SIGA TECHNOLOGIES INC
Form 10-K
March 10, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x	Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2009
	Or
o	Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the transition period from _____ to _____

Commission File No. 0-23047

SIGA Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	13-3864870 (IRS Employer Identification. No.)
35 East 62nd Street New York, NY (Address of principal executive offices)	10065 (zip code)

Registrant's telephone number, including area code: (212) 672-9100

Securities registered pursuant to Section 12(b) of the Act:	
Title of each class	Name of each exchange on which registered
common stock, $.0001 par value	Nasdaq Global Market

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

None

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

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

Note—Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

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 x No o.

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 o No o.

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. o.

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 definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one): Large Accelerated Filer o Accelerated Filer x Non-Accelerated Filer o Smaller Reporting Company o.

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2009 as reported on the Nasdaq Capital Market was approximately $314,569,000.

As of February 23, 2010 the registrant had outstanding 43,228,135 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

The following document is incorporated herein by reference:

Document	Parts Into Which Incorporated
Proxy Statement for the Company's 2010 Annual Meeting of Stockholders	Part III

SIGA Technologies, Inc.

Form 10-K

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Item 1. Business

Certain statements in this Annual Report on Form 10-K, including certain statements contained in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," constitute "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 words or phrases "can be," "expects," "may affect," "may depend," "believes," "estimate," "project" and similar words and phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to various known and unknown risks and uncertainties and SIGA cautions you that any forward-looking information provided by or on behalf of SIGA is not a guarantee of future performance. SIGA's actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond SIGA's control, including, but not limited to, (i) the risk that potential products that appear promising to SIGA or its collaborators cannot be shown to be efficacious or safe in subsequent pre-clinical or clinical trials, (ii) the risk that SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products, (iii) the risk that SIGA may not be able to obtain anticipated funding for its development projects or other needed funding, (iv) the risk that SIGA may not be able to secure funding from anticipated government contracts and grants, (v) the risk that SIGA may not be able to secure or enforce sufficient legal rights in its products, including patent protection, for its products, (vi) the risk that any challenge to our patent and other property rights, if adversely determined, could affect our business and, even if determined favorably, could be costly, (vii) the risk that regulatory requirements applicable to SIGA's products may result in the need for further or additional testing or documentation that will delay or prevent seeking or obtaining needed approvals to market these products, (viii) the risk that the U.S. Biomedical Advanced Research & Development Authority ("BARDA") may not complete the procurement set forth in its solicitation for the acquisition of smallpox antiviral for the strategic national stockpile, or may complete it on different terms, (ix) the risk that the volatile and competitive nature of the biotechnology industry may hamper SIGA's efforts, (x) the risk that the changes in domestic and foreign economic and market conditions may adversely affect SIGA's ability to advance its research or its products, and (xi) the effect of federal, state, and foreign regulation on SIGA's businesses.All such forward-looking statements are current only as of the date on which such statements were made. SIGA does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Introduction

SIGA Technologies, Inc. is referred to throughout this report as "SIGA," "the Company," "we" or "us."

Since we were incorporated in Delaware on December 28, 1995, SIGA has pursued the research, development and commercialization of novel products for the prevention and treatment of serious infectious diseases, including products for use in defense against biological warfare agents such as smallpox and Arenaviruses. Our lead product, ST-246®, is an orally administered antiviral drug that targets orthopox viruses. In December 2006 the FDA granted Orphan Drug designation to ST-246® for the prevention and treatment of smallpox. In May 2009, we submitted a response to a Request for Proposal ("RFP") issued by BARDA with respect to the purchase of 1.7 million courses of a smallpox antiviral (the "BARDA Smallpox RFP"), and, in June 2009, BARDA informed us that our response to the BARDA Smallpox RFP was deemed technically acceptable and in the competitive range. There can be no assurance that SIGA or any other company will receive an award pursuant to this RFP. Further, any award on this RFP would be subject to negotiation of final contract terms and specifications; thus, the final terms under any contract with BARDA may be materially different than those indicated in the RFP.

Our antiviral programs are designed to prevent or limit the replication of the viral pathogen. As a result of the success of our efforts to develop products for use against agents of biological warfare, we have not spent significant resources to further the development of our anti-infective technologies.

Product Candidates and Market Potential

SIGA Biological Warfare Defense Product Portfolio

Anti-Orthopoxvirus Drug: Smallpox virus is classified as a Category A agent by the U.S. Centers for Disease Control and Prevention ("CDC") and is considered one of the most significant threats for use as a biowarfare agent. While deliberate introduction of any pathogenic agent would be devastating, we believe the one that holds the greatest potential for harming the general U.S. population is smallpox. At present there is no effective drug with which to treat or prevent smallpox infections. To address this serious risk, SIGA scientists have identified a lead drug candidate, ST-246®, which inhibits vaccinia, cowpox, ectromelia (mousepox), monkeypox, camelpox, and variola (smallpox) replication in cell culture and in various animal models, but not other unrelated viruses. Given the safety concerns with the current smallpox vaccine, there should be several uses for an effective smallpox antiviral drug: prophylactically, to protect the non-immune who are at risk to exposure; therapeutically, to reduce mortality and morbidity in those infected with the smallpox virus; and lastly, as an adjunct to the smallpox vaccine in order to reduce the frequency of serious adverse events due to the live virus used for vaccination. In December 2005, the FDA approved our IND application for ST-246®. In June 2006, we successfully completed the first human clinical safety study of ST-246®. The trial showed the drug to be well-tolerated in healthy human volunteers at all tested orally administered doses. In addition, data from blood level exposure was sufficient to support once a day dosing. The study was a double-blind, randomized, placebo controlled, and ascending single dose study. In 2006, ST-246® became the first drug ever to demonstrate 100% protection against human smallpox virus in a primate trial conducted at the CDC. Later in 2006, in two non-human primate trials the drug demonstrated 100% protection for animals injected with high doses of monkeypox virus. One study was sponsored by the National Institute of Allergy and Infectious Diseases ("NIAID") at the National Institutes of Health ("NIH"). The second study was conducted by the U.S. Army Medical Research Institute of Infectious Diseases ("USAMRIID") and was funded by the Department of Defense's Threat Reduction Agency ("DTRA"). In late 2006, ST-246® received Orphan Drug designation for both the treatment and prevention of smallpox. An additional Phase I clinical trial was started in February 2007. The trial was a 21 day, escalating, multiple-dose, Phase I safety, tolerability and pharmacokinetics study of ST-246® at three different dosages in healthy volunteers. The study was completed in December 2007 and as reported the preliminary results indicated that the drug is safe and well tolerated at all tests doses. In August 2008 a Phase I bioequivalence was performed at the Orlando Clinical Research Center in Orlando, Florida to compare ST-246® polymorph form I to form V. We submitted the final Clinical Study Report for that study to the FDA in May 2009. In June 2009 a two phase multiple dose safety/pharmacokinetics evaluation clinical trial was begun to evaluate the effectiveness of ST-246® at different dosage levels. We estimate the final Clinical Study Report for that study will be submitted to the FDA in the second quarter of 2010. During 2006, SIGA was awarded grants and contracts from the NIH totaling approximately $21 million for the continued development of ST-246®. In 2007, SIGA was awarded a grant from the NIH for a total of approximately $600,000, to support the development of ST-246® treatment of smallpox vaccine-related adverse events. In 2008, SIGA was awarded a $55 million contract from the NIH to support the development of additional formulations and orthopox-related indications for ST-246®. In 2008, SIGA was also awarded $20 million from the NIH in supplemental funding to the Company's existing $16.5 million contract. In September 2009, SIGA received a three-year, $3.0 million Phase II grant from the NIH to fund the continued development of ST-246® treatment of smallpox vaccine-related adverse events.

Anti-Arenavirus Drug: Arenaviruses are hemorrhagic fever viruses that have been classified as Category A agents by the CDC due to the great risk that they pose to public health and national safety. Among the Category A viruses recognized by the CDC, there are four hemorrhagic fever arenaviruses (Junin, Machupo, Guanarito and Sabia viruses) for which there are no FDA approved treatments available. In order to meet this threat, SIGA scientists have identified two lead drug candidates, ST-294 and ST-193, which have demonstrated significant antiviral activity in cell culture assays against arenavirus pathogens. We have also demonstrated the therapeutic efficacy of ST-193 in several animal challenge studies. SIGA also has programs against other hemorrhagic fever viruses, including Dengue Fever, Rift Valley Fever, Lymphocytic choriomeningitis virus and Ebola. We believe that the availability of hemorrhagic fever virus antiviral drugs will address national and global security needs by acting as a significant deterrent and defense against the use of arenaviruses as weapons of bioterrorism. In 2006, SIGA received a three-year grant of $6.0 million from the NIH to support the development of antiviral drugs for Lassa fever virus. In 2008, SIGA received a two-year Phase I grant of $1.0 million from the NIH to support the development of antiviral drugs against Dengue Fever.

Broad Spectrum Antiviral: Research and development efforts currently underway at SIGA are aimed at developing a comprehensive biodefense against those microbial agents most likely to be deployed as biological weapons. A broad-spectrum antiviral would have great utility against natural or intentional introduction of these agents into population centers, as well as provide a treatment option in areas where these pathogens are endemic. Screening for antivirals against specific CDC Category A and B pathogens, utilizing SIGA's high throughput screening program, led to the identification of a unique collection of compounds with broad spectrum antiviral activity. Compounds with potent, non-toxic activity against a diversity of virus families are currently being characterized with respect to antiviral mechanism(s) of action. SIGA chemi-informatics tools are being employed to explore and determine structure-activity relationships within lead compound series. To date, we have documented sub-micromolar activity of the broad spectrum antiviral candidate, ST-669, against viruses in the Poxviridae, Filoviridae, Bunyaviridae, Arenaviridae, Flaviviridae, Togaviridae, Retroviridae, and Picornaviridae families. Lead series are currently being assessed with respect to the mechanism of antiviral action, formulated for testing in vivo, and administered by multiple routes and dosing regimens to those small animal species traditionally used for modeling the pathogenesis of Category A viruses. In September 2009, the Company was awarded a two-year, $1.7 million grant from the NIAID to support the development of broad spectrum, small-molecule inhibitors of bunyaviruses. The grant was awarded under the American Recovery and Reinvestment Act of 2009 ("the Recovery Act").

Dengue antiviral: Dengue fever, dengue hemorrhagic fever, and dengue shock syndrome are caused by one of four serotypes of dengue virus of the genus Flavivirus. Dengue is considered by the World Health Organization to be the most important arthropod-borne viral disease with an estimated 50-100 million people infected with the virus each year. There is currently no approved antiviral or vaccine for the treatment or prevention of dengue-mediated disease. SIGA currently has four drug series in the pre-clinical development stage, each with activity against all four serotypes of virus. Compounds from two of these series have recently shown efficacy in a murine model of disease, including ST-610 and ST-148. In 2008, SIGA was awarded a $1.0 million, two-year grant from the NIH to support lead optimization and animal efficacy for our Dengue antiviral program.

Market for Biological Defense Programs

The market for biodefense countermeasures has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from development funding awarded by NIAID, BARDA and the Department of Defense ("DoD"), and procurement of countermeasures by The U.S. Department of Health and Human Services ("HHS"), the CDC and the DoD. The U.S. government is now the largest source of development and procurement funding for academic institutions and biotechnology companies conducting biodefense research or developing vaccines and immunotherapies directed at potential agents of bioterror or biowarfare.

The Project BioShield Act, which became law in 2004, authorizes the procurement of countermeasures for biological, chemical, radiological and nuclear attacks for the Strategic National Stockpile ("SNS"), which is a national repository of medical assets and countermeasures designed to provide federal, state and local public health agencies with medical supplies needed to treat those affected by terrorist attacks, natural disasters, industrial accidents and other public health emergencies. Project BioShield provided appropriations of $5.6 billion to be expended over ten years. The Pandemic and All-Hazards Preparedness Act ("the Preparedness Act"), passed in 2006, established BARDA as the agency responsible for awarding procurement contracts for biomedical countermeasures and providing development funding for advanced research and development in the biodefense arena. The Preparedness Act supplements the funding available under Project BioShield for radiological, nuclear, chemical and biological countermeasures, and provides funding for infectious disease pandemics. Funding for BARDA is created by annual appropriations by Congress. Congress also appropriates annual funding for the CDC for the procurement of medical assets and countermeasures for the SNS and for NIAID to conduct biodefense research. This appropriation funding supplements amounts available under Project BioShield.

Since 2002, HHS has provided over $10 billion to States and localities through various programs to enhance their emergency preparedness activities and to better enable them to respond to large-scale, natural or man-made public health emergencies, such as acts of bioterrorism or infectious disease outbreaks. One of the major concerns in the field of biological warfare agents is smallpox – although declared extinct in 1980 by the World Health Organization (WHO), there is a threat that a rogue nation or a terrorist group may have an illegal inventory of the virus that causes smallpox. The only legal inventories of the virus are held under extremely tight security at the CDC in Atlanta, Georgia and at a laboratory in Russia. As a result of this threat, the U.S. government has announced its intent to make significant expenditures on finding a way to counteract the virus if turned loose by terrorists or on a battlefield.

In addition to the U.S. government, we believe that other potential additional markets for the sale of biodefense countermeasures include:

- state and local governments, which we expect may be interested in these products to protect emergency responders, such as police, fire and emergency medical personnel;
- foreign governments, including both defense and public health agencies;
- non-governmental organizations and multinational companies, including transportation and security companies; and
- health care providers, including hospitals and clinics.

The FDA amended its regulations, effective June 30, 2002, so that certain new drug and biological products 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 only from appropriate animal studies and any additional supporting data. We believe that this change could make it possible for us to have our products which have been proven effective in animal studies to be approved for sale more quickly than under the standard regulatory path.

SIGA Antivirals Product Portfolio

SIGA currently has the following antiviral programs which are in various stages of development, ranging from initial research and screening to Phase I human clinical trials: Orthopox antiviral, New World Arenavirus antiviral, Old World Arenavirus antiviral, Filovirus (Ebola & Marburg) antivirals, Dengue Fever virus antiviral, and Bunyavirus antivirals. Currently there are no approved antivirals available against any of these viruses.

Technology

Antiviral Technology: Two Approaches

SIGA has two approaches to the discovery and development of new antiviral compounds: high-throughput screening (“HTS”) and rational drug design. For HTS SIGA uses whole cell virus inhibition assays, pseudotype virus inhibition assays, as well as validated target biochemical assays. SIGA currently has a 200,000 small molecule compound library in-house that is utilized for screening in these various assays. This strategy allows for both target specific and target neutral screening and identification of novel antiviral compounds. Compounds are also screened for toxicity in various cell lines to develop a therapeutic index (“TI”) which is the concentration that the compound is toxic to 50% of the cells (CC50) divided by the concentration of compound required to inhibit 50% of the virus (EC50) (TI= CC50/EC50). Once hits are identified with an acceptable TI they are selected for chemical optimization and proceed into the antiviral drug development pipeline.

For rational drug design SIGA applies advanced receptor structure-based Virtual Ligand Screening technology for ligand/inhibitor discovery. The analysis of the structure reveals potentially “drugable” pockets. The technology allows us to utilize the three-dimensional structure of the target receptor to screen large virtual compound collections as well as databases of commercially available compounds and prioritize them for subsequent experimental validation. Rational drug design is also used to develop structure activity relationships and lead optimization.

Collaborative Research and Licenses

We have entered into the following license agreements, collaborative research arrangements and contracts:

National Institutes of Health. On September 23, 2009, the Company was awarded a two-year, $1.7 million grant from the NIH to support the development of broad spectrum, small-molecule inhibitors of bunyaviruses. The grant was awarded under the Recovery Act. In September 2009, SIGA was awarded a three-year, $3.0 million Phase II grant from the NIH to fund the continued development of ST-246® treatment of smallpox vaccine-related adverse events. On September 1, 2008, we were awarded a five-year, $55.0 million contract from the NIAID to support the development of additional formulations and orthopox-related indications for ST-246, our lead orthopox drug candidate. In September 2008, we were awarded $20.0 million from the NIAID in supplemental funding to our existing $16.5 million contract, to accelerate process development related to large-scale manufacturing and packaging of ST-246® and commercial-scale validation. The term of the contract was extended through September 28, 2011. In September 2008, we received a two-year, $1.0 million Phase I grant from the NIH to fund lead optimization and animal efficacy for our Dengue antiviral program. In September 2007, we received a two-year, $600,000 grant supporting the development of ST-246® treatment of smallpox vaccine-related adverse events. In July 2007, the NIH awarded us a two-year grant for a total of $530,000 to support our Strep Bacterial Commensal Vector ("BCV") program as a subunit vaccine delivery system. In October and August 2006, the NIH awarded us a $16.5 million, 3-year contract and a $4.8 million, 3-year grant, respectively, both to advance the development of our lead drug candidate, ST-246®. In September 2006, the NIH awarded us a $6.0 million, 3-year grant for the development of an antiviral drug for Lassa fever virus. In August 2004, we were awarded four grants totaling approximately $11.1 million to support our work on smallpox and arenaviruses. For the years ending December 31, 2009, 2008, and 2007, we have recognized grants-related revenue of $3.1 million, $3.0 million, and $2.6 million, respectively, from grants with the NIH. In 2009, 2008 and 2007, we recognized $10.7 million, $5.0 million, and $2.2 million, respectively, in revenue from our contracts with the NIH.

SIGA receives cash payments from the NIH under its grants on monthly and semi-monthly bases, and under its contract on a monthly basis, as the work is performed and the related revenue is recognized. SIGA's current NIH grants and contracts do not include milestone payments. The agreements can be cancelled for non-performance and if cancelled, the Company will not receive funds for additional future work under the agreements.

For a discussion of research and development expenses, see Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations"

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and intense competition. Our competitors include most of the major pharmaceutical companies which have financial, technical and marketing resources significantly greater than ours. Biotechnology and other pharmaceutical competitors include Acambis, Achillion Pharmaceuticals, Arrow Therapeutics, Celldex Therapeutics, Inc., Bavarian Nordic AS, Chimerix Inc., Bioport, Emergent BioSolutions and Novartis. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint venture.

Our biodefense product candidates face significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures.

Our potential commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements, particularly requirements of the U.S. government with respect to biodefense products.

Human Resources and Research Facilities

As of February 15, 2010, we had 55 full-time employees. None of our employees is covered by a collective bargaining agreement, and we consider our employee relations to be good. Our research and development facilities are located in Corvallis, Oregon where we lease approximately 18,100 square feet under a lease agreement signed in January 2007, which expires in December 2011. Our facility in Oregon has been improved to meet the special requirements necessary for the operation of our research and development activities. In January 2010 we entered into a sublease agreement for a 5,700 square foot additional research facility in Corvallis, Oregon.

Intellectual Property and Proprietary Rights

Our commercial success will depend in part on our and our collaborators' ability to obtain and maintain patent protection for our proprietary technologies, drug targets and potential products and to effectively preserve our trade secrets. Because of the substantial length of time and expense associated with bringing potential products through the development and regulatory clearance processes to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the type and breadth of claims allowed in these patents.

We have exclusively licensed the rights to five issued U.S. patents and one issued European patent. These patents have varying lives and they are related to licensed technology for the strep and Gram-positive products. We have one additional patent application in the U.S. and one application in Europe relating to this technology. In addition, we have a nonexclusive license from Washington University of one issued patent in the U.S. This patent is for the technology used for the Gram-negative product opportunities. We are also exclusive owner of six U.S. patents and eleven U.S. utility patent applications. One of these U.S. utility applications relates to our DegP product opportunities. We are also exclusive owner of two U.S. provisional patent applications.

The following are our patent positions as of December 31, 2009:

PATENTS	Number Non-Exclusively Licensed from Washington Univ.	Number Owned by SIGA	Patent Expiration Dates
U.S.	1	6	2014 (4), 2015 (3), 2021 (1), 2016 (2), 2013 (1), 2017 (1)
Europe		2	2021 (1), 2015 (1), 2014 (1)

APPLICATIONS	Number Owned by SIGA
U.S. applications	11
U.S. provisionals	2
PCT	11
Australia	6
Canada	10
Europe	9
Japan	9

We also rely upon trade secret protection for our confidential and proprietary information. No assurance can be given that other companies will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or that we can meaningfully protect our trade secrets.

Government Regulation

Regulatory Approval Process. Regulation by governmental authorities in the United States and other countries will be a significant factor in the production and marketing of any biopharmaceutical products that we may develop. The nature and the extent to which such regulations may apply to us will vary depending on the nature of any such products. Virtually all of our potential biopharmaceutical products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures by the FDA and similar health authorities in foreign countries. Various federal statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of such products. The process of obtaining these approvals and the subsequent compliance with appropriate federal and foreign statutes and regulations requires the expenditure of substantial resources.

In order to test clinically, produce and market products for diagnostic or therapeutic use, a company must comply with mandatory procedures and safety standards established by the FDA and comparable agencies in foreign countries. Before beginning human clinical testing of a potential new drug in the United States, a company must file an IND and receive clearance from the FDA. This application is a summary of the pre-clinical studies that were conducted to characterize the drug, including toxicity and safety studies, as well as an in-depth discussion of the human clinical studies that are being proposed.

The pre-marketing program required for approval by the FDA of a new drug typically involves a time-consuming and costly three-phase process. In Phase I, trials are conducted with a small number of healthy patients to determine the early safety profile, the pattern of drug distribution and metabolism. In Phase II, trials are conducted with small groups of patients afflicted with a target disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large scale, multi-center comparative trials are conducted with patients afflicted with a target disease in order to provide enough data for statistical proof of efficacy and safety required by the FDA and others.

The FDA amended its regulations, effective June 30, 2002, so that certain new drug and biological products 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 only from appropriate animal studies and any additional supporting data.

The FDA closely monitors the progress of each of the three phases of clinical testing and may, in its discretion, reevaluate, alter, suspend or terminate the testing based on the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Estimates of the total time required for carrying out such clinical testing vary between two and ten years. Upon completion of such clinical testing, a company typically submits a New Drug Application ("NDA") or Product License Application ("PLA") to the FDA that summarizes the results and observations of the drug during the clinical testing. Based on its review of the NDA or PLA, the FDA will decide whether to approve the drug. This review process can be quite lengthy, and approval for the production and marketing of a new pharmaceutical product can require a number of years and substantial funding; there can be no assurance that any approvals will be granted on a timely basis, if at all.

Once the product is approved for sale, FDA regulations govern the production process and marketing activities, and a post-marketing testing and surveillance program may be required to monitor continuously a product's usage and its effects. Product approvals may be withdrawn if compliance with regulatory standards is not maintained. Other countries in which any products developed by us may be marketed could impose a similar regulatory process.

An alternative regulatory mechanism is also available. The Emergency Use Authorization authority allows the FDA Commissioner to strengthen the public health protections against biological, chemical, radiological, and nuclear agents that may be used to attack the American people or the U.S. armed forces. Under this authority, the FDA Commissioner may allow medical countermeasures to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there is no adequate, approved, and available alternative.

Legislation and Regulation Related to Bioterrorism Counteragents and Pandemic Preparedness. Because some of our drug candidates are intended for the treatment of diseases that may result from acts of bioterrorism or for pandemic preparedness, they may be subject to the specific legislation and regulation described below and elsewhere herein.

Project BioShield. The Project BioShield Act of 2004 provides expedited procedures for bioterrorism related procurement and awarding of research grants, making it easier for HHS to quickly commit funds to countermeasure projects. Project BioShield relaxes procedures under the Federal Acquisition Regulation for procuring property or services used in performing, administering or supporting biomedical countermeasure research and development. In addition, if the Secretary of HHS deems that there is a pressing need, Project BioShield authorizes the Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts and cooperative agreements related to biomedical countermeasure research and development activity.

Under Project BioShield, the Secretary of HHS, with the concurrence of the Secretary of the Department of Homeland Security and upon the approval of the President, can contract to purchase unapproved countermeasures for the SNS in specified circumstances. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the SNS is paid on delivery of a substantial portion of the countermeasure. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there are sufficient and satisfactory clinical results or research data, including data, if available, from pre-clinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. To exercise this authority, the Secretary of HHS must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- 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 HHS to circumvent the FDA approval process, its use would likely be limited to rare circumstances.

Public Readiness and Emergency Preparedness Act. The Public Readiness and Emergency Preparedness Act, or PREP Act, provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products", including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. Since 2007, the Secretary of HHS has issued 8 declarations under the PREP Act to protect from liability countermeasures that are necessary to prepare the nation for potential pandemics or epidemics, including a declaration on October 10, 2008, that provides immunity from tort liability as it relates to smallpox countermeasures.

Foreign Regulation. As noted above, in addition to regulations in the United States, we might be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our drug candidates. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The actual time required to obtain clearance to market a product in a particular foreign jurisdiction may vary substantially, based upon the type, complexity and novelty of the pharmaceutical drug candidate, the specific requirements of that jurisdiction, and in some countries whether the FDA has previously approved the drug for marketing. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary from country to country.

Regulations Regarding Government Contracting. The status of an organization as a government contractor in the United States and elsewhere means that the organization is also subject to various statutes and regulations, including the Federal Acquisition Regulation, which governs the procurement of goods and services by agencies of the United States and other countries. These governing statutes and regulations can impose stricter penalties than those normally applicable to commercial contracts, such as criminal and civil damages liability and suspension and debarment from future government contracting. In addition, pursuant to various statutes and regulations, government contracts can be subject to unilateral termination or modification by the government for convenience in the United States and elsewhere, detailed auditing requirements, statutorily controlled pricing, sourcing and subcontracting restrictions and statutorily mandated processes for adjudicating contract disputes.

American Recovery and Reinvestment Act. The Recovery Act was passed on February 13, 2009 in response to the current economic crisis. The Recovery Act is designed to spur job creation and preservation, increase economic activity and investment in long-term economic growth, and improve levels of accountability and transparency in government spending, in part through grants like the one we were awarded in September 2009. Recipients of Recovery Act funds are required to report quarterly on the amount of funds spent, the status of the funded project, the number of jobs created and/or saved as a result of the funded project, and other details, all of which are made available to the public through the federal government's official Recovery Act website, Recovery.gov. Compliance with Recovery Act requirements will thus involve increased public disclosure regarding our activities, and may increase our costs.

Availability of Reports and Other Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934 (the "Exchange Act"). The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at www.sec.gov.

In addition, our company website can be found on the Internet at www.siga.com. The website contains information about us and our operations. Copies of each of our filings with the SEC on Form 10-K, Form 10-Q, and Form 8-K, and all amendments to those reports, can be viewed and downloaded free of charge as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC. To view the reports, access www.siga.com, click on “Investor Relations” and “SEC Filing”.

The following corporate governance related documents are also available on our website:

- Code of Ethics and Business Conduct
- Amended and Restated Audit Committee Charter
- Compensation Committee Charter
- Nominating and Corporate Governance Committee Charter
- Procedure for Sending Communications to the Board of Directors
- Procedures for Security Holder Submission of Nominating Recommendations
- 2004 Policy on Confidentiality of Information and Securities Trading

To review these documents, access www.siga.com and click on “Corporate Governance”.

Any of the above documents can also be obtained in print by any shareholder upon request to the Secretary, SIGA Technologies, Inc., 35 East 62nd Street, New York, New York 10065.

Item 1A. Risk Factors

This report contains forward-looking statements and other prospective information relating to future events. These forward-looking statements and other information are subject to risks and uncertainties that could cause our actual results to differ materially from our historical results or currently anticipated results including the following:

Risks Related to Our Financial Position and Need for Additional Financing

We have incurred operating losses since our inception and expect to incur net losses and negative cash flow for the foreseeable future.

We incurred net losses of approximately $17.6 million, $8.6 million, and $5.6 million, for the years ended December 31, 2009, 2008, and 2007, respectively. On January 1, 2009, we recognized a $2.7 million increase in our opening accumulated deficit balance reflecting the cumulative effect of a change in accounting principle recorded in connection with certain warrants to acquire shares of the Company's common stock. As of December 31, 2009, 2008, and 2007, our accumulated deficit was approximately $90.9 million, $70.6 million, and $62.0 million, respectively. We expect to continue to have significant operating expenses. We will need to generate significant revenues to achieve and maintain profitability.

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 slower 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 might include acquisitions of other businesses, acquisition expenses and any cash used to make these acquisitions will reduce our available cash.

Our business will suffer if we are unable to raise additional equity funding.

Unless and until we successfully sell any of our products, such as pursuant to the BARDA Smallpox RFP, we will continue to be dependent on our ability to raise money through the exercise of existing options or warrants or through the issuance of new equity. There is no guarantee that we will continue to be successful in raising such funds. If we are unable to raise additional equity funds, we may be forced to discontinue or cease certain operations. We currently have sufficient operating capital to finance our operations beyond the next twelve months. Our annual operating needs vary from year to year depending upon the amount of revenue generated through grants, contracts and licenses and the amount of projects we undertake, as well as the amount of resources we expend, in connection with acquisitions all of which may materially differ from year to year and may adversely affect our business.

Any additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Risks Related to Our Common Stock

Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.

The volatile price of our stock makes it difficult for investors to predict the value of their investments, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- initiating, completing or analyzing, or a delay or failure in initiating, completing or analyzing, pre-clinical or clinical trials or the design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenues and other results of operations; and
- changes in financial estimates by securities analysts.

Additionally, because the volume of trading in our stock fluctuates significantly at times, any information about SIGA in the media may result in significant volatility in our stock price.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

A future issuance of preferred stock may adversely affect the rights of the holders of our common stock.

Our certificate of incorporation allows our Board of Directors to issue up to 10,000,000 shares of preferred stock and to fix the voting powers, designations, preferences, rights and qualifications, limitations or restrictions of these shares without any further vote or action by the stockholders. The rights of the holders of common stock will be subject to, and could be adversely affected by, the rights of the holders of any preferred stock that we may issue in the future. The issuance of preferred stock, while providing desirable flexibility in connection with our future activities, could also have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock, thereby delaying, deferring or preventing a change in control.

Concentration of ownership of our capital stock could delay or prevent a change of control.

Our directors, executive officers and principal stockholders beneficially own a significant percentage of our common stock. They also have, through the exercise or conversion of certain securities, the right to acquire additional common stock. As a result, these stockholders, if acting together, have the ability to significantly influence the outcome of corporate actions requiring shareholder approval. Additionally, this concentration of ownership may have the effect of delaying or preventing a change in control of SIGA. As of December 31, 2009, directors, officers and principal stockholders beneficially owned approximately 31.0% of our stock.

Risks Related to Our Dependence on U.S. Government Contracts and Grants

Most 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.

Until and unless we successfully sell any of our products, our ability to generate revenues will largely depend on our ability to enter into additional research grants, collaborative agreements, strategic alliances, contracts and license agreements with third parties or maintain the agreements we currently have in place. Substantially all of our revenues for the years ended December 31, 2009, 2008, and 2007, respectively, were derived from grants and contracts. Our current revenue is primarily derived from contract work being performed for the NIH under grants and two major contracts which are scheduled to expire from September 2011 through September 2013.

Our future business may be harmed as a result of the government contracting process, which is a competitive bidding process that involves risks not present in the commercial contracting process.

- We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, including:
- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the risk that the government will issue a request for proposal to which we would not be eligible to respond;
- the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

The U.S. government may choose to award future contracts for the supply of smallpox anti-virus and other biodefense product candidates that we are developing to our competitors instead of to us. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, BARDA has issued a request for proposal for treatment courses for symptomatic individuals exposed to smallpox for the SNS. We have submitted a proposal responding to this request for proposal. We expect that our ability to secure an award will depend primarily on the technical merits of ST-246®. The U.S. government may purchase another company’s product candidate instead. If we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition, and operating results could be materially adversely affected.

The success of our business with the U.S. government depends on our compliance with regulations and obligations under our U.S. government contracts and various federal statutes and regulations.

Our business with the U.S. government is subject to specific procurement regulations and a variety of other legal compliance obligations. These laws and rules include those related to:

- procurement integrity;
- export control;
- government security regulations;
- employment practices;
- protection of the environment;

- accuracy of records and the recording of costs; and
- foreign corrupt practices.

In addition, before awarding us any contracts, the U.S. government could require that we respond satisfactorily to a request to substantiate our commercial viability and industrial capabilities. Compliance with these obligations increases our performance and compliance costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations would have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

Unfavorable provisions in government contracts, some of which may be customary, may harm our future business, financial condition and potential operating results.

Government contracts customarily contain provisions that give the government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the government to:

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including through the use of equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount specified in a contract;
- decline to exercise an option to purchase the maximum amount specified in a contract;
- claim rights to products, including intellectual property, developed under the contract;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination.

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. Our government contracts could be terminated under these circumstances. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

Risks Related to Product Development

Our business depends significantly on our success in completing development of and commercializing drug candidates that are still under development. If we are unable to commercialize these drug candidates, or experience significant delays in doing so, our business will be materially harmed.

We have invested a substantial majority of our efforts and financial resources in the development of our drug candidates. Our ability to generate near-term revenue is particularly dependent on the success of our smallpox antiviral drug candidate ST-246®. The commercial success of our drug candidates will depend on many factors, including:

- successful development, formulation and cGMP scale-up of drug manufacturing that meets FDA requirements;
- successful development of animal models;
- successful completion of non-clinical development, including studies in approved animal models;
- our ability to pay the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- a determination by BARDA that our biodefense drug candidates should be purchased for the SNS prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements on reasonable terms with contract manufacturers;
- manufacturing stable commercial supplies of drug candidates, including availability of raw materials;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

We expect to rely on FDA regulations known as the “animal rule” to obtain approval for our biodefense drug candidates. The animal rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval. These regulations are relatively new, and we have limited experience in the application of these rules to the drug candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our drug candidates in humans. If we are not successful in completing the development and commercialization of our drug candidates, our business could be harmed.

We will not be able to commercialize our drug candidates if our pre-clinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or animal studies do not demonstrate efficacy.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive pre-clinical development, clinical trials to demonstrate the safety of our drug candidates and clinical or animal trials to demonstrate the efficacy of our drug candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results.

A failure of one or more of our clinical trials or animal efficacy studies can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, pre-clinical testing and the clinical trial or animal efficacy study process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional pre-clinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; and
- the effects of our drug candidates may not be the desired effects or may include undesirable side effects or the drug candidates may have other unexpected characteristics.

We are in various stages of product development and there can be no assurance of successful commercialization.

In general, our research and development programs are at an early stage of development. To obtain FDA approval for our biological warfare defense products we will be required to perform at least one animal efficacy model and provide animal and human safety data. Our other products will be subject to the usual FDA regulatory requirements which include a number of phases of testing in humans.

The FDA has not approved any of our biopharmaceutical product candidates. Any drug candidate we develop will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercial sale. We cannot be sure our approach to drug discovery will be effective or will result in the development of any drug. We cannot predict with certainty whether any drug resulting from our research and development efforts will be commercially available within the next several years, or if they will be available at all.

Even if we receive initially positive pre-clinical or clinical results, such results do not mean that similar results will be obtained in later stages of drug development, such as additional pre-clinical testing or human clinical trials. All of our potential drug candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that none of our drug candidates will or can:

- be safe, non-toxic and effective;
- otherwise meet applicable regulatory standards;
- receive the necessary regulatory approvals;
- develop into commercially viable drugs;
- be manufactured or produced economically and on a large scale;
- be successfully marketed;
- be reimbursed by government and private insurers; and
- achieve customer acceptance.

In addition, third parties may preclude us from marketing our drugs through enforcement of their proprietary rights that we are not aware of, or third parties may succeed in marketing equivalent or superior drug products. Our failure to develop safe, commercially viable drugs would have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Commercialization

Because we must obtain regulatory clearance or otherwise operate under strict legal requirements in order to test and market our products in the U. S., we cannot predict whether or when we will be permitted to commercialize our products.

A pharmaceutical product cannot generally be marketed in the U.S. until it has completed rigorous pre-clinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Pharmaceutical products typically take many years to satisfy regulatory requirements and require the expenditure of substantial resources depending on the type, complexity and novelty of the product and its intended use.

Before commencing clinical trials in humans, we must submit and receive clearance from the FDA by means of an IND application. Institutional review boards and the FDA oversee clinical trials and such trials:

- must be conducted in conformance with the FDA regulations;
- must meet requirements for institutional review board oversight;
- must meet requirements for informed consent;
- must meet requirements for good clinical and manufacturing practices;
- are subject to continuing FDA oversight;
- may require large numbers of test subjects; and
- may be suspended by us or the FDA at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in any of the Company’s IND applications or the conduct of these trials.

Before receiving FDA clearance to market a product in the absence of a medical or public health emergency, we must demonstrate that the product is safe and effective on the patient population that will be treated. Data we obtain from pre-clinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory clearances. Additionally, we have limited experience in conducting and managing the clinical trials and manufacturing processes necessary to obtain regulatory clearance.

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If full regulatory clearance of a product is granted, this clearance will be limited only to those states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious. We cannot ensure that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive full marketing clearance.

The biopharmaceutical market in which we compete and will compete is highly competitive.

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 also are many companies, 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 companies have substantially greater financial, technical, research and development resources, and human resources than us. Competitors may develop products or other technologies that are more effective than any that are being developed by us or may obtain FDA approval for products more rapidly than us. If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have no experience. Many of these companies also have manufacturing facilities and established marketing capabilities that would enable such companies to market competing products through existing channels of distribution. Three companies with similar profiles are VaxGen, Inc., which is developing vaccines against anthrax, smallpox and HIV/AIDS; Avant Immunotherapeutics, Inc., which has vaccine programs for agents of biological warfare; and Chimerix, Inc., which is developing an alternative smallpox therapeutic.

Our potential products may not be acceptable in the market or eligible for third-party reimbursement resulting in a negative impact on our future financial results.

Any product we develop may not achieve market acceptance. The degree of market acceptance of any of our products will depend on a number of factors, including:

- the establishment and demonstration in the medical community of the clinical efficacy and safety of such products;
- the potential advantage of such products over existing treatment methods;
- the cost of our products relative to their perceived benefits; and
- reimbursement policies of government and third-party payors.

Physicians, patients or the medical community in general may not accept or utilize any product we may develop. Our ability to generate revenues and income with respect to drugs, if any, developed through the use of our technology will depend, in part, upon the extent to which reimbursement for the cost of such drugs will be available from third-party payors, such as government health administration authorities, private healthcare insurers, health maintenance organizations, pharmacy benefits management companies and other organizations. Third-party payors are increasingly disputing the prices charged for pharmaceutical products. If third-party reimbursement was not available or sufficient to allow profitable price levels to be maintained for drugs we develop, it could adversely affect our business.

If our products harm people, we may experience product liability claims that may not be covered by insurance.

We face an inherent business risk of exposure to potential product liability claims in the event that drugs we develop are alleged to cause adverse effects on patients. Such risk exists for products being tested in human clinical trials, as well as products that receive regulatory approval for commercial sale. We have obtained and intend to keep in place product liability insurance with respect to drugs we develop. However, we may not be able to obtain such insurance. Even if such insurance is obtainable, it may not be available at a reasonable cost or in a sufficient amount to protect us against liability.

We may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market, which could harm sales of the affected products.

If we or others identify side effects after any of our products are on the market, or if manufacturing problems occur:

- regulatory approval may be withdrawn;
- reformulation of our products, additional clinical trials, changes in labeling of our products may be required;
- changes to or re-approvals of our manufacturing facilities may be required;
- sales of the affected products may drop significantly;
- our reputation in the marketplace may suffer; and
- lawsuits, including class action suits, may be brought against us.

Any of the above occurrences could harm or prevent sales of the affected products or could increase the costs and expenses of commercializing and marketing these products.

Healthcare reform and controls on healthcare spending may limit the price we charge for any products and the amounts that we can sell.

The U.S. government and private insurers have considered ways to change, and have changed, the manner in which healthcare services are provided in the U.S. Potential approaches and changes in recent years include controls on healthcare spending and the creation of large purchasing groups. In the future, the U.S. government may institute further controls and limits on healthcare spending, including through the Medicare and Medicaid programs. These controls and limits might affect the payments we could collect from sales of any products. Uncertainties regarding future healthcare reform and private market practices could adversely affect our ability to sell any of our products profitably in the U.S. At present, we do not foresee any change in FDA regulatory policies that would adversely affect our development programs.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

As we continue to expand our operations outside of the United States, we must comply with numerous laws and regulations relating to international business operations. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside of the United States will require us to dedicate additional resources to compliance with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA's accounting provisions.

Risks Related to Manufacturing and Manufacturing Facilities

Problems related to large-scale commercial manufacturing could cause us to delay product launches or experience shortages of products.

Our drug candidates require several manufacturing steps, and may involve complex techniques to assure quality and sufficient quantity, especially as the manufacturing scale increases. Our products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including obtaining materials, filling, labeling, packaging, storage and shipping and quality control and testing, some of which all pharmaceutical companies, including SIGA, experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. We will not be able to sell any lot that fails to satisfy release testing specifications.

If third parties do not manufacture our drug candidates or products in sufficient quantities and at an acceptable cost or in compliance with regulatory requirements and specifications, the development and commercialization of our drug candidates could be delayed, prevented or impaired.

We currently rely on third parties to manufacture drug candidates that we require for pre-clinical and clinical development. In addition, we indicated in our response to the BARDA Smallpox RFP that we intend to manufacture ST-246® using contract manufacturers. Any significant delay in obtaining adequate supplies of our drug candidates could adversely affect our ability to develop or commercialize these drug candidates. We expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of drug candidates that we successfully develop. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, the success of those products may be jeopardized. Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our ability to develop drug candidates and commercialize any product that receives regulatory approval on a timely and competitive basis.

We currently rely on third parties to demonstrate regulatory compliance and for quality assurance with respect to the drug candidates manufactured for us. We intend to continue to rely on these third parties for these purposes with respect to production of commercial supplies of drugs that we successfully develop. Manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with applicable regulations.

We cannot be certain that our present or future manufacturers will be able to comply with these regulations and other FDA regulatory requirements or similar regulatory requirements outside the U.S. While our contracts call for compliance with all applicable regulatory requirements, we do not control compliance by these manufacturers with these regulations and standards. If we or these third parties fail to comply with applicable regulations, sanctions could be imposed on us, which could significantly and adversely affect supplies of our drug candidates.

Our activities may involve hazardous materials, use of which may subject us to environmental regulatory liabilities.

Our biopharmaceutical research and development sometimes involves the controlled use of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for damages, and this liability could exceed our resources. The research and development activities of our company do not produce any unusual hazardous products. We do use small amounts of radioactive isotopes commonly used in pharmaceutical research, which are stored, used and disposed of in accordance with Nuclear Regulatory Commission regulations. We maintain liability insurance in the amount of approximately $5,000,000 and we believe this should be sufficient to cover any contingent loss.

We believe that we are in compliance in all material respects with applicable environmental laws and regulations and currently do not expect to make material additional capital expenditures for environmental control facilities in the near term. However, we may have to incur significant costs to comply with current or future environmental laws and regulations.

Risks Related to Sales of Biodefense Products to the U.S. Government

Our business could be adversely affected by a negative audit by the U.S. government.

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

The DCAA also reviews the adequacy of, and a contractor’s compliance with, its internal control systems and policies, including the contractor’s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, 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 of prohibition from doing business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us.

We may be subject to sanction for past non-compliance with certain regulatory audit requirements.

In June 2009 we became aware that we did not comply with certain Department of Health and Human Services (“DHHS”) regulations requiring the submission of yearly audited statements to the Office of the Inspector General (“OIG”) Office of Audit Services. On September 30, 2009, we submitted the required audits and related statements to the OIG Office of Audit Services. We have asked that the OIG not take any enforcement action in this matter. There can be no assurance that no enforcement action will be taken in this matter and, if taken, whether such enforcement action would have a material adverse impact on our operations.

Laws and regulations affecting government contracts might 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 do business with federal, state and local government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, 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 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.

Risks Related to Regulatory Approvals

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

Our drug candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a drug candidate will prevent us from commercializing the drug candidate. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations and consultants to assist us in this process. Securing FDA approval requires the submission to the FDA of extensive pre-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information in order to establish the drug candidate’s safety and efficacy. Our future products may not be effective, may be only moderately effective, or may prove to have significant side effects, toxicities, or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to have our products marketed outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval.

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We and our potential future collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

The Fast Track designation for ST-246® may not actually lead to a faster development or regulatory review or approval process.

We have obtained a "Fast Track" designation from the FDA for ST-246®. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

Risks Related to Our Dependence on Third Parties

If third parties on whom we rely for clinical trials or certain animal trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business may suffer.

We do not have the ability to independently conduct the clinical trials, and certain animal trials, required to obtain regulatory approval for our products. We depend on independent investigators, contract research organizations and other third party service providers to conduct trials of our drug candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our drug candidates.

Risks Related to Our Intellectual Property

Our ability to compete may decrease if we do not adequately protect our intellectual property rights.

Our commercial success will depend in part on our ability to obtain and maintain patent protection for our proprietary technologies, drug targets and potential products and to effectively preserve our trade secrets. Because of the substantial length of time and expense associated with bringing potential products through the development and regulatory clearance processes to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the type and breadth of claims allowed in these patents.

We have a nonexclusive license from Washington University with respect to one issued U.S. patent. We are also exclusive owner of six U.S. patents and eleven U.S. patent applications. We are also the exclusive owner of two U.S. provisional patent applications. The issued patents have varying lives.

We included a summary of our patent positions as of December 31, 2009 in Part I, Item 1 of this document.

We also rely on trade secrets, know-how, continuing technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of trade secrets and proprietary information, we require our employees, consultants and some collaborators to execute confidentiality and invention assignment agreements upon commencement of a relationship with us. These agreements may not provide meaningful protection for our trade secrets, confidential information or inventions in the event of unauthorized use or disclosure of such information, and adequate remedies may not exist in the event of such unauthorized use or disclosure.

If our technologies are alleged or found to infringe the patents or proprietary rights of others, we may be sued, we may have to pay damages or be barred from pursuing a technology, or we may have to license those rights to or from others on unfavorable terms. Even if we prevail, such litigation may be costly.

Our commercial success will depend significantly on our ability to operate without infringing the patents or proprietary rights of third parties. Our technologies, or the technologies of third parties on which we may depend, may infringe the patents or proprietary rights of others. If there is an adverse outcome in any dispute concerning rights to these technologies, then we could be subject to significant liability, required to license disputed rights from or to other parties and/or required to cease using a technology necessary to carry out our research, development and commercialization activities. At present, we are unaware of any patent infringement claim relating to any of our products that is likely to be asserted.

The costs to establish or defend against claims of infringement or interference with patents or other proprietary rights can be expensive and time-consuming, even if the outcome is favorable. An outcome of any patent or proprietary rights administrative proceeding or litigation that is unfavorable to us may have a material adverse effect on us. We could incur substantial costs if we are required to defend ourselves in suits brought by third parties or if we initiate such suits. We may not have sufficient funds or resources in the event of litigation. Additionally, we may not prevail in any such action.

Any dispute resulting from claims based on patents and proprietary rights could result in a significant reduction in the coverage of the patents or proprietary rights owned, optioned by or licensed to us and limit our ability to obtain meaningful protection for our rights. If patents are issued to third parties that contain competitive or conflicting claims, we may be legally prohibited from researching, developing or commercializing potential products or be required to obtain licenses to these patents or to develop or obtain alternative technology. We may be legally prohibited from using technology owned by others, may not be able to obtain any license to the patents or technologies of third parties on acceptable terms, if at all, or may not be able to obtain or develop alternative technologies.

In December 2006, PharmAthene, Inc. (“PharmAthene”) filed an action against us in the Delaware Court of Chancery captioned PharmAthene, Inc. v. SIGA Technologies, Inc., C.A. No. 2627-N. In its amended complaint, PharmAthene asks the Court to order us to enter into a license agreement with PharmAthene with respect to ST-246®, as well as issue a declaration that we are obliged to execute such a license agreement, and award damages resulting from our supposed breach of that obligation. PharmAthene also alleges that we breached an obligation to negotiate such a license agreement in good faith, as well as seeks damages for promissory estoppel and unjust enrichment based on supposed information, capital and assistance that PharmAthene allegedly provided to us during the negotiation process. In January 2008, the Court of Chancery denied our motion to dismiss the original complaint, and discovery proceeded. In May 2009, PharmAthene amended its complaint with respect to its claim for breach of an obligation to negotiate in good faith, and we filed our answer to the amended complaint and counterclaim denying the new claim and asserting defenses.

PharmAthene has submitted an expert report asserting several alternative theories of damages, including amounts in a wide range of up to one billion dollars. We believe that the expert’s damages analyses are flawed and methodologically unsound. We also continue to believe that we have meritorious defenses to the claims. No trial date has been set. It is not currently possible to estimate a range of loss, if any.

In addition, like many biopharmaceutical companies, we may from time to time hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. It is possible that we and/or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations.

Other Risks

We may have difficulty managing our growth.

We might experience growth in the number of our employees and the scope of our operations. This potential future growth could place a significant strain on our management and operations. Our ability to manage this potential growth will depend upon our ability to broaden our management team and our ability to attract, hire and retain skilled employees. Our success will also depend on the ability of our officers and key employees to continue to implement and improve our operational and other systems and to hire, train and manage our employees.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters are located in New York City and our research and development facilities are located in Corvallis, Oregon. In New York, we occupy approximately 1,800 square feet under an Office Service Agreement with an affiliate of a shareholder, that is cancelable upon 60 days notice. In Corvallis, we lease approximately 18,100 square feet under an amended lease agreement signed in January 2007, which expires in December 2011. Our facility in Oregon has been improved to meet the special requirements necessary for the operation of our research and development activities. In January 2010 we entered into a sublease agreement for 5,700 square feet of additional research facility in Corvallis, Oregon. In the opinion of the management, these facilities are sufficient to meet the current and anticipated future requirements of SIGA.

Item 3. Legal Proceedings

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Item 4. Reserved

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Price Range of Common Stock

Our common stock trades under the symbol "SIGA". Our common stock has been traded on the Nasdaq Global Market since September 3, 2009 and, prior to such date, had been traded on the Nasdaq Capital Market since September 9, 1997. Prior to that time there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low sales prices for the common stock, as reported on the Nasdaq Capital Market or Nasdaq Global Market, as applicable.

Price Range		
2008	High	Low
First Quarter	$ 3.27	$ 1.78
Second Quarter	$ 3.91	$ 2.12
Third Quarter	$ 4.19	$ 2.29
Fourth Quarter	$ 3.80	$ 1.94
2009	High	Low
First Quarter	$ 5.86	$ 3.15
Second Quarter	$ 8.88	$ 4.73
Third Quarter	$ 8.63	$ 6.25
Fourth Quarter	$ 10.09	$ 4.83

The following line graph compares the cumulative total stockholder return through December 31, 2009, assuming reinvestment of dividends, by an investor who invested $100 on December 31, 2004 in each of (i) our common stock, (ii) the Nasdaq National Market-US; and (iii) the Nasdaq Pharmaceutical Index.

Value of Initial Investment	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08	12/31/09
SIGA Technologies, Inc.	$ 100.00	$ 57.23	$ 225.90	$ 185.54	$ 196.99	$ 349.40
NASDAQ Composite Index	$ 100.00	$ 101.37	$ 111.03	$ 121.92	$ 72.49	$ 104.31
NASDAQ Biotech Composite Index	$ 100.00	$ 102.84	$ 103.89	$ 108.65	$ 94.93	$ 109.77

As of February 23, 2010, the closing bid price of our common stock was $6.36 per share. There were 54 holders of record as of February 23, 2010. We believe that the number of beneficial owners of our common stock is substantially greater than the number of record holders, because a large portion of common stock is held in broker “street names”.

We have paid no dividends on our common stock and do not expect to pay cash dividends in the foreseeable future. We are not under any restriction as to our present or future ability to pay dividends. We currently intend to retain any future earnings to finance the growth and development of our business.

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”.

Item 6. Selected Financial Data (in thousands, except share and per share data)

The following table sets forth selected financial information derived from our audited consolidated financial statements as of and for the years ended December 31, 2009, 2008, 2007, 2006, and 2005.

The year ended December 31,	Revenues	Selling, general & administrative	Research and development	Patent preparation fees
2009	$ 13,812	$ 7,533	$ 17,423	$ 734
2008	$ 8,066	$ 4,608	$ 11,613	$ 582
2007	$ 6,699	$ 3,704	$ 9,943	$ 515
2006	$ 7,258	$ 4,624	$ 9,149	$ 295
2005	$ 8,477	$ 2,481	$ 8,295	$ 232

The year ended December 31,	Operating loss	Net loss	Net loss per share: basic & diluted	Weighted average shares outstanding: basic and diluted
2009	$ (11,879)	$ (17,618)	$ (0.47)	37,463,255
2008	$ (8,737)	$ (8,599)	$ (0.25)	34,732,625
2007	$ (7,463)	$ (5,639)	$ (0.17)	33,330,814
2006	$ (6,810)	$ (9,899)	$ (0.35)	28,200,130
2005	$ (2,532)	$ (2,288)	$ (0.09)	24,824,824

As of and for the year ended December 31,	Total assets	Cash & cash equivalents	Long term obligations	Total stockholders' equity	Net cash used in operating activities
2009	$ 25,915	$ 14,496	$ 6,398	$ 10,488	$ (8,471)
2008	$ 8,797	$ 2,322	$ 2,924	$ 1,555	$ (7,198)
2007	$ 10,589	$ 6,832	$ 3,243	$ 5,228	$ (5,448)
2006	$ 14,028	$ 10,640	$ 4,696	$ 7,282	$ (4,438)
2005	$ 6,132	$ 1,772	$ 642	$ 3,231	$ (1,392)

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 and notes to those statements and other financial information appearing elsewhere in this Annual Report. In addition to historical information, the following discussion and other parts of this Annual Report contain forward-looking information that involves risks and uncertainties.

Overview

Since our inception on December 28, 1995, SIGA has pursued the research, development and commercialization of novel products for the prevention and treatment of serious infectious diseases, including products for use in defense against biological warfare agents such as smallpox and Arenaviruses. Our lead product, ST-246®, is an orally administered antiviral drug that targets orthopox viruses. In December 2006 the FDA granted Orphan Drug designation to ST-246® for the prevention and treatment of smallpox. In September 1, 2008, we were awarded a five-year, $55.0 million contract from the NIAID, to support the development of additional formulations and orthopox-related indications for ST-246, our lead orthopox drug candidate. In September 2008, we were awarded $20.0 million from the NIAID in supplemental funding to our existing $16.5 million contract, to accelerate process development related to large-scale manufacturing and packaging of ST-246® and commercial-scale validation. The term of the contract was extended through September 28, 2011. In May 2009, we submitted the BARDA Smallpox RFP, and, in June 2009, BARDA informed us that our response to the BARDA Smallpox RFP was deemed technically acceptable and in the competitive range. There can be no assurance that SIGA or any other company will receive an award pursuant to this RFP. Further, any award on this RFP would be subject to negotiation of final contract terms and specifications; thus, the final terms under any contract with BARDA may be materially different than those indicated in the RFP.

Our anti-viral programs are designed to prevent or limit the replication of the viral pathogen. As a result of the success of our efforts to develop products for use against agents of biological warfare, we have not spent significant resources to further the development of our anti-infective technologies.

Critical Accounting Estimates

The methods, estimates and judgments we use in applying our accounting policies have a significant impact on the results we report in our consolidated financial statements, which we discuss under the heading "Results of Operations" following this section of our Management's Discussion and Analysis. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Our most critical accounting estimates include the assessment of recoverability of goodwill, which could affect goodwill impairments; and the assessment of recoverability of long-lived assets, which primarily would affect operating income if an impairment exists. Below, we discuss these policies further, as well as the estimates and judgments involved. Other key accounting policies, including revenue recognition, are less subjective and involve a lower degree of estimates and judgment.

Significant Accounting Policies

The following is a brief discussion of the more significant accounting policies and methods used by us in the preparation of our consolidated financial statements. Note 2 of the Notes to the Consolidated Financial Statements includes a summary of all of the significant accounting policies.

Share-based Compensation

The Company accounts for its stock-based compensation programs under the provisions Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC") 718Compensation – Stock Compensation ("ASC 718"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to the Employee Stock Purchase Plan ("employee stock purchases") based on estimated fair values. ASC 718 requires companies to estimate the fair value of share-based awards on the grant date using an option pricing model. The value of the portion of the award that is ultimately expected to vest is recorded as expense over the requisite periods in the Company's consolidated statement of operations. SIGA calculates the fair value of options awarded under its Employee Stock Purchase Plan using the Black-Scholes model with weighted average assumptions for the expected volatility, risk-free interest rate, expected holding period, and dividend yield. It is reasonably likely that future assumptions may change, in which case the fair value of future option awards may exceed or fall short of historical calculated fair values.

Fair value of financial instruments

The carrying value of cash and cash equivalents, accounts receivables, short-term investments, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Common stock warrants which are classified as liabilities under the provisions of FASB ASC 815 Derivatives and Hedging ("ASC 815"), are recorded at their fair market value as of each reporting period.

The Company applies FASB ASC 820 Fair value Measurements and Disclosures ("ASC 820") for financial assets and liabilities that are required to be measured at fair value, and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis.

ASC 820 provides that the measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1 – Quoted prices for identical instruments in active markets.
- Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.
- Level 3 – Instruments where significant value drivers are unobservable to third parties.

SIGA uses model-derived valuations where inputs are observable in active markets to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants in Level 2. At December 31, 2009 and December 31, 2008, the fair value of such warrants was as follows:

	December 31, 2009	December 31, 2008
Common stock warrants classified as current liabilities	$ 3,260,000	$ -
Common stock warrants classified as long term liabilities	6,398,216	2,923,532
Total	$ 9,658,216	$ 2,923,532

ASC 820-10 applies to non-financial assets and non-financial liabilities measured on a nonrecurring basis and was effective January 1, 2009. The adoption of this standard had no impact on the Company in 2009.

As of December 31, 2009 the Company held approximately $5.0 million in United States Treasury Bills, classified as a Level 1 security. SIGA does not hold any Level 3 securities.

Revenue Recognition

The Company recognizes revenue from contract research and development and research progress payments in accordance FASB ASC 605 Revenue Recognition, ("ASC 605"). In accordance with ASC 605, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, collectability is reasonably assured, contractual obligations have been satisfied and title and risk of loss have been transferred to the customer. The Company recognizes revenue from non-refundable up-front payments, not tied to achieving a specific performance milestone, over the period which the Company is obligated to perform services or based on the percentage of costs incurred to date, estimated costs to complete and total expected contract revenue. Payments for development activities are recognized as revenue is earned, over the period of effort. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, providing there is no future service obligation associated with that milestone. In situations where the Company receives payment in advance of the performance of services, such amounts are deferred and recognized as revenue as the related services are performed.

Goodwill

Goodwill is recorded when the purchase price paid for an acquisition exceeds the estimated fair value of the net identified tangible and intangible assets acquired.

The Company evaluates goodwill for impairment annually, in the fourth quarter of each year. In addition, the Company would test goodwill for recoverability between annual evaluations whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. Examples of such events could include a significant adverse change in legal matters, liquidity or in the business climate, an adverse action or assessment