

SOLIGENIX, INC.  
Form 10-Q  
August 10, 2012

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934

For the Quarterly Period Ended June 30, 2012

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. 000-16929  
\_\_\_\_\_

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of  
incorporation or organization)

41-1505029

(I.R.S. Employer  
Identification Number)

29 EMMONS DRIVE, SUITE  
C-10 PRINCETON, NJ

(Address of principal executive  
offices)

08540

(Zip Code)

(609) 538-8200

(Registrant's telephone number,  
including area code)

Indicate by check whether the registrant (1) 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 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, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer" and "large accelerated filer" in Rule 112b-2 of the

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Exchange Act (Check one).

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

As of August 8, 2012, 11,132,544 shares of the registrant's common stock (par value, \$.001 per share) were outstanding.

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SOLIGENIX, INC.

## Index

|                   | Description   | Page |
|-------------------|---|------|
| <b>Part I</b>     | <b>FINANCIAL INFORMATION</b>  |      |
| <b>Item 1</b>     | Consolidated Financial Statements   | 3    |
|                   | Consolidated Balance Sheets as of June 30, 2012 and December 31, 2011                             | 3    |
|                   | Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2012 and 2011   | 4    |
|                   | Consolidated Statements of Changes in Shareholders' Equity for the Six Months Ended June 30, 2012 | 5    |
|                   | Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2012 and 2011             | 6    |
|                   | Notes to Consolidated Financial Statements  | 7    |
| <b>Item 2</b>     | Management's Discussion and Analysis of Financial Condition and Results of Operations             | 17   |
| <b>Item 3</b>     | Quantitative and Qualitative Disclosures About Market Risk  | 32   |
| <b>Item 4</b>     | Controls and Procedures   | 32   |
| <b>Part II</b>    | <b>OTHER INFORMATION</b>  |      |
| <b>Item 1A</b>    | Risk Factors  | 33   |
| <b>Item 6</b>     | Exhibits  | 33   |
| <b>SIGNATURES</b> |   | 34   |

## PART I - FINANCIAL INFORMATION

## ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries  
Consolidated Balance Sheets

|  | June 30,<br>2012<br>(Unaudited) | December 31,<br>2011 |
|--|---------------------------------|----------------------|
| Assets   |                                 |                      |
| Current assets:  |                                 |                      |
| Cash and cash equivalents  | \$4,431,288                     | \$5,996,668          |
| Grants receivable  | 239,599                         | 362,473              |
| Other receivable   | -                               | 574,157              |
| Prepaid expenses   | 249,978                         | 195,762              |
| Total current assets   | 4,920,865                       | 7,129,060            |
| Office furniture and equipment, net  | 16,223                          | 15,032               |
| Intangible assets, net   | 974,377                         | 1,079,566            |
| Total assets   | \$5,911,465                     | \$8,223,658          |
| Liabilities and shareholders' equity   |                                 |                      |
| Current liabilities:   |                                 |                      |
| Accounts payable   | \$1,219,568                     | \$1,303,555          |
| Accrued compensation   | 71,486                          | 129,061              |
| Total current liabilities  | 1,291,054                       | 1,432,616            |
| Commitments and contingencies  |                                 |                      |
| Shareholders' equity:  |                                 |                      |
| Preferred stock; 250,000 shares authorized;<br>none issued or outstanding  | -                               | -                    |
| Common stock, \$.001 par value; 50,000,000 shares and 20,000,000 in 2011<br>authorized; 11,132,544 shares and 11,105,532 shares issued and outstanding in<br>2012 and 2011, respectively | 11,133                          | 11,106               |
| Additional paid-in capital   | 125,145,284                     | 124,897,309          |
| Accumulated deficit  | (120,536,006)                   | (118,117,373)        |
| Total shareholders' equity   | 4,620,411                       | 6,791,042            |
| Total liabilities and shareholders' equity   | \$5,911,465                     | \$8,223,658          |

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

Soligenix, Inc. and Subsidiaries  
Consolidated Statements of Operations  
For the Three and Six Months Ended June 30, 2012 and 2011  
(Unaudited)

|  | Three Months Ended June |                | Six Months Ended June 30, |                |
|--|-------------------------|----------------|---------------------------|----------------|
|  | 2012                    | 30,<br>2011    | 2012                      | 2011           |
| Revenues, principally from grants                            | \$762,851               | \$405,820      | \$1,410,269               | \$1,213,825    |
| Cost of revenues   | (616,330 )              | (349,511 )     | (1,172,901 )              | (903,548 )     |
| Gross profit   | 146,521                 | 56,309         | 237,368                   | 310,277        |
| Operating expenses:  |                         |                |                           |                |
| Research and development                                     | 500,980                 | 1,513,722      | 1,377,774                 | 2,886,526      |
| General and administrative                                   | 627,218                 | 475,377        | 1,282,261                 | 1,079,387      |
| Total operating expenses                                     | 1,128,198               | 1,989,099      | 2,660,035                 | 3,965,913      |
| Loss from operations   | (981,677 )              | (1,932,790 )   | (2,422,667 )              | (3,655,636 )   |
| Other income:  |                         |                |                           |                |
| Interest income, net   | 1,799                   | 1,473          | 4,034                     | 3,908          |
| Net loss   | \$(979,878 )            | \$(1,931,317 ) | \$(2,418,633 )            | \$(3,651,728 ) |
| Basic and diluted net loss per share                         | \$(0.09 )               | \$(0.18 )      | \$(0.22 )                 | \$(0.34 )      |
| Basic and diluted weighted average common shares outstanding | 11,124,359              | 10,899,902     | 11,121,814                | 10,871,249     |

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

Soligenix, Inc. and Subsidiaries  
 Consolidated Statements of Changes in Shareholders' Equity  
 For the Six Months Ended June 30, 2012  
 (Unaudited)

|   | Common Stock<br>Shares | Par Value | Additional<br>Paid-In<br>Capital | Accumulated<br>Deficit | Total        |
|---|------------------------|-----------|----------------------------------|------------------------|--------------|
| Balance, December 31, 2011                      | 11,105,532             | \$ 11,106 | \$ 124,897,309                   | \$(118,117,373)        | \$ 6,791,042 |
| Issuance of restricted common stock to employee | 16,667                 | 17        | 9,983                            | -                      | 10,000       |
| Issuance of common stock to vendor              | 10,345                 | 10        | 2,990                            | -                      | 3,000        |
| Stock-based compensation expense                | -                      | -         | 235,002                          | -                      | 235,002      |
| Net loss  | -                      | -         | -                                | (2,418,633 )           | (2,418,633)  |
| Balance, June 30, 2012                          | 11,132,544             | \$ 11,133 | \$ 125,145,284                   | \$(120,536,006)        | \$ 4,620,411 |

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

Soligenix, Inc. and Subsidiaries  
Consolidated Statements of Cash Flows  
For the Six Months Ended June 30,  
(Unaudited)

|   | 2012          | 2011          |
|---|---------------|---------------|
| Operating activities:   |               |               |
| Net loss  | \$(2,418,633) | \$(3,651,728) |
| Adjustments to reconcile net loss to net cash used in operating activities: |               |               |
| Amortization and depreciation   | 108,753       | 105,443       |
| Common stock or warrants issued in exchange for services                    | 3,000         | 11,184        |
| Restricted Stock issued to employee   | 10,000        | -             |
| Stock-based compensation  | 235,002       | 388,636       |
| Change in operating assets and liabilities:                                 |               |               |
| Grants receivable   | 122,874       | (215,773 )    |
| Other receivable  | 574,157       | 247,542       |
| Prepaid expenses  | (54,216 )     | 95,859        |
| Accounts payable  | (83,987 )     | (300,201 )    |
| Accrued compensation  | (57,575 )     | (187,279 )    |
| Total adjustments   | 858,008       | 145,411       |
| Net cash used in operating activities                                       | (1,560,625)   | (3,506,317)   |
| Investing activities:   |               |               |
| Acquisition of intangible assets  | -             | (112,398 )    |
| Purchase of office equipment  | (4,755 )      | -             |
| Net cash used in investing activities                                       | (4,755 )      | (112,398 )    |
| Financing activities:   |               |               |
| Proceeds from sale of common stock pursuant to equity line                  | -             | 255,000       |
| Proceeds from exercise of options and warrants                              | -             | 68,750        |
| Net cash provided by financing activities                                   | -             | 323,750       |
| Net decrease in cash and cash equivalents                                   | (1,565,380)   | (3,294,965)   |
| Cash and cash equivalents at beginning of period                            | 5,996,668     | 7,451,714     |
| Cash and cash equivalents at end of period                                  | \$4,431,288   | \$4,156,749   |

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

Soligenix, Inc.  
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the “Company”, “we” or “us”) is a development stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Soligenix’s BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, while the Company’s collaboration partner, Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) will commercialize orBec® and oral BDP in North America and Europe, if approved. On September 15, 2011, the Company’s confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”) was stopped at the recommendation of an independent Data Safety Monitoring Board (“DSMB”), due to the fact that there were no differences between the orBec® group and placebo group for the primary endpoint, as well as for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, the Company has terminated the development of orBec® for the treatment of acute GI GVHD.

The Company is actively developing oral BDP in other therapeutic indications, such as pediatric Crohn’s disease and acute radiation enteritis. Soligenix’s Vaccines/BioDefense business segment includes active development programs for RiVax™, its ricin toxin vaccine, and VeloThrax™, its anthrax vaccine, and OrbeShield™, its gastrointestinal acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of the vaccine programs is currently supported by the heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding.

The Company generates revenues primarily from the National Institutes of Health (the “NIH”) under two active grants and could generate license fees from Sigma-Tau by achieving certain milestones.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with FDA regulations, litigation, and product liability.

Liquidity

As of June 30, 2012, the Company had cash and cash equivalents of \$4,431,288 as compared to \$5,996,668 as of December 31, 2011, representing a decrease of \$1,565,380 or 26%. As of June 30, 2012, the Company had working capital of \$3,629,811 as compared to working capital of \$5,696,444 as of December 31, 2011, representing a decrease of \$2,066,633 or 36%. The decrease in cash and working capital was primarily the result of cash used in operating activities over the six month period. For the six months ended June 30, 2012, the Company’s cash used in operating activities was \$1,560,625 as compared to \$3,506,317 for the same period in 2011, representing a decrease of \$1,945,692. The decrease is primarily related to the termination of the Company’s pivotal phase 3 trial with Orbec® for the treatment of acute GI GVHD.

Management’s business strategy can be outlined as follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203, in pediatric Crohn’s disease;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal (“GI”) tract such as prevention of acute radiation enteritis and treatment of chronic GI GVHD;





Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology known as ThermoVax™ to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

Continue to apply for and secure additional government funding for each of its BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;

Acquire or in-license new clinical-stage compounds for development; and

Explore other business development and acquisition strategies.

Based on the Company's current rate of cash outflows, cash on hand, proceeds from its grant-funded programs, reductions in headcount and expected proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet its anticipated cash needs for working capital and capital expenditures into the third quarter of 2013.

The Company's plans with respect to its liquidity management include the following:

The Company has instituted a cost reduction plan which has reduced headcount and will continue to reduce costs wherever possible.

The Company has approximately \$5.0 million in active grant funding still available to support its associated research programs into 2014. The Company plans to submit additional grant applications for further support of its programs with various funding agencies.

The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.

The Company will pursue sales of Net Operating Losses ("NOL") in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$574,157 in proceeds from the sale of NJ NOL in 2011, the Company expects to participate in the program during 2012 and beyond; and

The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

## Reverse Stock Split

On February 1, 2012, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1-for-20, whereby, every 20 shares of its common stock was exchanged for one share of its common stock. Its common stock began trading on the OTCBB on a reverse split basis on February 2, 2012. All share and per share data have been restated to reflect this reverse stock split.

## Note 2. Summary of Significant Accounting Policies

### Principles of Consolidation

The consolidated financial statements include Soligenix, Inc., and its wholly and majority owned subsidiaries. All significant intercompany accounts and transactions have been eliminated as a result of consolidation.

### Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how

to allocate resources to an individual segment and in assessing the performance of the segment. The Company divides its operations into two operating segments: BioTherapeutics and Vaccines/BioDefense.

#### Grants Receivable

Grants receivable consist of unbilled amounts due from various grants from the NIH for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the NIH in the month subsequent to period end and collected shortly thereafter. The Company considers the grants receivable to be fully collectible. Accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

#### Intangible Assets

One of the most significant estimates or judgments that the Company makes is whether to capitalize or expense patent and license costs. The Company makes this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, the Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for its current products in both the domestic and international markets. The Company believes that patent rights are one of its most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from Soligenix's academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents and perhaps extending the lives of the patents. The Company capitalizes such costs and amortizes intangibles over their expected useful life – generally a period of 11 to 16 years.

The Company did not incur any capitalized patent related costs during the six months ended June 30, 2012; the Company capitalized \$112,398 in patent related costs during the six months ended June 30, 2011.

#### Impairment of Long-Lived Assets

Office furniture, equipment and intangible assets are reviewed and evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company did not record any impairment of long-lived assets for the six months ended June 30, 2012 or 2011.

#### Fair Value of Financial Instruments

Accounting principles generally accepted in the U.S. require that fair values be disclosed for the Company's financial instruments. The carrying amounts of the Company's financial instruments, which include grants receivable and current liabilities, are considered to be representative of their respective fair values.

## Revenue Recognition

Principally all of the Company's revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant. Licensing and associated milestone revenues are recorded when earned.

## Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, Research and Development. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries stock based compensation, employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

## Stock-Based Compensation

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed. Stock-based compensation expense recognized during the period is based on the fair value of the portion of share-based payment awards that is ultimately expected to vest during the period. Typically these instruments vest upon issuance and therefore the entire stock compensation expense is recognized upon issuance to the vendors and/or consultants.

Stock options are issued with an exercise price equal to the market price on the date of issuance. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees vest 25% immediately as of the grant date, then 25% each subsequent year for a period of three years. Stock options vest over each three month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals remain employees or directors. In general when an employee or director terminates their position the options will expire within three months, unless otherwise extended by the Board.

Stock compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employee directors is amortized as the options vest. The option's price is re-measured using the Black-Scholes model at the end of each three month reporting period.

The fair value of options in accordance with FASB ASC 718, Stock Compensation, was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions:

a dividend yield of 0%;  
an expected life of 4 years;  
volatility of 160% and 123% for 2012 and 2011, respectively;

forfeitures at a rate of 12%; and  
risk-free interest rates of 0.51% and 1.21% in 2012 and 2011, respectively.

The Company estimates these values based on the assumptions that have been historically available. The fair value of options granted is estimated on the date of each grant using the Black-Scholes option pricing model and is then amortized ratably over the option's vesting periods, which approximates the service period.

#### Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through June 30, 2012 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2012 and 2011. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at June 30, 2012 or 2011. The income tax returns for 2009, 2010 and 2011 are subject to examination by the Internal Revenue Service ("IRS") and other various taxing authorities, generally for three years after they were filed.

#### Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period as adjusted for the 1-for-20 reverse stock split effective February 1, 2012. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented. No options or warrants were included in the 2012 and 2011 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses or options and warrants for which the strike price exceeds the quoted market value at period end.

Shares issuable upon the exercise of options and warrants outstanding at June 30, 2012 and 2011 were 1,596,898 and 1,376,084 shares issuable upon the exercise of outstanding stock options, and 2,576,341 and 2,707,819 shares issuable upon the exercise of outstanding warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at June 30, 2012 were \$3.50 and \$4.32 per share, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at June 30, 2011 were \$4.80 and \$4.40 per share, respectively.

#### Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of warrants, stock options and recovery of the useful life of intangibles that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.





## Note 3. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

|                      | Weighted<br>Average<br>Amortization<br>Period (years) | Cost         | Accumulated<br>Amortization | Net Book<br>Value |
|----------------------|---|--------------|-----------------------------|-------------------|
| June 30,<br>2012     |   |              |                             |                   |
| Licenses             | 8.2   | \$ 462,234   | \$ 238,288                  | \$ 223,946        |
| Patents              | 3.1   | 1,893,185    | 1,142,754                   | 750,431           |
| Total                | 4.1   | \$ 2,355,419 | \$ 1,381,042                | \$ 974,377        |
| December<br>31, 2011 |   |              |                             |                   |
| Licenses             | 8.7   | \$ 462,234   | \$ 224,708                  | \$ 237,526        |
| Patents              | 3.3   | 1,893,185    | 1,051,145                   | 842,040           |
| Total                | 4.4   | \$ 2,355,419 | \$ 1,275,853                | \$ 1,079,566      |

Amortization expense was \$49,534 and \$52,208 for the three months ended June 30, 2012 and 2011, respectively and \$105,189 and \$101,845 for the six months ended June 30, 2012 and 2011, respectively.

Based on the balance of licenses and patents at June 30, 2012, the expected annual amortization expense for each of the succeeding five years is estimated to be as follows:

|      | Amortization<br>Expense |
|------|-------------------------|
| 2012 | \$ 222,800              |
| 2013 | \$ 222,800              |
| 2014 | \$ 222,800              |
| 2015 | \$ 222,800              |
| 2016 | \$ 83,200               |

License fees and royalty payments are expensed annually if incurred, as the Company does not attribute any future benefits other than within that period.

## Note 4. Income Taxes

At June 30, 2012, the Company had NOLs of approximately \$76,000,000 for federal tax purposes and approximately \$19,000,000 of New Jersey NOL carry forwards remaining after the sale of unused NOL carry forwards, portions of which are currently expiring each year until 2031. In addition, the Company had \$3,462,000 of various tax credits that started expiring in December 2011 and will continue to expire until 2030. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.



The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to Federal income tax assessment for years before 2008 and 2007 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service and state authorities for purposes of determining the amount of net operating loss carryforward that can be used to reduce taxable income.

The Company has no tax provision for the three and six month periods ended June 30, 2012 and 2011 due to losses and full valuation allowances against net deferred tax assets.

#### Note 5. Shareholders' Equity

##### Preferred Stock

The Company has 250,000 shares of preferred stock authorized, none of which are issued or outstanding.

##### Common Stock

On June 21, 2012, the Company's shareholders approved the Second Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 20,000,000 to 50,000,000.

The following items represent transactions in the Company's common stock for the three months ended June 30, 2012:

In June 2012, the Company issued 10,345 shares of common stock as part of consideration for services performed. The fair value of such shares was \$3,000 and was recognized as an expense in the quarter ended June 30, 2012.

#### Note 6. Commitments and Contingencies

The Company has commitments of approximately \$365,000 at June 30, 2012 to several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

On February 7, 2012, the Company entered into a lease agreement through March 31, 2015 for existing office space. The rent for the first 12 months is approximately \$8,000 per month, or approximately \$18.25 per square foot. This rent increases to approximately \$8,310 per month, or approximately \$19.00 per square foot, for the remaining 24 months. Rent expense is recognized on a straight-line basis.

In February 2007, the Company's Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by it's Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 50,000 common shares to Dr. Schaber; and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes its obligation to issue such shares if such event occurs.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment. On February 15, 2012, Mr. Myrianthopoulos' employment agreement was terminated. The Company recognized an expense of \$95,625 at March 31, 2012 and at June 30, 2012 there is \$37,795 of severance and healthcare benefits due to Mr. Myrianthopoulos.



As a result of the above agreements, the Company has future contractual obligations over the next five years as follows:

| Year  | Research and<br>Development | Property<br>and<br>Other<br>Leases | Severance | Total      |
|-------|-----------------------------|------------------------------------|-----------|------------|
| 2012  | \$ 65,000                   | \$ 50,802                          | \$ 37,795 | \$ 153,597 |
| 2013  | 75,000                      | 104,559                            | -         | 179,559    |
| 2014  | 75,000                      | 101,198                            | -         | 176,198    |
| 2015  | 75,000                      | 24,938                             | -         | 99,938     |
| 2016  | 75,000                      | -                                  | -         | 75,000     |
| Total | \$ 365,000                  | \$ 281,497                         | \$ 37,795 | \$ 684,292 |

#### Note 7. Subsequent Event

On July 17, 2012, the Company announced receiving a Small Business Innovation Research (“SBIR”) grant from the National Institute of Allergy and Infectious Diseases (“NIAID”) to further support preclinical development of OrbeShield™ as a treatment for GI ARS. This will provide the Company with approximately \$600,000 over a two-year period to conduct the study.

## Note 8. Business Segments

The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Each segment includes an element of overhead costs specifically associated with its operations, with its corporate shared services group responsible for support functions generic to both operating segments.

|                                       | Three Months Ended |               |
|---------------------------------------|--------------------|---------------|
|                                       | June 30,           |               |
|                                       | 2012               | 2011          |
| Revenues, Principally from Grants     |                    |               |
| Vaccines/BioDefense                   | \$710,237          | \$335,029     |
| BioTherapeutics                       | 52,614             | 70,791        |
| Total                                 | \$762,851          | \$405,820     |
| Loss from Operations                  |                    |               |
| Vaccines/BioDefense                   | \$(2,144 )         | \$(67,425 )   |
| BioTherapeutics                       | (481,817 )         | (1,663,402)   |
| Corporate                             | (497,716 )         | (201,963 )    |
| Total                                 | \$(981,677 )       | \$(1,932,790) |
| Amortization and Depreciation Expense |                    |               |
| Vaccines/BioDefense                   | \$24,954           | \$10,183      |
| BioTherapeutics                       | 25,892             | 43,290        |
| Corporate                             | 562                | 542           |
| Total                                 | \$51,408           | \$54,015      |
| Interest Income, Net                  |                    |               |
| Corporate                             | \$1,799            | \$1,473       |
| Stock-Based Compensation              |                    |               |
| Vaccines/BioDefense                   | \$2,130            | \$18,416      |
| BioTherapeutics                       | 56,194             | 188,255       |
| Corporate                             | 59,064             | 25,198        |
| Total                                 | \$117,388          | \$231,869     |

|  | Six Months Ended<br>June 30, |                       |
|--|------------------------------|-----------------------|
|  | 2012                         | 2011                  |
| <b>Revenues, Principally from Grants</b>     |                              |                       |
| Vaccines/BioDefense                          | \$1,307,842                  | \$ 871,615            |
| BioTherapeutics                              | 102,427                      | 342,210               |
| <b>Total</b>                                 | <b>\$1,410,269</b>           | <b>\$ 1,213,825</b>   |
| <b>Income (Loss) from Operations</b>         |                              |                       |
| Vaccines/BioDefense                          | \$(130,509 )                 | \$ 52                 |
| BioTherapeutics                              | (1,207,859)                  | (3,044,729)           |
| Corporate                                    | (1,084,299)                  | (610,959 )            |
| <b>Total</b>                                 | <b>\$(2,422,667)</b>         | <b>\$ (3,655,636)</b> |
| <b>Amortization and Depreciation Expense</b> |                              |                       |
| Vaccines/BioDefense                          | \$52,951                     | \$ 19,872             |
| BioTherapeutics                              | 54,733                       | 84,491                |
| Corporate                                    | 1,069                        | 1,080                 |
| <b>Total</b>                                 | <b>\$108,753</b>             | <b>\$ 105,443</b>     |
| <b>Interest Income, Net</b>                  |                              |                       |
| Corporate                                    | \$4,034                      | \$ 3,908              |
| <b>Stock-Based Compensation</b>              |                              |                       |
| Vaccines/BioDefense                          | \$4,260                      | \$ 36,832             |
| BioTherapeutics                              | 112,614                      | 286,508               |
| Corporate                                    | 118,128                      | 65,296                |
| <b>Total</b>                                 | <b>\$235,002</b>             | <b>\$ 388,636</b>     |
|  | As of                        | As of                 |
|  | June 30,                     | December              |
|  | 2012                         | 31,                   |
|  |                              | 2011                  |
| <b>Identifiable Assets</b>                   |                              |                       |
| Vaccines/BioDefense                          | \$557,211                    | \$689,266             |
| BioTherapeutics                              | 658,593                      | 753,767               |
| Corporate                                    | 4,695,661                    | 6,780,625             |
| <b>Total</b>                                 | <b>\$5,911,465</b>           | <b>\$8,223,658</b>    |

## ITEM 2 – MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL AND RESULTS OF OPERATIONS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes including Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2011. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as “believes,” “anticipates,” “expects,” “intends,” “may,” “will” “plans” and other similar expression, however, these words are not exclusive means of identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the SEC or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

### Overview:

#### Business Overview

Soligenix, Inc. was incorporated in Delaware in 1987. We are a development stage biopharmaceutical company focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense. Our BioTherapeutics business segment intends to develop orBec® (“oral beclomethasone dipropionate, or oral BDP”) and other biotherapeutic products, while our collaboration partner, Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) will commercialize orBec® and oral BDP in North America and Europe if approved. On September 15, 2011, our confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”) was stopped at the recommendation of an independent Data Safety Monitoring Board (“DSMB”) due to the fact that there were no differences between the orBec® group and placebo group for the primary endpoint, as well as for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, we have terminated the development of orBec® for the treatment of acute GI GVHD.

We are actively developing oral BDP in other therapeutic indications, such as pediatric Crohn’s disease and radiation enteritis. Our Vaccines/BioDefense business segment includes RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) programs. The advanced development of the vaccine programs is currently supported by ThermoVax™, our heat stabilization technology under existing and ongoing government grant funding.

Our business strategy can be outlined as follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203, in pediatric Crohn’s disease;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal (“GI”) tract such as prevention of acute radiation enteritis and treatment of chronic GI GVHD;





Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology known as ThermoVax™ to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas; Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccine/BioDefense programs through grants, contracts and/or procurements;

Acquire or in-license new clinical-stage compounds for development; and

Explore other business development and acquisition strategies.

Our principal offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

### Our Products in Development

The following tables summarize the products that we are currently developing:

#### BioTherapeutic Products

| Soligenix Product | Therapeutic Indication            | Stage of Development   |
|-------------------|-----------------------------------|--|
| SGX203            | Pediatric Crohn's disease         | Phase 1/2 clinical program planned                                     |
| SGX201            | Acute Radiation Enteritis         | Phase 1/2 trial complete; safety and preliminary efficacy demonstrated |
| orBec®            | Treatment of Chronic GI GVHD      | Phase 2 trial planned  |
| LPM™ Leuprolide   | Endometriosis and Prostate Cancer | Pre-clinical   |

#### Vaccine Thermostability Platform

| Soligenix Product | Indication                                      | Stage of Development |
|-------------------|---|----------------------|
| ThermoVax™        | Thermostability of aluminum adjuvanted vaccines | Pre-clinical         |

#### Vaccines/BioDefense Products

| Soligenix Product | Indication                            | Stage of Development   |
|-------------------|---------------------------------------|--|
| RiVax™            | Vaccine against Ricin Toxin Poisoning | Phase 1B trial enrollment complete; data expected in 2H 2012   |
| VeloThrax™        | Vaccine against Anthrax Poisoning     | Pre-clinical   |
| OrbeShield™       | Therapeutic against GI ARS            | Follow-on pre-clinical study planned; Initial pre-clinical study complete; successful protection of dogs |

### BioTherapeutics Overview

orBec® and Oral BDP

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GI GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs to treat GI GVHD. The active ingredient in orBec® is beclomethasone dipropionate (“BDP”), a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. orBec® is specifically formulated for oral administration as a single product consisting of two tablets. One tablet is intended to release BDP in the upper sections of the GI tract and the other tablet is intended to release BDP in the lower sections of the GI tract.

On September 15, 2011, our confirmatory Phase 3 clinical trial for orBec® in the treatment of acute GI GVHD was stopped at the recommendation of an independent DSMB due to the fact that there were no differences between the orBec® group and placebo group for the primary endpoint, as well as for the pre-specified secondary endpoints upon further analysis. Given the outcome of the Phase 3 study, we have terminated the development of orBec® for the treatment of acute GI GVHD.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec® would benefit from orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD, as well as an orphan drug designation in the U.S. for the treatment of chronic GI GVHD. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S. and Europe, respectively.

#### Commercialization and Market

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®/Oral BDP. Sigma-Tau is a pharmaceutical company that develops novel therapies for the unmet needs of patients with rare diseases. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec®/Oral BDP in the U.S., Canada and Mexico (“the Territory”). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. Total remaining milestone payments due from Sigma-Tau for orBec®/oral BDP under the agreement could reach up to \$9 million. Sigma-Tau will pay us a 35% royalty (Soligenix to provide finished drug product) on net sales in the Territory as well as pay for commercialization expenses, including launch activities.

The Collaboration and Supply Agreement with Sigma-Tau expires on a country-by-country basis on the later of: (i) 10 years after the date of the first commercial sale of orBec® by Sigma-Tau in such country; or (ii) the expiration of the last to expire of the Company’s patents and patent applications relating to orBec® in such country. Upon the expiration of the initial term, on a country-by-country basis, the agreement is automatically renewed for periods of five years. During such renewal periods, we and Sigma-Tau have the right to terminate the agreement for convenience upon six months and 18 months, respectively, prior written notice. If we terminate the agreement for convenience, we are required to transfer to Sigma-Tau or its designee, for no consideration, the U.S. Food and Drug Administration (“the FDA”) and European Medicines Agency (“EMA”) authorizations which are necessary for the marketing, use, distribution and sale of orBec® and all relevant data and know-how necessary to manufacture and commercialize orBec® in the country and grant to Sigma-Tau a royalty-free, fully paid, perpetual and irrevocable license, with the right to sublicense, to the trademark “orBec” and such know-how.

Either party may terminate the agreement: (i) in the event the other party breaches any material obligation; or (ii) upon the initiation of a proceeding in bankruptcy (voluntary or involuntary), reorganization, dissolution, liquidation or similar proceeding or occurrence. We also have the right to terminate the agreement in the event that Sigma-Tau challenges or assists any third party in the challenge of the validity of any of our patents or patent applications relating to orBec®/oral BDP.

Upon termination other than for breach by Sigma-Tau, Sigma-Tau has the right to process and sell its inventory for a period of three months following the date of termination, subject to the payment of the amounts owed under the agreement, to us and continued compliance with the terms of the agreement.

On July 28, 2011, we announced the expansion and amendment of our North American licensing partnership with Sigma-Tau for the development and commercialization of orBec®/oral BDP into the “European Territory” (as defined in the amendment). Pursuant to this amendment, we received an up-front non-refundable payment of \$5 million and granted Sigma-Tau an exclusive license to commercialize orBec®/oral BDP in the European territory. The amendment requires Sigma-Tau to make additional payments to us in the aggregate amount of \$11 million upon the achievement of certain milestones. The amendment also requires Sigma-Tau to pay us a 40% royalty (Soligenix to provide finished drug product) on net sales in the European Territory and pay for all commercialization expenses, including launch activities.

We believe the potential worldwide market for orBec®/oral BDP is in excess of \$500 million for all GI applications, namely, Crohn’s disease, radiation enteritis, GI ARS, and GVHD.

#### Future Potential Indications of orBec® and Oral BDP

Based on its pharmacological characteristics, orBec®/oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following HCT, as well as GVHD which also occurs following organ allograft transplantation. We also have European Patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia. We are planning for/pursuing development programs in the treatment of pediatric Crohn’s disease, acute radiation enteritis, chronic GI GVHD and GI ARS pending further grant funding. We are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with Ulcerative Colitis, among other indications.

#### SGX203 – Oral BDP for Treating Pediatric Crohn’s Disease

SGX203 is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has awarded SGX203 Orphan Drug Designation for the treatment of pediatric Crohn's disease. We plan to initiate a Phase 2 clinical trial in pediatric Crohn’s disease in 2012.

#### About Pediatric Crohn's Disease

Crohn's disease is an ongoing disorder that causes inflammation of the GI tract. Crohn's disease can affect any area of the GI tract, from the mouth to the anus, but it most commonly affects the lower part of the small intestine, called the ileum. The swelling caused by the disease extends deep into the lining of the affected organ. The swelling can induce pain and can make the intestines empty frequently, resulting in diarrhea. Because the symptoms of Crohn's disease are similar to other intestinal disorders, such as irritable bowel syndrome and ulcerative colitis, it can be difficult to diagnose. People of Ashkenazy Jewish heritage have an increased risk of developing Crohn's disease.

Crohn's disease can appear at any age, but it is most often diagnosed in adults in their 20s and 30s. However, approximately 30% of people with Crohn's disease develop symptoms before 20 years of age. Pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the United States. Crohn’s disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (25-40%) of pediatric Crohn’s patients have involvement of their upper gastrointestinal tract.

Crohn's disease presents special challenges for children and teens. In addition to bothersome and often painful symptoms, the disease can stunt growth, delay puberty, and weaken bones. Crohn's disease symptoms may sometimes prevent a child from participating in enjoyable activities. The emotional and psychological issues of living with a chronic disease can be especially difficult for young people.

## SGX201 - Oral BDP for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. We recently completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study were to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. The study demonstrated that oral administration of SGX201 was safe and well tolerated across all four dose groups. There was also evidence of a potential dose response with respect to diarrhea, nausea and vomiting and the assessment of enteritis according to National Cancer Institute (“NCI”) Common Terminology Criteria for Adverse Events for selected gastrointestinal events. In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population. This program was supported in part by a \$500,000 two-year Small Business Innovation Research (“SBIR”) grant awarded by the NIH. These data are currently under review with our Radiation Enteritis medical advisory board to determine potential next steps forward with the clinical development program.

We have received “Fast Track” designation from the FDA for SGX201 for radiation enteritis. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a New Drug Application (“NDA”) for SGX201 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

## About Acute Radiation Enteritis

External radiation therapy is used to treat most types of cancer, including cancer of the bladder, uterine, cervix, rectum, prostate, and vagina. During delivery of treatment, some level of radiation will also be delivered to healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very sensitive to radiation and the larger the dose of radiation the greater the damage to normal bowel tissue. Radiation enteritis is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiation therapy to the abdomen, pelvis, or rectum. Most tumors in the abdomen and pelvis need large doses, and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization. With diarrhea, the gastrointestinal tract does not function normally, and nutrients such as fat, lactose, bile salts, and vitamin B12 are not well absorbed.

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

There are over 100,000 patients annually in the U.S. who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis.

#### orBec® – Oral BDP for Treating Chronic GI GVHD

orBec® is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP to treat the gastrointestinal manifestation of chronic GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs such as prednisone to treat chronic GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the US and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma.

#### About Chronic GVHD

GVHD is a major complication of allogeneic hematopoietic cell transplantation. GVHD is an inflammatory disease initiated by T cells in the donor graft that recognize histocompatibility and other tissue antigens of the host, and is mediated by a variety of effector cells and inflammatory cytokines. GVHD presents in both acute and chronic forms. The symptoms of chronic GVHD typically present at between 100 days and three years post-transplant.

Chronic GVHD has features resembling autoimmune and other immunologic disorders such as scleroderma, Sjögren syndrome, primary biliary cirrhosis, wasting syndrome, bronchiolitis obliterans (BO), immune cytopenias and chronic immunodeficiency. The manifestations of chronic GVHD may be restricted to a single organ or tissue or may be widespread. Chronic GVHD can lead to debilitating consequences, e.g., joint contractures, loss of sight, end-stage lung disease, or mortality resulting from profound chronic immune suppression leading to recurrent or life-threatening infections.

Treatment of chronic GVHD is a challenge because it can be refractory to frontline immunosuppression. High-dose systemic corticosteroids are used with some success but carry significant toxicity. The risks of prolonged immunosuppression include local and disseminated infections, Epstein-Barr virus associated lymphoproliferative disease, hypothalamic-pituitary-adrenal (“HPA”) axis suppression, myopathy, glucose intolerance, neuropsychiatric disease and bone demineralization.

#### LPM™ – Leuprolide for Treating Endometriosis and Prostate Cancer

Our Lipid Polymer Micelle (“LPM™”) oral drug delivery system is a proprietary platform technology designed to allow for the oral administration of peptide drugs that are water-soluble but poorly permeable through the gastrointestinal tract. We have previously demonstrated in pre-clinical animal models that the LPM™ technology is adaptable to oral delivery of peptide drugs and that high systemic levels after intestinal absorption can be achieved with the peptide hormone drug leuprolide. The LPM™ system utilizes a lipid based delivery system that can incorporate the peptide of interest in a thermodynamically stable configuration called a “reverse micelle” that, through oral administration, can promote intestinal absorption. Reverse micelles are structures that form when certain classes of lipids come in contact with small amounts of water. This results in a drug delivery system in which a stable clear dispersion of the water soluble drug can be evenly dispersed within the lipid phase. LPM™ is thought to promote intestinal absorption due to the ability of the micelles to open up small channels through the epithelial layer of the intestines that allow only molecules of a certain dimension to pass through while excluding extremely large molecules such as bacteria and viruses. The reverse micelles also structurally prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inhibition by surfactant(s) in the formulation.





In pre-clinical studies, the LPM™ delivery technology significantly enhanced the ability of leuprolide to pass through the intestinal epithelium in comparison to leuprolide alone. Leuprolide is a synthetic peptide agonist of gonadotropin releasing hormone, which is used in the treatment of prostate cancer in men and endometriosis in women. Leuprolide exhibits poor intestinal absorption from an aqueous solution with the oral bioavailability being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2.2% for the control oral solution. Based on these promising pre-clinical data, we anticipate preparing for a Phase 1 study in humans to confirm these findings, pending further funding.

An oral version of leuprolide may provide a significant advantage over the currently marketed “depot” formulations. Leuprolide is one of the most widely used anti-cancer agents for advanced prostate cancer in men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide annual sales of more than \$1 billion in recent years. Injectable leuprolide is also widely used in non-cancer indications, such as endometriosis in women (a common condition in which cells normally found in the uterus become implanted in other areas of the body), uterine fibroids in women (noncancerous growths in the uterus) and central precocious puberty in children (a condition causing children to enter puberty too soon). Leuprolide is currently available only in injectable, depot and subcutaneous implant routes of delivery which limits its use and utility.

#### Vaccines/BioDefense Overview

##### ThermoVax™ – Thermostability Technology

Soligenix’s Thermostability technology, ThermoVax™, is a novel method of rendering aluminum salt (known colloquially as Alum) adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax™ lies in its potential ability to eliminate the need for cold-chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve companies of the high costs of producing and maintaining vaccines under refrigerated conditions. The World Health Organization (“WHO”) reports that 50% of all vaccines around the world are wasted due to thermostability issues. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius (“C”) and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. The savings realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. Elimination of the cold chain would also further facilitate the use of these vaccines in the lesser developed parts of the world. On the Vaccines/BioDefense side, ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

Initial proof-of-concept preclinical studies with ThermoVax™ indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with Soligenix’s aluminum-adjuvanted ricin toxin vaccine, RiVax™, made under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the ricin A chain, the immunogenic compound of the vaccine. When RiVax™ was kept at 40 degrees C for over three months, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. Confirmatory results have extended the stability to more than three months when the vaccine is kept at 40 degrees C. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C.



Near term progress with ThermoVax™ will allow Soligenix to seek out potential partnerships with companies marketing FDA/ex-U.S. health authority approved Alum adjuvanted vaccines that are interested in eliminating the need for cold chain for their products. ThermoVax™ will further enable Soligenix to expand its vaccine development expertise beyond biodefense into the infectious disease space and also has the potential to allow for the development of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

ThermoVax™ is the subject of U.S. patent application number 60/896,429 filed on March 22, 2007 entitled “Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition.” This patent and its corresponding foreign filings are pending and licensed to Soligenix by the University of Colorado and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable vaccines for biodefense as well as other potential vaccine indications.

#### RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin. With RiVax™, Soligenix is a world leader in ricin toxin vaccine research. The immunogen in RiVax™ induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin. One Phase 1 human clinical trial was completed, and a second trial is currently being conducted. The development of RiVax™ has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to Soligenix and to the University of Texas Southwestern Medical Center (“UTSW”) where the vaccine originated. The second clinical trial is being supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately \$15 million in grant funding from the NIH for RiVax™. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies anticipated to protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of the study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, PNAS, 105:2268-2273). The second trial, sponsored by UTSW, is currently evaluating a more potent formulation of RiVax™ that contains a conventional adjuvant (salts of aluminum), anticipated to result in higher antibody titers of longer duration in human subjects. This trial is expected to complete in the 2H 2012. Soligenix has adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and is further establishing correlates of the human immune response in non-human primates.

RiVax™ is the subject of three issued U.S. patent numbers 6,566,500, 6,960,652, and 7,829,668, all entitled “Compositions and methods for modifying toxic effects of proteinaceous compounds.” This patent family includes composition of matter claims for the modified ricin toxin A chain which is the immunogen contained in RiVax™, and issued in 2003, 2005 and 2010 respectively. The initial filing date of these patents is March 2000 and they are expected to expire in March 2020. The issued patents contain claims that describe alteration of sequences within the ricin A chain that affect vascular leak, one of the deadly toxicities caused by ricin toxin. Another U.S. patent number 7,175,848 entitled “Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin,” was filed in October of 2000 and is expected to expire in October 2020. RiVax™ has also been granted Orphan Drug Designation by the FDA for the prevention of ricin intoxication.

## About Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigation Bioterror report released in November 2007 entitled *Terrorism 2002-2005*, which states that “Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations” ([http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02\\_05.pdf](http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf)). The Centers for Disease Control (“CDC”) has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

## VeloThrax™ – Anthrax Vaccine

VeloThrax™ is Soligenix’s newly acquired proprietary vaccine based on a recombinant Protective Antigen (rPA) derivative intended for use against anthrax. Soligenix has entered into an exclusive license option with Harvard College to license VeloThrax™ (also known as DNI for dominant negative inhibitor). VeloThrax™ is a translocation-deficient mutant of PA with double mutations of K397D and D425K that impede the conformational changes necessary for endosomal membrane translocation into the cell cytoplasm. In the absence of that PA translocation step, anthrax toxin trafficking and function cease. VeloThrax™ is also considered a more immunogenic candidate than native rPA. This apparent increase in immunogenicity suggests that the DNI rPA is processed and presented to the immune system more efficiently by cellular antigen processing pathways, which is consistent with known properties of the molecule.

DNI versions of rPA such as VeloThrax™ are also capable of inducing antibodies that neutralize the activity of the anthrax toxin complex. Unlike fully-functional rPA, VeloThrax™ might be given to a patient post-exposure without risk of enhancing intoxication during an infection, although clinical tests involving intravenous administration of potentially therapeutic levels of DNI rPA resulted in serious adverse events and so further development of this product as a therapeutic biological for blocking the effects of infection by *B. anthracis* was discontinued. Soligenix intends to test VeloThrax™ at a 1,000 fold lower dose than previously tested for an intramuscular or intradermal vaccine.

Initial development work on VeloThrax™ has begun and will be conducted pursuant to Soligenix’s \$9.4 million NIAID grant enabling development of thermo-stable ricin and anthrax vaccines. VeloThrax™’s greater immunogenicity could lead to a vaccine that can be administered in the fewest possible doses to induce the highest level of toxin neutralizing antibodies. Utilizing ThermoVax™, Soligenix believes that it will be able to develop VeloThrax™ into a vaccine with an improved stability profile, an issue that has proven challenging in the development of other anthrax vaccines. Extended stability at ambient temperatures would be a significant improvement for stockpiled vaccines and one which is not expected from conventional vaccines. Further, a large-scale, cGMP production methodology has already been completed. Assuming long-term stability can be met; VeloThrax™ could be stockpiled for general prophylactic as well as a post exposure use.

The overall objective of the VeloThrax™ program is to rapidly and efficiently develop a next generation anthrax vaccine which combines a well established, safe and relatively low risk vaccine development and dosing approach with targeted, proven innovative strategies. VeloThrax™ will potentially be a combination of a stable, readily manufactured mutant rPA subunit antigen with next generation, clinically compatible adjuvants from Infectious Disease Research Institute (“IDRI”) which have been demonstrated to enhance potency and reduce the time and number of vaccine doses

required to achieve protective titer using a variety of vaccine antigens. This blend of proven yet innovative technologies will provide the Public Health Emergency Medical Countermeasures Enterprise (“PHEMCE”) and the Department of Defense (“DoD”) with a safe and stable alternative to the existing licensed anthrax vaccine product. Soligenix also proposes to adapt newly developed glassification technology (initially developed under an ongoing NIAID grant to stabilize exceptionally unstable ricin toxin/adjuvant formulations) to enable a thermostable, dried, single vial, pre-formulated adjuvanted rPA vaccine which is suitable for both long term storage and field use without typical cold chain constraints.

## About Anthrax

Anthrax is an acute infectious disease that is easily transmitted to humans by environmentally durable spores that are produced by *Bacillus anthracis*. Because the spores are robust and contagious, anthrax is considered a Category A bioterror threat. Anthrax infection can occur in three forms: cutaneous (skin), inhalation, and gastrointestinal. Inhaled spores can cause a rapidly progressing form of anthrax since the spores are transported to lymph nodes near the lungs where they germinate, releasing vegetative bacteria into the bloodstream. Bacteria synthesize a complex series of toxin components that make up anthrax toxin, resulting in overwhelming toxemia that causes shock and organ failure. Treatment of anthrax involves long-term antibiotic therapy, since ungerminated spores can lie dormant in the lungs for up to 60 days. Only a few inhaled spores can cause inhalational anthrax. Once the toxin has entered the bloodstream, antibiotics are ineffective, and only toxin-specific therapy is effective. Passively transferred antibodies can neutralize anthrax toxins and can be used post-exposure in conjunction with antibiotics. Because of the long residence time of spores in the lung, it is possible to vaccinate post-exposure, but the onset of neutralizing antibodies must occur during the period of antibiotic therapy.

## OrbeShield™ – Oral BDP for Gastrointestinal Acute Radiation Syndrome (GI ARS)

OrbeShield™ (an oral immediate and delayed release formulation of the topically active corticosteroid BDP is being developed for the treatment of GI ARS. Corticosteroids are the best understood and most widely used class of anti-inflammatory drugs. BDP is a corticosteroid with predominantly topical activity that is approved for use in asthma, psoriasis and allergic rhinitis.

OrbeShield™ has demonstrated positive preclinical results in a canine GI ARS model which indicate that dogs treated with OrbeShield™ demonstrated statistically significant ( $p=0.04$ ) improvement in survival with dosing at either 2 hours or 24 hours after exposure to lethal doses of total body irradiation (“TBI”) when compared to control dogs. OrbeShield™ appears to significantly mitigate the damage to the GI epithelium caused by exposure to high doses of radiation using a well-established canine model of GI ARS.

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. This is the same type of toxicity that occurs in radiation-induced GI ARS. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a “dual use” compound, a desirable characteristic which is a specific priority of Biomedical Advanced Research and Development Authority (“BARDA”) for ARS and other medical countermeasure indications.

The application of OrbeShield™ to acute GI ARS originated from other programs for oral BDP and is based on the properties of BDP to act locally in the GI to modulate local inflammation and epithelial cellular apoptosis. Development of OrbeShield™ for GI ARS is a natural extension of Soligenix’s radiation enteritis clinical program with SGX201. Killing cancer cells with radiation therapy or chemotherapy must be done in ways that minimize toxicity to the rest of the body, but often leads to an inflammatory condition in the GI tract when administered in that general vicinity. In most radiation scenarios, injury to the hematopoietic (blood) system and GI tract are the main determinants of survival.

To date, development of OrbeShield™ has been largely supported by a \$1 million NIH grant to Soligenix's academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, the Company received a SBIR grant from NIAID of approximately \$600,000 to support further preclinical development of OrbeShield™ for the treatment of acute GI ARS.

#### About GI ARS

The potential occurrence of industrial radiation accidents and the threat of terrorist events involving radioactive material mandate the development and implementation of effective treatments of radiation injury. The GI tract is highly sensitive to radiation damage. Substantial injury to the GI tract after radiation exposure results in death. In most radiation scenarios, injury to the hematopoietic system and gastrointestinal tract are the main determinants of survival. There is an urgent need to develop specific countermeasures against the lethality caused by intestinal exposure to radiation and against the pathophysiological manifestations of radiation-induced gastrointestinal injury.

#### Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. We evaluate these estimates and judgments on an on-going basis.

#### Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, we capitalized payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. We believe that patent rights are one of our most valuable assets. Patents and patent applications are key components of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents designed to protect, preserve, maintain and perhaps extending the lives of the patents. We capitalize such costs and amortize intangibles over their expected useful life, generally a period of 11 to 16 years.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the related asset or group of assets.

#### Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, Research and Development. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries stock based compensation, employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there



is no alternative future use as of the date of acquisition.

## Revenue Recognition

Principally our revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant. Licensing and associated milestone revenues are recorded when earned.

## Accounting for Warrants

We considered FASB ASC 815, Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. We evaluated the warrants' provisions and determined that they were indexed to our own stock and therefore to be accounted for as an equity instrument for the six months ended June 30, 2012 and 2011.

## Stock-Based Compensation

From time to time, we issue restricted shares of common stock to vendors and consultants as compensation for services performed. These shares are typically issued as restricted stock, unless issued to non-affiliates under the 2005 Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrictive legend removed if the shares underlying the certificate are sold pursuant to an effective registration statement, which we must file and have approved by the SEC, if the shares underlying the certificate are sold pursuant to Rule 144, provided certain conditions are satisfied, or if the shares are sold pursuant to another exemption from the registration requirements of the Securities Act of 1933, as amended.

We determine stock-based compensation expense for options, warrants and shares of common stock granted to non-employees in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The option's price is remeasured using the Black-Scholes model at the end of each quarterly reporting period. Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

## Material Changes in Results of Operations

### Three and Six Months Ended June 30, 2012 Compared to 2011

For the three months ended June 30, 2012, we had a net loss of \$979,878 as compared to a net loss of \$1,931,317 for the same period in the prior year, representing a decrease in the net loss of \$951,439 or 49%. For the six months ended June 30, 2012, we had a net loss of \$2,418,633 as compared to a net loss of \$3,651,728 for the same period in the prior year, representing a decrease of \$1,233,095 or 34%.

For the three and six months ended June 30, 2012, revenues and associated costs related to NIH grants awarded supported development of our thermostable vaccines and orBec®. For the three months ended June 30, 2012, we had revenues of \$762,851 as compared to \$405,820 for the same period in the prior year, representing an increase of \$357,031 or 88%. For the six months ended June 30, 2012, we had revenues of \$1,410,269 as compared to \$1,213,825 for the same period in the prior year, representing an increase of \$196,444 or 16%. The increases in revenues during both periods were a result of increases in NIH grant drawdowns and the associated development work underlying them.

We incurred costs related to those revenues for the three months ended June 30, 2012 and 2011 of \$616,330 and \$349,511, respectively, representing an increase of \$266,819. For the six months ended June 30, 2012, costs related to revenues were \$1,172,901 as compared to \$903,548 for the same period in the prior year, representing an increase of \$269,353, or 30%. These costs relate to payments made to subcontractors in connection with research performed pursuant to the grants. The increases are due to work performed on the NIH grants discussed above.

Our gross profit for the three months ended June 30, 2012 was \$146,521 as compared to \$56,309 for the same period in 2011, representing an increase of \$90,212 or 160%. The increase in gross profit is directly related to the increase in grant revenue. For the six months ended June 30, 2012, gross profit was \$237,368 as compared to \$310,277 for the same period in the prior year representing a decrease of \$72,909 or 23%. The decrease in gross profit is primarily related to the reimbursement in first quarter 2011 of certain salary costs.

Research and development expenses decreased by \$1,012,742 to \$500,980 for the three months ended June 30, 2012 as compared to \$1,513,722 for the same period in 2011. The significant decrease is a result of the discontinuation of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD. For the six months ended June 30, 2012, research and development expenses were \$1,377,774 compared to \$2,886,526 for the same period in 2011, reflecting a spending decrease of \$1,508,752 related to the discontinued Phase 3 orBec® clinical trial.

General and administrative expenses increased by \$151,841, or 32%, to \$627,218 for the three months ended June 30, 2012, as compared to \$475,377 for the same period in 2011. For the six months ended June 30, 2012, general and administrative expenses was \$1,282,261 representing an increase of \$202,874, or 19% compared to \$1,079,387 for the same period in 2011. These increases are primarily attributable to a greater share of allocated salaries to general administrative resulting from a reduction in the number of specifically identifiable research and development programs.

## Financial Condition

### Cash and Working Capital

As of June 30, 2012, we had cash and cash equivalents of \$4,431,288 as compared to \$5,996,668 as of December 31, 2011, representing a decrease of \$1,565,380 or 26%. As of June 30, 2012, we had working capital of \$3,629,811 as compared to working capital of \$5,696,444 as of December 31, 2011, representing a decrease of \$2,066,633 or 36%. The decrease in cash and working capital was primarily the result of cash used in operating activities over the six month period. For the six months ended June 30, 2012, our cash used in operating activities was \$1,560,625.

Based on the Company's current rate of cash outflows, cash on hand, proceeds from its grant-funded programs, reductions in headcount and expected proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet its anticipated cash needs for working capital and capital expenditures into the third quarter of 2013.



Our plans with respect to our liquidity management include, but are not limited to, the following:

We have instituted a cost reduction plan which has reduced headcount and will continue to reduce costs wherever possible.

We have approximately \$5.0 million in active grant funding still available to support our associated research programs into 2014. We plan to submit additional grant applications for further support of these programs with various funding agencies.

We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future.

We will pursue sales of Net Operating Losses (“NOL”) sales in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$574,157 in proceeds from the sale of NJ NOL in 2011, the Company expects to participate in the program during 2012 and beyond; and

We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

#### Reverse Stock Split

On February 1, 2012, we completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1-for-20, whereby, every 20 shares of its common stock was exchanged for one share of its common stock. Its common stock began trading on the OTCBB on a reverse split basis on February 2, 2012. All share and per share data have been restated to reflect this reverse stock split.

#### Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately \$3.3 million before any grant reimbursements, of which \$1.3 million relates to the BioTherapeutics business and \$2.0 million relates to the Vaccines/BioDefense business. We anticipate grant revenues in the next 12 months of approximately \$2.1 million to offset research and development expenses, primarily for the development of our ThermoVax™ vaccine technology, and very limited contribution to the wind down costs of the Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD.

The table below details our costs for research and development by program and amounts reimbursed under grants for the six months ended June 30:

|                                  | 2012        | 2011        |
|----------------------------------|-------------|-------------|
| Research & Development Expenses  |             |             |
| orBec®                           | \$516,982   | \$1,713,193 |
| RiVax™ and thermostable vaccines | 743,918     | 845,916     |
| Oraprine™                        | -           | 1,500       |
| LPM™-Leuprolide and Other        | 116,874     | 325,917     |
| Total                            | \$1,377,774 | \$2,886,526 |
| Reimbursed under Grants          |             |             |
| orBec®                           | \$98,828    | \$328,503   |
| RiVax™ and thermostable vaccines | 1,074,073   | 575,045     |
| Total                            | 1,172,901   | 903,548     |
| Grand Total                      | \$2,550,675 | \$3,790,074 |

#### Contractual Obligations

The Company has commitments of approximately \$365,000 as of June 30, 2012 relating to several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

On February 7, 2012, we entered into a lease agreement through March 31, 2015 for our existing office space. The rent for the first 12 months is approximately \$8,000 per month, or approximately \$18.25 per square foot on an annualized basis. This rent increases to approximately \$8,310 per month, or approximately \$19.00 per square foot on an annualized basis, for the remaining 24 months.

In February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber, and Dr. Brey and certain other employees and a consultant, upon the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of its assets are transferred from us and/or our stockholders to a third party: 50,000 common shares to Dr. Schaber; and 10,000 common shares to Dr. Brey. The employment agreement with Dr. Schaber has been amended to reflect this obligation.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment. On February 15, 2012, Mr. Myriantopoulos' employment agreement was terminated. However, he continues to serve the Company as a consultant on business development and other related matters.

As a result of the above agreements, the Company has future contractual obligations over the next five years as follows:

| Year  | Research and<br>Development | Property<br>and<br>Other<br>Leases | Severance | Total      |
|-------|-----------------------------|------------------------------------|-----------|------------|
| 2012  | \$ 65,000                   | \$ 50,802                          | \$ 37,795 | \$ 153,597 |
| 2013  | 75,000                      | 104,559                            | -         | 179,559    |
| 2014  | 75,000                      | 101,198                            | -         | 176,198    |
| 2015  | 75,000                      | 24,938                             | -         | 99,938     |
| 2016  | 75,000                      | -                                  | -         | 75,000     |
| Total | \$ 365,000                  | \$ 281,497                         | \$ 37,795 | \$ 684,292 |

### ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

### ITEM 4 - CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are the Company's controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the Exchange Act) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any 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 possible controls and procedures.

Our management has evaluated, with the participation of our principal executive officer and principal financial officer effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this report. Based upon that evaluation, our management, including our principal executive officer and principal financial officer has concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

#### Changes in Internal Controls

There was no change in our internal control over financial reporting identified in connection with the evaluation of such internal controls that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

On February 15, 2012, the employment agreement of Mr. Myriantopoulos, Chief Financial Officer and Senior Vice-President was terminated and Mr. Joseph M. Warusz was appointed the Acting Chief Financial Officer.



PART II - OTHER INFORMATION.

ITEM 1A – RISK FACTORS

We have identified no additional risk factors other than those included in Part I, Item 1A of our Form 10-K for the fiscal year ended December 31, 2011, as supplemented by Part II, Item 1A of our Form 10-Q for the quarter ended March 31, 2012. Readers are urged to carefully review our risk factors because they may cause our results to differ from the "forward-looking" statements made in this Report. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements, except as required by law.

ITEM 6 - EXHIBITS

EXHIBIT DESCRIPTION

NO.

|      |   |
|------|---|
| 31.1 | Certification of Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002). |
| 31.2 | Certification of Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under 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.                                       |

SIGNATURES

In accordance with 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.

SOLIGENIX, INC.

August 10, 2012

by

/s/ Christopher J. Schaber  
Christopher J. Schaber, PhD  
President and Chief Executive Officer  
(Principal Executive Officer)

August 10, 2012

by

/s/ Joseph M. Warusz  
Joseph M. Warusz, CPA  
Vice President, Finance and Acting Chief  
Financial Officer  
(Principal Financial and Accounting  
Officer)

EXHIBIT INDEX

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35

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