

SIGA TECHNOLOGIES INC  
Form 10-K  
March 06, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

**Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**  
For the fiscal year ended December 31, 2008

Or

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File 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.)

**420 Lexington Avenue, Suite 408  
New York, NY**

(Address of principal executive offices)

**10170**

(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 Capital 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.

## Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

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

Indicate by check mark 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. .

---

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one): Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer  Smaller Reporting Company .

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

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, 2008 as reported on the Nasdaq Capital Market was approximately \$109,509,000.

As of March 3, 2009 the registrant had outstanding 36,011,495 shares of common stock.

**DOCUMENTS INCORPORATED BY REFERENCE**

The following document is incorporated herein by reference:

<u>Document</u>	<u>Parts Into Which Incorporated</u>
Proxy Statement for the Company's 2009 Annual Meeting of Stockholders	Part III
<hr/>	
<hr/>	

# Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

SIGA Technologies, Inc.

Form 10-K

Table of Contents

	<b>Page No.</b>
<b>PART I</b>	
<u>Item 1.</u> <u>Business</u>	2
<u>Item 1A.</u> <u>Risk Factors</u>	11
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	23
<u>Item 2.</u> <u>Properties</u>	23
<u>Item 3.</u> <u>Legal Proceedings</u>	23
<u>Item 4.</u> <u>Submission of Matters to a Vote of Security Holders</u>	23
<b>PART II</b>	
<u>Item 5.</u> <u>Market For Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	24
<u>Item 6.</u> <u>Selected Financial Data</u>	25
<u>Item 7.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	26
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	35
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	55
<u>Item 9A.</u> <u>Controls and Procedures</u>	55
<u>Item 9B.</u> <u>Other Information</u>	56
<b>PART III</b>	
<u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance</u>	57
<u>Item 11.</u> <u>Executive Compensation</u>	57
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	57
<u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence</u>	58

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

Item 14.      Principal Accountant Fees and Services      58

**PART IV**

Item 15.      Exhibits, Financial Statements and Schedules      59

SIGNATURES      64

---

**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 (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 sufficient patent protection for its products, (vi) the risk that regulatory approval for SIGA’s products may require further or additional testing that will delay or prevent approval, (vii) the risk that the Biomedical Advanced Research & Development Authority may not complete the procurement set forth in a pre-solicitation for acquisition of smallpox antiviral for the strategic national stockpile, or may complete it on different terms; (viii) the volatile and competitive nature of the biotechnology industry, (ix) changes in domestic and foreign economic and market conditions, and (x) 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.”

SIGA is a biotechnology corporation incorporated in Delaware on December 28, 1995. We pursue the research, development and commercialization of novel anti-infectives for the prevention and treatment of serious infectious diseases. The major focus of our developmental and commercialization activities is on products for use in defense against biological warfare agents such as smallpox, arenaviruses (hemorrhagic fevers) and other Category A viral agents. Our lead product, ST-246®, is an orally administered antiviral drug that targets orthopox viruses. In December 2005 the Food and Drug Administration (FDA) accepted our Investigational New Drug (IND) application for ST-246® and granted the program “Fast-Track” status. In December 2006 the FDA granted Orphan Drug designation to ST-246® for the prevention and treatment of smallpox. 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 bacterial 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. 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 estimate that the final Clinical Study Report for that study will be submitted to the FDA in the second quarter of 2009. During 2006, SIGA received grants and contracts from the NIH totaling approximately \$21 million for the continued development of ST-246®. In 2007, we received 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.

*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 (LCMV) 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 SBIR 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.

*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, Biomedical Advanced Research and Development Authority (BARDA) and the Department of Defense (DoD), and procurement of countermeasures by The U.S. The 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.

From 2001 through 2008, the Federal Government has allocated over \$16 billion in State and local terrorism preparedness funding from the Departments of Homeland Security, Health and Human Services and Justice. In 2007, approximately \$5.0 billion was allocated for emergency, preparedness and response funding. A similar amount was enacted for 2008. 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;
- NGO's and multinational companies, including the U.S. Postal Service and 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 in to 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 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. The 2004 grants were acquired as part of our acquisition of certain assets from ViroPharma Incorporated (“Viropharma”). For the years ending December 31, 2008, 2007, and 2006, we have recognized grants-related revenue of \$3.0 million, \$2.6 million, and \$3.7 million, respectively, from grants with the NIH. In 2008, 2007 and 2006, we recognized \$5.0 million, \$2.2 million and \$171,000, 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.

**United States Air Force.** In November 2006, we received a \$1.4 million, one year contract with the Air Force Medical Service for the development of counter-measures against Dengue viruses and other water-related viral agents. In November 2006 we also received a one-year, \$900,000 contract to aid the USAF Special Operations Command (USAFSOC) in its development of specific anti-viral agents. For the years ended December 31, 2008, 2007 and 2006 we recognized revenues of \$38,000, \$1,921,000 and \$247,000, respectively, from these contracts. SIGA completed its work under the contracts in 2008. SIGA received cash payments from the USAF on a monthly basis, as the work was performed and the related revenue was recognized. SIGA’s contracts with the USAF did not include milestone payments.

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 Facilities**

As of February 15, 2009, we had 43 full-time employees. None of our employees is covered by a collective bargaining agreement, and we consider our employee relations to be good.

**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 licensed the rights to eight issued U.S. patents and three issued European patents. 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. We are joint owners with 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 seven U.S. patents and nine 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, 2008.

<b>PATENTS</b>	<b>Number Exclusively Licensed from Rockefeller Univ.</b>	<b>Number Co-Exclusively Licensed with Washington Univ.</b>	<b>Number Exclusively Licensed from UCLA</b>	<b>Number Owned by SIGA</b>	<b>Patent Expiration Dates</b>
U.S.	8	1	1	7	2013, 2014(6), 2015(3), 2016 (3), 2017, 2021, 2020
Australia	1		1	1	2020, 2009
Europe	3			4	2009, 2010, 2013, 2014, 2015, 2020, 2021
Hungary	1				2013
Japan	2				2009, 2010
Mexico	1				2016



APPLICATIONS	Number Exclusively Licensed from Rockefeller Univ.	Number Exclusively Licensed from Washington University	Number Exclusively Licensed from UCLA	Number Owned by SIGA
U.S. applications				9
U.S. provisionals				2
PCT				8
Australia	1			2
Canada	1		1	5
Europe			1	5
Japan			1	6
Hungary				

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.

## Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

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 (EUA) 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 is sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. 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. On February 1, 2007, the Secretary of HHS issued the first declaration under the PREP Act to protect countermeasures from liability that are necessary to prepare the nation for an avian influenza pandemic.

**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.

#### **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](http://www.sec.gov).

In addition, our company website can be found on the Internet at [www.siga.com](http://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](http://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](http://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., 420 Lexington Avenue, Suite 408, New York, New York 10170.

#### **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 \$8.6 million, \$5.6 million, and \$9.9 million, for the years ended December 31, 2008, 2007, and 2006, respectively. As of December 31, 2008, 2007, and 2006, our accumulated deficit was approximately \$70.6 million, \$62.0 million, and \$56.4 million, respectively. We expect to continue to incur significant operating expenditures. 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.*

We continue to be dependent on our ability to raise money in the equity markets. 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.

**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 investment, 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.

*The 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 possible acquisitions and other corporate purposes, could 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 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, 2008, directors, officers and principal stockholders beneficially owned approximately 34.0% 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 United States government and collaborative and license agreements and we may not achieve sufficient revenues from these agreements to attain profitability.*

Until and unless we successfully achieve approval to 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, 2008, 2007, and 2006, respectively, were derived from grants and contracts. Our current revenue is derived from contract work being performed for the NIH under two major contracts and grants which are scheduled to expire from September 2011 through September 2013. These contracts and grants are for specific work to be performed under the agreements and can only be canceled by the counter-party for non-performance.

**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 significant portion 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. 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 by the U.S. government;
- successful completion of non-clinical development, including studies in approved animal models;
- our ability to incur 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 the Secretary of HHS that our biodefense drug candidates should be purchased for the SNS prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements 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 preclinical 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 preclinical 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 preclinical 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, preclinical 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 preclinical 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 approval guidelines under 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 candidates developed by us 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 drugs 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 the 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 to test and market our products in the United States, 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;

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

- 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 preclinical 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.

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. Two companies with similar profiles are VaxGen, Inc., which is developing vaccines against anthrax, smallpox and HIV/AIDS; and Aviant Immunotherapeutics, Inc., which has vaccine programs for agents of biological warfare.

***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 products successfully developed by us or our collaborative partners 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, and
- reimbursement policies of government and third-party payors.

Physicians, patients or the medical community in general may not accept or utilize any products that we or our collaborative partners may develop. Our ability to receive 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 health care 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 developed by us or our collaborative partners, 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 may seek to obtain product liability insurance with respect to drugs we and/or our collaborative partners 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 thereof that we can sell.***

The U.S. federal 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 Medicare and Medicaid spending. 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 products profitably in the U.S. At present, we do not foresee any changes in FDA regulatory policies that would adversely affect our development programs.

#### **Risks Related to Manufacturing and Manufacturing Facilities**

***Our drug candidates are complex to manufacture, especially on a large scale commercial basis, which could cause us to delay product launches or experience shortages of products.***

Our drug candidates are complex to manufacture, especially in large quantities. The 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 we 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 lots that fail 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. Any significant delay in obtaining adequate supplies of our drug candidates could adversely affect our ability to develop or commercialize these drug candidates.

In addition, 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 products that receive regulatory approval on a timely and competitive basis.

We currently rely on third parties for regulatory compliance and quality assurance with respect to the supplies of our drug candidates that they produce for us. We also will rely for these purposes on any third party that we use for production of commercial supplies of drug candidates 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 cGMP regulations and other governmental regulations and corresponding foreign standards.

We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by 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 involve hazardous materials and may subject us to environmental regulatory liabilities.*

Our biopharmaceutical research and development 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 losses.

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, or the DCAA, routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from doing business with the U.S. government.

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

***Laws and regulations affecting government contracts 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 of extensive pre-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA 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.

**Risks Related to Our Dependence on Third Parties**

***If third parties on whom we rely for clinical 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 required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers to conduct the clinical trials of our drug candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical 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 clinical 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 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 licensed the rights to eight issued U.S. patents and three issued European patents. These patents have varying lives and they are related to the technology licensed from Rockefeller University for the Strep and Gram-positive products. We are joint owner with Washington University of one issued patent in the U.S. for the technology used for the Gram-negative product opportunities. We are also exclusive owner of seven U.S. patents and nine U.S. patent applications. One of these U.S. utility patent applications relates to our DegP product opportunities. We are also exclusive owner of two U.S. provisional patent applications.

We included a summary of our patent positions as of December 31, 2008 in Part I, Item 1 of this document.

We also rely on copyright protection, 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 or those of our collaborators are alleged or found to infringe the patents or proprietary rights of others, we may be sued or have to license those rights from others on unfavorable terms.***

Our commercial success will depend significantly on our ability to operate without infringing the patents and proprietary rights of third parties. Our technologies, along with our licensors' and our collaborators' technologies, may infringe the patents or proprietary rights of others. If there is an adverse outcome in litigation or an interference to determine priority or other proceeding in a court or patent office, then we, or our collaborators and licensors, could be subjected to significant liabilities, required to license disputed rights from or to other parties and/or required to cease using a technology necessary to carry out research, development and commercialization. At present we are unaware of any or potential infringement claims against our patent portfolio.

The costs to establish the validity of patents, to defend against patent infringement claims of others and to assert infringement claims against others can be expensive and time consuming, even if the outcome is favorable. An outcome of any patent prosecution or litigation that is unfavorable to us or one of our licensors or collaborators may have a material adverse effect on us. We could incur substantial costs if we are required to defend ourselves in patent suits brought by third parties, if we participate in patent suits brought against or initiated by our licensors or collaborators 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 conflicts resulting from third-party patent applications and patents could significantly reduce the coverage of the patents owned, optioned by or licensed to us or our collaborators and limit our ability or that of our collaborators to obtain meaningful patent protection. If patents are issued to third parties that contain competitive or conflicting claims, we, our licensors or our collaborators may be legally prohibited from researching, developing or commercializing of potential products or be required to obtain licenses to these patents or to develop or obtain alternative technology. We, our licensors and/or our collaborators may be legally prohibited from using patented technology, may not be able to obtain any license to the patents and 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 Court of Chancery in the State of Delaware, captioned *PharmAthene, Inc. v. SIGA Technologies, Inc.*, C.A. No. 2627-N. In its Complaint, PharmAthene asks the Court to order the Company 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 2007, we filed a motion to dismiss the Complaint in its entirety for failure to state a claim upon which relief can be granted. In January 2008, the Court of Chancery denied our motion to dismiss and lifted a related stay of discovery. Discovery is proceeding. The Company filed its answer to the Complaint denying all material allegations. While we believe that we have meritorious defenses to the claim, there

can be no assurance concerning the outcome. If PharmAthene were successful in obtaining a license through this litigation, the license may be on terms that are not favorable to the Company.

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. 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 requiring disclosure.

**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 lease approximately 3,000 square feet under a lease that expires on February 28, 2010. 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 the opinion of the management, these facilities are sufficient to meet the current and anticipated future requirements of SIGA.

**Item 3. Legal Proceedings**

In December 2006, PharmAthene, Inc. ("PharmAthene") filed an action against us in the Court of Chancery in the State of Delaware, captioned *PharmAthene, Inc. v. SIGA Technologies, Inc.*, C.A. No. 2627-N. In its Complaint, PharmAthene asks the Court to order the Company 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 2007, we filed a motion to dismiss the Complaint in its entirety for failure to state a claim upon which relief can be granted. In January 2008, the Court of Chancery denied our motion to dismiss and lifted a related stay of discovery. Discovery is proceeding. The Company filed its answer to the Complaint denying all material allegations.

**Item 4. Submission of Matters to a Vote of Security Holders**  
None.

## 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 has been traded on the Nasdaq Capital Market since September 9, 1997 and trades under the symbol "SIGA." 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.

**Price Range**

<b>2008</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 3.27	\$ 1.78
Second Quarter	\$ 3.91	\$ 2.12
Third Quarter	\$ 4.19	\$ 2.29
Fourth Quarter	\$ 3.80	\$ 1.94

<b>2007</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 6.04	\$ 3.36
Second Quarter	\$ 5.94	\$ 3.21
Third Quarter	\$ 4.70	\$ 2.52
Fourth Quarter	\$ 4.50	\$ 2.95

The following line graph compares the cumulative total stockholder return through December 31, 2008, assuming reinvestment of dividends, by an investor who invested \$100 on December 31, 2003 in each of (i) the Common Stock, (ii) the NASDAQ National Market-US; and (iii) the NASDAQ Pharmaceutical Index.

Value of Initial Investment	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08
SIGA Technologies, Inc.	\$ 100.00	\$ 72.49	\$ 41.48	\$ 163.76	\$ 134.50	\$ 142.79
NASDAQ Composite Index	\$ 100.00	\$ 108.59	\$ 110.08	\$ 120.56	\$ 132.39	\$ 78.72
NASDAQ Biotech Composite Index	\$ 100.00	\$ 106.13	\$ 109.14	\$ 110.25	\$ 115.30	\$ 100.75



Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

As of March 3, 2009, the closing bid price of our common stock was \$4.48 per share. There were 62 holders of record as of March 4, 2009. 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, 2008, 2007, 2006, 2005, and 2004.

The year ended December 31,	Revenues	Selling, general & administrative	Research and development	Patent preparation fees	In-process research and development	Impairment of intangible assets
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	\$ —	\$ —
2004	\$ 1,839	\$ 4,042	\$ 4,166	\$ 393	\$ 568	\$ 2,118

The year ended December 31,	Operating loss	Net loss	Net loss per share: basic & diluted	Weighted average shares outstanding: basic and diluted
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
2004	\$ (9,448)	\$ (9,373)	\$ (0.40)	23,724,026

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
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)
2004	\$ 6,111	\$ 2,021	\$ —	\$ 4,559	\$ (4,890)

**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 in December 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 the defense against biological warfare agents such as smallpox and Arenaviruses. 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 September 2007, we received a two-year 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. During the third quarter of 2006 we were awarded a 3-year, \$16.5 million contract from the NIH and an additional 3 year, \$4.8 million Phase II continuation grant from the NIH. Both awards support the continuing development of our smallpox drug candidate, ST-246®. Our efforts to develop ST-246® were also supported by previous grants from the NIH totaling \$5.8 million, a \$1.0 million agreement with Saint Louis University, and a \$1.6 million contract with the U.S. Army. Our initiative to advance SIGA's Arenavirus programs is supported by a 3-year, \$6.0 million grant from the NIH, received in September 2006 and previous grants from the NIH totaling \$6.3 million.

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.

**Liquidity and Capital Resources**

We do not have commercial products, and we cannot predict with certainty when our products will be able to be sold in substantial quantities. We will need additional funds to complete the development of our products. Our plans with regard to these matters include continued development of our products as well as seeking additional capital through a combination of collaborative agreements, strategic alliances, research grants, and future equity and debt financing. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining future financing on commercially reasonable terms or that we will be able to secure funding from anticipated government contracts and grants.

Management believes that its existing cash balances combined with cash flows primarily from proceeds from our investment commitment, continuing government grants and contracts, and anticipated new government grants and contracts will be sufficient to support SIGA's operations beyond the next twelve months, and that sufficient cash flows will be available to meet the Company's business objectives during that period. We believe that we have sufficient liquidity to support our operations beyond the next twelve months despite the disruption of the capital markets. We are not dependent on the availability of short-term debt facilities and the limited availability of credit in the market has not affected our liquidity or materially affected our funding.

Our technical operations are based in our research facility in Corvallis, Oregon. We continue to seek to fund a major portion of our ongoing antiviral, antibiotic and vaccine programs through a combination of government grants, contracts and strategic alliances. While we have had success in obtaining strategic alliances, contracts and grants, there is no assurance that we will continue to be successful in obtaining funds from these sources. Until additional relationships are established, we expect to continue to incur significant research and development costs and costs associated with the manufacturing of product for use in clinical trials and pre-clinical testing. It is

expected that general and administrative costs, including patent and regulatory costs, necessary to support clinical trials and research and development will continue to be significant in the future. We expect to incur operating losses for the foreseeable future and there can be no assurance that we will ever achieve profitable operations.

### **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 impact goodwill impairments; and the assessment of recoverability of long-lived assets, which primarily impacts operating income if 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 far 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 of Statement of Financial Accounting Standards No. 123 (revised 2004), “Share-Based Payment” (“SFAS 123(R)”), 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. SFAS 123(R) 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.

#### ***Fair value of financial instruments***

The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Common stock rights and warrants which are classified as assets or liabilities under the provisions of EITF 00-19 are recorded at their fair market value as of each reporting period. The Company applies the Black-Scholes pricing model to calculate the fair values of common stock rights and warrants using the contracted term of the instruments and expected volatility that is calculated as a combination of the Company’s historical volatility and the volatility of a group of comparable companies.

#### ***Revenue Recognition***

The Company recognizes revenue from contract research and development and research progress payments in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, (“SAB 104”). In accordance with SAB 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, collectibility 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 by a regulator or government organization, loss of key personnel, or new circumstances that would cause an expectation that it is more likely than not that we would sell or otherwise dispose of a reporting unit. Goodwill impairment is determined using a two-step approach in accordance with Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"). The impairment review process compares the fair value of the reporting unit in which goodwill resides to its carrying value. In 2008, the Company operated as one business and one reporting unit. Therefore, the goodwill impairment analysis was performed on the basis of the Company as a whole using the market capitalization of the Company as an estimate of its fair value. In the past, our market capitalization has been significantly in excess of the Company's carrying value. It is reasonably likely that the future market capitalization of SIGA may exceed or fall short of our current market capitalization, in which case a different amount for potential impairment would result. The use of the discounted expected future cash flows to evaluate the fair value of the Company as a whole is reasonably likely to produce different results than the Company's market capitalization.

### ***Recent accounting pronouncements***

In April 2008, the FASB issued EITF 07-05, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock", ("EITF 07-05"). EITF 07-05 provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in paragraph 11(a) of FAS 133. EITF 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and early application is not permitted. Management is evaluating what effect EITF 07-05 will have on SIGA's financial position and operating results.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities," ("SFAS No. 161"). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit-risk-related contingent features in derivative agreements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008. The adoption of SFAS No. 161 will not affect our consolidated financial condition and results of operations, but may require additional disclosures if we enter into derivative and hedging activities.

Effective January 1, 2008, the Company implemented SFAS No. 157, "Fair Value Measurement", (SFAS 157), for financial assets and liabilities that are required to be measured at fair value. The adoption of FAS 157 did not have an impact on our financial position or results of operations.

In February 2008, the FASB issued FASB Staff Position 157-2 (FSP 157-2), which delayed the implementation of FAS 157 until January 1, 2009, for non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. Pursuant to FSP 157-2, the Company did not adopt FAS 157 for non-financial assets and liabilities that include goodwill. We are currently assessing the impact of FAS 157-2 on our non-financial assets and liabilities.

## Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

SFAS 157 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.

We use 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. As of December 31, 2008, the fair value of such warrants was \$2,923,532.

### Results of Operations

The following table sets forth certain consolidated statements of income data as a percentage of net revenue for the periods indicated:

Revenue	100%	100%	100%
Selling, general and administrative	57%	55%	64%
Research and development	144%	148%	126%
Patent preparation fees	7%	8%	4%
In-process research and development	0%	0%	0%
Impairment of intangible assets	0%	0%	0%
<b>Operating loss</b>	<b>108%</b>	<b>111%</b>	<b>94%</b>

*Years ended December 31, 2008, 2007, and 2006.*

Revenues from research and development contracts and grants for the years ended December 31, 2008 and 2007, were \$8.1 million and \$6.7 million, respectively. The increase of \$1.4 million or 20.1% in revenue recorded for the year ended December 31, 2008 reflects an increase of \$3.0 million in revenues recognized from grants and contracts with the NIH supporting our lead programs. Revenue recognized from our programs with the USAF was \$38,000 and \$1.9 million for the years ended December 31, 2008 and 2007, respectively. In 2008, we completed our two, one-year programs with the USAF.

Revenues from research and development contracts and grants for the year ended December 31, 2007 were \$6.70 million, a decline of \$560,000 or 7.7% from the \$7.26 million in revenues recorded for the year ended December 31, 2006. During the year ended December 31, 2007, we recognized revenues of \$4.52 million from NIH grants and an agreement with the NIH supporting our lead programs. Revenues from NIH grants, an agreement with the NIH and an agreement with Saint Louis University, supporting these lead programs during the year ended December 31, 2006 were \$3.7 million. Revenues recorded from our programs with the USAF and the US Army were \$1.9 million and \$2.7 million for the years ended December 31, 2007 and 2006, respectively. The decline of \$800,000 in revenues generated from our agreements with the USAF and the US Army is mainly due to revenues generated in 2006 from a one-year agreement with the US Army, signed in September 2005 and completed in 2006. The decline in revenues recorded for the year ended December 31, 2007 was also due to the completion of a one year, \$500,000, Phase I grant from the NIH to support the development of our Bacterial Commensal Vector technology for the delivery of smallpox vaccine, which we completed on February 28, 2007. Revenues recorded in connection with this grant were \$82,000 and \$409,000, for the years ended December 31, 2007 and 2006, respectively. Revenues for the year ended December 31, 2006 also included \$412,000 related to a four-year agreement with the US Army, supporting our Strep program, which was completed in December 31, 2006. In July 2007, we were awarded a two-year grant for a total of \$530,000 to support our Strep program. For the year ended December 31, 2007 we recorded \$67,000 from this grant.

## Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

Selling, general and administrative expenses (“SG&A”) for the years ended December 31, 2008 and 2007 were \$4.6 million and \$3.7 million, respectively. The increase of \$900,000 or 24% is due to an increase of \$456,000 in legal fees attributed to litigation support, an increase of \$83,000 in insurance costs, an increase of \$230,000 in non-cash compensation recorded in accordance with FAS 123R, and an increase of \$71,000 in business development costs incurred in the current period.

SG&A for the years ended December 31, 2007 and 2006 were \$3.70 million and \$4.62 million, respectively. The decline of \$920,000 or 20% is mainly attributed to professional fees incurred during 2006 in connection with a business transaction and a non-cash consulting charge recorded in 2006. During the year ended December 31, 2006 we recorded legal, accounting, and consulting expenses of \$861,000, \$183,000, and \$132,000, respectively, for due diligence services, fairness opinion and legal advice related to a potential business transaction. During the year ended December 31, 2006, we also recorded non-cash consulting charge of \$156,000 related to the issuance of warrants to advisors. The decline in SG&A expenses was partially offset by legal expenses of \$240,000 incurred in connection with our defense against an action filed against SIGA, and accounting fees of \$110,000 related to the audit of our Sarbanes-Oxley compliance.

Research and development (“R&D”) expenses for the years ended December 31, 2008 and 2007 were \$11.6 million and \$9.9 million, respectively. The increase of \$1.7 million or 17% is mainly due to higher expenditures related to clinical and pre-clinical testing of our lead drug candidates, which increased \$1.7 million from the prior year. Employee related expenses for the year ended December 31, 2008 increased \$674,000 from the prior year, reflecting a transition to highly specialized workforce and an increase in non-cash compensation recorded in accordance with FAS 123R. Travel expenses for the year ended December 31, 2008 increased \$148,000 from the prior year. These increases were offset by a decline of \$790,000 in depreciation and amortization mainly related to fully depreciated leasehold improvements and fully amortized intangible assets; and a decline of \$324,000 in expenditures related to our agreements with the USAF, which were completed during 2008.

R&D expenses were \$9.94 million and \$9.15 million for the years ended December 31, 2007 and 2006, respectively, an increase of \$790,000 or 8.7% from the year ended December 31, 2006. Expenditures related to clinical and pre-clinical testing and manufacturing of our lead drug candidates increased \$1.1 million from the year ended December 31, 2006. Our payroll and related expense increased by \$350,000 in 2007, from the year ended December 31, 2006, reflecting the expansion and change in composition of our research and development workforce. In addition, depreciation expense for the year ended December 31, 2007 increased \$294,000 from the same period in 2006. These increases were partially offset by a decline of \$602,000 in amortization expense and a decline of \$351,000 in external R&D service charges related to our USAF and US Army contracts.

During the years ended December 31, 2008, 2007, and 2006, we spent \$5.4 million, \$3.2 million, and \$2.3 million, respectively, on the development of ST-246®. During the year ended December 31, 2008, we spent \$1.2 million on internal human resources dedicated to the drug’s development and \$4.2 million mainly on clinical trials and manufacturing. For the year ended December 31, 2007, we spent \$924,000 on internal human resources and \$2.24 million mainly on manufacturing and clinical testing. For the year ended December 31, 2006, we spent \$678,000 on internal human resources and \$1.6 million on clinical and pre-clinical testing of ST-246®. From inception of the ST-246® development program to-date, we invested a total of \$15.0 million in the program, of which \$3.7 million supported internal human resources, and \$11.3 million were used mainly for manufacturing, clinical and pre-clinical work. These resources reflect SIGA’s research and development expenses directly related to the program. They exclude additional expenditures such as the cost to acquire the program, patent costs, allocation of indirect expenses, and the value of other services received from the NIH and the DoD.

During the years ended December 31, 2008, 2007, and 2006, we spent \$930,000, \$1.3 million, and \$1.3 million, respectively, to support the development of ST-193, a drug candidate for Lassa fever virus, ST-294, a drug candidate for certain arenavirus pathogens, and other drug candidates for hemorrhagic fevers. During the year ended December 31, 2008, we invested \$254,000 in internal human resources dedicated to the development of these drugs, and \$676,000 mainly to support pre-clinical testing. For the year ended December 31, 2007, we spent \$227,000 on internal human resources and \$1.1 million mainly on pre-clinical testing. For the year ended December 31, 2006, we spent \$536,000 on internal human resources and \$729,000 on pre-clinical testing. From inception of our programs to develop ST-193, ST-294, and other drug candidates for hemorrhagic fevers, to-date, we spent a total

of \$5.5 million related to the programs, of which \$2.1 million and \$3.4 million were expended on internal human resources and pre-clinical work, respectively. These resources reflect SIGA's research and development expenses directly related to the programs. They exclude additional expenditures such as the cost to acquire the programs, patent costs, allocation of indirect expenses, and the value of other services received from the NIH and the DoD.

For the years ended December 31, 2008, 2007, and 2006, we spent \$102,000, \$1.3 million, and \$1.6 million, respectively, in expenses related to our USAF and US Army Agreements. For the year ended December 31, 2008, we spent \$77,000 on internal human resources and \$26,000 for external R&D services. During the year ended December 31, 2007, we spent \$910,000 on internal human resources and \$372,000 for external R&D services. During the year ended December 31, 2006, we spent \$693,000 and \$910,000 on internal human resources and external R&D services, respectively. Costs related to our work on the USAF Agreements from September 2005 to date were \$3.4 million, of which we spent \$1.8 million and \$1.6 million on internal human resources and external R&D services, respectively. These resources reflect SIGA's research and development expenses directly related to these agreements. They exclude additional expenditures such as patent costs and allocation of indirect expenses.

The majority of our product programs are in the early stage of development. At this stage of development, we cannot make reasonable estimates of the potential cost for most of our programs to be completed or the time it will take to complete the project. Our lead product, ST-246, is an orally administered anti-viral drug that targets the smallpox virus. In December 2005, the FDA accepted our IND application for ST-246® and granted it Fast-Track status. In December 2006, the FDA granted Orphan Drug designation to ST-246, for the prevention as well as the treatment of smallpox. We expect that costs to complete the program will approximate \$20 million to \$30 million, and that the project could be completed in 24 months to 36 months. There is a high risk of non-completion of any program, including ST-246, because of the lead time to program completion and uncertainty of the costs. Net cash inflows from any products developed from our programs is at least one to three years away. However, we could receive additional grants, contracts or technology licenses in the short-term. The potential cash and timing is not known and we cannot be certain if they will ever occur.

The risk of failure to complete any program is high, as each, other than our smallpox program, is in the relatively early stage of development. Products for the biological warfare defense market, such as the ST-246® smallpox anti-viral, could generate revenues in one to three years. We believe the products directed toward this market are on schedule. We expect the future research and development cost of our biological warfare defense programs to increase as the potential products enter animal studies and safety testing, including human safety trials. Funds for future development will be partially paid for by NIH contracts and grants, additional government funding and from future financing. If we are unable to obtain additional federal grants and contracts or funding in the required amounts, the development timeline for these products would slow or possibly be suspended. Delay or suspension of any of our programs could have an adverse impact on our ability to raise funds in the future, enter into collaborations with corporate partners or obtain additional federal funding from contracts or grants.

Patent preparation expenses for the years ended December 31, 2008 and 2007 were \$582,000 and \$515,000, respectively. The increase of \$66,000 or 12.9% is mainly due to additional filings related to our lead drug candidates.

Patent preparation costs for the years ended December 31, 2007 and 2006 were \$515,000 and \$295,000, respectively. Patent preparation expenses increased \$220,000, or 75%, mainly due to new filings related to our leading drug candidates.

Total operating loss for the years ended December 31, 2008 and 2007 was \$8.7 million and \$7.5 million, respectively. The increase of \$1.2 million or 16% in net operating loss relates mainly to the growth in SIGA's operations, including the transition to highly specialized R&D workforce, manufacturing of our lead drug candidate for testing, and clinical and pre-clinical testing of our leading programs. Our net operating loss also increased as a result of additional litigation related legal fees.

Total operating loss for the years ended December 31, 2007 and 2006 was \$7.5 million and \$6.8 million, respectively. Our operating loss increased mainly due to a decline of \$600,000 in revenues generated in 2007, and an increase in R&D and patent expenses of \$729,000 and \$220,000, respectively, partially offset by a decline of \$932,000 in G&A expenses.

Changes in the fair value of common stock rights and common stock warrants sold together with common stock in October 2006 and November 2005 are recorded as gains or losses. For the years ended December 31, 2008, 2007, and 2006, we recorded a gain of \$43,000, a gain of \$1.4 million and a loss of \$3.1 million, respectively, reflecting changes in the fair market value of warrants and rights to purchase common stock during the respective years. The warrants and rights to purchase common stock of SIGA were recorded at fair market value and classified as liabilities at the time of the transaction.

Other income for the years ended December 31, 2008, 2007, and 2006, was \$94,000, \$394,000, and \$1,600, respectively. Other income in 2008 and 2007 represented interest income on our cash and cash equivalents. Interest income declined as a result of lower cash balances and a decline in interest rates. For the year ended December 31, 2006, we recorded interest income of \$147,000 generated from higher cash balance subsequent to the October 2006 sale of SIGA common stock and warrants. Interest income in 2006 was offset by interest charges of \$114,000 relating to loans payable in the amount of \$3.0 million which we paid in full in October 2006.

### **Liquidity and Capital Resources**

On December 31, 2008, we had \$2.3 million in cash and cash equivalents. During the year ended December 31, 2008, we received net proceeds of \$3.2 million from exercises of warrants and options to purchase shares of the Company's Common stock.

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 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.

#### Operating activities

Net cash used in operations during the years ended December 31, 2008 and 2007 was \$7.2 million and \$5.4 million, respectively. The increase in net cash used in operations is mainly due to the use of additional cash to support the growth in SIGA's operations, including the transition to a highly specialized R&D workforce, manufacturing of our lead drug candidate for testing, and clinical and pre-clinical testing of our leading programs. During the year ended December 31, 2008, we also used additional funds for litigation related legal fees.

On December 31, 2008 and 2007, our accounts receivable balance was \$1.9 million and \$986,000, respectively. The increase in our account receivable balances reflects work performed during November and December of 2008 under our two contracts with the NIAID. Funds outstanding under these contracts were collected during January and February, 2009.

Our prepaid expenses balance as of December 31, 2008 and 2007, was \$1.4 million and \$130,000, respectively. The increase in our prepaid expenses is due to a deposit of \$1.25 million paid to a third party for the manufacturing of ST-246® for testing. In connection with the deposit, and the receipt of reimbursement from the NIAID for such deposit, we also booked the corresponding deferred revenue. The amount recorded as prepaid expense will be recognized as an expense as the related manufacturing takes place, and revenue will be recognized over the same period as manufacturing.



Investing activities

Capital expenditures during the years ended December 31, 2008 and 2007 were \$340,000 and \$1.2 million, respectively. During the year ended December 31, 2008, we invested mainly in laboratory equipment supporting the development of our lead drug candidates. Capital expenditures during the year ended December 31, 2007 supported the renovation of our research facility in Oregon.

Financing activities

Cash provided by financing activities was \$3.0 million and \$2.9 million during the years ended December 31, 2008 and 2007, respectively. During the years ended December 31, 2008 and 2007, we received net proceeds of \$3.2 million and \$3.0 million, respectively, from exercises of options and warrants to purchase common stock. In 2008, we paid \$159,000 for costs related to a financing transaction. In 2007, we repaid the entire balance of \$130,000 due on a loan payable to General Electric Capital Corporation.

Other

On June 19, 2008, we entered into a letter agreement (the "Letter Agreement"), with MacAndrews & Forbes, LLC ("M&F"), a related party, for M&F's commitment to invest, at SIGA's discretion, up to \$8 million over a one-year period (the "Investment Period") in exchange for (i) SIGA common stock at per share price equal to the lesser of (A) \$3.06 and (B) the average of the volume-weighted average price per share for the 5 trading days immediately preceding each funding date, and (ii) warrants to purchase 40% of the number of SIGA shares acquired by the Investor, exercisable at 115% of the common stock purchase price on such funding date (the "Consideration Warrants"). The Consideration Warrants will be exercisable for up to four years following the issuance of such warrants. M&F has the option, during the Investment Period, to invest in the Company under the same investment terms.

In addition to and in consideration for the commitment of M&F, M&F received warrants to purchase 238,000 shares of SIGA common stock, exercisable at \$3.06 (the "Commitment Warrants"). The Commitment Warrants are exercisable until June 19, 2012. SIGA recorded all costs related to the Letter Agreement, including the fair value of the Commitment Warrants, as deferred transaction costs. The deferred costs will reduce our additional paid-in capital upon issuance of common stock and warrants under the Letter Agreement.

We have incurred cumulative net losses and expect to incur additional losses to perform further research and development activities. We do not have commercial products and have limited capital resources. Our plans with regard to these matters include continued development of our products as well as seeking additional capital through a combination of collaborative agreements, strategic alliances, research grants, and future equity and debt financing. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining future financing on commercially reasonable terms or that we will be able to secure funding from anticipated government contracts and grants.

We believe that our existing cash balances combined with cash flows primarily from continuing government grants and contracts, anticipated new government grants and contracts and potential proceeds from our investment commitment will be sufficient to support our operations beyond the next twelve months, and that sufficient cash flows will be available to meet our business objectives during that period. We believe that we have sufficient liquidity to support our operations beyond the next twelve months despite the disruption of the capital markets. We are not dependent on the availability of short-term debt facilities and the limited availability of credit in the market has not affected our liquidity or materially affected our funding.

Our working capital and capital requirements will depend upon numerous factors, including pharmaceutical research and development programs; pre-clinical and clinical testing; timing and cost of obtaining regulatory approvals; levels of resources that we devote to the development of manufacturing and marketing capabilities; technological advances; status of competitors; and our ability to establish collaborative arrangements with other organizations.

**Contractual Obligations, Commercial Commitments and Purchase Obligations**

As of December 31, 2008, our purchase obligations are not material. We lease certain facilities and office space under operating leases. Minimum future rental commitments under operating leases having non-cancelable lease terms in excess of one year are as follows:

Year ended December 31,	Lease obligations
2009	608,400
2010	495,200
2011	472,500
	<hr/>
Total	\$ 1,576,100
	<hr/>

**Off-Balance Sheet Arrangements**

SIGA does not have any off-balance sheet arrangements.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

None.

**Item 8. Financial Statements and Supplementary Data**  
**Index to the Consolidated Financial Statements**

<u>Report of Independent Registered Public Accounting Firm</u>	36
<u>Consolidated Balance Sheets as of December 31, 2008 and 2007</u>	37
<u>Consolidated Statements of Operations for the years ended December 31, 2008, 2007, and 2006</u>	38
<u>Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2008, 2007 and 2006</u>	39
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007, and 2006</u>	41
<u>Notes to Consolidated Financial Statements</u>	42

**Report of Independent Registered Public Accounting Firm**

*To the Board of Directors and Stockholders of SIGA Technologies, Inc.:*

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in stockholders' equity and of cash flows present fairly, in all material respects, the financial position of SIGA Technologies, Inc. and its subsidiary at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits (which were integrated audits in 2008 and 2007). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for uncertain tax positions effective January 1, 2007, and changed the manner in which it accounts for share-based compensation effective January 1, 2006.

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

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

/s/ PRICEWATERHOUSECOOPERS LLP

New York, New York  
March 6, 2009

## SIGA TECHNOLOGIES, INC.

## CONSOLIDATED BALANCE SHEETS

As of December 31, 2008 and 2007

	December 31, 2008	December 31, 2007
	<u>                    </u>	<u>                    </u>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 2,321,519	\$ 6,832,290
Accounts receivable	1,959,608	986,489
Deferred transaction costs	581,358	—
Prepaid expenses	1,392,607	130,115
	<u>                    </u>	<u>                    </u>
<b>Total current assets</b>	6,255,092	7,948,894
Property, plant and equipment, net	1,360,018	1,479,678
Goodwill	898,334	898,334
Other assets	283,856	261,766
	<u>                    </u>	<u>                    </u>
<b>Total assets</b>	\$ 8,797,300	\$ 10,588,672
	<u>                    </u>	<u>                    </u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,806,073	\$ 1,321,146
Accrued expenses and other	1,210,496	796,524
Deferred revenue	1,302,600	—
	<u>                    </u>	<u>                    </u>
<b>Total current liabilities</b>	4,319,169	2,117,670
Common stock warrants	2,923,532	3,242,797
	<u>                    </u>	<u>                    </u>
<b>Total liabilities</b>	7,242,701	5,360,467
Commitments and contingencies	—	—
<b>Stockholders' equity</b>		
Common stock (\$.0001 par value, 100,000,000 shares authorized, 35,383,720 and 33,937,549 issued and outstanding at December 31, 2008 and December 31, 2007, respectively)	3,538	3,394
Additional paid-in capital	72,156,614	67,230,987
Accumulated deficit	(70,605,553)	(62,006,176)
	<u>                    </u>	<u>                    </u>
<b>Total stockholders' equity</b>	1,554,599	5,228,205
	<u>                    </u>	<u>                    </u>
<b>Total liabilities and stockholders' equity</b>	\$ 8,797,300	\$ 10,588,672
	<u>                    </u>	<u>                    </u>

The accompanying notes are an integral part of these financial statements.

## SIGA TECHNOLOGIES, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2008, 2007 and 2006

	<u>2008</u>	<u>2007</u>	<u>2006</u>
<b>Revenues</b>			
Research and development	\$ 8,065,618	\$ 6,698,717	\$ 7,257,532
<b>Operating expenses</b>			
Selling, general and administrative	4,608,089	3,704,058	4,623,577
Research and development	11,612,892	9,942,503	9,149,327
Patent preparation fees	581,548	515,263	295,006
Total operating expenses	<u>16,802,529</u>	<u>14,161,824</u>	<u>14,067,910</u>
Operating loss	(8,736,911)	(7,463,107)	(6,810,378)
Decrease (increase) in fair market value of common stock rights and common stock warrants	43,482	1,430,301	(3,089,997)
Other income (expense), net	<u>94,052</u>	<u>394,249</u>	<u>1,667</u>
Net loss	<u>\$ (8,599,377)</u>	<u>\$ (5,638,557)</u>	<u>\$ (9,898,708)</u>
Weighted average shares outstanding: basic and diluted	<u>34,732,625</u>	<u>33,330,814</u>	<u>28,200,130</u>
Net loss per share: basic and diluted	<u>\$ (0.25)</u>	<u>\$ (0.17)</u>	<u>\$ (0.35)</u>

The accompanying notes are an integral part of these financial statements.

**SIGA TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**For the Years Ended December 31, 2008, 2007 and 2006**

	Series A Convertible Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount
<b>Balance at January 1, 2006</b>	68,038	\$ 58,672	26,500,648	\$ 2,650
Net proceeds allocated to the issuance of common stock (\$4.54 per share)			2,000,000	\$ 200
Conversion of preferred stock for common stock	(68,038)	(58,672)	68,038	7
Stock based compensation				
Stock issued for services				
Issuance of common stock upon exercise of stock options and warrants			2,383,524	238
Issuance of common stock upon exercise of common stock rights			1,500,000	150
Fair value of exercised common stock rights and warrants				
Net loss				
<b>Balance at December 31, 2006</b>	<u>—</u>	<u>\$ —</u>	<u>32,452,210</u>	<u>\$ 3,245</u>
Issuance of common stock upon exercise of stock options and warrants			1,485,339	149
Stock based compensation				
Net loss				
<b>Balance at December 31, 2007</b>	<u>—</u>	<u>\$ —</u>	<u>33,937,549</u>	<u>\$ 3,394</u>
Issuance of common stock upon exercise of stock options and warrants			1,446,171	144
Stock based compensation				
Fair value of warrants issued for financing commitment				
Fair value of exercised common stock warrants				
Net loss				
<b>Balance at December 31, 2008</b>	<u>—</u>	<u>\$ —</u>	<u>35,383,720</u>	<u>\$ 3,538</u>

The accompanying notes are an integral part of these financial statements.

(Continued)



**SIGA TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**For the Years Ended December 31, 2008, 2007 and 2006**

	<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
<b>Balance at January 1, 2006</b>	\$ 49,638,619	\$ (46,468,911)	\$ 3,231,030
Net proceeds allocated to the issuance of common stock (\$4.54 per share)	\$ 5,948,328		5,948,528
Conversion of preferred stock for common stock	58,665		—
Stock based compensation	470,892		470,892
Stock issued for services	156,470		156,470
Issuance of common stock upon exercise of stock options and warrants	4,337,604		4,337,842
Issuance of common stock upon exercise of common stock rights	1,534,350		1,534,500
Fair value of exercised common stock rights and warrants	1,501,296		1,501,296
Net loss		(9,898,708)	(9,898,708)
<b>Balance at December 31, 2006</b>	<u>\$ 63,646,224</u>	<u>\$ (56,367,619)</u>	<u>\$ 7,281,850</u>
Issuance of common stock upon exercise of stock options and warrants	3,013,841		3,013,990
Stock based compensation	570,922		570,922
Net loss		(5,638,557)	(5,638,557)
<b>Balance at December 31, 2007</b>	<u>\$ 67,230,987</u>	<u>\$ (62,006,176)</u>	<u>\$ 5,228,205</u>
Issuance of common stock upon exercise of stock options and warrants	3,186,220		3,186,364
Stock based compensation	1,041,293		1,041,293
Fair value of warrants issued for financing commitment	422,331		422,331
Fair value of exercised common stock warrants	275,783		275,783
Net loss		(8,599,377)	(8,599,377)
<b>Balance at December 31, 2008</b>	<u>\$ 72,156,614</u>	<u>\$ (70,605,553)</u>	<u>\$ 1,554,599</u>

The accompanying notes are an integral part of these financial statements.

**SIGA TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**For the Years Ended December 31, 2008, 2007 and 2006**

	<u>2008</u>	<u>2007</u>	<u>2006</u>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (8,599,377)	\$ (5,638,557)	\$ (9,898,708)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	459,882	1,083,705	788,014
Amortization of intangible assets	—	165,243	767,492
(Increase) decrease in fair market value of rights and warrants	(43,482)	(1,430,301)	3,089,997
Stock based compensation	1,041,293	570,922	470,892
Non-cash consulting expense	—	—	156,470
<b>Changes in assets and liabilities:</b>			
Accounts receivable	(973,119)	(369,457)	266,022
Prepaid expenses	(1,262,492)	10,917	19,112
Other assets	(22,090)	(15,565)	(12,075)
Deferred revenue	1,302,600	—	(347,319)
Accounts payable and accrued expenses	898,899	175,260	262,098
<b>Net cash used in operating activities</b>	<b>(7,197,886)</b>	<b>(5,447,833)</b>	<b>(4,438,005)</b>
<b>Cash flows from investing activities:</b>			
Capital expenditures	(340,222)	(1,243,068)	(884,182)
<b>Net cash used in investing activities</b>	<b>(340,222)</b>	<b>(1,243,068)</b>	<b>(884,182)</b>
<b>Cash flows from financing activities:</b>			
Net proceeds from issuance of common stock and derivatives	—	—	8,424,406
Proceeds from issuance of notes payable	—	—	3,000,000
Net proceeds from exercise of common stock rights	—	—	1,534,500
Net proceeds from exercise of warrants and options	3,186,364	3,013,990	4,337,842
Deferred transaction costs	(159,027)	—	—
Repayment of notes payable	—	(130,329)	(3,107,520)
<b>Net cash provided by financing activities</b>	<b>3,027,337</b>	<b>2,883,661</b>	<b>14,189,228</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(4,510,771)</b>	<b>(3,807,240)</b>	<b>8,867,041</b>
Cash and cash equivalents at beginning of period	6,832,290	10,639,530	1,772,489
<b>Cash and cash equivalents at end of period</b>	<b>\$ 2,321,519</b>	<b>\$ 6,832,290</b>	<b>\$ 10,639,530</b>
Cash paid for interest on notes payable	\$ —	\$ 10,192	\$ 135,055
<b>Non-cash supplemental information:</b>			
Conversion of preferred stock to common stock	\$ —	\$ —	\$ 58,672
Cashless exercise of warrants to purchase common stock	\$ 176,164	\$ 153,804	\$ —

**The accompanying notes are an integral part of these financial statements.**



**SIGA TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Basis of Presentation**

*Organization*

SIGA Technologies, Inc. ("SIGA" or the "Company") is a bio-defense company engaged in the discovery, development and commercialization of products for use in defense against biological warfare agents such as smallpox and arenaviruses. The Company is also engaged in the discovery and development of other novel anti-infectives, vaccines, and antibiotics for the prevention and treatment of serious infectious diseases. The Company's anti-viral programs are designed to prevent or limit the replication of viral pathogens. SIGA's anti-infectives programs target the increasingly serious problem of drug resistant bacteria and emerging pathogens.

*Basis of presentation*

The accompanying consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred cumulative net losses and expects to incur additional losses to perform further research and development activities. The Company does not have commercial products and has limited capital resources. Management's plans with regard to these matters include continued development of its products as well as seeking additional capital through a combination of collaborative agreements, strategic alliances, research grants, and future equity and debt financing. Although management will continue to pursue these plans, there is no assurance that the Company will be successful in obtaining future financing on commercially reasonable terms or that the Company will be able to secure funding from anticipated government contracts and grants.

Management believes that existing cash balances combined with cash flows primarily from proceeds from the Company's investment commitment (see Note 5), continuing government grants and contracts, and anticipated new government grants and contracts will be sufficient to support its operations beyond the next twelve months, and will fund the Company's business objectives during that period. If the Company is unable to raise adequate capital or achieve profitability, future operations will need to be scaled back or discontinued. Continuance of the Company as a going concern is dependent upon, among other things, the success of the Company's research and development programs and the Company's ability to obtain adequate future financing. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

**2. Summary of Significant Accounting Policies**

*Use of Estimates*

The consolidated financial statements and related disclosures are prepared in conformity with accounting principles generally accepted in the United States of America. Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and revenue and expenses during the period reported. These estimates include the realization of deferred tax assets, useful lives and impairment of goodwill, and tangible and intangible assets, and the value of options and warrants granted or issued by the Company. Estimates and assumptions are reviewed periodically and the effects of revisions are reflected in the financial statements in the period they are determined to be necessary. Actual results could differ from these estimates.

*Cash and cash equivalents*

Cash and cash equivalents consist of short term, highly liquid investments, with original maturities of less than three months when purchased and are stated at cost. Interest is accrued as earned.

*Property, Plant and Equipment*

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is provided on the straight-line method over the estimated useful lives of the various asset classes. Estimated lives are 5 years for

laboratory equipment; 3 years for computer equipment; 7 years for furniture and fixtures; and the life of the lease for leasehold improvements. Maintenance, repairs and minor replacements are charged to expense as incurred. Upon retirement or disposal of assets, the cost and related accumulated depreciation are removed from the Balance Sheet and any gain or loss is reflected in the Statement of Operations.

### ***Revenue Recognition***

The Company recognizes revenue from contract research and development and research payments in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition, ("SAB 104"). In accordance with SAB 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed or determinable, collectibility 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 as 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 in which 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.

For the years ended December 31, 2008, 2007, and 2006, revenues from National Institutes of Health ("NIH") contracts and grants was 99.5%, 71%, and 53%, respectively, of total revenues recognized by the Company.

### ***Accounts Receivable***

Accounts receivable are recorded net of provisions for doubtful accounts. At December 31, 2008 and 2007, 92% and 97%, respectively, of accounts receivables represented receivables from NIH. An allowance for doubtful accounts is based on specific analysis of the receivables. At December 31, 2008, 2007, and 2006, the Company had no allowance for doubtful accounts.

### ***Research and development***

Research and development expenses include costs directly attributable to the conduct of research and development programs, including employee related costs, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside contractors, and facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred. Costs related to the acquisition of technology rights, for which development work is still in process, and that have no alternative future uses, are expensed as incurred.

### ***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 by a regulator or government organization, loss of key personnel, or new circumstances that would cause an expectation that it is more likely than not that we would sell or otherwise dispose of a reporting unit. Goodwill impairment is determined using a two-step approach in accordance with Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"). The impairment review process compares the fair value of the reporting unit in which goodwill resides to its carrying value. In 2008 and 2007, the Company operated as one business and one reporting unit. Therefore, the goodwill impairment analysis was performed on the basis of the Company as a whole using the market capitalization of the Company as an estimate of its fair value.

***Income taxes***

Income taxes are accounted for under the asset and liability method prescribed by Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or the entire deferred tax asset will not be realized.

The Company applies the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement 109* ("FIN 48"). FIN 48 prescribes a comprehensive model for the manner in which a company should recognize, measure, present and disclose in its financial statements all material uncertain tax positions that the Company has taken or expects to take on a tax return.

The Company has no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months from December 31, 2008. As of December 31, 2008, the only tax jurisdiction to which the Company is subject is the United States. Open tax years relate to years in which unused net operating losses were generated. Thus, upon adoption of FIN 48, the Company's open tax years extend back to 1995. In the event that the Company concludes that it is subject to interest and/or penalties arising from uncertain tax positions, the Company will present interest and penalties as a component of income taxes. No amounts of interest or penalties were recognized in the Company's Consolidated Statements of Operations or Consolidated Balance Sheets on December 31, 2007 or as of and for the year ended December 31, 2008.

***Net loss per common share***

The Company computes, presents and discloses earnings per share in accordance with SFAS 128 "Earnings Per Share" ("EPS") which specifies the computation, presentation and disclosure requirements for earnings per share of entities with publicly held common stock or potential common stock. The statement defines two earnings per share calculations, basic and diluted. The objective of basic EPS is to measure the performance of an entity over the reporting period by dividing income (loss) by the weighted average shares outstanding. The objective of diluted EPS is consistent with that of basic EPS, that is to measure the performance of an entity over the reporting period, while giving effect to all dilutive potential common shares that were outstanding during the period. The calculation of diluted EPS is similar to basic EPS except the denominator is increased for the conversion of potential common shares unless the impact of such common shares is anti-dilutive.

The Company incurred losses for the years ended December 31, 2008, 2007, and 2006, and as a result, certain equity instruments are excluded from the calculation of diluted loss per share. At December 31, 2008, 2007, and 2006, outstanding options to purchase 7,696,054, 8,159,768, and 7,736,145, shares, respectively, of the Company's common stock with exercise prices ranging from \$0.94 to \$4.63 have been excluded from the computation of diluted loss per share as the effect of such shares is anti-dilutive. At December 31, 2008, 2007, and 2006, outstanding warrants to purchase 6,825,567, 8,262,377, and 9,441,915, shares, respectively, of the Company's common stock, with exercise prices ranging from \$1.18 to \$4.99 have been excluded from the computation of diluted loss per share as they are anti-dilutive.

***Fair value of financial instruments***

The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Common stock rights and warrants which are classified as assets or liabilities under the provisions of EITF 00-19, are recorded at their fair market value as of each reporting period.

***Concentration of credit risk***

The Company has cash in bank accounts that exceed the Federal Deposit Insurance Corporation insured limits. The Company has not experienced any losses on its cash accounts. No allowance has been provided for potential credit losses because management believes that any such losses would be minimal. The Company's accounts payable consist of trade payables due to creditors.

### ***Share-based Compensation***

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), 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. SFAS 123(R) 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.

### ***Segment information***

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and only has one reportable segment as defined by SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information."

### ***Recent accounting pronouncements***

In April 2008, the FASB issued EITF 07-05, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock", ("EITF 07-05"). EITF 07-05 provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in paragraph 11(a) of FAS 133. EITF 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and early application is not permitted. Management is evaluating what effect EITF 07-05 will have on SIGA's financial position and operating results.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities," ("SFAS No. 161"). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit-risk-related contingent features in derivative agreements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008. The adoption of SFAS No. 161 will not affect our consolidated financial condition and results of operations, but may require additional disclosures if we enter into derivative and hedging activities.

Effective January 1, 2008, the Company implemented SFAS No. 157, "Fair Value Measurement", (SFAS 157), for financial assets and liabilities that are required to be measured at fair value. The adoption of FAS 157 did not have an impact on our financial position or results of operations.

In February 2008, the FASB issued FASB Staff Position 157-2 (FSP 157-2), which delayed the implementation of FAS 157 until January 1, 2009, for non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. Pursuant to FSP 157-2, the Company did not adopt FAS 157 for non-financial assets and liabilities. The Company is currently assessing the impact of FAS 157-2 on its non-financial assets and liabilities.

SFAS 157 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. As of December 31, 2008, the fair value of such warrants was \$2,923,532.

### 3. Research Agreements

Effective September 1, 2008, the Company was awarded a five-year, \$55.0 million contract from the National Institute of Allergy and Infectious Diseases (“NIAID”) of the NIH, to support the development of additional formulations and smallpox-related indications for ST-246, the Company’s lead smallpox drug candidate.

In September 2008, SIGA was awarded \$20.0 million from the NIAID in supplemental funding to the Company’s 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. On December 31, 2008, the Company’s prepaid expenses included a deposit of \$1.25 million paid to a third party for the manufacturing of ST-246® for testing. In connection with the deposit, and the receipt of reimbursement from the NIAID for such deposit, the Company also recorded the corresponding deferred revenue. The amount recorded as prepaid expense will be recognized as operating expense as the related manufacturing takes place, and revenue will be recognized over the same period.

In September 2008, SIGA received a two-year, \$1.0 million Phase I grant from the NIH to fund lead optimization and animal efficacy trials for the Company’s Dengue antiviral program.

In September 2007, we received a two-year grant for a total of approximately \$600,000 supporting our development of ST-246® treatment of smallpox vaccine-related adverse events. In July 2007, we were awarded a two-year grant for a total of \$530,000 to support our Strep program.

### 4. Intangible Assets

During the year ended December 31, 2008, the Company did not acquire any intangible assets. The following table presents the components of the Company’s acquired intangible assets with finite lives, as of December 31, 2007:

	December 31, 2007		
	Gross Carrying Amount	Accumulated Amortization	Net
Acquired Grants	\$ 1,962,693	\$ 1,962,693	\$ —
Customer contract and grants	83,571	83,571	—
Covenants not to compete	202,000	202,000	—
Acquired technology	330,483	330,483	—
	<u>\$ 2,578,747</u>	<u>\$ 2,578,747</u>	<u>\$ —</u>

For the year ended December 31, 2007, the Company recorded \$165,243 for the amortization of acquired technology.

### 5. Stockholders’ Equity

On December 31, 2008, the Company’s authorized share capital consisted of 110,000,000 shares, of which 100,000,000 are designated common shares and 10,000,000 are designated preferred shares. The Company’s Board of Directors is authorized to issue preferred shares in series with rights, privileges and qualifications of each series determined by the Board.



### *2008 Financing*

On June 19, 2008, SIGA entered into a letter agreement (the "Letter Agreement"), with MacAndrews & Forbes, LLC ("M&F"), a related party, for M&F's commitment to invest, at SIGA's discretion, up to \$8 million over a one-year period (the "Investment Period") in exchange for (i) SIGA common stock at per share price equal to the lesser of (A) \$3.06 and (B) the average of the volume-weighted average price per share for the 5 trading days immediately preceding each funding date, and (ii) warrants to purchase 40% of the number of SIGA shares acquired by the Investor, exercisable at 115% of the common stock purchase price on such funding date (the "Consideration Warrants"). The Consideration Warrants will be exercisable for up to four years following the issuance of such warrants. M&F has the option, during the Investment Period, to invest in the Company under the same investment terms.

In addition to and in consideration for the commitment of M&F, M&F received warrants to purchase 238,000 shares of SIGA common stock, exercisable at \$3.06 (the "Commitment Warrants"). The Commitment Warrants are exercisable until June 19, 2012. The Company recorded all costs related to the Letter Agreement, including the fair value of the Commitment Warrants, as deferred transaction costs. The deferred costs will reduce the Company's additional paid-in capital upon issuance of common stock and warrants under the Letter Agreement.

### *2006 and 2005 Placements*

On October 19, 2006, the Company sold 2,000,000 shares of the Company's common stock at \$4.54 per share and warrants to purchase 1,000,000 shares of the Company's common stock. The warrants have an initial exercise price of \$4.99 per share and may be exercised at any time and from time to time through and including the seventh anniversary of the closing date. As of December 31, 2008, warrants to acquire 1,000,000 shares of common stock were outstanding.

In November 2005, the Company sold 2,000,000 shares of the Company's common stock at \$1.00 per share and warrants to purchase 1,000,000 shares of the Company's common stock at an initial exercise price of \$1.18 per share, at any time and from time to time through and including the seventh anniversary of the closing date. As of December 31, 2008, warrants to acquire 579,192 shares of common stock were outstanding.

The Company accounted for the transactions under the provisions of EITF 00-19 which requires that free-standing derivative financial instruments that require net cash settlement be classified as assets or liabilities at the time of the transaction, and recorded at their fair value. EITF 00-19 also requires that any changes in the fair value of the derivative instruments be reported in earnings or loss as long as the derivative contracts are classified as assets or liabilities. At December 31, 2008, the fair market value of the warrants issued in 2006 and 2005 was \$1.5 million and \$1.4 million, respectively. The Company applied the Black-Scholes model to calculate the fair values of the respective derivative instruments using the contracted term of the warrants. Management estimates the expected volatility using a combination of the Company's historical volatility and the volatility of a group of comparable companies. SIGA recorded a gain of \$43,000 representing the decline in the instruments' fair value from January 1, 2008 to December 31, 2008.

### **Preferred Stock**

Holders of the Series A Convertible Preferred Stock are entitled to (i) cumulative dividends at an annual rate of 6% payable when and if declared by the Company's board of directors; (ii) in the event of liquidation of the Company, each holder is entitled to receive \$1.4375 per share (subject to certain adjustments) plus all accrued but unpaid dividends; (iii) convert each share of Series A to a number of fully paid and non-assessable shares of common stock as calculated by dividing \$1.4375 by the Series A Conversion Price (shall initially be \$1.4375); and (iv) vote with the holders of other classes of shares on an as-converted basis.

During the year ended December 31, 2006 certain preferred stockholders converted 68,038 Series A convertible preferred stock into 68,038 shares of common stock.

On December 31, 2008, no shares of Series A Convertible Preferred Stock were outstanding.

**6. Stock option plan and warrants***Amended and Restated 1996 Incentive and Non-Qualified Stock Option Plan*

In January 1996, the Company implemented its 1996 Incentive and Non-Qualified Stock Option Plan (the "Plan"). The Plan as amended provides for the granting of up to 11,000,000 shares of the Company's common stock to employees, consultants and outside directors of the Company. The exercise period for options granted under the Plan, except those granted to outside directors, is determined by a committee of the Board of Directors. Stock options granted to outside directors pursuant to the Plan must have an exercise price equal to or in excess of the fair market value of the Company's common stock at the date of grant.

For the years ended December 31, 2008 and 2007, the Company recorded compensation expense of \$1.0 million and \$571,000, respectively, related to stock options. The total fair value of options vested during each year was \$595,000 and \$350,500 for 2007 and 2006, respectively. The total compensation cost not yet recognized related to non-vested awards at December 31, 2008 is \$1.9 million. The weighted average period over which total compensation cost is expected to be recognized is 1.30 years.

SIGA calculated the fair value of options awarded during the three years ended December 31, 2008, 2007, and 2006 using the Black-Scholes model with the following weighted average assumptions:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
<b>Weighted Average Assumptions</b>			
Expected volatility	68.50%	66.00%	60.00%
Dividend Yield	0.00%	0.00%	0.00%
Risk-free interest rate	2.79%	4.61% - 4.83%	4.49%
Expected holding period	5 Yrs	5 Yrs	5 Yrs

The Company calculates the expected volatility using a combination of SIGA's historical volatility and the volatility of a group of comparable companies. The risk-free interest rate assumption is based upon observed interest rate appropriate for the term of the Company's employee stock options. The dividend yield assumption is based on the Company's intent not to issue a dividend in the foreseeable future. The expected holding period assumption was estimated based on historical experience and expectation of employee exercise behavior in the future giving consideration to the contractual terms of the award.

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

Stock options activity of the Company is summarized as follows:

	<i>Number of Shares</i>	<i>Average Exercise Price (\$)</i>
Options outstanding at January 1, 2006	9,404,561	2.00
Granted	337,500	2.26
Forfeited	(1,265,167)	1.30
Expired	(33,334)	1.50
Exercised	(897,415)	1.74
Options outstanding at December 31, 2006	7,546,145	2.07
Granted	935,000	3.17
Forfeited	(92,086)	2.29
Expired	(50,393)	5.04
Exercised	(368,898)	1.71
Options outstanding at December 31, 2007	7,969,768	\$ 2.28
Granted	900,000	2.93
Forfeited	(26,167)	3.20
Expired	(190,834)	4.34
Exercised	(1,146,713)	2.45
Options outstanding at December 31, 2008	7,506,054	\$ 2.28

	<i>Number of Shares</i>	<i>Weighted Average Intrinsic Value (\$)</i>
Nonvested options at December 31, 2007	972,058	0.22
Nonvested options at December 31, 2008	1,452,291	0.41
Options vested during 2008	402,264	0.43
Options available for future grant at December 31, 2008	862,963	
Weighted average fair value of options granted during 2008	\$ 1.72	
Weighted average fair value of options granted during 2007	\$ 1.87	
Weighted average fair value of options granted during 2006	\$ 1.24	
Weighted average fair value of options forfeited during 2008	\$ 1.70	
Weighted average fair value of options forfeited during 2007	\$ 1.33	
Weighted average fair value of options forfeited during 2006	\$ 1.02	
Total intrinsic value of options exercised during 2008	\$ 937,630	
Total intrinsic value of options exercised during 2007	\$ 506,000	

The following table summarizes information about options outstanding at December 31, 2008:

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

<i>Range of Exercise Price(\$)</i>	<i>Number of Options Outstanding at December 31, 2008</i>	<i>Weighted Average Remaining Contractual Life (Years)</i>	<i>Weighted Average Exercise Price (\$)</i>	<i>Number Fully Vested &amp; Exercisable at December 31, 2008</i>	<i>Weighted Average Exercise Price (\$)</i>	<i>Aggregate Intrinsic Value at December 31, 2008</i>
0.94 - 1.85	2,233,054	5.37	1.34	2,189,096	1.34	\$ 4,217,133
2.00 - 2.75	3,816,000	3.43	2.43	3,311,000	2.43	2,829,370
3.10 - 5.50	1,457,000	8.38	3.32	553,667	3.46	35,401
	<hr/>			<hr/>		<hr/>
	7,506,054			6,053,763		\$ 7,081,904
	<hr/>			<hr/>		<hr/>

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

The following tables summarize information about warrants outstanding at December 31, 2008:

	<u>Number of Warrants</u>	<u>Weighted Average Exercise Price</u>	<u>Expiration Dates</u>
Outstanding at January 1, 2006	9,439,022	\$ 2.26	
Granted	1,949,002	3.81	10/19/2013
Exercised	(1,421,109)	1.88	
Canceled / Expired	(525,000)	3.60	
	<u>9,441,915</u>	<u>\$ 2.52</u>	
Outstanding at December 31, 2006	9,441,915	\$ 2.52	
Granted	—	—	
Exercised	(1,179,538)	2.26	
Canceled / Expired	—	—	
	<u>8,262,377</u>	<u>\$ 2.55</u>	
Outstanding at December 31, 2007	8,262,377	\$ 2.55	
Granted	238,000	3.06	6/19/2012
Exercised	(595,624)	2.62	
Canceled / Expired	(1,079,186)	3.34	
	<u>6,825,567</u>	<u>\$ 2.44</u>	
Outstanding at December 31, 2008	6,825,567	\$ 2.44	

<u>Number of Warrants Outstanding</u>	<u>Exercise Price \$</u>
4,656,466	1.18 - 1.90
896,700	2.00 - 3.06
1,272,401	4.99
<u>6,825,567</u>	

## 7. Related Parties

During the year ended December 31, 2008, the Company incurred costs of \$5,700 related to work performed by a related party and its affiliate, in connection with the Company's lead products. On December 31, 2008, there were no outstanding payables due to related parties.

On June 19, 2008, SIGA entered into a Letter Agreement with M&F, a related party, for M&F's commitment to invest, at SIGA's discretion, up to \$8 million over a one-year period in exchange for (i) SIGA common stock, and (ii) warrants to purchase 40% of the number of SIGA shares acquired by the Investor. M&F has the option, during the Investment Period, to invest in the Company under the same investment terms (see Note 5).

Additionally, a member of the Company's Board of Directors is a member of the Company's outside counsel.

**8. Property, Plant and Equipment**

Property, plant and equipment consisted of the following at December 31, 2008 and 2007:

	<b>2008</b>	<b>2007</b>
Laboratory equipment	\$ 2,104,673	\$ 1,933,072
Leasehold improvements	2,868,848	2,809,559
Computer equipment	136,540	178,644
Furniture and fixtures	310,899	290,637
	<u>5,420,960</u>	<u>5,211,912</u>
Less - accumulated depreciation	(4,060,942)	(3,732,234)
Property, plant and equipment, net	<u>\$ 1,360,018</u>	<u>\$ 1,479,678</u>

**9. Accrued Expenses and Other**

Accrued expenses and other consisted of the following at December 31, 2008 and 2007:

	<b>2008</b>	<b>2007</b>
Vacation	\$ 158,000	\$ 121,000
Bonuses	292,000	202,000
Legal	360,000	25,000
Other	400,496	448,524
	<u>1,210,496</u>	<u>796,524</u>
Total Accrued Expenses and Other	<u>\$ 1,210,496</u>	<u>\$ 796,524</u>

**10. Notes Payable**

On March 20, 2006, SIGA entered into a Bridge Note Purchase Agreement ("Note Purchase Agreement") with a third party for the sale of three 8% Notes by SIGA, for \$1,000,000 each. The first, second and third Notes were issued on March 20, 2006, April 19, 2006, and June 19, 2006, respectively. The proceeds of the Notes were used by the Company for (i) expenses directly related to the development of ST-246, (ii) expenses related to a potential business transaction with the third party and (iii) corporate overhead. On October 23, 2006, the Company paid the third party \$3,114,400 in full repayment of the three notes and interest accrued thereon.

On May 20, 2005, the Company borrowed approximately \$276,000 under a Promissory Note payable to General Electric Capital Corporation. The note was payable in 36 monthly installments of principal and interest of 10.31% per annum. The note was collateralized by a master security agreement dated as of April 29, 2005 and by specific property listed under the master security agreement. On September 2, 2007, the Company repaid the entire balance and related interest outstanding under the Promissory Note.

**11. Income Taxes**

The Company has incurred losses since inception, which have generated net operating loss carryforwards of approximately \$43.8 million at December 31, 2008 for federal and state income tax purposes. These carryforwards are available to offset future taxable income and begin expiring in 2010 for federal income tax purposes. As a result of a previous change in stock ownership, the annual utilization of the net operating loss carryforwards is subject to limitation. The net operating loss carryforwards and temporary differences, arising primarily from deferred research and development expenses and differences in the treatment of intangible assets, result in a noncurrent deferred tax asset at December

31, 2008 and 2007 of approximately \$24.5 million and \$21.6, respectively. In consideration of

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

the Company's accumulated losses and the uncertainty of its ability to utilize this deferred tax asset in the future, the Company has recorded a valuation allowance of an equal amount on such date to fully offset the deferred tax asset.

At December 31, 2008 and 2007, the Company's deferred tax assets (in thousands) are comprised of the following:

	2008	2007
Net Operating Losses	17,271	14,579
Deferred Research and Development Costs	5,607	5,037
Amortization of Acquired Assets	683	779
Stock Based Compensation	0	406
Depreciation of Property Plant and Equipment	984	820
	<u>          </u>	<u>          </u>
Total Deferred Tax Asset	24,545	21,621
Valuation Allowance	(24,545)	(21,621)
	<u>          </u>	<u>          </u>
Net Deferred Tax Assets	\$ —	\$ —

Following is a summary of changes in our valuation allowance for deferred tax assets as of and for the years ended December 31, 2008, 2007, and 2006 (in thousands):

December 31,	Balance at Beginning of Year	Additions Charged to Costs and Expenses	Deductions	Balance at End of Year
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
2008	\$ 21,621	\$ 3,020	\$ 96	\$ 24,545
2007	\$ 19,057	\$ 2,603	\$ 39	\$ 21,621
2006	\$ 16,411	\$ 2,646	\$ —	\$ 19,057

For the years ended December 31, 2008 and 2007, the Company's effective tax rate differs from the federal statutory rate principally due to net operating losses and other temporary differences for which no benefit was recorded, state taxes and other permanent differences.

The Company's effective tax rate differs from the U.S. Federal Statutory income tax rate of 34% as follows:

	2008	2007
Statutory federal income tax rate	-34.00%	-34.00%
State tax benefit, net of federal taxes	-4.84%	-6.69%
Other	3.95%	-8.62%
Valuation allowance on deferred tax assets	34.89%	49.31%
	<u>          </u>	<u>          </u>
Effective tax rate	0.00%	0.00%



**12. Commitments and Contingencies***Operating lease commitments*

As of December 31, 2008, our purchase obligations are not material. The Company leases certain facilities and office space under operating leases. Minimum future rental commitments under operating leases having non-cancelable lease terms in excess of one year and future minimum payments under notes payable are as follows:

Year ended December 31,	Lease obligations
2009	608,400
2010	495,200
2011	472,500
Total	\$ 1,576,100

*Other*

In December 2006, PharmAthene, Inc. ("PharmAthene") filed an action against the Company in the Court of Chancery in the State of Delaware, captioned *PharmAthene, Inc. v. SIGA Technologies, Inc.*, C.A. No. 2627-N. In its Complaint, PharmAthene asks the Court to order the Company to enter into a license agreement with PharmAthene with respect to ST-246®, as well as issue a declaration that the Company is obliged to execute such a license agreement, and award damages resulting from the Company's supposed breach of that obligation. PharmAthene also alleges that SIGA 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 SIGA during the negotiation process. In January 2007, SIGA filed a motion to dismiss the Complaint in its entirety for failure to state a claim upon which relief can be granted. In January 2008, the Court of Chancery denied the Company's motion to dismiss and lifted a related stay of discovery. Discovery is proceeding. The Company filed its answer to the Complaint denying all material allegations.

As of December 31, 2008, the Company believes that a possible loss or range of loss cannot be reasonably estimated because PharmAthene, in its complaint, seeks injunctive and declaratory relief as well as unspecified monetary damages and the Company asserted what it believes to be meritorious defenses. Therefore, the Company has concluded that it is not possible to reasonably estimate a range of loss.

From time to time, the Company is involved in disputes or legal proceedings arising in the ordinary course of business. The Company believes that there is no other dispute or litigation pending that could have, individually or in the aggregate, a material adverse effect on its financial position, results of operations or cash flows.

**13. Financial Information By Quarter (Unaudited) (in thousands, except for per share data)**

<b>2008 For The Quarter Ended</b>	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>	<b>Total</b>
Revenues	\$ 1,983	\$ 1,732	\$ 1,863	\$ 2,488	\$ 8,066
Selling, general & administrative	\$ 1,005	\$ 1,165	\$ 945	\$ 1,493	\$ 4,608
Research and development	\$ 2,836	\$ 2,500	\$ 2,853	\$ 3,424	\$ 11,613
Patent preparation fees	\$ 130	\$ 134	\$ 198	\$ 120	\$ 582
Operating loss	\$ (1,988)	\$ (2,067)	\$ (2,134)	\$ (2,548)	\$ (8,737)
Net income (loss)	\$ (858)	\$ (3,141)	\$ (3,029)	\$ (1,571)	\$ (8,599)
Net loss per share: basic and diluted	\$ (0.03)	\$ (0.09)	\$ (0.09)	\$ (0.04)	\$ (0.25)
Market price range for common stock					
High	\$ 3.06	\$ 3.80	\$ 4.00	\$ 3.57	\$ 4.00
Low	\$ 1.93	\$ 2.18	\$ 2.36	\$ 2.19	\$ 1.93

<b>2007 For The Quarter Ended</b>	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>	<b>Total</b>
Revenues	\$ 1,867	\$ 1,460	\$ 1,609	\$ 1,763	\$ 6,699
Selling, general & administrative	\$ 877	\$ 1,142	\$ 793	\$ 892	\$ 3,704
Research and development	\$ 2,650	\$ 2,201	\$ 2,342	\$ 2,750	\$ 9,943
Patent preparation fees	\$ 138	\$ 127	\$ 59	\$ 191	\$ 515
Operating loss	\$ (1,797)	\$ (2,010)	\$ (1,585)	\$ (2,071)	\$ (7,463)
Net income (loss)	\$ (3,142)	\$ 527	\$ (2,493)	\$ (531)	\$ (5,639)
Net loss per share: basic and diluted	\$ (0.10)	\$ 0.02	\$ (0.07)	\$ (0.02)	\$ (0.17)
Market price range for common stock					
High	\$ 6.04	\$ 5.94	\$ 4.70	\$ 4.50	\$ 5.94
Low	\$ 3.36	\$ 3.21	\$ 2.52	\$ 2.95	\$ 2.52

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

None.

**Item 9A. Controls and Procedures  
Management's Responsibility for Financial Statements**

Our management is responsible for the integrity and objectivity of all information presented in this annual report. The consolidated financial statements were prepared in conformity with accounting principles generally accepted in the United States of America and include amounts based on management's best estimates and judgments. Management believes the consolidated financial statements fairly reflect the form and substance of transactions and that the financial statements fairly represent the Company's financial position and results of operations.

The Audit Committee of the Board of Directors, which is composed solely of independent directors, meets regularly with the independent registered public accounting firm, PricewaterhouseCoopers LLP and representatives of management to review accounting, financial reporting, internal control and audit matters, as well as the nature and extent of the audit effort. The Audit Committee is responsible for the engagement of the independent auditors. The independent auditors have free access to the Audit Committee.

**Disclosure Controls and Procedures**

We have established disclosure controls and procedures to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the officers who certify the Company's financial reports and to other members of senior management and the Board of Directors. Based on their evaluation as of December 31, 2008, our chief executive officer and acting chief financial officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to the Company's management, including its chief executive office and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

**Management's Report on Internal Control over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) or Rule 15d-15(f) of the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and disposition of the Company's assets; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and the directors of the Company; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

Management conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of December 31, 2008 based on the framework set forth in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2008.

The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in this Form 10-K.

**Item 9B. Other Information**

None.

## PART III

**Item 10. Directors and Executive Officers of the Registrant**

Information required by this item is incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Shareholders.

**Item 11. Executive Compensation**

Information required by this item is incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Shareholders.

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

Information required by this item is incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Shareholders.

**Equity Compensation Plan Information**

The following table sets forth certain compensation plan information with respect to both equity compensation plans approved by security holders and equity compensation plans not approved by security holders as of December 31, 2008:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	7,506,054	\$ 2.28	862,963
Equity compensation plans not approved by security holders	190,000	\$ 2.00	—
<b>Total</b>	<b>7,696,054</b>	<b>\$ 2.27</b>	<b>862,963</b>

(1) SIGA Technologies, Inc., Amended and Restated 1996 Incentive and Non-Qualified Stock Option Plan.

As of December 31, 2008, options awarded outside of the Company's equity compensation plan included 125,000 options awarded to an employee and 65,000 options awarded to consultants. In May 2000, the Company awarded its Chief Scientific Officer options to acquire 125,000 shares of the Company's common stock at an exercise price of \$2.00 per share. In July 2000, the Company entered into an agreement with a consultant to serve as the Company's public relations agent and awarded the consultant options to acquire shares of the Company's common stock. As of December 31, 2008, the consultant holds 27,500 options and 37,500 options with an exercise price of \$1.50 per share and \$1.75 per share, respectively.

**Item 13. Certain Relationships and Related Transactions**

Information required by this item is incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Shareholders.

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

Information required by this item is incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Shareholders.

**PART IV**

Item 15. Exhibits and Financial Statement Schedules

**(a) (1) and (2). Financial Statements and Financial Statements Schedule.**

See Index to Financial Statements under Item 8 in Part II hereof where these documents are listed.

**(a) (3). Exhibits.**

The following is a list of exhibits:

Exhibit No.	Description
3(a)	Restated Articles of Incorporation of the Company (Incorporated by reference to Form S-3 Registration Statement of the Company dated May 10, 2000 (No. 333-36682)).
3(b)	Form of Certificate of Amendment of the Restated Certificate of Incorporation of SIGA Technologies, Inc. (incorporated by reference to the Company's Proxy Statement on Schedule 14A dated June 15, 2007).
<u>3(c)</u>	<u>Amended and Restated Bylaws of the Company (filed herewith).</u>
4(a)	Form of Common Stock Certificate (Incorporated by reference to Form SB-2 Registration Statement of the Company dated March 10, 1997 (No. 333-23037)).
4(b)	Warrant Agreement dated as of September 15, 1996 between the Company and Vincent A. Fischetti (1) (Incorporated by reference to Form SB-2 Registration Statement of the Company dated March 10, 1997 (No. 333-23037)).
4(c)	Warrant Agreement dated as of November 18, 1996 between the Company and David de Weese (1) (Incorporated by reference to Form SB-2 Registration Statement of the Company dated March 10, 1997 (No. 333-23037)).
4(d)	Warrant Agreement between the Company and Stefan Capital, dated September 9, 1999 (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1999).
4(e)	Registration Rights Agreement, dated as of May 23, 2003, between the Company and Plexus Vaccine Inc. (Incorporated by reference to Form 8-K of the Company filed June 9, 2003).
4(f)	Registration Rights Agreement, dated as of August 13, 2003, between the Company and MacAndrews & Forbes Holdings Inc. (Incorporated by reference to Form 8-K of the Company filed August 18, 2003).
4(g)	Form of Warrant to purchase shares of common stock of the Company, issued to MacAndrews & Forbes, LLC on June 19, 2008 (Incorporated by reference to Form 8-K of the Company filed June 23, 2008).
10(a)	License and Research Support Agreement between the Company and The Rockefeller University, dated as of January 31, 1996; and Amendment to License and Research Support Agreement between the Company and The Rockefeller University, dated as of October 1, 1996(2) (Incorporated by reference to Form SB-2 Registration Statement of the Company dated March 10, 1997 (No. 333-23037)).
10(b)	Research Agreement between the Company and Emory University, dated as of January 31, 1996(2) (Incorporated by reference to Form SB-2 Registration Statement of the Company dated March 10, 1997 (No. 333-23037)).





## Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

- 10(c) Research Support Agreement between the Company and Oregon State University, dated as of January 31, 1996(2) (Incorporated by reference to Form SB-2 Registration Statement of the Company dated March 10, 1997 (No. 333-23037)). Letter Agreement dated as of March 5, 1999 to continue the Research Support Agreement (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1999).
- 10(d) Option Agreement between the Company and Oregon State University, dated as of November 30, 1999 and related Amendments to the Agreement (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1999).
- 10(h) Clinical Trials Agreement between the Company and National Institute of Allergy and Infectious Diseases, dated as of July 1, 1997 (Incorporated by reference to Amendment No. 1 to Form SB-2 Registration Statement of the Company dated July 11, 1997 (No. 333-23037)).
- 10(i) Research Agreement between the Company and The Research Foundation of State University of New York, dated as of July 1, 1997(2) (Incorporated by reference to Amendment No. 1 to Form SB-2 Registration Statement of the Company dated July 11, 1997 (No. 333-23037)).
- 10(j) Collaborative Research and License Agreement between the Company and Wyeth, dated as of July 1, 1997(2) (Incorporated by reference to Amendment No. 3 to Form SB-2 Registration Statement of the Company dated September 2, 1997 (No. 333-23037)).
- 10(k) Research Collaboration and License Agreement between the Company and The Washington University, dated as of February 6, 1998 (2) (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1997).
- 10(l) Settlement Agreement and Mutual Release between the Company and The Washington University, dated as of February 17, 2000 (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1999).
- 10(m) Technology Transfer Agreement between the Company and MedImmune, Inc., dated as of February 10, 1998 (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1997).
- 10(p) Option Agreement between the Company and Ross Products Division of Abbott Laboratories, dated February 28, 2000 (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1999).
- 10(q) Agreement between the Company and Oregon State University for the Company to provide contract research services to the University dated September 24, 2000 (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2000).
- 10(r) License and Research Agreements between the Company and the Regents of the University of California dated December 6, 2000 (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2000).
- 10(s) Amended and Restated 1996 Incentive and Non-Qualified Stock Option Plan dated August 15, 2001 (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2001), as amended (as set forth in the Form 8-K of the Company filed May 27, 2005).
- 10(u) Research and License Agreement between the Company and TransTech Pharma, Inc. dated October 1, 2002 (Filed with the Company's Annual Report on Form 10-KSB for the year ended December 31, 2002 initially filed with the Securities and Exchange Commission on March 31, 2003).

## Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

- 10(x) Contract between the Company and the Department of the US Army dated December 12, 2002 (Filed with the Company's Annual Report on Form 10-KSB for the year ended December 31, 2002 initially filed with the Securities and Exchange Commission on March 31, 2003).
- 10(y) Contract between the Company and Four Star Group dated February 5, 2003 (Filed with the Company's Annual Report on Form 10-KSB for the year ended December 31, 2002 initially filed with the Securities and Exchange Commission on March 31, 2003).
- 10(aa) Securities Purchase Agreement, dated as of August 13, 2003, between the Company and MacAndrews & Forbes Holdings Inc. (Incorporated by reference to Form 8-K of the Company filed August 18, 2003).
- 10(bb) Letter Agreement dated October 8, 2003 among the Company, MacAndrews & Forbes Holdings Inc. and TransTech Pharma, Inc. (Incorporated by reference to Form 8-K of the Company filed August 18, 2003).
- 10(dd) Non-Employee Director Compensation Summary Sheet (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005).
- 10(ee) Director Compensation Program, effective April 21, 2005 (as set forth in the Form 8-K of the Company filed April 26, 2005).
- 10(ff) Service Agreement, dated as of April 27, 2005, between the Company and TransTech Pharma, Inc. (Incorporated by reference to Form 8-K of the Company filed May 3, 2005).
- 10(gg) Master Security Agreement, dated as of April 29, 2005, between General Electric Capital Corporation and the Company (Incorporated by reference to Form 8-K of the Company filed May 3, 2005).
- 10(hh) Letter Agreement, dated as of August 5, 2005, between the Company and John Odden (Incorporated by reference to Form 8-K of the Company filed August 11, 2005).
- 10(ii) Agreement, dated as of September 14, 2005, between Saint Louis University and the Company (Incorporated by reference to Form 8-K of the Company filed September 20, 2005).
- 10(jj) Agreement, dated as of September 22, 2005, between the United States Army Medical Research and Material Command and the Company (Incorporated by reference to Form 8-K of the Company filed September 27, 2005).
- 10(kk) Securities Purchase Agreement, dated as of November 2, 2005, between Iroquois Master Fund Ltd., Cranshire Capital, L.P., Omicron Master Trust, Smithfield Fiduciary LLC and the Company (Incorporated by reference to Form 8-K of the Company filed November 4, 2005).
- 10(ll) Exclusive Finder's Agreement, dated as of November 1, 2005, between the Shemano Group, Inc. and the Company (Incorporated by reference to Form 8-K of the Company filed November 4, 2005).
- 10(mm) Letter Agreement, dated as of February 1, 2006, between the Company and Thomas N. Konatich (Incorporated by reference to Form 8-K of the Company filed February 7, 2006).
- 10(oo) Bridge Note Purchase Agreement, dated as of March 20, 2006, between the Company and PharmAthene, Inc. (Incorporated by reference to Form 8-K of the Company filed March 22, 2006).
- 10(pp) Security Agreement, dated as of March 20, 2006, between the Company and PharmAthene, Inc. (Incorporated by reference to Form 8-K of the Company filed March 22, 2006).
- 10(qq) 8% Note, dated as of March 20, 2006, between the Company and PharmAthene, Inc. (Incorporated by reference to Form 8-K of the Company filed March 22, 2006).

## Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

- 10(rr) Separation Agreement, dated as of March 31, 2006, between the Company and Bernard Kasten (Incorporated by reference to Form 8-K of the Company filed April 3, 2006).
- 10(ss) 8% Note, dated as of April 19, 2006, between the Company and PharmAthene, Inc. (Incorporated by reference to Form 8-K of the Company filed April 20, 2006).
- 10(tt) Voting Agreement, dated as of June 8, 2006, among the Company, TransTech Pharma, Inc., MacAndrews & Forbes, Inc., Howard Gittis, Donald G. Drapkin, James J. Antal, Thomas E. Constance, Mehmet C. Oz, Eric A. Rose and Paul G. Savas (Incorporated by reference to Form 8-K of the Company filed June 13, 2006).
- 10(uu) Agreement and Plan of Merger, dated as of June 8, 2006, among the Company, SIGA Acquisition Corp. and PharmAthene, Inc. (Incorporated by reference to Form 8-K of the Company filed June 13, 2006).
- 10(vv) 8% Note, dated as of June 19, 2006, between the Company and PharmAthene, Inc. (Incorporated by reference to Form 8-K of the Company filed June 20, 2006).
- 10(ww) Agreement, dated as of September 29, 2006, between SIGA Technologies, Inc. and the National Institute of Allergy and Infectious Diseases of the National Institutes for Health (Incorporated by reference to Form 10-Q/A of the Company filed November 13, 2006).
- 10(xx) Finder's Agreement, dated as of October 18, 2006, between the Company and Empire Financial Group, Inc. (Incorporated by reference to Form 8-K of the Company filed October 20, 2006).
- 10(yy) Securities Purchase Agreement, dated as of October 18, 2006, between the Company, Iroquois Master Fund Ltd., Cranshire Capital, L.P., Omicron Master Trust, Rockmore Investment Master Fund, Ltd., and Smithfield Fiduciary LLC (Incorporated by reference to Form 8-K of the Company filed October 20, 2006).
- 10(zz) Amended and Restated Employment Agreement, dated as of January 22, 2007, between the Company and Dennis E. Hruby (Incorporated by reference to Form 8-K of the Company filed January 22, 2007).
- 10(aaa) Amended and Restated Employment Agreement, dated as of January 22, 2007, between the Company and Thomas N. Konatich (Incorporated by reference to Form 8-K of the Company filed January 22, 2007).
- 10(bbb) Letter Agreement, dated as of June 19, 2008, between the Company and MacAndrews & Forbes, LLC (Incorporated by reference to Form 8-K of the Company filed June 23, 2008).
- 10(ccc) Contract, dated September 1, 2008, between the Company and the National Institutes of Health, DHHS (Incorporated by reference to Form 10-Q of the Company filed November 6, 2008).
- 10(ddd) Modification of Contract, dated September 17, 2008, between the Company and the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (Incorporated by reference to Form 10-Q of the Company filed November 6, 2008).
- 10(eee) Amended and Restated Employment Agreement, dated as of November 17, 2008 between the Company and Eric A. Rose (filed herewith).
- 14 The Company's Code of Ethics and Business Conduct (Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2003).

### 21 Subsidiaries of the Registrant.

#### 23.1 Consent of Independent Registered Public Accounting Firm.

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

- 31.1            Certification pursuant to Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 – Chief Executive Officer.
- 31.2            Certification pursuant to Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 – Acting Chief Financial Officer.
- 32.1            Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 – Chief Executive Officer.
- 32.2            Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 – Acting Chief Financial Officer.

- 
- (1)    These agreements were entered into prior to the reverse split of the Company's Common Stock and, therefore, do not reflect such reverse split.
- (2)    Confidential information is omitted and identified by an \* and filed separately with the SEC with a request for Confidential Treatment.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SIGA TECHNOLOGIES, INC.  
(Registrant)

Date: March 6, 2009

By: */s/ Eric A. Rose*

\_\_\_\_\_  
Eric A. Rose, M.D.  
Chief Executive Officer

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

<b>Signature</b>	<b>Title of Capacities</b>	<b>Date</b>
<i>/s/ Eric A. Rose, M.D.</i> _____ Eric A. Rose, M.D.	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 6, 2009
<i>/s/ Ayelet Dugary</i> _____ Ayelet Dugary	Acting Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 6, 2009
<i>/s/ Steven L. Fasman</i> _____ Steven L. Fasman	Director	March 6, 2009
<i>/s/ James J. Antal</i> _____ James J. Antal	Director	March 5, 2009
<i>/s/ Thomas E. Constance</i> _____ Thomas E. Constance	Director	March 6, 2009
<i>/s/ Adnan M. Mjalli, Ph.D.</i> _____ Adnan M. Mjalli, Ph.D.	Director	March 6, 2009
<i>/s/ Mehmet C. Oz, M.D.</i> _____ Mehmet C. Oz, M.D.	Director	March 6, 2009
<i>/s/ Scott Hammer, M.D.</i> _____		

Edgar Filing: SIGA TECHNOLOGIES INC - Form 10-K

Scott Hammer, M.D. Director March 5, 2009

*/s/ Paul G. Savas*

---

Paul G. Savas Director March 5, 2009

*/s/ Judy S. Slotkin*

---

Judy S. Slotkin Director March 6, 2009

*/s/ Michael Weiner, M.D.*

---

Michael Weiner, M.D. Director March 6, 2009

*/s/ Michael J. Bayer*

---

Michael J. Bayer Director March 6, 2009

*/s/ Bruce Slovin*

---

Bruce Slovin Director March 5, 2009

This Page Intentionally left Blank

---