

SIGA TECHNOLOGIES INC
Form 10-Q
August 01, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended June 30, 2011

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

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

10065
(zip code)

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐.

(Do not check if a smaller reporting company)

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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.

As of July 15, 2011, the registrant had 51,314,017 shares of common stock outstanding.

SIGA TECHNOLOGIES, INC.
FORM 10-Q

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PART I – FINANCIAL INFORMATION

Item 1 – Financial Statements.

SIGA TECHNOLOGIES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	June 30, 2011	December 31, 2010
ASSETS		
Current assets		
Cash and cash equivalents	\$ 5,000,364	\$ 6,332,053
Short term investments	9,999,850	14,999,350
Accounts receivable	1,808,640	3,002,144
Prepaid expenses and other current assets	431,978	369,017
Total current assets	17,240,832	24,702,564
Property, plant and equipment, net	894,258	1,150,257
Goodwill	898,334	898,334
Deferred income tax asset, net	32,653,550	-
Other assets	281,608	280,648
Total assets	\$ 51,968,582	\$ 27,031,803
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,377,339	\$ 2,884,259
Accrued expenses and other current liabilities	1,870,688	1,378,921
Total current liabilities	3,248,027	4,263,180
Common stock warrants	5,751,035	10,524,660
Deferred income tax liability	-	175,175
Other liabilities	20,925	-
Total liabilities	9,019,987	14,963,015
Stockholders' equity		
Common stock (\$.0001 par value, 100,000,000 shares authorized, 51,314,017 and 49,019,433 issued and outstanding at June 30, 2011, and December 31, 2010, respectively)	5,131	4,902
Additional paid-in capital	146,267,297	134,524,304
Accumulated other comprehensive income	-	4,067
Accumulated deficit	(103,323,833)	(122,464,485)
Total stockholders' equity	42,948,595	12,068,788
Total liabilities and stockholders' equity	\$ 51,968,582	\$ 27,031,803

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

SIGA TECHNOLOGIES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues				
Research and development	\$ 2,491,056	\$ 4,446,753	\$ 4,187,777	\$ 9,521,964
Operating expenses				
Selling, general and administrative	9,350,541	2,233,825	13,600,596	4,202,616
Research and development	3,835,386	4,929,961	7,401,664	10,756,984
Patent preparation fees	413,048	305,661	754,875	626,000
Total operating expenses	13,598,975	7,469,447	21,757,135	15,585,600
Operating loss	(11,107,919)	(3,022,694)	(17,569,358)	(6,063,636)
Decrease (increase) in fair value of common stock warrants	2,039,851	(2,228,082)	3,802,809	(4,124,269)
Other income, net	2,006	-	12,100	-
Loss before benefit from income taxes	(9,066,062)	(5,250,776)	(13,754,449)	(10,187,905)
Benefit from income taxes	32,907,988	-	32,895,101	-
Net income (loss)	\$ 23,841,926	\$ (5,250,776)	\$ 19,140,652	\$ (10,187,905)
Basic earnings (loss) per share	\$ 0.47	\$ (0.12)	\$ 0.38	\$ (0.23)
Diluted earnings (loss) per share	\$ 0.44	\$ (0.12)	\$ 0.35	\$ (0.23)
Weighted average shares outstanding, basic	50,879,599	43,620,212	50,422,014	43,408,287
Weighted average shares outstanding: diluted	54,671,403	43,620,212	54,507,838	43,408,287

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

SIGA TECHNOLOGIES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Six Months Ended June 30,	
	2011	2010
Cash flows from operating activities:		
Net income (loss)	\$ 19,140,652	\$ (10,187,905)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and other amortization	347,314	300,751
(Decrease) increase in fair value of warrants	(3,802,809)	4,124,269
Stock based compensation	8,258,944	1,068,227
Changes in assets and liabilities:		
Accounts receivable	1,193,504	(1,039,486)
Accrued interest on short-term investments	(7,572)	-
Prepaid expenses	3,842	979,169
Other assets	(960)	36,086
Deferred income taxes, net	(32,895,528)	-
Accounts payable, accrued expenses, and other current liabilities	(1,015,153)	(15,966)
Other liabilities	20,925	-
Net cash used in operating activities	(8,756,841)	(4,734,855)
Cash flows from investing activities:		
Capital expenditures	(95,382)	(726,905)
Proceeds from maturity of short term investments	30,000,000	8,750,000
Purchases of short term investments	(24,992,928)	(12,495,741)
Net cash provided by (used in) investing activities	4,911,690	(4,472,646)
Cash flows from financing activities:		
Net proceeds from exercise of warrants and options	3,607,398	1,251,191
Repurchase of common stock	(1,093,936)	-
Net cash provided by financing activities	2,513,462	1,251,191
Net decrease in cash and cash equivalents	(1,331,689)	(7,956,310)
Cash and cash equivalents at beginning of period	6,332,053	14,496,313
Cash and cash equivalents at end of period	\$ 5,000,364	\$ 6,540,003
Supplemental disclosure of non-cash financing activities:		
Reclass of common stock warrant liability to additional paid-in capital upon exercise	\$ 970,816	\$ -

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

SIGA TECHNOLOGIES, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Interim Condensed Consolidated Financial Statements

The condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and the rules and regulations of the Securities and Exchange Commission (the "SEC") for quarterly reports on Form 10-Q and should be read in conjunction with the Company's consolidated audited financial statements and notes thereto for the year ended December 31, 2010, included in the 2010 Annual Report on Form 10-K. All terms used but not defined elsewhere herein have the meaning ascribed to them in the Company's 2010 Annual Report on Form 10-K filed on March 9, 2011. In the opinion of management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement of the results of the interim periods presented have been included. The 2010 year-end balance sheet data was derived from the audited financial statements but does not include all disclosures required by U.S. GAAP. The results of operations for the three and six months ended June 30, 2011 are not necessarily indicative of the results expected for the full year.

The accompanying condensed 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 expense to perform further research and development activities. The Company has limited capital resources and will need additional funds to complete the development of our products. Management plans to fund continuing development work and operations through sources of cash that may include: collaborative agreements, strategic alliances, research grants, future equity and debt financing, and procurement contracts. There is no assurance that we will be successful in obtaining future sources of cash on commercially reasonable terms. Management believes that existing funds combined with cash flows primarily from our procurement contract with BARDA and continuing government grants and contracts will be sufficient to support its operations for at least the next twelve months. The success of the Company is dependent upon generating commercial revenues and the Company's ability to obtain adequate future funding. If the Company is unable to raise adequate capital and/or achieve profitable operations, future operations might need to be scaled back or discontinued. 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. ST-246® BARDA Agreement

On May 13, 2011, we signed the BARDA Contract pursuant to which we agreed to deliver two million courses of ST-246 to the SNS. The five-year base contract award is worth approximately \$433 million, and the BARDA Contract also includes various options. As originally issued, the BARDA Contract included an option for the purchase of up to 12 million additional courses of ST-246; however, following a protest by a competitor of the Company, BARDA issued a contract modification on June 24, 2011 pursuant to which it deleted the option to purchase the additional courses. Under the BARDA Contract as modified, SIGA will sell to BARDA 1.7 million courses of ST-246. Additionally, SIGA will contribute to BARDA 300,000 courses manufactured using federal funds provided by HHS under prior development contracts. The BARDA Contract as modified also contains options that will permit SIGA to continue its work on pediatric and geriatric versions of the drug as well as use of ST-246 for smallpox prophylaxis.

3. Research Agreements

The Company obtains funding in the form of grants or contracts (collectively, the "Grants") from various agencies of the U.S. government to support its research and development activities. Since inception, the Company has recognized \$36.5 million of revenue from current Grants. Currently, the Company has five active Grants with varying expiration dates through August 2016 that provide for potential future aggregate research and development funding for specific projects of approximately \$46 million, as amended. This amount includes, among other things, options that may or may not be exercised at the U.S. government's discretion. The Grants contain customary terms and conditions including the U.S. government's right to terminate or restructure a grant for convenience at any time.

4. Per Share Data

The Company computes, presents and discloses earnings per share in accordance with the authoritative guidance which specifies the computation, presentation and disclosure requirements for earnings per share of entities with publicly held common stock or potential common stock. 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, which 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 following is a reconciliation of the basic and diluted net income (loss) per share computations for the periods presented below. As a result of the Company's net loss for the periods ended in 2010, the computation of diluted net loss per share in those periods excludes all potential common shares outstanding, as the effect would be anti-dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net income (loss)	\$ 23,841,926	\$ (5,250,776)	\$ 19,140,652	\$ (10,187,905)
Weighted-average shares - basic	50,879,599	43,620,212	50,422,014	43,408,287
Effect of potential common shares	3,791,804	-	4,085,824	-
Weighted-average shares - diluted	54,671,403	43,620,212	54,507,838	43,408,287
Earnings (loss) per share - basic	\$ 0.47	\$ (0.12)	\$ 0.38	\$ (0.23)
Earnings (loss) per share - diluted	\$ 0.44	\$ (0.12)	\$ 0.35	\$ (0.23)
Antidilutive employee share-based awards, excluded	337,000	10,791,300	367,168	10,791,300

Diluted shares outstanding include the dilutive effect of warrants, in-the-money options, unvested restricted stock and restricted stock units. The dilutive effect of such equity awards is calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount the employee must pay for exercising stock options, the amount of compensation cost for future service that the Company has not yet recognized, and the amount of tax benefits that would be recorded in additional paid-in capital when the award becomes deductible, are collectively assumed to be used to repurchase shares.

5. Stockholders' Equity

As of June 30, 2011, 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.

In 2006 and 2005 the Company sold shares of its common stock and warrants to purchase shares of common stock. In 2006, the Company issued warrants to acquire 1,000,000 shares of common stock with an initial exercise price of \$4.99 per share (the "2006 Warrants"). In 2005, the Company issued warrants to acquire 1,000,000 shares of common stock with an initial exercise price of \$1.18 per share (the "2005 Warrants"). As of December 31, 2010, all of the 2005 Warrants were exercised. The 2006 Warrants may be exercised through and including October 19, 2013. Due to the effect of certain anti-dilution provisions in such warrants, the Company adjusted the number of shares issuable under the 2006 Warrants by 652,038 through June 30, 2011. The exercise prices of the warrants issued in these placements were also adjusted. During the six months ended June 30, 2011, 100,000 of the 2006 Warrants were exercised. At June 30, 2011, 815,568 of the 2006 Warrants at an exercise price of \$2.92 were outstanding. The number of shares issuable pursuant to the warrants may be subject to further adjustment as a result of the effect of future equity issuances on anti-dilution provisions in the related warrant agreements.

The Company accounted for the 2006 and 2005 Warrants in accordance with the authoritative guidance 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. Any changes in the fair value of the derivative instruments are reported in earnings or loss as long as the derivative contracts are classified as assets or liabilities. At June 30, 2011, the fair market value of the 2006 Warrants was \$5.8 million. The Company applied the Black-Scholes model to calculate the fair values of the respective derivative instruments using the contractual 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. For the six months ended June 30, 2011, the Company recorded a gain of \$3.8 million as a result of a decrease in fair value of the 2006 Warrants.

6. Comprehensive Income

Comprehensive income includes net loss adjusted for the change in net unrealized gain (loss) on short-term investments. For the three and six months ended June 30, 2011 and 2010, the components of comprehensive income were:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net income (loss)	\$ 23,841,926	\$ (5,250,776)	\$ 19,140,652	\$ (10,187,905)
Unrealized gain on securities	-	3,361	-	3,361
Total comprehensive income (loss)	\$ 23,841,926	\$ (5,247,415)	\$ 19,140,652	\$ (10,184,544)

7. Fair Value Measurements

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 warrants which are classified as liabilities are recorded at their fair market value as of each reporting period.

The Company applies the applicable authoritative guidance for financial assets and liabilities that are required to be measured at fair value, and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis.

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.

The Company 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. The Company utilizes the Black-Scholes model consisting of the following variables: (i) the closing price of SIGA's common stock; (ii) the expected remaining life of the warrant; (iii) the expected volatility using a weighted-average of historical volatilities from a combination of SIGA and comparable companies; and (iv) the risk-free market rate. At June 30, 2011 and December 31, 2010, the fair value of such warrants is \$5,751,035 and \$10,524,660, respectively, and included in long-term liabilities.

As of June 30, 2011, the Company held approximately \$10.0 million in United States Treasury Bills, classified as a Level 1 security. SIGA does not hold any Level 3 securities.

In January 2010, the FASB issued updated accounting guidance for fair value measurements. This update provides amendments that require new disclosure as follows: (1) A reporting entity should disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair-value measurements and describe the reasons for the transfers. (2) In the reconciliation for fair value measurements using significant unobservable inputs (Level 3), a reporting entity should present separately information about purchases, sales, issuances, and settlements (that is, on a gross basis rather than as one net number). This update provides amendments that clarify existing disclosures as follows: (1) A reporting entity should provide fair value measurement disclosures for each class of assets and liabilities. A class is often a subset of assets or liabilities within a line item in the statement of financial position. A reporting entity needs to use judgment in determining the appropriate classes of assets and liabilities. (2) A reporting entity should provide disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements. Those disclosures are required for fair value measurements that fall in either Level 2 or Level 3. The new disclosures and clarifications of existing disclosures were effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances, and settlements in the roll-forward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. The Company has adopted the amendments. The adoption did not have a material impact on the condensed consolidated financial statements.

8. Stock Compensation Plans

In May 2010, the Company adopted its 2010 Incentive Stock Option Plan (the "2010 Plan") to supersede its 1996 Incentive and Non-Qualified Stock Option Plan (the "1996 Plan"). The 2010 Plan provides for the granting of up to 2,000,000 shares of the Company's common stock to employees, consultants and outside directors of the Company. The awards that may be provided under the 2010 Plan include: incentive stock options, nonqualified stock options, shares of restricted stock and shares of unrestricted stock.

For the six months ended June 30, 2011 and 2010, the Company recorded compensation expense of approximately \$8.3 million and \$1.0 million, respectively, related to employees and directors stock awards. The total fair value of stock options vested during the six months ended June 30, 2011 and 2010, was approximately \$1.7 million and \$708,000, respectively. The total fair value of restricted stock and restricted stock units vested during the six months ended June 30, 2011 and 2010 was approximately \$4.8 million and \$0, respectively. The total compensation cost not yet recognized related to non-vested awards at June 30, 2011 is \$5.7 million. The weighted average period over which total compensation cost is expected to be recognized is 0.8 years.

9. Income Taxes

Deferred tax assets, net were \$32.7 million at June 30, 2011 and \$0 at December 31, 2010, respectively, net of valuation allowances of \$4.2 million and \$33.1 million, respectively.

The Company has incurred losses since inception, which have generated net operating loss carryforwards of approximately \$68.7 million at December 31, 2010 for federal and state income tax purposes. These carryforwards are available to offset future taxable income and expire beginning in 2011 for federal income tax purposes. As a result of a previous change in stock ownership, the annual utilization of the net operating loss carryforwards for years prior to 2004 may be subject to limitation.

The recognition of a valuation allowance for deferred taxes requires management to make estimates and judgments about the Company's future profitability which are inherently uncertain. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

During the quarter ended June 30, 2011, the Company recorded an income tax benefit of approximately \$32.9 million primarily due to a partial reduction of its valuation allowance as a significant portion of its deferred tax assets became realizable on a more-likely-than-not basis primarily as a result of the execution of the BARDA Contract and current forecasts of pre-tax earnings. The Company maintains a valuation allowance with respect to certain net operating losses and other deferred tax assets which may expire prior to realization.

10. Related Party Transactions

On December 1, 2009, the Company entered into an Office Service Agreement with an affiliate of M&F to occupy office space for approximately \$8,000 per month. The agreement is cancelable upon 60 days notice by the Company or the affiliate.

A member of the Company's Board of Directors is a member of the Company's outside counsel. During the six months ended June 30, 2011 and 2010, the Company incurred costs of \$1.8 million and \$1.4 million, respectively, related to services provided by the outside counsel. On June 30, 2011, the Company's account payables and accrued expenses included \$348,000 to the outside counsel.

11. Commitments and Contingencies

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

PharmAthene has submitted an expert report asserting several alternative theories of damages, in a wide range of up to one billion dollars. We believe that the expert's damages analyses are flawed and methodologically unsound. The Company continues to believe that we have meritorious defenses to the claims. The Company filed a partial summary judgment motion on March 19, 2010, regarding certain aspects of PharmAthene's claims and damage assessments. On November 23, 2010, the Court of Chancery denied the motion for partial summary judgment. A trial was held before Vice Chancellor Donald F. Parsons, Jr. in January 2011, and closing arguments took place in April 2011. It is not currently possible to estimate a range of loss, if any.

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.

Item 2 – 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 Quarterly Report. In addition to historical information, the following discussion and other parts of this Quarterly Report contain forward-looking information that involves risks and uncertainties.

Overview

Since our incorporation in Delaware on December 28, 1995, we have pursued the research, development and commercialization of novel products for the prevention and treatment of serious infectious diseases. Our efforts are focused on developing therapeutic solutions for some of the most lethal disease-causing pathogens. Our smallpox, dengue and Lassa fever antiviral programs are designed to prevent or limit the replication of the viral pathogens or the damage that the pathogens can cause.

Commercial Product:

ST-246®

Our lead product, ST-246® is an oral therapeutic agent active against orthopoxviruses including smallpox. ST-246 acts by blocking the ability of the virus to spread to other cells, preventing it from causing disease. We believe ST-246 will be the first entirely new small-molecule drug delivered to the Strategic National Stockpile under Project Bioshield. The FDA has designated ST-246 for “fast-track status, creating a path for expedited FDA review and eventual regulatory approval.

On May 13, 2011, we signed the BARDA Contract pursuant to which we agreed to deliver two million courses of ST-246 to the SNS. The five-year base contract award is worth approximately \$433 million, and the BARDA Contract also includes various options. As originally issued, the BARDA Contract included an option for the purchase of up to 12 million additional courses of ST-246; however, following a protest by a competitor of the Company, BARDA issued a contract modification on June 24, 2011 pursuant to which it deleted the option to purchase the additional courses. Under the BARDA Contract as modified, SIGA will sell to BARDA 1.7 million courses of ST-246. Additionally, SIGA will contribute to BARDA 300,000 courses manufactured using federal funds provided by HHS under prior development contracts. The BARDA Contract as modified also contains options that will permit SIGA to continue its work on pediatric and geriatric versions of the drug as well as use of ST-246 for smallpox prophylaxis.

Results of Operations

Three months ended June 30, 2011 and 2010

Revenue from research and development grants and contracts was \$2.5 million and \$4.4 million for the three months ended June 30, 2011 and 2010, respectively. The decrease of \$1.9 million is primarily due to a \$917,000 decrease in revenue generated from our federal grants and contracts supporting the development of ST-246® and a decrease of \$490,000 due to the conclusion of our contract with DTRA for the development of a broad spectrum antiviral counter measure. Also contributing to the revenue decrease was the conclusion of certain federal grants mainly related to Lassa fever.

Selling, general and administrative (“SG&A”) expenses for the three months ended June 30, 2011 and 2010 were \$9.3 million and \$2.2 million, respectively, reflecting an increase of approximately \$7.1 million. The increase in SG&A expenses mainly relates to a \$6.6 million increase in employee compensation, which includes an increase in non-cash stock-based compensation of approximately \$6.3 million.

Research and development (“R&D”) expenses were \$3.8 million for the three months ended June 30, 2011, a decrease of \$1.1 million from the \$4.9 million incurred for the three months ended June 30, 2010. The decrease is mainly due to a \$709,000 decrease in expenditures supporting the development of ST-246® as well as a decrease of \$442,000 in expenditures supporting the development of antiviral drugs for arenavirus. These decreases were partially offset by an increase in employee compensation expense of approximately \$231,000. The increase in compensation expense is primarily due to the hiring of additional R&D personnel.

During the three months ended June 30, 2011 and 2010, we spent \$1.5 million and \$2.3 million, respectively, on the development of ST-246®. For the three months ended June 30, 2011, we spent \$413,000 on internal human resources dedicated to the drug's development and \$1.1 million mainly on manufacturing and clinical testing. For the three months ended June 30, 2010, we spent \$449,000 on internal human resources and \$1.9 million mainly on manufacturing and clinical testing.

During the three months ended June 30, 2011, we spent \$360,000 for the development of drug candidates for dengue fever and Lassa fever of which \$192,000 was spent mainly on human resources and \$168,000 was spent mainly on the optimization and chemistry of the lead antiviral compounds. For the three months ended June 30, 2010, we spent \$640,000 for dengue fever, Lassa virus and other drug candidates for certain arenavirus pathogens and hemorrhagic fevers, of which \$98,000 was mainly for internal human resources and \$542,000 for medicinal chemistry and pre-clinical testing of our drug candidates.

During the three months ended June 30, 2011, we spent \$345,000 to support the development of a broad-spectrum antiviral drug candidate, of which \$175,000 was spent mainly on internal human resources, and \$170,000 mainly on the optimization and chemistry of lead antiviral compounds. For the three months ended June 30, 2010, \$162,000 was incurred mainly on internal human resources and \$251,000 was incurred to support medicinal chemistry.

Patent preparation expenses increased to \$413,000 for the three months ended June 30, 2011, from \$306,000 for the same period in the prior year mainly as a result of our continuing efforts to protect our lead drug candidates in expanded geographic territories.

Changes in the fair value of warrants to acquire SIGA's common stock are recorded as gains or losses. For the three months ended June 30, 2011 and 2010, we recorded a gain of \$2.0 million and a loss of \$2.2 million, respectively, reflecting changes in the fair market value of warrants to purchase common stock during the respective three-month periods. The warrants were recorded at fair market value and classified as liabilities.

Prior to June 30, 2011, we provided a tax valuation allowance in our United States ("U.S.") federal and state deferred tax assets based on our evaluation that such assets were not "more likely than not" to be realized. We continuously evaluated additional facts representing positive and negative evidence in the determination of the realizability of deferred tax assets. Such deferred tax assets consist primarily of net operating loss carryforwards and temporary differences on intangible assets, depreciation and deferred research and development costs. In the second quarter of 2011, we determined that it was more likely than not that certain deferred tax assets would be realized, mainly due to the execution of the BARDA contract, the scheduling of deferred tax assets and liabilities and future taxable income from operating activities. Accordingly, we released a portion of the related valuation allowance from deferred tax assets resulting in a benefit to deferred tax expense of approximately \$32.9 million. Our U.S. federal net operating loss carryforwards begin expiring in 2011.

Six months ended June 30, 2011 and 2010

Revenue from research and development grants and contracts was \$4.2 million and \$9.5 million for the six months ended June 30, 2011 and 2010, respectively. The decrease of \$5.3 million is mostly due to a \$4.1 million decrease in revenue generated from our federal grants and contracts supporting the development of ST-246®. Also contributing to the revenue decrease was the conclusion of certain federal grants mainly related to Lassa fever.

SG&A expenses for the six months ended June 30, 2011 and 2010 were \$13.6 million and \$4.2 million, respectively, reflecting an increase of approximately \$9.4 million. The increase in SG&A expenses mainly relates to a \$7.9 million increase in employee compensation, which includes an increase in non-cash stock-based compensation of approximately \$7.3 million, and an increase of approximately \$1.1 million in fees for legal and accounting services.

R&D expenses were \$7.4 million for the six months ended June 30, 2011, a decrease of \$3.4 million from the \$10.8 million incurred for the six months ended June 30, 2010. The decrease is mainly due to a \$3.7 million decrease in expenditures supporting the development of ST-246® partially offset by an increase in employee compensation expense of approximately \$728,000. The increase in compensation expense is primarily due to the hiring of additional R&D personnel.

During the six months ended June 30, 2011 and 2010, we spent \$2.5 million and \$6.3 million, respectively, on the development of ST-246®. For the six months ended June 30, 2011, we spent \$809,000 on internal human resources dedicated to the drug's development and \$1.7 million mainly on clinical testing and manufacturing. For the six months ended June 30, 2010, we spent \$906,000 on internal human resources and \$5.4 million mainly on manufacturing. From inception of the ST-246® development program to-date, we invested a total of \$40.5 million in the program, of which \$7.7 million supported internal human resources and \$32.8 million was used mainly for manufacturing, clinical and pre-clinical work. These resources reflect research and development expenses directly related to the program. The costs exclude additional expenditures such as patent costs, allocation of indirect expenses, and other services provided by the NIH and the DoD.

During the six months ended June 30, 2011, we spent \$399,000 for the development of drug candidates for dengue fever and Lassa fever of which \$215,000 was spent mainly on human resources and \$184,000 was spent mainly on the optimization and chemistry of the lead antiviral compounds. For the six months ended June 30, 2010, we spent \$746,000 for dengue fever, Lassa virus and other drug candidates for certain arenavirus pathogens and hemorrhagic fevers, of which \$139,000 was mainly for internal human resources and \$607,000 for medicinal chemistry and pre-clinical testing of our drug candidates. From inception of our programs to develop drug candidates for hemorrhagic fevers, to-date, we spent a total of \$8.6 million related to the programs, of which \$2.6 million and \$6.0 million were expended on internal human resources and pre-clinical work, respectively. These resources reflect research and development expenses directly related to the programs. They exclude additional expenditures such as patent costs, allocation of indirect expenses, and other services provided by the NIH and the DoD.

During the six months ended June 30, 2011, we spent \$742,000 to support the development of a broad-spectrum antiviral drug candidate, of which \$259,000 was spent mainly on internal human resources, and \$483,000 mainly on the optimization and chemistry of lead antiviral compounds. For the six months ended June 30, 2010, \$212,000 was incurred mainly on internal human resources and \$356,000 was incurred to support medicinal chemistry. From the inception of our program to develop a broad-spectrum antiviral drug, to-date, we have spent a total of \$3.4 million related to the program, of which \$945,000 was expended on internal human resources, \$1.3 million spent to support medicinal chemistry and the optimization of lead antiviral compounds, and \$1.1 million for purchases of machinery to support these studies. These resources reflect expenses directly related to the program. The costs exclude additional expenditures such as patent costs, allocation of indirect expenses, and other services provided by the NIH and DoD.

Patent preparation expenses increased to \$755,000 for the six months ended June 30, 2011, from \$626,000 for the same period in the prior year mainly as a result of our continuing efforts to protect our lead drug candidates in expanded geographic territories.

Changes in the fair value of warrants to acquire SIGA's common stock are recorded as gains or losses. For the six months ended June 30, 2011 and 2010, we recorded a gain of \$3.8 million and a loss of \$4.1 million, respectively, reflecting changes in the fair market value of warrants to purchase common stock during the respective three-month periods. The warrants were recorded at fair market value and classified as liabilities.

Liquidity and Capital Resources

On June 30, 2011, we had \$5.0 million in cash and cash equivalents and \$10.0 million in short-term investments.

Operating activities

Net cash used in operations during the six months ended June 30, 2011 and 2010 was approximately \$8.8 million and \$4.7 million, respectively. The increase in net cash used in operating activities was due to several factors: (i) the increase in litigation expenses in connection with the PharmAthene legal proceeding; (ii) an increase in regulatory legal and advisory expenses; and (iii) an increase in payroll due to the hiring of certain personnel.

Investing activities

During the six months ended June 30, 2011, net cash provided by investing activities was approximately \$4.9 million and during the six months ended June 30, 2010, net cash used in investing activities was approximately \$4.5 million, respectively. The increase in net cash from investing activities relates to timing of purchases and maturities of U.S. Treasury bills.

Financing activities

Cash provided by financing activities during the six months ended June 30, 2011 and 2010 was \$2.5 million and \$1.3 million, respectively, generated from exercises of options and warrants to purchase SIGA common stock partially offset by the repurchase of common stock to meet minimum statutory tax withholding requirements.

Other

We have incurred cumulative net losses and expect to incur additional expense to perform further research and development activities. We have limited capital resources and will need additional funds to complete the development of our products. We plan to fund continuing development work and operations through sources of cash that may include: commercial sales, collaborative agreements, strategic alliances, research grants and future equity and debt financing. There is no assurance that we will be successful in obtaining additional future sources of cash on commercially reasonable terms.

We believe that our existing funds combined with cash flows primarily from commercial sales and continuing government grants and contracts will be sufficient to support our operations for at least the next 12 months. The success of the Company is dependent upon commercial sales and the Company's ability to obtain adequate future financing. If the Company is unable to raise adequate capital and/or achieve profitable operations, future operations might need to be scaled back or discontinued. 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.

Off-Balance Sheet Arrangements

SIGA does not have any off-balance sheet arrangements.

Safe Harbor Statement

This report contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements relating to the safety and efficacy of our products, the progress of our development programs and timelines for bringing products to market, the enforceability of the BARDA Contract and the resolution of our ongoing litigation with PharmAthene, Inc. Forward-looking statements are based on management's estimates, assumptions and projections, and are subject to uncertainties, many of which are beyond the control of SIGA. Actual results may differ materially from those anticipated in any forward-looking statement. Factors that may cause such differences include (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 or current 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, (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 one or more protests could be filed and upheld in whole or in part or other governmental action taken, in either case leading to a delay of performance under the BARDA Contract, (ix) the risk that the BARDA Contract is modified or cancelled at the request or requirement of the U.S. government, (x) the risk that the volatile and competitive nature of the biotechnology industry may hamper SIGA's efforts, (xi) 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 (xii) the effect of federal, state, and foreign regulation, including drug regulation and international trade regulation, on SIGA's businesses. More detailed information about SIGA and risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this presentation, is set forth in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K, for the fiscal year ended December 31, 2010, and in other documents that SIGA has filed with the Commission. SIGA urges investors and security holders to read those documents free of charge at the Commission's Web site at <http://www.sec.gov>. Interested parties may also obtain those documents free of charge from SIGA. Forward-looking statements speak only as of the date they are made, and except for our ongoing obligations under the United States of America federal securities laws, we undertake no obligation to publicly update any forward-looking statements whether as a result of new information, future events or otherwise.

Item 3 Quantitative and Qualitative Disclosures About Market Risk.

Our investment portfolio includes cash, cash equivalents and short-term investments. Our main investment objectives are the preservation of investment capital and the maximization of after-tax returns on our investment portfolio. We believe that our investment policy is conservative, both in the duration of our investments and the credit quality of the investments we hold. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions to manage exposure to interest rate changes. Accordingly, we believe that, while the securities we hold are subject to changes in the financial standing of the issuer of such securities and our interest income is sensitive to changes in the general level of U.S. interest rates, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

Item 4 Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2011. The term “disclosure controls and procedures” is defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2011, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time specified in the SEC’s rules and forms.

Changes in Internal Control over Financial Reporting

There have not been any changes in the Company’s internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

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

PharmAthene has submitted an expert report asserting several alternative theories of damages, including amounts in a wide range of up to one billion dollars. We believe that the expert’s damages analyses are flawed and methodologically unsound. We also continue to believe that we have meritorious defenses to the claims. We filed a partial summary judgment motion on March 19, 2010, regarding certain aspects of PharmAthene’s claims and damage assessments. On November 23, 2010, the Court of Chancery denied our motion for partial summary judgment. A trial was held before Vice Chancellor Donald F. Parsons, Jr. in January 2011, and closing arguments took place in April 2011. It is not currently possible to estimate a range of loss, if any.

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 may not experience profitability in future periods or on a consistent basis.

We have incurred cumulative net losses of approximately \$103.3 million. As of December 31, 2010, 2009, and 2008, our accumulated deficit was approximately \$122.5 million, \$94.3 million, and \$72.2 million, respectively. We expect to continue to have significant operating expenses and will need to generate significant revenues to achieve and maintain profitability.

Our profitability is substantially dependent on revenues from ST-246® product sales. If we do achieve profitability, we cannot guarantee that we can sustain or increase profitability on a quarterly or annual basis in the future and we expect that revenues will fluctuate significantly from quarter to quarter based on several factors, including the timing of fulfilling orders for the U.S. government. 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 may include the acquisition of other businesses, acquisition and integration expenses and any cash required to fund these acquisitions will reduce our available cash.

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

Until we begin to receive payments related to our performance under the BARDA Contract, 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 cash generated through the BARDA Contract, grants, contracts and licenses, the amount of projects we undertake, and 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.

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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.

We have identified a material weakness, which has been remediated, in our internal control over financial reporting that resulted in the restatement of our consolidated financial statements included in our 2009 Annual Report on Form 10-K/A.

Our management is responsible for maintaining internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009, and identified a material weakness related to the failure to ensure timely application of certain anti-dilution provisions contained in certain outstanding warrant arrangements. As a result of this material weakness, our management concluded that our internal control over financial reporting and our disclosure controls and procedures were not effective as of December 31, 2009.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The effectiveness of any controls or procedures is subject to certain limitations, and as a result, there can be no assurance that

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our controls and procedures will detect all errors or fraud. A control can provide only reasonable, not absolute, assurance that the objectives of the control system will be attained. We also cannot assure you that other material weaknesses will not arise as a result of failures to maintain adequate internal controls and procedures or that circumvention of those controls and procedures will not occur. Additionally, even our improved controls and procedures may not be adequate to prevent or identify errors or irregularities or ensure that our financial statements are prepared in accordance with generally accepted accounting principles. If we cannot maintain and execute adequate internal control over financial reporting or implement required new or improved controls that provide reasonable assurance of the reliability of the financial reporting and preparation of our financial statements for external use, we could suffer harm to our reputation, fail to meet our public reporting requirements on a timely basis, or be unable to properly report on our business and the results of our operations, and the market price of our securities could be materially adversely affected.

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 March 15, 2011, directors, officers and principal stockholders beneficially owned approximately 50.3% of our outstanding stock.

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

We currently expect to derive substantially all of our foreseeable future revenue from sales of ST-246® under the BARDA Contract in addition to grants and contracts from the various agencies of the U.S. government. If BARDA demand for ST-246® is reduced, our business, financial condition and operating results could be materially harmed.

Our existing contract with BARDA does not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. The success of our business and our operating results for the foreseeable future are substantially dependent on the terms of our ST-246® sales to the U.S. government, including price per dose, the number of doses and the timing of deliveries.

Furthermore, substantially all of our revenues for the years ended December 31, 2010, 2009, and 2008, respectively, and the period from January 1, 2011 to date, were derived from grants and contracts. Our current revenue is primarily derived from contract work being performed for the NIH and BARDA under grants and two major contracts which are scheduled to expire in September 2011 and August 2013, respectively. There can be no assurance that we will receive the revenue from the BARDA Contract in the time periods we anticipate or at all, or that we will be able to secure future grants. Failure to receive such revenue or secure such grants could have an adverse effect on our results of operations.

The pricing under our fixed price government contracts is based on estimates of the time, resources and expenses required to perform those contracts. If our estimates are not accurate, we may not be able to earn an adequate return or may incur a loss under these contracts.

Our existing contract for the supply of ST-246® with BARDA includes fixed price components. We expect that our future contracts with the U.S. government for ST-246® as well as contracts for biodefense product candidates that we successfully develop also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur and to absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss, which could in turn harm our operating results.

Our U.S. government contracts require ongoing funding decisions by the government. Reduced or discontinued funding of these contracts could cause our financial condition and operating results to suffer materially.

Our principal customer for ST-246® is the U.S. government. We anticipate that the U.S. government will also be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program, such as Project BioShield, may be implemented through the award of many different individual contracts and subcontracts. The funding of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to political considerations and stringent budgetary constraints. Additionally, government-funded development contracts typically consist of a base period of performance followed by successive option periods for performance of certain future activities. The value of these optional services, which options are exercisable in the sole discretion of the government, may constitute the majority of the total value of the underlying contract. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

Our future business may be harmed as a result of the government contracting process, which can be a competitive bidding process that may involve 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, which may be awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, which may include:

- 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's 2009 request for proposal with respect to acquisition of a smallpox antiviral was open to all qualifying small businesses for which we were determined not to qualify. If we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition, and operating results could be materially adversely affected.

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

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

- procurement integrity;
- export control;
- government security regulations;
- employment practices;

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

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

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

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

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

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

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. Our government contracts, including the BARDA Contract, could be terminated under these circumstances. Some government contracts permit 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.

Political or social factors, including related litigation, may delay or impair our ability to market ST-246® and our biodefense product candidates and may require us to spend time and money to address these issues.

Products developed to treat diseases caused by or to combat the threat of bioterrorism will be subject to changing political and social environments. The political and social responses to bioterrorism have been highly charged and unpredictable. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, any of which would harm our business.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties such as activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns.

Additional lawsuits, publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of, and thereby limit the demand for, ST-246® and our biodefense product candidates. In such event, our ability to market and sell such products may be hindered and the commercial success of ST-246® and other products we develop will be harmed, thereby reducing our revenues.

Risks Related to Product Development

Our business depends significantly on our success in completing development and commercialization of 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;
- establishing commercial manufacturing processes of our own or arrangements on reasonable terms with contract manufacturers;
- manufacturing stable commercial supplies of drug candidates, including availability of raw materials;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

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

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

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

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

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

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

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

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

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

- be safe, non-toxic and effective;
- otherwise meet applicable regulatory standards;
- receive the necessary regulatory approvals;

- develop into commercially viable drugs;
- be manufactured or produced economically and on a large scale;
- be successfully marketed;
- be reimbursed by government and private insurers; and
- achieve customer acceptance.

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

Risks Related to Commercialization

If we fail to achieve significant sales of ST-246® to customers in addition to the U.S. government, our opportunities for growth could be harmed.

An element of our business strategy is to establish a market for sales of ST-246® to customers in addition to the U.S. government. These potential customers include foreign governments and state and local governments, which we expect will be interested in utilizing ST-246® as a means to protect emergency responders such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals.

The market for sales of ST-246® to customers other than the U.S. government is undeveloped, and we may not be successful in generating meaningful sales of ST-246® to these potential customers.

Government regulations may make it difficult for us to achieve significant sales of ST-246® to customers other than the U.S. government. For example, many foreign governments require licensure of ST-246® in their jurisdiction before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of ST-246® and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of ST-246® to foreign governments and other foreign customers. In addition, U.S. government demand for a smallpox therapeutic may limit supplies of ST-246® available for sale to non-U.S. government customers.

If we fail to significantly increase our sales of ST-246® to customers other than the U.S. government, our business and opportunities for growth could be materially harmed.

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

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

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

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

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

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. In addition, there 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.

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

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

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

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

Product liability lawsuits could cause us to incur substantial liabilities and require us to limit commercialization of any products that we may develop.

We face an inherent business risk of exposure related to the sale of ST-246® and any other products that we successfully develop and the testing of our product candidate in clinical trials.

ST-246® is currently identified as a covered countermeasure under a PREP Act declaration issued in October 2008, which provides us with immunity with respect to the manufacture, administration or use of ST-246®. Under our ST-246® contract with BARDA, the U.S. government agreed to indemnify us against claims by third parties for death, personal injury and other damages related to ST-246®, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

If we cannot successfully defend ourselves against future claims that our product or product candidates caused injuries and we are not entitled to indemnity by the U.S. government with respect to such claims, or if the U.S. government does not honor its indemnification obligations, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of a product from the market;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently have product liability insurance for coverage up to a \$10 million annual aggregate limit and up to \$10 million per occurrence. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to maintain or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Additionally, a successful product liability claim or series of claims brought against us could cause our stock price to fall and could decrease our financial resources and materially and adversely affect our business.

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

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

- regulatory approval may be withdrawn;
- reformulation of our products, additional clinical trials, changes in labeling of our products may be required;
- changes to or re-approvals of our manufacturing facilities may be required;
- sales of the affected products may drop significantly;
- our reputation in the marketplace may suffer; and

- lawsuits, including class action suits, may be brought against us.

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

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

The U.S. government and private insurers have considered ways to change, and have changed, the manner in which healthcare services are provided in the U.S. Potential approaches and changes in recent years include controls on healthcare spending and the creation of large purchasing groups. In the future, the U.S. government may institute further controls and limits on healthcare spending, including through the Medicare and Medicaid programs. These controls and limits might affect the payments we could collect from sales of any products. Uncertainties regarding future healthcare reform and private market practices could adversely affect our ability to sell any of our products profitably in the U.S.

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

We have begun to expand our operations outside of the United States, and we must comply with numerous laws and regulations relating to our business operations in each jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

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

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

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

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

We have a small sales and marketing group. If we are unable to expand our internal capabilities or enter into agreements with third parties, we may be unable to generate revenue from product sales to customers other than the U.S. government.

To achieve commercial success for any approved product, we must either further develop our own sales and marketing capabilities, enter into collaborations with third parties able to perform these services or outsource these functions to third parties.

We currently market and sell ST-246® through a small, targeted sales and marketing group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. If we are unable to do this we may be unable to achieve our revenue goals in respect of ST-246®, which could have an adverse effect on our growth.

Risks Related to Manufacturing and Manufacturing Facilities

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

Manufacturing drug products, especially in large quantities, is complex. Our drug candidates require several manufacturing steps, and may involve complex techniques to assure quality and sufficient quantity, especially as the manufacturing scale increases. Our products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including obtaining materials, filling, labeling, packaging, storage, shipping, quality control and testing, some of which all pharmaceutical companies, including SIGA, experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs. We may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and/or cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of contract, lead to delays in our clinical trials or result in litigation or regulatory action.

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

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

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

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

Our biopharmaceutical research and development sometimes involves the controlled use of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for damages, and this liability could exceed our resources. The research and development activities of our company do not produce any unusual hazardous products. We do use small amounts of radioactive isotopes commonly used in pharmaceutical research, which are stored, used and disposed of in accordance with Nuclear Regulatory Commission regulations. Our general liability policy provides coverage up to annual aggregate limits of \$2 million and coverage of \$2 million per occurrence.

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

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

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

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

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

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

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

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

In June 2009, we became aware that we had not complied with certain Department of Health and Human Services (“DHHS”) regulations requiring the submission of yearly audited statements to the Office of the Inspector General (“OIG”) Office of Audit Services. We submitted the required audits and related statements to the OIG Office of Audit Services. No enforcement action has been taken in this matter, but there can be no assurance that no enforcement action will be taken at some future time with respect to this matter or any similar matter if similar or related problems are uncovered at some future time.

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

Risks Related to Regulatory Approvals

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

Risks Related to Our Intellectual Property

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

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

We exclusively own 5 U.S. patents. We are also exclusive owner of 3 U.S. provisional patent applications, 15 U.S. utility patent applications, 5 international PCT patent applications and 96 foreign patent applications.

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

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

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

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

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

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

PharmAthene has submitted an expert report asserting several alternative theories of damages, including amounts in a wide range of up to one billion dollars. We believe that the expert's damages analyses are flawed and methodologically unsound. We also continue to believe that we have meritorious defenses to the claims. We filed a partial summary judgment motion on March 19, 2010, regarding certain aspects of PharmAthene's claims and damage assessments. On November 23, 2010, the Court of Chancery denied our motion for partial summary judgment. A trial was held before Vice Chancellor Donald F. Parsons, Jr. in January 2011 and closing arguments took place in April 2011. It is not currently possible to estimate a range of loss, if any.

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

Risks Related to Our Business

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.

Our ability to use our net operating loss carryforwards may be limited.

As of June 30, 2011, we had federal net operating loss carryforwards, or NOLs, of \$83.6 million to offset future taxable income, which expire in various years through 2030, if not utilized. Under the provisions of the Internal Revenue Code, substantial changes in our ownership, in certain circumstances, will limit the amount of NOLs that can be utilized annually in the future to offset taxable income. In particular, section 382 of the Internal Revenue Code imposes limitations on a company's ability to use NOLs if a company experiences a more-than-50% ownership change over a three-year period. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to utilize our NOLs fully.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Reserved.

Item 5. Other Information.

None.

Item 6. Exhibits.

* 31.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

* 31.2 Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

* 32.1 Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* 32.2 Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

*Filed herein

SIGNATURES

Pursuant to the requirements 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: August 1, 2011

By: /s/ Daniel J. Luckshire

Daniel J. Luckshire
Executive Vice President and
Chief Financial Officer