SOLIGENIX, INC.
Form 424B3
November 12, 2015

**Prospectus Supplement No. 3** **Filed Pursuant to Rule 424(b)(3)**

(To Prospectus dated March 27, 2015) **File No. 333-192908**

**SOLIGENIX, INC.**

**3,905,440 SHARES OF COMMON STOCK**

This Prospectus Supplement No. 3 (this "Prospectus Supplement") supplements the prospectus dated March 27, 2015 (the "Final Prospectus"), relating to the offer and sale of up to 3,905,440 shares of our common stock, par value $0.001 per share, by Lincoln Park Capital Fund, LLC.

This Prospectus Supplement contains the Quarterly Report on Form 10-Q that we filed with the Securities and Exchange Commission on November 12, 2015. This Prospectus Supplement should be read in conjunction with, and may not be utilized without, the Final Prospectus, which is to be delivered with this Prospectus Supplement. This Prospectus Supplement is qualified by reference to the Final Prospectus except to the extent that the information in this Prospectus Supplement updates and supersedes the information contained in the Final Prospectus, including any supplements or amendments thereto.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

Prospectus Supplement No. 3 dated November 12, 2015.

**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 September 30, 2015**

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**<br>(State or other jurisdiction of incorporation or organization) | **41-1505029**<br>(I.R.S. Employer Identification Number) |
| **29 EMMONS DRIVE, SUITE C-10 PRINCETON, NJ**<br>(Address of principal executive offices) | **08540**<br>(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 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 November 2, 2015; 27,242,393 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

**SOLIGENIX, INC.**

**Index**

**PART I - FINANCIAL INFORMATION**

**ITEM 1 - Financial Statements**

**Soligenix, Inc. and Subsidiaries**

**Consolidated Balance Sheets**

| | September 30, 2015 (Unaudited) | December 31, 2014 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $4,033,326 | $5,525,094 |
| Contracts and grants receivable | 1,864,743 | 794,767 |
| Prepaid expenses | 158,158 | 172,928 |
| Total current assets | 6,056,227 | 6,492,789 |
| | | |
| Office furniture and equipment, net | 54,398 | 51,510 |
| Intangible assets, net | 244,661 | 409,949 |
| Total assets | $6,355,286 | $6,954,248 |
| | | |
| Liabilities and shareholders' deficiency | | |
| Current liabilities: | | |
| Notes payable | $286,399 | $- |
| Accounts payable | 4,347,421 | 3,003,545 |
| Warrant liability | 2,139,599 | 3,789,562 |
| Accrued compensation | 48,086 | 315,030 |
| Total current liabilities | 6,821,505 | 7,108,137 |
| | | |
| Commitments and contigencies | | |
| | | |
| Shareholders' equity deficiency: | | |
| Preferred stock; 350,000 shares authorized; none issued or outstanding | - | - |
| Common stock, $.001 par value; 50,000,000 shares authorized; 27,066,511 shares and 23,936,568 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively | 27,067 | 23,937 |
| Additional paid-in capital | 144,325,731 | 138,868,523 |
| Accumulated deficit | (144,819,017) | (139,046,349) |
| Total shareholders' deficiency | (466,219) | (153,889) |
| Total liabilities and shareholders' deficiency | $6,355,286 | $6,954,248 |

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

**Soligenix, Inc. and Subsidiaries**

**Consolidated Statements of Operations**

**For the Three and Nine Months Ended September 30, 2015 and 2014**

**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Revenues | | | | |
| Contract revenue | $3,874,199 | $2,194,909 | $5,668,746 | $3,753,406 |
| Grant revenue | 5,476 | 592,800 | 127,042 | 1,363,148 |
| Total revenues | 3,879,675 | 2,787,709 | 5,795,788 | 5,116,554 |
| Cost of revenues | (3,050,814 ) | (2,109,530 ) | (4,394,915 ) | (3,773,095 ) |
| Gross profit | 828,861 | 678,179 | 1,400,873 | 1,343,459 |
| Operating expenses: | | | | |
| Research and development | 1,259,015 | 1,089,179 | 3,731,813 | 3,333,024 |
| Acquired in-process research and development | - | 4,000,000 | - | 4,000,000 |
| Research and development | 1,259,015 | 5,089,179 | 3,731,813 | 7,333,024 |
| General and administrative | 839,512 | 730,378 | 2,531,744 | 2,437,553 |
| Total operating expenses | 2,098,527 | 5,819,557 | 6,263,557 | 9,770,577 |
| Loss from operations | (1,269,666 ) | (5,141,378 ) | (4,862,684 ) | (8,427,118 ) |
| Other income (expense): | | | | |
| Change in fair value of warrant liability | 4,047,742 | 791,395 | (907,368 ) | (203,703 ) |
| Interest income (expense), net | (3,728 ) | 428 | (2,616 ) | 1,041 |
| Net income (loss) | $2,774,348 | $(4,349,555 ) | $(5,772,668 ) | $(8,629,780 ) |
| Basic net income / (loss) per share | $0.10 | $(0.21 ) | $(0.23 ) | $(0.43 ) |
| Diluted net loss per share | $(0.05 ) | $(0.21 ) | $(0.23 ) | $(0.43 ) |
| Basic weighted average common shares outstanding | 26,482,402 | 20,671,097 | 25,539,296 | 20,120,035 |
| Diluted weighted average common shares outstanding | 28,290,584 | 20,671,097 | 25,539,296 | 20,120,035 |

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

4

**Soligenix, Inc. and Subsidiaries**

**Consolidated Statements of Changes in Shareholders' Deficiency**

**For the Nine Months Ended September 30, 2015**

**(Unaudited)**

| | Common Stock | | Additional Paid-In | Accumulated | |
|---|---|---|---|---|---|
| | Shares | Par Value | Capital | Deficit | Total |
| Balance, December 31, 2014 | 23,936,568 | $23,937 | $138,868,523 | $(139,046,349) | $(153,889) |
| Issuance of common stock pursuant to Lincoln Park equity line | 613,611 | 614 | 1,114,411 | - | 1,115,025 |
| Issuance of common stock pursuant to Equity Line Purchase Agreement | 609,535 | 610 | 499,390 | - | 500,000 |
| Stock issuance cost associated with Equity Line Purchase Agreement | - | - | (453,162) | - | (453,162) |
| Issuance of common stock to vendors | 127,243 | 127 | 190,134 | - | 190,261 |
| Reclassification of warrant liability upon partial exercise of warrants issued in unit offering | - | - | 2,557,331 | - | 2,557,331 |
| Warrants exercises | 1,746,429 | 1,746 | 1,115,775 | - | 1,117,521 |
| Issuance of shares from exercise of stock options | 33,125 | 33 | 19,217 | - | 19,250 |
| Share-based compensation expense | - | - | 414,112 | - | 414,112 |
| Net loss | - | - | - | (5,772,668) | (5,772,668) |
| Balance, September 30, 2015 | 27,066,511 | $27,067 | $144,325,731 | $(144,819,017) | $(466,219) |

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

**Soligenix, Inc. and Subsidiaries**

**Consolidated Statements of Cash Flows**

**For the Nine Months Ended September 30,**

**(Unaudited)**

| | 2015 | 2014 |
|---|---|---|
| Operating activities: | | |
| Net loss | $(5,772,668) | $(8,629,780) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization and depreciation | 184,496 | 183,960 |
| Warrants issued to vendors | - | 4,775 |
| Change in fair value of warrant liability | **907,368** | 203,703 |
| Issuances of common stock for acquisition of in-process research and development | - | 4,000,000 |
| Issuances of common stock to vendors | 190,261 | 106,042 |
| Amortization of discount on debt | 4,328 | - |
| Share-based compensation | 414,112 | 458,914 |
| Change in operating assets and liabilities: | | |
| Grants receivable | (1,069,976) | (470,957) |
| Taxes receivable | - | 750,356 |
| Prepaid expenses | 14,770 | (70,116) |
| Accounts payable | 1,343,876 | 1,539,036 |
| Accrued compensation | (266,942) | (173,755) |
| Total adjustments | 1,722,293 | 6,531,958 |
| Net cash used in operating activities | (4,050,375) | (2,097,822) |
| | | |
| Investing activities: | | |
| | | |
| Purchase of fixed assets | (22,098) | (47,025) |
| Net cash used in investing activities | (22,098) | (47,025) |
| | | |
| Financing activities: | | |
| Proceeds from issuance of common stock pursuant to equity lines | 1,615,025 | 470,475 |
| Stock issuance costs associated with equity line purchase agreement | (171,091) | - |
| Proceeds from exercise of warrants and options | 1,136,771 | 28,079 |
| Net cash provided by financing activities | 2,580,705 | 498,554 |
| | | |
| Net decrease in cash and cash equivalents | (1,491,768) | (1,646,293) |
| Cash and cash equivalents at beginning of period | 5,525,094 | 5,856,242 |
| Cash and cash equivalents at end of period | $4,033,326 | $4,209,949 |
| | | |
| Supplemental disclosure of non cash investing and financing activities: | | |
| Reclassification of warrant liability to additional paid in capital upon partial exercise of warrants issued in unit offering | $2,557,331 | $1,055,490 |

| | | |
|---|---|---|
| Notes payable issued in connection with Equity Purchase Agreement | $282,071 | $- |

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

**Soligenix, Inc.**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

**Note 1. Nature of Business**

Basis of Presentation

Soligenix, Inc. (the "Company") is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense.

The Company's BioTherapeutics business segment is developing a first-in-class photodynamic therapy (SGX301) utilizing safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"), proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201), and its novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis.

The Company's Vaccines/BioDefense business segment includes active development programs for RiVax™, its ricin toxin vaccine candidate, VeloThrax™, an anthrax vaccine candidate, OrbeShield™, a GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, a melioidosis therapeutic candidate. The development of the vaccine programs currently supported by the heat stabilization technology, known as ThermoVax™, under existing and on-going government contract funding. With awarded government contracts from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Company will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. The Company plans to use the funds received under the government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID to advance the development of OrbeShield™ for the treatment of GI ARS.

The Company generates revenues under government grants primarily from the National Institutes of Health (the "NIH") and government contracts from BARDA and NIAID.

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 the United States Food and Drug Administration (the U.S. “FDA”) regulations, litigation, and product liability. Results for the three and nine months ended September 30, 2015 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of September 30, 2015, the Company had cash and cash equivalents of $4,033,326 as compared to $5,525,094 as of December 31, 2014, representing a decrease of $1,491,768 or 27%. As of September 30, 2015, the Company had working capital of $1,374,321, which excludes the non-cash warrant liability of $2,139,599, as compared to working capital of $3,174,214, which excludes a non-cash warrant liability of $3,789,562 as of December 31, 2014, representing a decrease of $1,799,893, or 57%. The decrease is primarily related to expenditures to support the Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer and manufacture of clinical supplies to support the Phase 3 clinical trial of SGX301 for the treatment of CTCL.

Based on the Company’s current rate of cash outflows, cash on hand, proceeds from its government contract and grant programs, availability of funds from equity lines and proceeds from the state of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures for at least the next twelve months.

Management's business plan can be outlined as follows:

Initiate a Phase 3 clinical trial of SGX301 for the treatment of CTCL;
Conduct a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
Initiate a Phase 3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;
Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis;
Develop RiVax™ and VeloThrax™ in combination with the Company's 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;
Advance the preclinical and manufacturing development of OrbeShield™ as a biodefense medical countermeasure for the treatment of GI ARS;
Continue to apply for and secure additional government funding for each of the Company's 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 merger/acquisition strategies.

The Company's plans with respect to its liquidity management include, but are not limited to, the following:

The Company has up to $45.6 million in active government contract and grant funding still available to support its associated research programs through 2015 and beyond. The Company plans to submit additional grant and contract 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 Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $616,872 in proceeds of the sale of NJ NOL in 2014, the Company expects to participate in the program during 2015 and beyond.
The Company has an aggregate of $17.9 available from equity facilities through 2016.
The Company may seek additional capital in the private and/or public equity markets, pursue government contracts and grants as well as business development activities to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is evaluating additional equity financing opportunities on an ongoing basis 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.

**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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Contracts and Grants Receivable

Contracts and grants receivable consist of unbilled amounts due from various grants from the NIH and contracts from BARDA and NIAID, an institute of NIH, for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the respective governmental agencies in the month subsequent to period end and collected shortly thereafter. 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 industry 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 designed to protect, preserve, maintain the Company's

rights and perhaps extend the lives of the patents. The Company capitalizes such costs and amortizes intangibles on a straight-line basis 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. No such write downs have occurred during the three and nine months ended September 30, 2015 and 2014.

The Company did not capitalize any patent related costs during the three and nine months ended September 30, 2015 and 2014.

Impairment of Long-Lived Assets

Office furniture and equipment and intangible assets are evaluated and reviewed 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 involves significant judgment.

The Company did not record any impairment of long-lived assets for the three and nine months ended September 30, 2015 and 2014.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on September 30, 2015. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.
Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair value based on the short-term maturity of these instruments. The Company recognizes all derivative financial instruments as assets or liabilities in the financial statements and measures them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with the Company's June 2013 registered public offering were accounted for as derivatives. See Note 4, *Warrant Liability*.

Revenue Recognition

The Company's revenues are primarily generated from government contracts and grants. Revenue is recognized in accordance with FASB ASC 605, *Revenue Recognition,* and/or ASC 605-25 *Revenue Recognition – Multiple Element Arrangements*. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs reimbursable internal expenses that are related to the government contracts and grants.

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.

Accounting for Warrants

The Company 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. The Company evaluated the provisions in our outstanding warrants and determined that warrants issued in connection with the Company's June 2013 registered public offering contains provisions that protect holders from a decline in the issue price of the Company's common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants are recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. All other warrants issued were indexed to the Company's stock and therefore are accounted for as equity instruments for 2015 and 2014.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. 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% on 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.

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed. Share-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 share-based compensation expense is recognized upon issuance to the vendors and/or consultants.

Share-based 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-employees is amortized as the options vest. The fair value is remeasured each reporting period until performance is complete.

During the nine months ended September 30, 2015 the Company issued 125,340 stock options at a weighted average exercise price of $1.44 per share. The fair value of options issued during the nine months ended September 30, 2015 and 2014 was estimated using the Black-Scholes option-pricing model and the following assumptions:

a dividend yield of 0%;
an expected life of 4 years;
volatilities ranging from 136% - 141% and 129% - 165% for 2015 and 2014, respectively;
forfeitures at a rate of 12%; and
risk-free interest rates ranging from 0.99% - 1.34% and 1.05% - 1.43% for 2015 and 2014, respectively.

The weighted average fair value of each option grant made during 2015 and 2014 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option 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 September 30, 2015 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 2015 and 2014. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at September 30, 2015 or December 31, 2014.

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. 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.

| | **Three Months Ended September 30, 2015** | **Three Months Ended September 30, 2014** | **Nine Months Ended September 30, 2015** | **Nine Months Ended September 30, 2014** |
|---|---|---|---|---|
| Numerator: | | | | |
| Net income/(loss) for basic earnings per share | **$ 2,774,348** | $ (4,349,555) | **$ (5,772,668)** | $ (8,629,780) |
| Less change in fair value of warrant liability | **4,047,742** | - | **-** | - |
| Net loss for diluted earnings per share | **$ (1,273,394)** | $ (4,349,555) | **$ (5,772,668)** | $ (8,629,780) |
| Denominator: | | | | |
| Weighted-average basic common shares outstanding | **26,482,402** | 20,671,097 | **25,539,296** | 20,120,035 |
| Assumed conversion of dilutive securities: | **1,808,182** | - | **-** | - |
| Denominator for diluted earnings per share – adjusted weighted-average shares | **28,290,584** | 20,671,097 | **25,539,296** | 20,120,035 |
| Basic net income/(loss) per share | **$ 0.10** | $ (0.21) | **$ (0.23)** | $ (0.43) |
| Diluted net loss per share | **$ (0.05)** | $ (0.21) | **$ (0.23)** | $ (0.43) |

The following table summarizes potentially dilutive adjustments to the weighted average number of common shares which were excluded from the calculation because their effect would be anti-dilutive.

| | Three Months Ended September 30, 2015 | Three Months Ended September 30, 2014 | Nine Months Ended September 30, 2015 | Nine Months Ended September 30, 2014 |
|---|---|---|---|---|
| Common stock purchase warrants | 1,889,191 | 6,100,182 | 4,926,119 | 6,100,182 |
| Stock options | 2,300,737 | 2,200,147 | 2,300,737 | 2,200,147 |
| Total | 4,189,928 | 8,300,329 | 7,226,856 | 8,300,329 |

The weighted average exercise price of the Company’s stock options and warrants outstanding at September 30, 2015 were $2.33 and $0.80 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 and 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.

13

**Note 3. Intangible Assets**

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

| | Weighted Average Remaining Amortization Period (years) | Cost | Accumulated Amortization | Net Book Value |
|---|---|---|---|---|
| September 30, 2015 | | | | |
| Licenses | 4.0 | $462,234 | $ 326,867 | $135,367 |
| Patents | 1.3 | 1,893,185 | 1,783,891 | 109,294 |
| Total | 2.0 | $2,355,419 | $ 2,110,758 | $244,661 |
| December 31, 2014 | | | | |
| Licenses | 4.7 | $462,234 | $ 306,495 | $155,739 |
| Patents | 1.9 | 1,893,185 | 1,638,975 | 254,210 |
| Total | 2.6 | $2,355,419 | $ 1,945,470 | $409,949 |

Amortization expense was $55,929 and $56,265 for the three months ended September 30, 2015 and 2014, respectively, and $165,288 and $166,298 for the nine months ended September 30, 2015 and 2014, respectively.

Based on the balance of licenses and patents at September 30, 2015, the expected annual amortization expense for each of the succeeding five years is expected to approximate as follows:

| Year | Amortization Expense |
|---|---|
| October 1 through December 31, 2015 | $ 50,900 |
| 2016 | $ 81,900 |
| 2017 | $ 37,300 |
| 2018 | $ 37,300 |
| 2019 | $ 37,300 |

License fees and royalty payments are expensed as incurred as the Company does not attribute any future benefits to such payments.

**Note 4. Notes Payable**

On July 29, 2015, the Company entered into equity purchase agreements (the “Equity Line Purchase Agreements”) and registration rights agreements with certain accredited institutional investors. Under the Equity Line Purchase Agreements, the investors have agreed to purchase from the Company up to an aggregate of $10 million worth of shares of common stock, from time to time.

In consideration for entering into the Equity Line Purchase Agreements, the Company issued to the investors promissory notes having an aggregate principal amount of $300,000 for stock issuance costs. The promissory notes are payable by April 15, 2016, with an issuance date present value of $282,071. The promissory notes did not include terms for interest, therefore the interest was imputed. Total discount amortization of $4,328 was recorded as interest expense during each of the three and nine months ended September 30, 2015. The discount is being accreted over the term of the promissory notes using the effective interest rate method.

**Note 5. Warrant Liability**

Warrants issued in connection with the Company's June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of its common stock (or "down-round" provision) and contain net settlement provisions. As a result, the Company accounts for these warrants as liabilities instead of equity instruments. Down-round provisions reduce the exercise or conversion price of a warrant if the Company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed for fixed" option. As a result of the Company's December 2014 registered public unit offering, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to $0.61 per share.

The Company recognized these warrants as liabilities at their fair value on the date of grant and remeasures them to fair value on each reporting date.

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013 totaling $4,827,788, which was based on the June 25, 2013 closing price of a share of the Company's common stock as reported on OTC Markets of $0.96. On September 30, 2015, the closing price of the Company's common stock as reported on OTC Markets was $1.07. Due to the fluctuations in the market value of the Company's common stock from December 31, 2014 through September 30, 2015, the Company recognized a non-cash charge of $907,368 for the change in the fair value of the warrant liability for the nine months ended September 30, 2015.

The assumptions used in connection with the valuation of warrants issued were as follows:

| | December 31, 2014 | **Exercised During 2015** | September 30, 2015 |
|---|---|---|---|
| Number of shares underlying the warrants | 4,723,357 | 1,686,429 | 3,036,928 |
| Exercise price | $ 0.61 | $0.61 | $ 0.61 |
| Volatility | 128 % | 117-119 % | 83 % |
| Risk-free interest rate | 1.38 % | 0.81-1.06 % | 0.92 % |
| Expected dividend yield | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Expected warrant life (years) | 3.5 | 3.01-3.33 | 2.74 |
| Stock Price | $ 0.98 | $1.69-$2.22 | $ 1.07 |

15

*Recurring Level 3 Activity and Reconciliation*

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3). The table reflects losses for the nine months ended September 30, 2015 for the financial liability categorized as Level 3 as of September 30, 2015.

| | December 31, 2014 | Decrease from Warrants Exercised in 2015 | Increase in Fair Value | September 30, 2015 |
|---|---|---|---|---|
| Warrant liability | $ 3,789,562 | $(2,557,331) | $907,368 | $ 2,139,599 |

**Note 6. Income Taxes**

The Company had NOLs at December 31, 2014 of approximately $85,619,000 for federal tax purposes and approximately $4,748,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which will begin to expire in 2018. In addition, the Company has $3,556,000 of various tax credits from 2018 to 2034. 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 carry forwards 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 has no tax provision for the three and nine month periods ended September 30, 2015 and 2014 due to losses incurred and the recognition of full valuation allowances recorded against net deferred tax assets.

**Note 7. Shareholders’ Deficiency**

Preferred Stock

The Company has 350,000 shares of preferred stock authorized, none of which are issued or outstanding.

Common Stock

During the nine months ended September 30, 2015, the Company issued the following shares of common stock:

In several separate transactions, the Company issued 1,746,429 shares of common stock in connection with warrant exercises;
In several separate transactions, the Company issued 613,611 shares of common stock pursuant to the equity line with Lincoln Park Capital Fund, LLC;
The Company issued 609,535 shares of common stock pursuant to the Equity Line Purchase Agreement;
In several separate transactions, the Company issued 127,243 shares of common stock as partial consideration for services performed.
In three transactions, the Company issued 33,125 shares of common stock in connection with stock option exercises.

Equity Line Purchase Agreement

On July 29, 2015, the Company entered into the Equity Line Purchase Agreements and a registration rights agreements with accredited institutional investors, Kodiak Capital Group, LLC ("Kodiak Capital"), Kingsbrook Opportunities Master Fund LP ("Kingsbrook") and River North Equity, LLC ("River North" and, together with Kodiak Capital and Kingsbrook, the "Investors"). Under the Equity Line Purchase Agreements, the Investors agreed to purchase from the Company up to an aggregate of $10 million worth of shares of common stock, from time to time. In accordance with the registration rights agreements, the Company has filed with the U.S. Securities and Exchange Commission (the "SEC") a registration statement to register for resale under the Securities Act of 1933, as amended, the shares of common stock that may be issued to the Investors under the Equity Line Purchase Agreements.

From the date that the SEC declared the registration statement effective until December 31, 2016, the Company has the right to sell up to $5 million, $4 million and $1 million worth of shares of common stock to Kodiak Capital, Kingsbrook and River North, respectively. The Company will control the timing and amount of future sales, if any, of common stock to the Investors under the Equity Line Purchase Agreements. The purchase price of the shares will be equal to eighty percent (80%) of the lowest daily volume weighted average price of the common stock for any trading day during the five consecutive trading days immediately following the date of the Company's notice to the Investors requesting the purchase. There is no minimum amount that the Company may require the Investors to purchase at any one time. The Company may not require the Investors to purchase more than $3 million worth of shares of common stock during any seven day period and may not require any of the Investors to purchase shares of common stock if such purchase would result in such Investor's beneficial ownership exceeding 9.99% of the outstanding common stock.

The Equity Line Purchase Agreements contain customary representations, warranties, covenants, closing conditions, and indemnification and termination provisions. Each of the Investors has covenanted not to cause or engage in any manner whatsoever any direct or indirect short selling of the common stock.

In consideration for entering into the Equity Line Purchase Agreements, the Company issued to each of the Investors a promissory note having a principal amount equal to 3% of the total amount committed by such Investor. The principal amount due under the promissory notes does not accrue interest and is payable by April 15, 2016 (see Note 4).

The Equity Line Purchase Agreements may be terminated by the Company at any time at its discretion without any cost to the Company.

The initial drawdown under the Equity Line Purchase Agreements was $500,000 offset by issuance cost of $453,162, which is included in the Consolidated Statements of Changes in Shareholders' Deficiency. Issuance costs include

professional fees, 3% commitment fee (promissory notes payable by April 15, 2016) and SEC filing fees.

**Note 8. Commitments and Contingencies**

The Company has commitments of approximately $475,000 as of September 30, 2015 for several licensing agreements with consultants and universities. Additionally, the Company has collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

In December 2014, the Company entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months is approximately $12,300 per month, or approximately $20.85 per square foot. This rent increases to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months and approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease.

On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma’s synthetic hypericin product. As consideration for the assets acquired, the Company paid $250,000 in cash and issued 1,849,113 shares of common stock with a fair value based on the Company’s stock price on the date of grant of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company’s research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, the Company will be required to make additional payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company not to exceed 19.9% ownership of the Company’s outstanding stock.

In February 2007, the Company’s Board of Directors authorized the issuance of 50,000 shares of the Company’s common stock to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its 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. Dr. Schaber’s amended employment agreement includes the Company’s obligation to issue such shares if such event occurs.

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

| **Year** | Research and Development | **Property and Other Leases** | **Total** |
|---|---|---|---|
| October 1 through December 31, 2015 | $ 75,000 | $39,000 | $114,000 |
| 2016 | 100,000 | 157,000 | 257,000 |
| 2017 | 100,000 | 151,000 | 251,000 |
| 2018 | 100,000 | 52,000 | 152,000 |
| 2019 | 100,000 | - | 100,000 |
| Total | $ 475,000 | $399,000 | $874,000 |

**Note 9. Operating Segments**

The Company maintains two active operating 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 September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Contract/Grant Revenue | | |
| Vaccines/BioDefense | $3,879,675 | $2,729,854 |
| BioTherapeutics | - | 57,855 |
| Total | $3,879,675 | $2,787,709 |
| | | |
| Income (Loss) from Operations | | |
| Vaccines/BioDefense | $653,415 | $545,728 |
| BioTherapeutics | (959,065) | (4,855,765) |
| Corporate | (964,016) | (831,341) |
| Total | $(1,269,666) | $(5,141,378) |
| | | |
| Amortization and Depreciation Expense | | |
| Vaccines/BioDefense | $10,093 | $9,922 |
| BioTherapeutics | 50,673 | 49,985 |
| Corporate | 2,074 | 1,561 |
| Total | $62,840 | $61,468 |
| | | |
| Other Income, Net | | |
| Corporate | $4,044,014 | $791,823 |
| | | |
| Share-Based Compensation | | |
| Vaccines/BioDefense | $19,344 | $17,224 |
| BioTherapeutics | 29,180 | 33,118 |
| Corporate | 86,400 | 110,653 |
| Total | $134,924 | $160,995 |

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Contract/Grant Revenue | | |
| Vaccines/BioDefense | $5,781,816 | $4,928,284 |
| BioTherapeutics | 13,972 | 188,270 |
| Total | $5,795,788 | $5,116,554 |
| | | |
| Income (Loss) from Operations | | |
| Vaccines/BioDefense | $1,040,627 | $949,032 |
| BioTherapeutics | (3,094,883) | (6,541,832) |
| Corporate | (2,808,428) | (2,834,318) |
| Total | $(4,862,684) | $(8,427,118) |
| | | |
| Amortization and Depreciation Expense | | |
| Vaccines/BioDefense | $29,820 | $29,666 |
| BioTherapeutics | 148,913 | 148,995 |
| Corporate | 5,763 | 5,299 |
| Total | $184,496 | $183,960 |
| | | |
| Other (Expense), Net | | |
| Corporate | $(909,984 ) | $(202,662 ) |
| | | |
| Share-Based Compensation | | |
| Vaccines/BioDefense | $63,280 | $38,124 |
| BioTherapeutics | 88,615 | 142,374 |
| Corporate | 262,217 | 278,416 |
| Total | $414,112 | $458,914 |

| | **As of September 30, 2015** | **As of December 31, 2014** |
|---|---|---|
| Identifiable Assets | | |
| Vaccines/BioDefense | $2,041,905 | $1,025,220 |
| BioTherapeutics | 96,424 | 204,308 |
| Corporate | 4,216,957 | 5,724,720 |
| Total | $6,355,286 | $6,954,248 |

**ITEM 2 – Management's Discussion and Analysis OF FINANCIAL CONDITION 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. Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2014. 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 expressions, however, these words are not the 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 U.S. Securities and Exchange Commission 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 that we make in this report and our other reports filed with the U.S. Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business. We provide addresses to internet sites solely for the information of investors. We do not intend any addresses to be active links or to otherwise incorporate the contents of any website into this report.*

**Our Business Overview**

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a first-in-class photodynamic therapy (SGX301) utilizing safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"), proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203), and acute radiation enteritis (SGX201), and our novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis in head and neck cancer.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, VeloThrax™, our anthrax vaccine candidate, OrbeShield™, our GI acute radiation syndrome ("GI ARS") therapeutic candidate, and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs

currently is supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government contract funding. With the awarded government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID to advance the development of OrbeShield™ for the treatment of GI ARS.

An outline for our business strategy follows:

Initiate a Phase 3 clinical trial of SGX301 for the treatment of CTCL;
Conduct a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
Initiate a Phase 3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;
Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis;
Develop RiVax™ and VeloThrax™ in combination with our ThermoVax™ technology, 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;
Advance the preclinical and manufacturing development of OrbeShield™ as a biodefense medical countermeasure for the treatment of GI ARS;
Continue to apply for and secure additional government funding for each of our 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 merger/acquisition strategies.

**Corporate Information**

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, the Company merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to "Immunotherapeutics, Inc." We changed our name to "Endorex Corp." in 1996, to "Endorex Corporation" in 1998, to "DOR BioPharma, Inc." in 2001, and finally to "Soligenix, Inc." in 2009. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

**Our Product Candidates in Development**

The following tables summarize our product candidates under development:

**BioTherapeutic Product Candidates**

| Soligenix Product Candidate | Therapeutic Indication | Stage of Development |
|---|---|---|

| | | |
|---|---|---|
| | | Phase 2 trial completed; demonstrated significantly higher response rate (p-value < 0.04) |
| SGX301 | Cutaneous T-Cell Lymphoma | compared to placebo;<br>Phase 3 clinical trial planned for the second half of 2015, with data expected in the second half of 2016 |
| SGX942 | Oral Mucositis in Head and Neck Cancer | Phase 2 trial initiated in the second half of 2013, with data expected in the second half of 2015 |
| SGX203** | Pediatric Crohn's disease | Phase 1/2 clinical trial completed June 2013, data pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed;<br>Phase 3 clinical trial planned for the first half of 2016, with data expected in the second half of 2017 |
| SGX201** | Acute Radiation Enteritis | Phase 1/2 clinical trial complete;<br>safety and preliminary efficacy demonstrated;<br>Phase 2 trial planned for the second half of 2016, with data expected in the first half of 2017 |

**Vaccine Thermostability Platform****

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

**Vaccines/BioDefense Products****

| Soligenix Product Candidate | Indication | Stage of Development |
|---|---|---|
| RiVax™ | Vaccine against Ricin Toxin Poisoning | Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated; Phase 1/2 trial planned for the first half of 2016 |
| VeloThrax™ | Vaccine against Anthrax Poisoning | Pre-clinical; Phase 1 clinical trial planned for second half of 2016 |
| OrbeShield™ | Therapeutic against GI ARS | Pre-clinical program initiated |
| SGX943 | Melioidosis | Pre-clinical |

*** Contingent upon continued government contract/grant funding or other funding source*

**BioTherapeutics Overview**

***SGX301 – for Treating Cutaneous T-Cell Lymphoma***

SGX301 is a novel, first-in-class, photodynamic therapy that utilizes safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. Hypericin is also found in several species of *Hypericum* plants, although the drug used in SGX301 is chemically synthesized by a proprietary manufacturing process and not extracted from plants. Importantly, hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet light. Other light therapies using UVA light result in serious adverse effects including secondary skin cancers.

Combined with photoactivation, in clinical trials hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In both settings, it appears that the mode of action is an induction of cell death in a concentration as well as a light dose-dependent fashion. These effects appear to result, in part, from the generation of singlet oxygen during photoactivation of hypericin.

Hypericin is one of the most efficient known generators of singlet oxygen, the key component for phototherapy. The generation of singlet oxygen induces necrosis and apoptosis in adjacent cells. The use of topical hypericin coupled with directed visible light results in generation of singlet oxygen only at the treated site. We believe that the use of visible light (as opposed to cancer-causing ultraviolet light) is a major advance in photodynamic therapy. In a published Phase 2 clinical study in CTCL, after six weeks of twice weekly therapy, a majority of patients experienced a statistically significant (p-value $\leq 0.04$) improvement with topical hypericin treatment whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively.

SGX301 has received orphan drug designation as well as Fast Track designation from the U.S. FDA. The Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven year term of market exclusivity for SGX301 upon final FDA approval, orphan drug designation also positions us to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of FDA user fees for the potential submission of a New Drug Application ("NDA") for SGX301, and certain tax credits. In addition, 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 NDA for SGX301 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. SGX301 also was granted orphan drug designation from the European Medicines Agency Committee for Orphan Medical Products.

We anticipate initiating a Phase 3 clinical study of SGX301 in the treatment of CTCL in the second half of 2015.

We estimate the potential worldwide market for SGX301 is in excess of $250 million for all applications, including the treatment of CTCL. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

**Cutaneous T-Cell Lymphoma**

CTCL is a class of non-Hodgkin's lymphoma ("NHL"), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs, which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These skin-trafficking malignant T-cells migrate to the skin, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. Mycosis fungoides ("MF") is the most common form of CTCL. It generally presents with skin involvement only, manifested as scaly, erythematous patches. Advanced disease with diffuse lymph node and visceral organ involvement is usually associated with a poorer response rate to standard therapies. A relatively uncommon sub-group of CTCL patients present with extensive skin involvement and circulating malignant cerebriform T-cells, referred to as Sézary syndrome. These patients have substantially graver prognoses than those with MF.

CTCL mortality is related to stage of disease, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no FDA-approved drug for front-line treatment of early stage CTCL. Treatment of early-stage disease generally involves skin-directed therapies. One of the most common unapproved therapies used for early-stage disease is oral 5 or 8-methoxypsoralen ("Psoralen") given with ultraviolet A ("UVA") light, referred to as PUVA, which is approved for dermatological conditions such as disabling psoriasis not adequately responsive to other forms of therapy, idiopathic vitiligo and skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. Psoralen is a mutagenic chemical that interferes with DNA causing mutations and other malignancies. Moreover, UVA is a carcinogenic light source that when combined with the Psoralen, results in serious adverse effects including secondary skin cancers; therefore, the FDA requires a Black Box warning for PUVA.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the approximate 500,000 individuals living with NHL. We estimate, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL, that it affects over 20,000 individuals in the U.S., with approximately 2,800 new cases seen annually.

***SGX94***

SGX94 is an innate defense regulator ("IDR") that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing.

SGX94 is based on a new class of short, synthetic peptides known as IDRs that have a novel mechanism of action in that it is simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs represent a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs may be active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy.

SGX94 has demonstrated efficacy in numerous animal disease models including mucositis, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. SGX94 was shown to be safe and well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. SGX94 is the subject of an open Investigational New Drug ("IND") application which has been cleared by the FDA. We believe that market opportunities for SGX94 include mucositis, acute methicillin resistant *Staphylococcus aureus* (MRSA) bacterial infections, acinetobacter, melioidosis, acute radiation syndrome and as a vaccine adjuvant, with potential opportunities for non-dilutive funding to support the development.

***SGX942 – for Treating Oral Mucositis in Head and Neck Cancer***

SGX942 is our product candidate containing our IDR technology platform, SGX94, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the

treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA.

We initiated a Phase 2 clinical study of SGX942 in the treatment of oral mucositis in head and neck cancer patients in the second half of 2013 and expect to complete this trial in the fourth quarter of 2015.

We estimate the potential worldwide market for SGX942 is in excess of $500 million for all applications, including the treatment of oral mucositis. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

**Oral Mucositis**

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the U.S. per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The GI damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of oral mucositis, that oral mucositis is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (greater than 80% incidence of severe mucositis) and is common in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

***Oral BDP***

Oral BDP (beclomethasone 17,21-dipropionate) represents a first-of-its-kind oral, locally acting therapy tailored to treat GI inflammation. 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. Oral BDP 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.

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We are planning to pursue development programs in the treatment of pediatric Crohn’s disease, acute radiation enteritis, and GI ARS pending further grant funding. We are also exploring the possibility of testing oral BDP for local inflammation associated with ulcerative colitis, among

other indications.

We are pursuing orphan drug designations for relevant indications as appropriate in both the U.S. and Europe. An orphan drug designation provides for seven and ten years of market exclusivity upon approval in the U.S. and Europe, respectively.

***SGX203 –for Treating Pediatric Crohn's Disease***

SGX203 is a two tablet delivery system of BDP specifically designed for oral use that allows for administration of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has given SGX203 orphan drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease.

We anticipate initiating a Phase 3 clinical study of SGX203 in the treatment of pediatric Crohn’s disease in the first half of 2016.

We estimate the potential worldwide market for oral BDP is in excess of $500 million for all applications, including the treatment of pediatric Crohn’s disease. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

**Pediatric Crohn's Disease**

Crohn's disease 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 Ashkenazi 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. We estimate, based upon our review of historic published studies and reports, and an interpolation of data on the incidence of Pediatric Crohn’s disease, that Pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the U.S. with a comparable number in Europe. Crohn’s disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (approximately 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 – for Preventing Acute Radiation Enteritis***

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. In 2012, we 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 ("NIH") 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 and Research ("SBIR") grant awarded by the National Institutes of Health ("NIH"). We are currently working with our Radiation Enteritis medical advisory board in pursuing additional funding from the NIH to support the clinical development program.

We have received Fast Track designation from the FDA for SGX201 for acute radiation enteritis.

We estimate the potential worldwide market for oral BDP is in excess of $500 million for all applications, including the treatment of acute radiation enteritis. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

**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 B 12 are not well absorbed.

Symptoms will usually resolve within two to six 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.

We estimate, based upon our review of historic published studies and reports, and an interpolation of data on the treatment courses and incidence of cancers occurring in the abdominal and pelvic regions, there to be over 100,000 patients annually in the U.S., with a comparable number in Europe, who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis.

**Vaccines/BioDefense Overview**

***ThermoVax™ – Thermostability Technology***

Our 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. Based on historical reports from the World Health Organization and other scientific reports, we believe that a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. 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. We believe that the savings realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. We believe that elimination of the cold chain could further facilitate the use of these vaccines in the lesser developed parts of the world. ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

ThermoVax™ development was supported pursuant to our $9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax™) and anthrax (VeloThrax™) vaccines. 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 our aluminum-adjuvanted ricin toxin vaccine, RiVax™ and our aluminum-adjuvanted anthrax vaccine, VeloThrax™. Each vaccine was manufactured under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax™ was kept at 40 degrees C (104 degrees Fahrenheit) for up to one year, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. 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. When VeloThrax™ was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we have also demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists. Additionally, the University of Colorado conducted a study that demonstrated a heat stable vaccine formulation of a human papillomavirus (HPV) vaccine. The work was conducted by Drs. Randolph and Garcea and demonstrated the successful conversion of a commercial virus-like particle (VLP) based vaccine requiring cold chain storage to a subunit, alum-adjuvanted, vaccine which is stable at ambient temperatures. This work, funded by a University of Colorado Seed grant and the Specialized Program of Research Excellence (SPORE) in cervical cancer, is the first demonstration of the utility of ThermoVax™ technology for the development of a subunit based commercial vaccine. The HPV vaccine formulation was found to be stable for at least 12 weeks at 50 degrees C. In the study, mice immunized with the ThermoVax™-stabilized HPV subunit vaccine were also found to achieve immune responses similar to the commercial HPV vaccine, Cervarix®, as measured by either total antibody levels or neutralizing antibody levels. Moreover, whereas the immune responses to Cervarix® were reduced after storage for 12 weeks at 50 degrees C, the ThermoVax™ formulated vaccine retained its efficacy. The results were published online in the European Journal of Pharmaceutics and Biopharmaceutics

(see http://www.sciencedirect.com/science/article/pii/S0939641115002416).

We also entered into a collaboration agreement with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawai i at Mānoa and Hawaii Biotech, Inc. (“HBI”) to develop a heat stable subunit Ebola vaccine. Dr. Lehrer, a co-inventor of the Ebola vaccine with HBI, has shown proof of concept efficacy with subunit Ebola vaccines in non-human primates. The most advanced Ebola vaccines involve the use of vesicular stomatitis virus and adenovirus vectors – live, viral vectors which complicate the manufacturing, stability and storage requirements. Dr. Lehrer’s vaccine candidate is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI have developed a robust manufacturing process for the required proteins. Application of ThermoVax™ may allow for a product that can avoid the need for cold chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world.

We intend to seek out potential partnerships with companies marketing FDA/ex-U.S. health authority approved Alum adjuvanted vaccines and currently developing Alum adjuvanted vaccines that are interested in eliminating the need for cold chain for their products. We believe that ThermoVax™ will enable us to expand our 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).

29

***RiVax™ – Ricin Toxin Vaccine***

RiVax™ is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin, and if approved, would be the first ricin vaccine. 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. RiVax™ has demonstrated statistically significant ($p < 0.0001$) preclinical survival results in a lethal aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, (PNAS Epub ahead of print March 9, 2015), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies that we believe may 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 this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial completed in September 2012, sponsored by University of Texas Southwestern Medical Center ("UTSW"), evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum). The results of the Phase 1B study indicated that Alum adjuvanted RiVax™ was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax™. The outcomes of this second study were published in the Clinical and Vaccine Immunology (Vitetta et al., 2012, Recombinant Ricin Vaccine Phase 1B Clinical Trial, Clin. Vaccine Immunol. 10:1697-9). We have adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and are further establishing correlates of the human immune response in non-human primates.

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 UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately $25 million in grant funding from the NIH for the development of RiVax™. In September 2014, we entered into a contract with the NIH for the development of RiVax™ that would provide up to an additional $24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH.

RiVax™ has been granted orphan drug designation by the FDA for the prevention of ricin intoxication.

Assuming development efforts are successful for RiVax™, we believe potential government procurement contract(s) could reach $200 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

**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 Investigations Bioterror report released in November 2007 titled *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). In recent years, Al Qaeda in the Arabian Peninsula has threatened the use of ricin toxin to poison food and water supplies and in connection with explosive devices. Domestically, the threat from ricin remains a concern for security agencies. As recently as April 2013, letters addressed to the President, a U.S. Senator and a judge tested positive for ricin.

The Center for Disease Control 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. The recent ricin threat to government officials has heightened the awareness of this toxic threat. 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 our proprietary vaccine candidate based on a recombinant protective antigen ("rPA") derivative intended for use against anthrax. We have entered into an exclusive license option with Harvard College to license VeloThrax™ (also known as DNI for dominant negative inhibitor) for a vaccine directed at the prevention of anthrax infection of humans. VeloThrax™ is a translocation-deficient mutant of a protective antigen 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 protective antigen translocation step, anthrax toxin trafficking and function cease. We believe that VeloThrax™ is 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. Our studies of VeloThrax™ will be at a dose 1,000 times lower than previously tested for an intramuscular or intradermal vaccine.

We believe that 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™, we believe that we 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, current Good Manufacturing Practice ("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. We expect that VeloThrax™ will combine a combination of a stable, readily manufactured mutant rPA subunit antigen with next generation, clinically compatible adjuvants 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. We believe that VeloThrax™ has the potential to 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. We also intend 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.

Assuming development efforts are successful for VeloThrax™, we believe potential government procurement contract(s) could reach $500 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

**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™ – for Treating GI Acute Radiation Syndrome***

OrbeShield™ is an oral immediate and delayed release formulation of the topically active corticosteroid BDP and is being developed for the treatment of GI ARS. Corticosteroids are a 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 two 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 the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. We are seeking to treat the same type of toxicity in our acute radiation enteritis clinical program with SGX201. As a result, we believe that OrbeShield™ has the potential to be a “dual use” compound, a desirable characteristic which is a specific priority of BARDA for ARS and other medical countermeasure indications. The FDA has cleared the IND application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS.

In September 2013, we received two government contracts from BARDA and NIAID for the advanced preclinical and manufacturing development of OrbeShield™ leading to FDA approval to treat GI ARS. The BARDA contract contains a two year base period with two contract options, exercisable by BARDA, for a total of five years and up to $26.3 million. The NIAID contract consists of a one year base period and two contract options, exercisable by NIAID, for a total of three years and up to $6.4 million. Previously, development of OrbeShield™ had been largely supported by a $1 million NIH grant to Soligenix's academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, we received an SBIR grant from NIAID of approximately $600,000 to support further preclinical development of OrbeShield™ for the treatment of acute GI ARS. The FDA has given OrbeShield™ orphan drug designation and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

Assuming development efforts are successful for OrbeShield™, we believe potential government procurement contracts could reach as much as $450 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

**GI Acute Radiation Syndrome**

ARS occurs after toxic radiation exposure and involves several organ systems, notably the bone marrow, the GI tract and later the lungs. In the event of a nuclear disaster or terrorist detonation of a nuclear bomb, casualties exposed to greater than 2 grays ("Gy") of absorbed radiation are at high risk for development of clinically significant ARS. Exposure to high doses of radiation exceeding 10-12 Gy causes acute GI injury which can result in death. The GI tract is highly sensitive due to the continuous need for crypt stem cells and production of mucosal epithelium. The extent of injury to the bone marrow and the GI tract are the principal determinants of survival after exposure to TBI. Although the hematopoietic syndrome can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. As a result, we believe there is an urgent medical need for specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

***SGX943– for Treating Melioidosis***

SGX943 uses the same active ingredient as SGX94 and is being developed in preclinical studies as a potential treatment for melioidosis. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), we believe it is particularly relevant for antibiotic-resistant bacteria. The bacteria which causes melioidosis, *Burkholderia pseudomallei,* is known to be resistant to most antibiotics and to require prolonged treatment with the few antibiotics that do work. In February 2014, we were awarded a one-year NIAID SBIR award of

approximately $300,000 to further evaluate SGX943 as a potential treatment for melioidosis. Preclinical results to date have demonstrated that SGX943 treatment, in combination with standard of care antibiotics such as doxycycline, can statistically significantly enhance survival in a lethal murine pneumonic melioidosis model ($p< 0.001$).

**Melioidosis**

Melioidosis is a potentially fatal infection caused by the Gram-negative bacillus, *Burkholderia pseudomallei* (“Bp”). Highly resistant to many antibiotics, Bp can cause an acute disease characterized by a fulminant pneumonia and a chronic condition that can recrudesce. There is no preventive vaccine or effective immunotherapy for melioidosis. We believe that there is an unmet medical need for improved prevention and therapy.

Bp infection (melioidosis) is a major public health concern in the endemic regions of Southeast Asia and Northern Australia. In Northeast Thailand, which has the highest incidence of melioidosis, the mortality rate associated with Bp infection is over 40 percent, making it the third most common cause of death from infectious disease in that region after HIV/AIDS and tuberculosis. Bp activity is seen in Southeast Asia, South America, Africa, the Middle East, India, and Australia. The highest pockets of disease activity occur in Northern Australia and Northeast Thailand with increasing recognition of disease activity in coastal regions of India.

Beyond its public health significance, Bp and the closely-related *Burkholderia mallei* ("Bm") are considered possible biological warfare agents by the DHHS because of the potential for widespread dissemination through aerosol. Bp, like its relative Bm, the cause of Glanders, was studied by the U.S. as a potential biological warfare agent, but was never weaponized. It has been reported that the Soviet Union was also experimenting with Bp as a biological warfare agent. Both Bp and Bm have been designated high priority threats by the DHHS in its PHEMCE Strategy released in 2012 and are classified as Category B Priority Pathogens by NIAID.

**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 rights for our current product candidates 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 industry partners. These rights can also be sold or sub-licensed as part of our strategy to partner our product candidates 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 extend the lives of the patents. We capitalize such costs and amortize intangibles on a straight-line basis 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. No such write downs have occurred during the three and nine months ended September 30, 2015 and 2014.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us on September 30, 2015. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.
Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.
Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair value based on the short-term maturity of these instruments. We recognize all derivative financial instruments as assets or liabilities in the financial statements and measure them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with our June 2013 offering were accounted for as derivatives.

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 government contracts and grants. Recording of revenue is applied in accordance with FASB ASC 605, *Revenue Recognition,* ASC 605-25 and/or ASU, 2009-13, *Revenue Recognition – Multiple Element Arrangements*. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when we incur reimbursable internal expenses that are related to the government contracts and grants.

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 provisions in our outstanding warrants and determined that warrants issued in connection with our June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of our common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants are recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. All other warrants issued were indexed to our own stock and therefore are accounted for as equity instruments for 2015 and 2014.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. 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% on 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.

From time to time, we issue restricted shares of our common stock to vendors and consultants as compensation for services performed. Share-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.

We determine share-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. Share-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 Nine Months Ended September 30, 2015 Compared to September 30, 2014***

For the three months ended September 30, 2015, we had net income of $2,774,348 as compared to a net loss of $4,349,555 for the same period in the prior year, representing an increase of $7,123,903 or 164%. For the nine months ended September 30, 2015, we had a net loss of $5,772,668 as compared to a net loss of $8,629,780 for the same period in the prior year, representing a decrease of $2,857,112 or 33%. Included in the net income for the three months and the net loss for the nine months ended September 30, 2015 is the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public financing. The change in the fair value of the warrant liability for the three months ended September 30, 2015 and 2014 resulted in income of $4,047,742 and $791,395, respectively. The change in the fair value of the warrant liability is attributable to an increase/decrease in warrants as a result of warrants exercised, a decrease in the remaining warrant term and change in our closing stock price. For the nine months ended September 30, 2015 and 2014, the change in fair value resulted in an expense of ($907,368) and ($203,703), respectively.

For the three and nine months ended September 30, 2015, revenues relate to government contracts and grants awarded in support of our development of OrbeShield™ for the treatment of GI ARS and RiVax™, and other development programs. For the three months ended September 30, 2015, we had revenues of $3,879,675 as compared to $2,787,709 for the same period in the prior year, representing an increase of $1,091,966 or 39%. For the nine months ended September 30, 2015, we had revenues of $5,795,788 as compared to $5,116,554 for the same period in the prior year, representing an increase of $679,234 or 13%. The increase in revenues is primarily related to continued progress on our OrbeShield™ and RiVax™ contracts.

We incurred costs related to those revenues for the three months ended September 30, 2015 and 2014 of $3,050,814 and $2,109,530, respectively, representing an increase of $941,284, or 45%. For the nine months ended September 30, 2015, costs related to revenues were $4,394,915 as compared to $3,773,095 for the same period in the prior year, representing an increase of $621,820, or 16%. These costs relate to allocated employee costs and payments due to subcontractors in connection with research performed pursuant to our contracts and grants.

Our gross profit for the three months ended September 30, 2015 was $828,861 as compared to $678,179 for the same period in 2014, representing an increase of $150,682 or 22%. For the nine months ended September 30, 2015, gross profit was $1,400,873 as compared to $1,343,459 for the same period in the prior year, representing an increase of $57,414, or 4%. The increase is primarily due to our government contracts which provide a management fee and higher negotiated reimbursement for fixed overhead as compared to our government grants.

Research and development expense for the three months ended September 30, 2015 was $1,259,015 as compared to $5,089,179 for the same period in 2014, representing a decrease of $3,830,164, or 75%. This decrease is primarily related to the acquisition of certain assets related to a synthetic hypericin product candidate, which we refer to as SGX301, from Hy Biopharma, Inc. (“Hy Biopharma”) for $4,000,000, which was charged to research and development expense due to the fact the acquired assets will be used in our current research and development program activities and do not have alternate future use pursuant to generally accepted accounting principles in the United States. For the nine months ended September 30, 2015, research and development expense was $3,731,813 as compared to $7,333,024 for the same period in the prior year, representing a decrease of $3,601,211 or 49%. This decrease is primarily a result of the acquisition of assets from Hy Biopharma.

General and administrative expenses for the three months ended September 30, 2015 were $839,512 as compared to $730,378 for the same period in 2014, representing an increase of $109,134 or 15%. For the nine months ended September 30, 2015, general and administrative expenses were $2,531,744 as compared to $2,437,553, representing an increase of $94,191 or 4%. The increase for the three and nine months ended September 30, 2015 is due to increased spending on outside professional services.

Other income for the three months ended September 30, 2015 was $4,044,014 as compared to $791,823, reflecting an increase in income of $3,252,191. For the nine months ended September 30, 2015 other (expense) was $(909,984) as compared to $(202,662), reflecting an increase in expense of ($707,322). The change in both the three and nine months ended September 30, 2015 is primarily due to the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering.

**Financial Condition**

***Cash and Working Capital***

As of September 30, 2015, we had cash and cash equivalents of $4,033,326 as compared to $5,525,094 as of December 31, 2014, representing a decrease of $1,491,768 or 27%. As of September 30, 2015, we had working capital of $1,374,321, which excludes a non-cash warrant liability of $2,139,599, as compared to working capital of $3,174,214, which excludes a non-cash warrant liability of $3,789,562, as of December 31, 2014, representing a decrease of $1,799,893 or 57%. The decrease is primarily related to expenditures to support the Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer and manufacture of clinical supplies to support the Phase 3 clinical trial of SGX301 for the treatment of CTCL.

Based on the Company’s current rate of cash outflows, cash on hand, proceeds from our government contract and grant programs, proceeds available from various equity lines and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures for at least the next twelve months.

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

We have up to approximately $45.6 million in active contract and grant funding still available to support our associated research programs through 2015 and beyond. We plan to submit additional grant and contract 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 NOL sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $616,872 in proceeds from the sale of NJ NOL in 2014, we expect to participate in the program during 2015 and beyond as the program is available;
We have an aggregate of $17.9 million available from equity facilities through 2016.

We may seek additional capital in the private and/or public equity markets, pursue government contracts and grants as well as business development activities to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are evaluating additional equity financing opportunities on an ongoing basis 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.

***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 $17.7 million before any grant reimbursements, of which $8.0 million relates to the BioTherapeutics business and $9.7 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately $9.7 million to offset research and development expenses of the Vaccines/BioDefense business segment.

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

| | 2015 | 2014 |
|---|---|---|
| Research & Development Expenses | | |
| Oral BDP | $548,061 | $867,374 |
| RiVax™ and ThermoVax™ Vaccines | 381,172 | 475,370 |
| SGX943 | 10,671 | - |
| SGX301 | 1,310,279 | 4,000,000 |
| SGX942 | 1,179,335 | 1,817,446 |
| Other | 302,295 | 172,834 |
| Total | $3,731,813 | $7,333,024 |
| | | |
| Reimbursed under Government Contracts and Grants | | |
| Oral BDP | 3,748,875 | 2,948,995 |
| RiVax™ and ThermoVax™ Vaccines | 561,297 | 645,802 |
| Other | 84,743 | 178,298 |
| Total | 4,394,915 | 3,773,095 |
| | | |
| Grand Total | $8,126,728 | $11,106,119 |

***Contractual Obligations***

We have commitments of approximately $475,000 as of September 30, 2015 relating to several licensing agreements with consultants and universities. Additionally, we have collaboration and license agreements, which upon clinical or commercialization success may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

In December 2014, we entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months is approximately $12,300 per month, or approximately $20.85 per square foot. This rent increases to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months, and thereafter to approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease.

On September 3, 2014, we entered into an asset purchase agreement with Hy Biopharma pursuant to which we acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of a synthetic hypericin product candidate, SGX301. As consideration for the assets acquired, we paid $250,000 in cash and issued

1,849,113 shares of common stock with a fair value of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in our research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, we will be required to make payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company not to exceed 19.9% ownership of its outstanding stock.

In February 2007, our Board of Directors authorized the issuance of 50,000 shares of our common stock to Dr. Schaber immediately prior to 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 our assets are transferred from us and/or our stockholders to a third party. Dr. Schaber's amended employment agreement includes our obligation to issue such shares if such event occurs.

As a result of these above agreements, we have future contractual obligations over the next five years as follows:

| Year | Research and Development | Property and Other Leases | Total |
|---|---|---|---|
| October 1 through December 31, 2015 | $ 75,000 | $39,000 | $114,000 |
| 2016 | 100,000 | 157,000 | 257,000 |
| 2017 | 100,000 | 151,000 | 251,000 |
| 2018 | 100,000 | 52,000 | 152,000 |
| 2019 | 100,000 | - | 100,000 |
| Total | $ 475,000 | $399,000 | $874,000 |

**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, the 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.

**PART II - OTHER INFORMATION.**

**ITEM 1A – RISK FACTORS**

Our business faces significant risks. These risks include those disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as supplemented by the additional risk factors included below. If any of the events or circumstances described in the referenced risks actually occur, our business, financial condition or results of operations could be materially adversely affected and such events or circumstances could cause our actual results to differ materially from the results contemplated by the “forward-looking” statements contained in this report. These risks should be read in conjunction with the other information set forth in this Quarterly Report as well as in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in our periodic reports on Form 10-Q and Form 8-K. 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.

***The sale of our common stock pursuant to the terms of the Equity Line Purchase Agreements could cause the price of our common stock to decline.***

On July 29, 2015, we entered into equity purchase agreements (the “Equity Line Purchase Agreements”) with certain accredited investors (the “Investors”). Pursuant to the Equity Line Purchase Agreements, the Investors have committed to purchase up to an aggregate of $10 million of our common stock. The shares that may be sold pursuant to the Equity Line Purchase Agreements in the future may be sold by us to the Investors at our sole discretion from time to time, commencing on August 21, 2015, the date on which the U.S. Securities and Exchange Commission declared effective the registration statement registering the resale of the shares of common stock that may be issued to the Investors under the Equity Line Purchase Agreements, until December 31, 2016. The per share purchase price for the shares that we may sell to the Investors under the Equity Line Purchase Agreements will fluctuate based on the price of our common stock, and will be equal to 80% of the lowest daily volume weighted average price of the common stock for the five consecutive trading days immediately following our request for the Investors to purchase the shares. Depending on market liquidity at the time, sale of such shares may or may not cause the trading price of our common stock to decline.

**ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

On August 31, 2015, the Company issued 50,000 shares of common stock to a vender for partial consideration for services performed. The per share issuing price of the Company's common stock was $1.43.

The Company believes the issuance of these shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering. The recipients of the securities in each of these transactions represented their intentions to acquire securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. The recipients either have enough knowledge and experience in finance and business matters to be able to evaluate the risks and merits of the investment or are able to bear the investment's economic risk. All recipients either received or had adequate access, through their business or other relationships with the Company, to information about the Company.

**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.**

November 12, 2015 by /s/ Christopher J. Schaber
Christopher J. Schaber, PhD

President and Chief Executive Officer

(Principal Executive Officer)

November 12, 2015 by /s/ Joseph M. Warusz
Joseph M. Warusz, CPA

Vice President, Finance and
Acting Chief Financial Officer

(Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

| EXHIBIT NO. | DESCRIPTION |
|---|---|
| 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. |

**EXHIBIT 31.1**

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)**

**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Christopher J. Schaber, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of the Soligenix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 12, 2015 **/s/ Christopher J. Schaber**
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**EXHIBIT 31.2**

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)**

**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Joseph M. Warusz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of the Soligenix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 12, 2015 **/s/ Joseph M. Warusz**
Joseph M. Warusz, CPA
Vice President of Finance,
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

**EXHIBIT 32.1**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906**

**OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Form 10-Q of Soligenix, Inc. (the "Company") for the fiscal quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 12, 2015 **/s/ Christopher J. Schaber**
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**EXHIBIT 32.2**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906**

**OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Form 10-Q of Soligenix, Inc. (the "Company") for the fiscal quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 12, 2015 **/s/ Joseph M. Warusz**
Joseph M. Warusz, CPA
Vice President of Finance,
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)