

SIGA TECHNOLOGIES INC
Form 10-K
March 10, 2010

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, 2009

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 13-3864870
(State or other jurisdiction of (IRS Employer Identification. No.)
incorporation or organization)

35 East 62nd Street 10065
New York, NY (zip code)
(Address of principal executive offices)

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

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

Title of each class	Name of each exchange on which registered
common stock, \$.0001 par value	Nasdaq Global Market

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

None

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

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

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.

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

The following document is incorporated herein by reference:

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

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SIGA Technologies, Inc.

Form 10-K

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Item 1. Business

Certain statements in this Annual Report on Form 10-K, including certain statements contained in “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases “can be,” “expects,” “may affect,” “may depend,” “believes,” “estimate,” “project” and similar words and phrases are intended to identify such forward-looking statements. Such forward-looking statements are subject to various known and unknown risks and uncertainties and SIGA cautions you that any forward-looking information provided by or on behalf of SIGA is not a guarantee of future performance. SIGA’s actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond SIGA’s control, including, but not limited to, (i) the risk that potential products that appear promising to SIGA or its collaborators cannot be shown to be efficacious or safe in subsequent pre-clinical or clinical trials, (ii) the risk that SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products, (iii) the risk that SIGA may not be able to obtain anticipated funding for its development projects or other needed funding, (iv) the risk that SIGA may not be able to secure funding from anticipated government contracts and grants, (v) the risk that SIGA may not be able to secure or enforce sufficient legal rights in its products, including patent protection, for its products, (vi) the risk that any challenge to our patent and other property rights, if adversely determined, could affect our business and, even if determined favorably, could be costly, (vii) the risk that regulatory requirements applicable to SIGA’s products may result in the need for further or additional testing or documentation that will delay or prevent seeking or obtaining needed approvals to market these products, (viii) the risk that the U.S. Biomedical Advanced Research & Development Authority (“BARDA”) may not complete the procurement set forth in its solicitation for the acquisition of smallpox antiviral for the strategic national stockpile, or may complete it on different terms, (ix) the risk that the volatile and competitive nature of the biotechnology industry may hamper SIGA’s efforts, (x) the risk that the changes in domestic and foreign economic and market conditions may adversely affect SIGA’s ability to advance its research or its products, and (xi) the effect of federal, state, and foreign regulation on SIGA’s businesses. All such forward-looking statements are current only as of the date on which such statements were made. SIGA does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Introduction

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

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

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

Product Candidates and Market Potential

SIGA Biological Warfare Defense Product Portfolio

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

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

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

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

Market for Biological Defense Programs

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

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

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

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

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

The FDA amended its regulations, effective June 30, 2002, so that certain new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances may be approved for use in humans based on evidence of effectiveness derived only from appropriate animal studies and any additional supporting data. We believe that this change could make it possible for us to have our products which have been proven effective in animal studies to be approved for sale more quickly than under the standard regulatory path.

SIGA Antivirals Product Portfolio

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

Technology

Antiviral Technology: Two Approaches

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

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

Collaborative Research and Licenses

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

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

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

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

Competition

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

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

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

Human Resources and Research Facilities

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

Intellectual Property and Proprietary Rights

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

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

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

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

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

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

Government Regulation

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

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

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

The FDA amended its regulations, effective June 30, 2002, so that certain new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances may be approved for use in humans based on evidence of effectiveness derived only from appropriate animal studies and any additional supporting data.

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

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

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

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

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

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

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- the product may reasonably be believed to be effective in detecting, diagnosing, treating or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks; and
- there is no adequate alternative to the product that is approved and available.

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

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

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

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

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

Availability of Reports and Other Information

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

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

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

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

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

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

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Need for Additional Financing

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Product Development

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

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

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

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

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

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

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

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

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

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

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

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

- be safe, non-toxic and effective;
- otherwise meet applicable regulatory standards;
- receive the necessary regulatory approvals;
- develop into commercially viable drugs;