$ 62,873,360      |
| Fixed assets/intangibles                             | 114,826            | 49,389             |
| Research and development credits/loss carry forwards | 3,278,995          | 3,291,651          |
| Stock based compensation                             | 3,047,573          | 2,611,770          |
| Accrued expenses and other                           | 2,789,776          | 1,368,036          |
| Total deferred tax assets                            | <u>67,565,243</u>  | <u>70,194,206</u>  |
| <i>Deferred tax liabilities:</i>                     |                    |                    |
| Intercompany bad debt                                | <u>(3,978,944)</u> | <u>(6,209,959)</u> |

|                                |                     |                     |
|--------------------------------|---------------------|---------------------|
| Total deferred tax liabilities | <u>(3,978,944)</u>  | <u>(6,209,959)</u>  |
| Net deferred tax assets        | 63,586,299          | 63,984,247          |
| Less: valuation allowance      | <u>(63,781,796)</u> | <u>(63,984,247)</u> |
| Net deferred tax assets        | <u>\$ (195,497)</u> | <u>\$ -</u>         |

For the years ended December 31, 2012 and 2011, we increased the valuation allowance to fully reserve for the value of deferred tax assets. Due to continued operating losses, there is no indication that it is more likely than not that we will be able to utilize our deferred tax assets. As such, there have been no recoveries of previously recorded valuation allowances in 2012 or 2011.

The U.S. federal net operating loss carry forwards of approximately \$134.3 million will begin to expire in various years beginning in 2021. Under Section 382 of the U.S. Internal Revenue Code, the Company's net operating loss carry forwards may be limited due to underlying ownership of its common stock. The Canadian federal net operating loss carry forwards of approximately \$3.6 million will begin to expire in 2030. The Quebec Provincial net operating loss carry forwards of approximately \$3.6 million will begin to expire in 2030. The UK net operating loss carry forwards of approximately \$19.6 million have an unlimited life.

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some or all of the deferred tax asset will not be realized. The ultimate realization of the deferred tax asset is dependent upon the generation of future taxable income during the periods in which the net operating loss carry forwards are available. We consider projected future taxable income, the scheduled reversal of deferred tax liabilities and available tax planning strategies that can be implemented by us in making this assessment on a jurisdiction-by-jurisdiction basis. Based upon these factors, we have established a full valuation allowance against the net deferred tax asset in 2012, consistent with 2011. The Company has a deferred tax liability related to tax deductible goodwill. The scheduled reversal of this deferred tax liability is not determinable. As such, that deferred tax liability cannot be used as a source of future taxable income with which to realize the deferred tax assets. The cumulative amount of this deferred tax liability is \$195,497.

We have analyzed tax positions in all jurisdictions where the Company is required to file an income tax return and have concluded that we do not have any material unrecognized tax benefits. As such, we believe that any of our uncertain tax positions would not result in adjustments to our effective income tax rate.

#### Note 10 – Supplemental Financial Information (Unaudited)

Quarterly financial information for the years ended December 31, 2012 and 2011 is presented in the following tables:

|                                      | <b>Three months ended</b> |                 |                      |                     |
|--------------------------------------|---------------------------|-----------------|----------------------|---------------------|
|                                      | <b>March 31,</b>          | <b>June 30,</b> | <b>September 30,</b> | <b>December 31,</b> |
| <b>Fiscal year 2012</b>              |                           |                 |                      |                     |
| Revenue                              | \$ 6,149,052              | \$ 6,316,998    | \$ 6,696,126         | \$ 6,013,711        |
| Loss from operations                 | (1,590,696)               | (1,458,204)     | (1,790,377)          | (1,427,113)         |
| Net loss                             | (2,679,888)               | (756,543)       | (213,936)            | (1,269,748)         |
| Net loss per share, basic            | (0.06)                    | (0.02)          | 0.00                 | (0.03)              |
| Net loss per share, diluted          | (0.06)                    | (0.02)          | 0.00                 | (0.03)              |
| <b>Fiscal year 2011</b>              |                           |                 |                      |                     |
| Revenue                              | \$ 6,337,722              | \$ 6,428,840    | \$ 5,260,057         | \$ 6,239,655        |
| Loss from operations                 | (4,539,935)               | (3,081,320)     | (3,021,914)          | (1,082,562)         |
| Net (loss) income                    | (2,075,657)               | (2,437,613)     | (33,496)             | 749,193             |
| Net (loss) income per share, basic   | (0.04)                    | (0.05)          | 0.00                 | 0.02                |
| Net (loss) income per share, diluted | (0.04)                    | (0.05)          | 0.00                 | 0.02                |



