SOLIGENIX, INC.
Form 424B3
August 19, 2011

Prospectus Supplement dated August 19, 2011 Filed Pursuant to Rule 424(b)(3)
File No. 333-157322

SOLIGENIX, INC.

This prospectus supplement supplements:

the prospectus dated April 22, 2011 relating to the offer and sale by the selling stockholders identified in the prospectus of up to 44,491,610 shares of our common stock.

This prospectus supplement contains the Form 10-Q that we filed with the Securities and Exchange Commission on August 12, 2011. This prospectus supplement should be read in conjunction with, and may not be utilized without, the relevant prospectus, which is to be delivered with this prospectus supplement. This prospectus supplement is qualified by reference to the relevant prospectus except to the extent that the information in this prospectus supplement updates and supersedes the information contained in such 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 determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Quarterly Period Ended June 30, 2011

or

o 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 | 41-1505029 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |
| 29 EMMONS DRIVE, SUITE C-10 PRINCETON, NJ | 08540 |
| (Address of principal executive offices) | (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 x No o

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 o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer,

or a smaller reporting company. See definition of “accelerated filer” and “large accelerated filer” in Rule 112b-2 of the Exchange Act (Check one).

| Large accelerated filer o | Accelerated filer o | Non-accelerated filer o | Smaller reporting company x |
|---|---|---|---|

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

As of August 9, 2011, 220,791,077 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

SOLIGENIX, INC.

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets
(Unaudited)

| | June 30, 2011 | December 31, 2010 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $4,156,749 | $7,451,714 |
| Grants receivable | 336,560 | 120,787 |
| Other receivable | 4,322 | 251,864 |
| Prepaid expenses | 91,635 | 187,494 |
| Total current assets | 4,589,266 | 8,011,859 |
| | | |
| Office furniture and equipment, net | 17,100 | 20,699 |
| Intangible assets, net | 1,246,543 | 1,235,989 |
| Total assets | $5,852,909 | $9,268,547 |
| | | |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $1,373,974 | $1,674,175 |
| Accrued compensation | 49,302 | 236,581 |
| Total current liabilities | 1,423,276 | 1,910,756 |
| Commitments and contingencies | | |
| Shareholders' equity: | | |
| Preferred stock; 5,000,000 shares authorized; none issued or outstanding | - | - |
| Common stock, $.001 par value; 400,000,000 shares authorized; 218,240,167 shares and 216,192,360 shares issued and outstanding in 2011 and 2010, respectively | 218,240 | 216,192 |
| Additional paid-in capital | 123,601,900 | 122,880,378 |
| Accumulated deficit | (119,390,507) | (115,738,779) |
| Total shareholders' equity | 4,429,633 | 7,357,791 |
| Total liabilities and shareholders' equity | $5,852,909 | $9,268,547 |

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Three and Six Months Ended June 30, 2011 and 2010
(Unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Revenues, principally from grants | $405,820 | $444,642 | $1,213,825 | $780,438 |
| Cost of revenues | (349,511) | (349,093) | (903,548) | (622,866) |
| Gross profit | 56,309 | 95,549 | 310,277 | 157,572 |
| | | | | |
| Operating expenses: | | | | |
| Research and development | 1,307,051 | 1,070,711 | 2,563,186 | 2,669,002 |
| General and administrative | 450,179 | 544,506 | 1,014,091 | 1,082,603 |
| Stock-based compensation – research and development | 206,671 | 39,948 | 323,340 | 80,152 |
| Stock-based compensation – general and administrative | 25,198 | 20,654 | 65,296 | 42,713 |
| Total operating expenses | 1,989,099 | 1,675,819 | 3,965,913 | 3,874,470 |
| | | | | |
| Loss from operations | (1,932,790) | (1,580,270) | (3,655,636) | (3,716,898) |
| | | | | |
| Other income: | | | | |
| Interest income, net | 1,473 | 2,977 | 3,908 | 3,345 |
| Net loss | $(1,931,317) | $(1,577,293) | $(3,651,728) | $(3,713,553) |
| | | | | |
| Basic and diluted net loss per share | $(0.01) | $(0.01) | $(0.02) | $( 0.02) |
| | | | | |
| Basic and diluted weighted average common shares outstanding | 217,998,049 | 190,751,511 | 217,424,979 | 188,644,289 |

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Shareholders' Equity
For the Six Months Ended June 30, 2011
(Unaudited)

| | Common Stock | | Additional Paid-In | Accumulated | |
|---|---|---|---|---|---|
| | Shares | Par Value | Capital | Deficit | Total |
| Balance, December 31, 2010 | 216,192,360 | $216,192 | $122,880,378 | $(115,738,779) | $7,357,791 |
| Issuance of common stock pursuant to equity line agreement – Fusion | 1,422,807 | 1,423 | 253,577 | - | 255,000 |
| Issuance of common stock for stock option and warrant exercises | 625,000 | 625 | 68,125 | - | 68,750 |
| Fair value of common stock warrants to vendors | - | - | 11,184 | - | 11,184 |
| Stock-based compensation expense | - | - | 388,636 | - | 388,636 |
| Net loss | - | - | - | (3,651,728) | (3,651,728) |
| Balance, June 30, 2011 | 218,240,167 | $218,240 | $123,601,900 | $(119,390,507) | $4,429,633 |

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

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

| | 2011 | 2010 |
|---|---|---|
| Operating activities: | | |
| Net loss | $(3,651,728) | $(3,713,553) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization and depreciation | 105,443 | 85,779 |
| Common stock or warrants issued in exchange for services | 11,184 | 122,197 |
| Stock-based compensation | 388,636 | 122,865 |
| Capitalized patent write-off | - | 378,501 |
| | | |
| Change in operating assets and liabilities: | | |
| Grants receivable | (215,773) | (87,665) |
| Other receivable | 247,542 | (8,000) |
| Inventory | - | 7,733 |
| Prepaid expenses | 95,859 | (18,228) |
| Accounts payable | (300,201) | 923,946 |
| Accrued compensation | (187,279) | (319,930) |
| Total adjustments | 145,411 | 1,207,198 |
| Net cash used in operating activities | (3,506,317) | (2,506,355) |
| | | |
| Investing activities: | | |
| | | |
| Acquisition of intangible assets | (112,398) | (168,102) |
| Purchase of office equipment | - | (947) |
| Net cash used in investing activities | (112,398) | (169,049) |
| | | |
| Financing activities: | | |
| Net proceeds from sale of common stock | - | 5,679,856 |
| Proceeds from sale of common stock pursuant to equity line | 255,000 | 70,000 |
| Proceeds from exercise of options and warrants | 68,750 | 45,540 |
| Net cash provided by financing activities | 323,750 | 5,795,396 |
| | | |
| Net increase/(decrease) in cash and cash equivalents | (3,294,965) | 3,119,992 |
| Cash and cash equivalents at beginning of period | 7,451,714 | 7,692,011 |
| Cash and cash equivalents at end of period | $4,156,749 | $10,812,003 |

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

Soligenix, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. ("Soligenix," the "Company," "we" or "us") is a late-stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. The Company maintains two active business segments: BioTherapeutics and BioDefense. Soligenix's BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, while the Company's collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® in North America and Europe, once approved. Soligenix's BioDefense business segment intends to use RiVaxTM, its ricin toxin vaccine, to support development efforts with its heat stabilization technology, and SGX202, its radiation injury program, to convert from early stage development to advanced development with the assistance of ongoing government grant funding.

The Company currently generates revenues primarily from the National Institutes of Health (the "NIH") under three active grants and from its license with Sigma-Tau, once milestones are achieved.

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

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States of America. The accompanying consolidated financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements have been condensed or omitted from this report, as is permitted by such rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The unaudited consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010. Results for interim periods are not necessarily indicative of results for the full year. The Company has experienced significant quarterly fluctuations in operating results and it expects those fluctuations will continue.

Liquidity

As of June 30, 2011, the Company had cash and cash equivalents of $4,156,749 as compared to $7,451,714 as of December 31, 2010, representing a decrease of $3,294,965. As of June 30, 2011, the Company had working capital of $3,165,990 as compared to working capital of $6,101,103 as of December 31, 2010, representing a decrease of $2,935,113 or 48%. The decrease in cash and working capital was the result of cash used in operating activities over the six month period, offset by $255,000 in proceeds from issuances of common stock under the common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). For the six months ended June 30, 2011, the Company's cash used in operating activities was $3,506,317 as compared to $2,506,355 for the same period in 2010, representing an increase of $999,962. Based on our current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, recently announced European territory license with

Sigma-Tau, which provided a $5,000,000 up front payment, proceeds from our grant-funded programs, and potential proceeds from the Fusion Capital transaction, we believe that our current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter of 2013.

Management's business strategy can be outlined as follows:

- complete the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD");
- Identify a development and marketing partner for orBec® for territories outside of North America and Europe;
- complete and report data from the Phase 1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute GVHD, treatment of chronic GI GVHD, radiation injury, and Crohn's disease;
- continue to secure additional government funding for each of our BioTherapeutics and BioDefense programs through grants, contracts and/or procurements;
- use RiVaxTM to support development efforts with our heat stabilization 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;
- acquire or in-license new clinical-stage compounds for development; and
- explore other business development and acquisition strategies.

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

- The Company has approximately $8.4 million in active grant funding still available to support its research programs through 2011 and beyond. The Company has also submitted additional grant applications for further support of its programs with various funding agencies, and has received encouraging feedback to date on the likelihood of additional funding.
- The Company has approximately $7.4 million in available capacity under the Company's Fusion Capital equity facility through October 2011. Although the Company has historically drawn down modest amounts under this agreement, the Company could draw more within certain contractual parameters;
- The Company will seek non-dilutive funding through completion of partnerships for its orBec®/oral BDP programs in territories outside North America and Europe;
- 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 Losses ("NOL") sales in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $245,810 in proceeds pursuant to NOL sales in 2010 and assuming its application is accepted, the Company expects to participate in the expanded program during 2011 and beyond; and
- The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

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 BioDefense.

Grants Receivable

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

Intangible Assets

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

The Company capitalized $112,398 and $168,102 in patent related costs during the six months ended June 30, 2011 and 2010, respectively.

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 involve significant judgment.

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The Company did not record any impairment of long-lived assets for the six months ended June 30, 2011 or 2010.

Inventory

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method and includes the cost of materials and overhead. The Company records an allowance as needed for excess inventory. During the fourth quarter of 2010, the Company disposed of certain inventory valued at $30,211 due to product expiration dates.

Revenue Recognition

Substantially all of the Company's revenues are generated from NIH grants. The Company also generates revenues from the achievement of licensing milestones (in prior periods). The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant. Licensing milestone revenues are recorded when earned.

Research and Development Costs

Research and development costs are charged to expense when incurred. 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 and employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Stock-Based Compensation

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

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

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

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

- a dividend yield of 0%;
- an expected life of 4 years;
- volatilities of 123% and 129% for 2011 and 2010, respectively;
- forfeitures at a rate of 12%; and
- risk-free interest rates of 1.21% and 1.91% in 2011 and 2010, respectively.

The Company estimates these values based on the assumptions that have been historically available. The fair value of each option grant made during 2011 and 2010 was estimated on the date of each grant using the Black-Scholes option pricing model and is then amortized ratably over the option's vesting periods, which approximates the service period.

There were 625,000 options exercised and 1,431,250 options expired or were forfeited during the 6 months ended June 30, 2011. As of June 30, 2011, the Company has 27,521,677 outstanding and exercisable options.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through June 30, 2011 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 2010 and 2009. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at June 30, 2011 or 2010. The income tax returns for 2007, 2008 and 2009 are subject to examination by the IRS and other various taxing authorities, generally for three years after they were filed.

Earnings per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented. No options and warrants were included in the 2011 and 2010 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

| | Three Months Ended June 30, | | | | | |
|---|---|---|---|---|---|---|
| | 2011 | | | 2010 | | |
| | Net Loss | Shares | EPS | Net Loss | Shares | EPS |
| Basic & Diluted EPS | $(1,931,317) | 217,998,049 | $(0.01) | $(1,577,293) | 190,751,511 | $(0.01) |

| | Six Months Ended June 30, | | | | | |
|---|---|---|---|---|---|---|
| | 2011 | | | 2010 | | |
| | Net Loss | Shares | EPS | Net Loss | Shares | EPS |
| Basic & Diluted EPS | $(3,651,728) | 217,424,979 | $(0.02) | $(3,713,553) | 188,644,289 | $(0.02) |

Shares issuable upon the exercise of options and warrants outstanding at June 30, 2011 and 2010 were 27,521,677 and 18,685,414 shares issuable upon the exercise of options, and 54,156,373 and 60,933,156 shares issuable upon the exercise of warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at June 30, 2011 were $0.24 and $0.22 per share, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at June 30, 2010 were $0.25 and $0.24 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 that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

New Accounting Pronouncements

In April 2010, the FASB issued Accounting Standards Update ("ASU") 2010-17, Revenue Recognition—Milestone Method (Topic 605) - Milestone Method of Revenue Recognition - a consensus of the FASB Emerging Issues Task Force, which provides guidance to vendors on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all of the following criteria to be considered substantive. Determining whether a milestone is substantive is a matter of judgment made at the inception of the arrangement. To be considered substantive, the following criteria must be met. The consideration earned by achieving the milestone should:

- Be commensurate with either of the following:
  - The vendor's performance to achieve the milestone
  - The enhancement of the value of the item delivered as a result of a specific outcome resulting from the vendor's performance to achieve the milestone
- Relate solely to past performance
- Be reasonable relative to all deliverables and payment terms in the arrangement

A milestone should be considered substantive in its entirety. An arrangement may include more than one milestone, and each milestone should be evaluated separately to determine whether the milestone is substantive. A vendor's decision to use the milestone method of revenue recognition for transactions within the scope of ASU 2010-17 is a policy election, and certain disclosures are required for each arrangement that includes milestone consideration accounted for in accordance with ASU 2010-17. Other proportional revenue recognition methods also may be applied as long as the application of those other methods does not result in the recognition of consideration in its entirety in the period the milestone is achieved.

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The amendments in ASU 2010-17 were effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 and had no impact to the Company upon adoption.

Note 3. Office Furniture and Equipment

Office furniture and equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. Office equipment and furniture consisted of the following:

| | June 30, 2011 | December 31, 2010 |
|---|---|---|
| Office equipment | $37,828 | $37,828 |
| Office furniture | 2,889 | 2,889 |
| | 40,717 | 40,717 |
| Less: Accumulated depreciation | (23,617) | (20,018) |
| Office furniture and equipment, net | $17,100 | $20,699 |

Depreciation expense was $1,809 and $1,546 for the three months ended June 30, 2011 and 2010, respectively, and $3,599 and $3,283 for the six months ended June 30, 2011 and 2010, respectively.

Note 4. Intangible Assets

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

| | Weighted Average Amortization Period (years) | Cost | Accumulated Amortization | Net Book Value |
|---|---|---|---|---|
| June 30, 2011 | | | | |
| Licenses | 9.2 | $462,234 | $ 210,976 | $251,258 |
| Patents | 3.9 | 2,025,182 | 1,029,897 | 995,285 |
| Total | 4.9 | $2,487,416 | $ 1,240,873 | $1,246,543 |
| December 31, 2010 | | | | |
| Licenses | 9.7 | $462,234 | $ 197,469 | $264,765 |
| Patents | 4.2 | 1,912,784 | 941,559 | 971,224 |
| Total | 5.3 | $2,375,018 | $ 1,139,028 | $1,235,989 |

Amortization expense was $52,208 and $37,982 for the three months ended June 30, 2011 and 2010, respectively and $101,845 and $82,496 for the six months ended June 30, 2011 and 2010, respectively. For the six months ended June 30, 2010, the Company incurred $378,501 in a one-time patent write off cost related to its return of the Botulinum toxin vaccine license and abandonment of related patents. This cost is reflected in research and development expense in the consolidated statement of operations.

Based on the balance of licenses and patents at June 30, 2011, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

| | Amortization Expense |
|---|---|
| 2011 | $ 225,000 |
| 2012 | $ 225,000 |
| 2013 | $ 225,000 |
| 2014 | $ 225,000 |
| 2015 | $ 225,000 |

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

Note 5. Income Taxes

At June 30, 2011, the Company had NOLs of approximately $78,000,000 for federal tax purposes and approximately $21,000,000 of New Jersey NOLs remaining after the sale of unused NOLs, portions of which are currently expiring each year until 2030. In addition, the Company had $2,948,000 of various tax credits that start expiring in December 2011 and will continue to expire through December 2030. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code (“IRC”) Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points over a three year period. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of its NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to Federal income tax assessment for years before 2007 and 2006 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service and state authorities for purposes of determining the amount of net operating loss carryforward that can be used to reduce taxable income.

The net changes in the valuation allowance for the three and six months ended June 30, 2011 and for the year ended December 31, 2010 were an increase of approximately $1,500,000 and $1,652,000, respectively, both resulting primarily from net operating losses generated. As a result of the Company’s continuing tax losses, it has recorded a full valuation allowance against a net deferred tax asset.

The Company has no tax provision for the three and six month periods ended June 30, 2011 and 2010 due to losses and full valuation allowances against net deferred tax assets.

Note 6. Shareholders’ Equity

Preferred Stock

The Company has 5 million shares of preferred stock authorized, none of which are issued or outstanding.

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Common Stock

The following items represent transactions in the Company's common stock for the three months ended June 30, 2011:

- In thirteen separate transactions during the six months ended June 30, 2011, the Company issued an aggregate of 1,422,807 shares of common stock under its existing Fusion Capital equity facility. The Company received an aggregate of $255,000 in proceeds which approximated the shares' fair market value on the date of issuance.

- As a result of stock option exercises, 625,000 shares were issued during the six months ended June 30, 2011. The Company received an aggregate of $68,750 in proceeds from these exercises.

Warrants

During 2011, the Company issued warrants to purchase 95,000 shares of common stock to consultants in exchange for their services. Expense charges of $8,498 and $11,184 were recorded during the three and six months ended June 30, 2011, respectively, as a result of these issuances which represented the estimated fair value of the services provided.

Note 7. Commitments and Contingencies

The Company has commitments of approximately $505,000 at June 30, 2011 in connection with an agreement with Numoda Corporation for electronic data capture in connection with its confirmatory Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD that began in September 2009 and is expected to complete in the second half of 2011.

The Company also has several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

On April 1, 2009, the Company entered into a sub-lease agreement through March 31, 2012 for office space in Princeton, New Jersey. The Company was required to provide 4 months of rent as a security deposit. The rent for the first 18 months was approximately $7,500 per month, or $17.00 per square foot. This rent increased to approximately $7,650 per month, or $17.50 per square foot, for the remaining 18 months. The Company records rent on a straight line basis.

In February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, upon the completion of a transaction, or series or a combination of related transactions negotiated by the Company's Board of Directors whereby, directly or indirectly, a majority of the Company's capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 450,000 common shares to employees and a consultant shall be issued.

Employees with employment contracts have severance agreements that may provide separation benefits from the Company if they are involuntarily separated from employment.

Note 8. Subsequent Events

On July 28, 2011, the Company announced the expansion and amendment of its North American licensing partnership with Sigma-Tau for the development and commercialization of orBec® into the "European Territory" (as defined in amendment). Pursuant to this amendment, the Company received an up-front payment of $5 million and granted Sigma-Tau an exclusive license to commercialize orBec® in the European Territory. The amendment requires Sigma-Tau to make additional payments to the Company in the aggregate amount of $11 million upon the achievement of milestones. Total milestone payments due from Sigma-Tau under the agreement, including the amendment, could reach up to $20 million The next milestone, a $2 million payment, will be made upon the successful completion of the confirmatory Phase 3 clinical trial of orBec® for the treatment of GI GVHD. The amendment also requires Sigma-Tau to pay the Company a 40% royalty (Soligenix to provide finished drug product) on net sales in the European Territory. Sigma-Tau will also cover all commercialization expenses, including launch activities.

On July 26, 2011, the Company and George B. McDonald, MD ("Dr. McDonald") entered into an amendment (the "License Agreement Amendment") to the Exclusive License Agreement dated November 24, 1998, as amended (the "License Agreement"). Under the License Agreement, Dr. McDonald would have been entitled to receive (i) $1,250,000 upon the closing of the Sigma-Tau Amendment; and (ii) $250,000 upon an approval of orBec® by the European Medicines Agency. Pursuant to the License Agreement Amendment, the Company paid Dr. McDonald (i) $612,500 in cash and issued 1,337,793 common shares of the Company, representing $400,000 (based upon the closing price of the Company's common stock on July 26, 2011) upon the closing of the Sigma-Tau Amendment and (ii) $400,000 in cash to be paid upon an approval of orBec® by the European Medicines Agency.

Note 9. Business Segments

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

| | Three Months Ended June 30, | |
|---|---|---|
| | 2011 | 2010 |
| Revenues, Principally from Grants | | |
| BioDefense | $335,029 | $338,104 |
| BioTherapeutics | 70,791 | 106,538 |
| Total | $405,820 | $444,642 |
| | | |
| Loss from Operations | | |
| BioDefense | $(67,425) | $(133,730) |
| BioTherapeutics | (1,663,402) | (1,237,500) |
| Corporate | (201,963) | (209,040) |
| Total | $(1,932,790) | $(1,580,270) |
| Amortization and Depreciation Expense | | |
| BioDefense | $10,183 | $13,966 |
| BioTherapeutics | 43,290 | 25,097 |
| Corporate | 542 | 465 |
| Total | $54,015 | $39,528 |
| | | |
| Interest Income, Net | | |

| | | |
|---|---|---|
| Corporate | $1,473 | $2,977 |
| | | |
| Stock-Based Compensation | | |
| BioDefense | $18,416 | $12,941 |
| BioTherapeutics | 188,255 | 27,006 |
| Corporate | 25,198 | 20,655 |
| Total | $231,869 | $60,602 |

| | Six Months Ended June 30, | |
|---|---|---|
| | 2011 | 2010 |
| Revenues, Principally from Grants | | |
| BioDefense | $871,615 | $601,894 |
| BioTherapeutics | 342,210 | 178,544 |
| Total | $1,213,825 | $780,438 |
| | | |
| Income (Loss) from Operations | | |
| BioDefense (1) | $52 | $(725,156) |
| BioTherapeutics | (3,044,729) | (2,379,256) |
| Corporate | (610,959) | (612,486) |
| Total | $(3,655,636) | $(3,716,898) |
| | | |
| Amortization and Depreciation Expense | | |
| BioDefense | $19,872 | $37,075 |
| BioTherapeutics | 84,491 | 47,718 |
| Corporate | 1,080 | 986 |
| Total | $105,443 | $85,779 |
| | | |
| Interest Income, Net | | |
| Corporate | $3,908 | $3,345 |
| | | |
| Stock-Based Compensation | | |
| BioDefense | $36,832 | $25,881 |
| BioTherapeutics | 286,508 | 54,269 |
| Corporate | 65,296 | 42,715 |
| Total | $388,636 | $122,865 |

(1) During the six months ended June 30, 2010, the Company incurred $378,501 in a one-time patent write off cost related to its anticipated return of the botulinum toxin vaccine license and abandonment of related patents. This cost is reflected in research and development expense in the consolidated statement of operations.

| | As of June 30, 2011 | As of December 31, 2010 |
|---|---|---|
| Identifiable Assets | | |
| BioDefense | $693,399 | $480,995 |
| BioTherapeutics | 896,468 | 927,973 |
| Corporate | 4,263,042 | 7,859,579 |
| Total | $5,852,909 | $9,268,547 |

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

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes including Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2010. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expression, however, these words are exclusive means of identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the SEC or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Overview:

Business Overview and Strategy

Soligenix, Inc. was incorporated in Delaware in 1987. We are a late-stage research and development biopharmaceutical company focused on developing products to treat the life-threatening side effects of cancer treatment and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. We maintain two active business segments: BioTherapeutics and BioDefense. Our BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, while our collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® in North America and Europe once approved by the U.S. Food and Drug Administration (the "FDA"). Our BioDefense business segment intends to use RiVaxTM, our ricin toxin vaccine, to support development efforts with our heat stabilization technology, and SGX202, our radiation injury program, to convert from early stage development to advanced development with the assistance of ongoing government grant funding.

Our business strategy can be outlined as follows:

- complete the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD");
- Identify a development and marketing partner for orBec® for territories outside of North America and Europe;
- complete and report data on the Phase 1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute GVHD, treatment of chronic GI GVHD, radiation injury, and Crohn's disease;
- continue to secure additional government funding for each of our BioTherapeutics and BioDefense programs through grants, contracts and/or procurements;
- use RiVaxTM to support development efforts with our heat stabilization 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;
- acquire or in-license new clinical-stage compounds for development; and
- explore other business development and acquisition strategies.

Our executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08550 and our telephone number is (609) 538-8200.

Our Products in Development

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

BioTherapeutic Products

| Soligenix Product | Therapeutic Indication | Stage of Development |
|---|---|---|
| orBec® | Treatment of Acute GI GVHD | Pivotal Phase 3 confirmatory trial enrolling; expected to complete in 2H 2011 |
| orBec® | Prevention of Acute GVHD | Phase 2 trial completed |
| orBec® | Treatment of Chronic GI GVHD | Phase 2 trial potentially to be initiated in 2H 2011 |
| SGX201 | Acute Radiation Enteritis | Phase 1/2 trial enrollment complete; Data expected in 4Q 2011 |
| LPM™ Leuprolide | Endometriosis and Prostate Cancer | Pre-clinical |

BioDefense Products

| Soligenix Product | Indication | Stage of Development |
|---|---|---|
| RiVaxTM | Vaccine against Ricin Toxin Poisoning | Phase 1B trial enrollment complete; data expected in 2H 2011 |
| SGX202 | Radiation Injury | Pre-clinical |

BioTherapeutics Overview

orBec® and oral BDP

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

Based on data from the prior Phase 3 study of orBec®, the current confirmatory Phase 3 study is a highly powered, double-blind, randomized, placebo-controlled, multi-center trial that is expected to enroll an estimated 166 patients. This trial is supported in part by a $1.2 million FDA Orphan Products grant awarded to Soligenix. The primary endpoint is the treatment failure rate at Study Day 80. This endpoint was successfully measured as a secondary endpoint (p-value 0.005) in the previous Phase 3 study as a key measure of durability following a 50-day course of treatment with orBec® (i.e., 30 days following cessation of treatment).

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

Historical Background

Two prior randomized, double-blind, placebo-controlled Phase 2 and 3 clinical trials support the ability of orBec® to provide clinically meaningful outcomes when compared with the current standard of care, including a lowered exposure to systemic corticosteroids following allogeneic transplantation. Currently, there are no approved products to treat GI GVHD. The first trial was a 60-patient Phase 2 single-center clinical trial conducted at the Fred Hutchinson Cancer Research Center (“FHCRC”) in Seattle, Washington. The second trial was a 129-patient pivotal Phase 3 multi-center clinical trial of orBec® conducted at 16 leading bone marrow/stem cell transplantation centers in the U.S. and France. Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely median time-to-treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in other key secondary endpoints such as the proportion of patients free of GVHD at Day 50 (p-value 0.05) and Day 80 (p-value 0.005) and the median time-to-treatment failure through Day 80 (p-value 0.0226), as well as a 66% reduction in mortality among patients randomized to orBec® at 200 days post-transplant with only 5 patient (8%) deaths in the orBec® group compared to 16 patient (24%) deaths in the placebo group (p-value 0.0139). Within one year after randomization in the pivotal Phase 3 trial, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died (46% reduction in mortality, p-value 0.04).

In the Phase 2 study, the primary endpoint was the clinically relevant determination of whether GI GVHD patients at Day 30 (the end of treatment) had a durable GVHD treatment response as measured by whether or not they were able to consume at least 70% of their estimated caloric requirement. The GVHD treatment response at Day 30 was 22 of 31 (71%) vs. 12 of 29 (41%) in the orBec® and placebo groups, respectively (p-value 0.02). Additionally, the GVHD treatment response at Day 40 (10 days post cessation of therapy) was 16 of 31 (52%) vs. 5 of 29 (17%) in the orBec® and placebo groups, respectively (p-value 0.007).

Based on the data from the above referenced Phase 2 and Phase 3 studies, on September 21, 2006, we filed a new drug application (“NDA”) for our lead product orBec® with the FDA for the treatment of acute GI GVHD. On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of acute GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of this letter.

In December 2008, we reached agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating orBec® for the treatment of acute GI GVHD under the FDA's Special Protocol Assessment ("SPA") procedure. An agreement via the SPA procedure is an agreement with the FDA that a Phase 3 clinical trial design (e.g., endpoints, sample size, control group and statistical analyses) is acceptable to support a regulatory submission seeking new drug approval. After the study begins, the FDA can only change a SPA for very limited reasons. Further, in June 2009, we received Protocol Assistance feedback from the European Medicines Agency ("EMEA") on the design of the Phase 3 clinical trial for orBec®. The EMEA agreed that should the new confirmatory Phase 3 study produce positive results, the data would be sufficient to support a marketing authorization in all 27 European Union member states. The confirmatory Phase 3 trial is actively enrolling patients and is expected to complete in the second half of 2011.

If the confirmatory Phase 3 trial is successful, we will file a complete response to the FDA action letter. This response is expected to be designated a class II response with a corresponding FDA review time frame of 6 months.

Mortality Results

| | Phase 3 Trial | | Phase 2 Trial | |
|---|---|---|---|---|
| | orBec® | Placebo | orBec® | Placebo |
| Number of patients randomized | 62 | 67 | 31 | 29 |
| Number (%) who died | 5 (8%) | 16 (24%) | 3 (10%) | 6 (21%) |
| Hazard ratio (95% confidence interval) | 0.33 (0.12, 0.89) | | 0.47 (0.12, 1.87) | |
| Death with infection* | 3 (5%) | 9 (13%) | 2 (6%) | 5 (17%) |
| Death with relapse* | 3 (5%) | 9 (13%) | 1 (3%) | 4 (14%) |

*Some patients died with both infection and relapse of their underlying malignancy.

Among the data from the Phase 3 clinical study of orBec® reported in the January 2007 issue of Blood, the peer-reviewed Journal of the American Society of Hematology, survival at the pre-specified endpoint of 200 days post-transplantation showed a clinically meaningful and statistically significant result. According to the manuscript, "the risk of mortality during the 200-day post-transplantation period was 67% lower with orBec® treatment compared to placebo treatment (hazard ratio 0.33; 95% CI: 0.12, 0.89; p-value 0.03, Wald chi-square test)." The most common proximate causes of death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying hematologic malignancy had contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 (4.8%) in the BDP arm. Acute or chronic GVHD was the proximate cause of death in 3/67 patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

In addition, a subgroup analysis also revealed that patients dosed with orBec® who had received stem cells from unrelated donors had a 94% reduction in the risk of mortality 200 days post-transplantation.

In this Phase 3 study, orBec® showed continued survival benefit when compared to placebo one year after randomization. Overall, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died within one year of randomization (46% reduction in mortality, p-value 0.04). Results from the Phase 2 trial also demonstrated enhanced long-term survival benefit with orBec® versus placebo. In that study, at one year after randomization, 6 of 31 patients (19%) in the orBec® group had died while 9 of 29 patients (31%) in the placebo group had died (45% reduction in mortality, p-value 0.26). Pooling the survival data from both trials demonstrated that the survival benefit of orBec® treatment was sustained long after orBec® was discontinued and extended well beyond 3 years after the transplantation. As of September 25, 2005, median follow-up of patients in the two trials was 3.5 years (placebo patients) and 3.6 years (orBec® patients), with a range of 10.6 months to 11.1 years. The risk of mortality

was 37% lower for patients randomized to orBec® compared with placebo (p-value 0.03).

A retrospective analysis of survival at 200 days post-transplantation in the supportive Phase 2 clinical trial showed consistent response rates with the Phase 3 trial; three patients (10%) who had been randomized to orBec® had died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduced hazard of day-200 mortality, although not statistically significantly different. Detailed analysis of the likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy were both reduced in the same proportion after treatment with orBec® compared to placebo. By transplantation day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in the orBec® arm and 4 of 29 patients (14%) in the placebo arm. Infection contributed to the deaths of 2 of 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in study drug discontinuation were all comparable to that of the placebo group in both trials. Patients who remained on orBec® until Day 50 in the Phase 3 study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo. This effect was far less pronounced than those seen in patients on high dose prednisone.

Commercialization and Market

We anticipate the market potential for orBec® for the treatment of acute GI GVHD to be approximately 50% of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) for the commercialization of orBec®. Sigma-Tau is a pharmaceutical company that develops novel therapies for the unmet needs of patients with rare diseases. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec® in the U.S., Canada and Mexico (the “Territory”). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment of $1 million was made in connection with the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD in September 2009. Total additional milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $9 million. Sigma-Tau will pay us a 35% royalty (Soligenix to provide finished drug product) on net sales in the Territory as well as pay for commercialization expenses, including launch activities. In connection with the execution of the collaboration and supply agreement, we entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 25 million shares of our common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price was equal to one hundred fifty percent (150%) of the average trading price of our common stock over the five trading days prior to February 11, 2009. On November 26, 2008, prior to entering the collaboration agreement, we sold Sigma-Tau 16,666,667 common shares at $0.09 per share (the market price at the time) for proceeds of $1,500,000 in exchange for the exclusive right to negotiate a collaboration deal with us until March 1, 2009.

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

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Total milestone payments due from Sigma-Tau under the agreement, including the amendment, could reach up to $20 million.

We believe the potential worldwide market for orBec® to be approximately $400 million for all GVHD applications, namely, treatment of acute and chronic GI GVHD and prevention of acute GVHD.

About GVHD

GVHD occurs in patients following allogeneic stem cell transplantation in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes from the donor (graft) marrow. Patients with mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GI GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50% of the more than 10,000 annual allogeneic transplantation patients in the U.S. will develop some form of acute GI GVHD.

GI GVHD is one of the most common causes for the failure of stem cell transplantation. These procedures are being increasingly utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat acute GI GVHD. Currently used systemic immunosuppressives utilized to control GI GVHD substantially inhibit the highly desirable Graft-versus-Leukemia ("GVL") effect of stem cell transplantations, leading to high rates of aggressive forms of relapse, as well as substantial rates of mortality due to opportunistic infection.

About Allogeneic Hematopoietic Cell Transplantation

Allogeneic hematopoietic cell transplantation ("HCT") is considered a potentially curative option for many leukemias as well as other forms of blood cancer. In an allogeneic HCT procedure, hematopoietic stem cells are harvested from the blood or bone marrow of a closely matched relative or unrelated person, and are transplanted into the patient following either high-dose chemotherapy or intense immunosuppressive conditioning therapy. The curative potential of allogeneic HCT is now partly attributed to the GVL or Graft-versus-Tumor effects of the newly transplanted donor cells to recognize and destroy malignant cells in the recipient patient.

The use of allogeneic HCT has grown substantially over the last decade due to advances in human immunogenetics, the establishment of unrelated donor programs, the use of cord blood as a source of hematopoietic stem cells and the advent of non-myeloablative conditioning regimens, or mini-transplants, that avoid the side effects of high-dose chemotherapy. Based on the latest statistics available, it is estimated that there are more than 10,000 allogeneic HCT procedures annually in the U.S. and a comparable number in Europe. Estimates as to the current annual rate of increase in these procedures are as high as 20%. High rates of morbidity and mortality occur in this patient population. Clinical trials are also underway testing allogeneic HCT for treatment of some metastatic solid tumors such as breast cancer, renal cell carcinoma, melanoma and ovarian cancer. Allogeneic transplantation has also been studied as a curative therapy for several genetic disorders, including immunodeficiency syndromes, inborn errors of metabolism, and sickle cell disease. The primary toxicity of allogeneic HCT, however, is GVHD in which the newly transplanted donor cells damage cells in the recipient's gastrointestinal tract, liver and skin.

Future Potential Indications of orBec® and oral BDP

Based on its pharmacological characteristics, orBec® may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following HCT, as well as GVHD which also occurs following organ allograft transplantation. We also have an issued U.S. patent 7,704,985 claiming the use of oral BDP to treat IBS, a painful gastrointestinal condition that affects approximately 15% of the population in the industrialized world. We also have European Patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia. We recently completed a Phase 2 trial of orBec® in the prevention of acute GVHD and announced preliminary results from this study. We are targeting to begin a Phase 2 clinical trial in the treatment of chronic GI GVHD in the second half of 2011, pending further funding. In addition, we are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with Crohn's Disease, Lymphocytic Colitis, IBS, Ulcerative Colitis, among other indications.

Prevention of Acute GVHD

We have recently completed an exploratory, randomized, double blind, placebo-controlled, Phase 2 "proof of concept" clinical trial of orBec® for the prevention of acute GVHD in patients undergoing myeloablative conditioning regimens with initiation of dosing prior to HCT and continuing through the post-transplantation period. The trial was conducted under an investigator-initiated IND by Paul Martin, M.D., at the FHCRC and was supported, in large part, by a grant from the National Institutes of Health. We did not receive any direct monetary benefit from this grant. The Phase 2 trial enrolled 140 patients with a 2:1 (orBec®:placebo) randomization plan. Preliminary results from this estimation study indicate that orBec® appears safe and well tolerated in this patient population, but did not achieve statistical significance in the primary endpoint, which was the proportion of subjects who developed acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. However, the use of orBec® resulted in fewer cases of more severe acute GVHD grades IIb-IV (21% vs. 33% of patients receiving placebo), although this difference was not statistically significant. This result has the potential to be clinically relevant because GVHD grades IIb-IV are associated with more severe disease involving the skin and liver as well as being associated with poorer outcomes, including mortality rates that approach 100% in the grade IV patient population. Further analysis of the complete dataset continues and is aimed at identifying other potential effects seen with orBec® in preventing acute GVHD.

SGX201 - Time Release Formulation of Oral BDP

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. We completed enrollment in a Phase 1/2 clinical trial testing SGX201 in acute radiation enteritis and subject follow-up is expected to be completed by the end of 2011. Patients with rectal cancer who are scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study are 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. This program is supported in part by a $500,000 two-year Small Business Innovation Research ("SBIR") grant awarded by the NIH.

We have received "Fast Track" designation from the FDA for SGX201 for radiation enteritis. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit

an NDA for SGX201 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

About Acute Radiation Enteritis

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

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

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

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

LPM™ – Leuprolide

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

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

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

BioDefense Overview

RiVax™

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin toxin vaccine to be clinically tested in humans. The vaccine is comprised of a recombinant nontoxic derivative of the ricin A chain which induces antibodies after immunization. Ricin is a potent glycoprotein toxin, derived from the beans of castor plants. It 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 entitled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations" (http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf). The Centers for Disease Control (“CDC”) has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

The initial Phase 1 clinical trial of RiVax™ was conducted by Ellen Vitetta, PhD at the University of Texas Southwestern Medical Center (“UTSW”) at Dallas, Soligenix's academic partner. The trial demonstrated that RiVax™ is well tolerated and induces antibodies in humans that neutralize the ricin toxin. The functional activity of the antibodies was confirmed by animal challenge studies in mice which survived exposure to ricin toxin after being injected with serum samples from the volunteers. The outcome of the study was published in the Proceedings of the National Academy of Sciences. A second Phase 1 trial supported by an FDA Orphan Products grant to UTSW has completed enrollment utilizing an adjuvant formulation of RiVax™. Preliminary results indicate that RiVax™ appears safe at all doses tested in volunteers. Analysis of human immunogenicity is expected during the second half of 2011.

The National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institutes of Health (“NIH”) has previously awarded us two grants: one for $6.4 million and one for $5.2 million for a total of $11.6 million for the development of RiVax™ covering process development, scale-up and current Good Manufacturing Practice (“cGMP”) manufacturing, and pre-clinical toxicology testing pursuant to the FDA’s “animal rule,” which has supported our research from 2004 to present.

In September 2009, we were awarded a $9.4 million grant from NIAID. The grant will fund, over a five-year period, the development of formulation and manufacturing processes for vaccines, including RiVax™, that are stable at elevated temperatures. The grant will also fund the development of improved thermostable adjuvants expected to result in rapidly acting vaccines that can be given with fewer injections over shorter intervals.

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In January 2011, we entered into a definitive license agreement with the University of Colorado ("CU") for novel technology for use in the development of subunit vaccines with long-term stability, including stability at elevated temperatures. This "heat stabilization" technology is the subject of the $9.4 million grant from NIAID. It is also the subject of several United States and foreign patent applications that address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable vaccines for biodefense as well as other potential vaccine indications. The novel technology involves the use of several unique process and formulation steps that fix sensitive vaccine ingredients in native configuration. For biodefense indications, we are using the stabilization technology to advance RiVax™, and a subunit vaccine for anthrax prevention. The underlying technology has been developed by Drs. Amber Clausi, John Carpenter and Theodore Randolph at CU-Boulder.

The development of heat-stable vaccines will combine several novel formulation processes with well characterized adjuvants that have been evaluated in numerous vaccine field trials. The formulation and process technology funded by the grant will be applied to the further development of RiVax™, a subunit vaccine for prevention of ricin toxin lethality and morbidity. The grant will also address the development of manufacturing processes and animal model systems necessary for the pre-clinical characterization of vaccine formulations. Further, the grant will fund the concurrent development of at least one other protein subunit vaccine, which is currently expected to be an anthrax vaccine. This could lead to new subunit vaccines that would bypass current cold chain requirements for storage and distribution. Vaccines to be stored in the Strategic National Stockpile ("SNS") and used under emergency situations for biodefense are expected to have long-term shelf life.

In December 2010, the United States Patent and Trademark Office ("USPTO") granted patent #7,829,668 entitled "Compositions and methods for modifying toxic effects of proteinaceous compounds." This patent includes composition claims for the modified ricin toxin A chain, which is the immunogen contained in RiVax™. The issued patent contains claims that describe alteration of sequences within the ricin A chain that affect vascular leak, one of the deadly toxicities caused by ricin toxin.

In January 2011, the FDA granted Orphan Drug Designation to RiVax™ for the prevention of ricin intoxication.

SGX202 – Oral BDP for GI Radiation Injury

In September 2007, our academic partner, the FHCRC, received a $1 million grant from the NIH to conduct pre-clinical studies of oral BDP, also the active ingredient in orBec®, for the treatment of GI radiation injury. In January 2011, we released promising preliminary results from this grant-supported preclinical study of SGX202 in a canine gastrointestinal acute radiation syndrome ("GARS") model. The results indicate that dogs treated with SGX202 demonstrated statistically significant (p=0.04) improvement in survival after exposure to lethal doses of total body irradiation ("TBI") when compared to control dogs. The aim of the study was to determine whether SGX202 could improve survival and GI recovery after TBI using a well-established GARS dog model. Six dogs were exposed to TBI (12 Gy administered at 70 cGy/min), and then given autologous bone marrow and SGX202 with supportive care; four dogs were used as controls and not treated with SGX202. Autologous bone marrow was given to reduce the duration and impact of the radiation-induced hematopoietic syndrome and allow for a focus on measures to treat the GI effects of TBI. SGX202 was administered two hours after TBI and daily until GI recovery (up to day 100 post exposure). Median survival post exposure in the control group was 8 days, compared to greater than 100 days in the SGX202 treated group. These results demonstrate that SGX202 has the potential to reduce the local inflammation in the radiation damaged GI tract. The principal investigator of the study is George E. Georges, M.D., Associate Member of the FHCRC. Our rights to the use of SGX202 are through our license with George McDonald, M.D.

The purpose of the studies funded by the grant was to evaluate the ability of three promising clinical-grade drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. 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 type of therapy, if successful, would benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism. In most radiation scenarios, injury to the hematopoietic (blood) system and gastrointestinal tract are the main determinants of survival.

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 all applicable outside legal and filing costs incurred in the procurement and defense of patents.

We capitalize and amortize intangibles over their expected useful life – generally a period of 11 to 16 years. We capitalize legal costs associated with the protection and maintenance of our patents and rights for our current products in both the domestic and international markets. As a late stage research and development company with drug and vaccine products in an often lengthy clinical research process, we believe that patent rights are one of our most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at each stage of development. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, our policy is to capitalize these costs and amortize them over the remaining useful life of the patents. We capitalize intangible assets’ alternative future use as referred to in FASB ASC 350, Intangibles – Goodwill and Other and FASB ASC 730, Research and Development.

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 the carrying value of the related asset or group of assets.

Research and Development Costs

Research and Development costs are charged to expense when incurred. 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 and 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

Our revenues are generated from NIH grants and the achievement of licensing milestones. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant. Licensing milestone revenues are recorded when earned.

Accounting for Warrants

We considered FASB ASC 815, Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. We evaluated the warrants' provisions and determined that they were indexed to our own stock and therefore to be accounted for as equity for the six months ended June 30, 2011 and 2010.

Stock-Based Compensation

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

We determine stock-based compensation expense for 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 is amortized as the options vest. The option's price is remeasured using the Black-Scholes model at the end of each quarterly reporting period. Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

New Accounting Pronouncements

See Note 2, New Accounting Pronouncements, of the financial statements for a discussion of new accounting pronouncements.

Material Changes in Results of Operations

Three and Six Months Ended June 30, 2011 Compared to 2010

For the three months ended June 30, 2011, we had a net loss of $1,931,317 as compared to a net loss of $1,577,293 for same period in the prior year, representing an increase in the net loss of $354,024 or 22%. For the six months ended June 30, 2011, we had a net loss of $3,651,728 as compared to a net loss of $3,713,553 for the same period in the prior year, representing a decrease of $61,825, or 2%.

For the three and six months ended June 30, 2011, revenues and associated costs related to NIH grants awarded in support of development of our ricin and thermostable vaccines and orBec®. For the three months ended June 30, 2011, we had revenues of $405,820 as compared to $444,642 for the same period in the prior year, representing a decrease of $38,822, or 9%. The decrease in revenues for the three months ended June 30, 2011 was a result of a decrease in NIH grant activities. For the six months ended June 30, 2011, we had revenues of $1,213,825 as compared to $780,438 for the same period in the prior year, representing an increase of $433,387, or 56%. The increases in revenues were a result of increases in NIH grant drawdowns and the associated development work underlying them.

We incurred costs related to those revenues for the three months ended June 30, 2011 and 2010 of $349,511 and $349,093, respectively, representing an increase of $418. For the six months ended June 30, 2011, costs related to revenues were $903,548 as compared to $622,866 for the same period in the prior year, representing an increase of $280,682, or 45%. These costs relate to payments made to subcontractors in connection with research performed pursuant to the grants. The increases are due to work performed on the NIH grant revenues discussed above.

Our gross profit for the three months ended June 30, 2011 was $56,309 as compared to $95,549 for the same period in 2010, representing a decrease of $39,240 or 41%. The decrease in gross profit is directly related to the decrease in grant revenue. For the six months ended June 30, 2011, gross profit was $310,277 as compared to $157,572 for the same period in the prior year representing an increase of $152,705, or 97%. The increase in gross profit is due to the increase in grant revenues discussed above and a 2011 reimbursement of certain prior period salary costs for which there is no current period cost.

Research and development expenses increased by $236,340 or 22%, to $1,307,051 for the three months ended June 30, 2011 as compared to $1,070,711 for the same period in 2010. This increase is primarily attributable to increased patient enrollment and activity in connection with the confirmatory Phase 3 clinical trial of orBec®. For the six months ended June 30, 2011, research and development expenses were $2,563,186 compared to $2,699,002 for the same period in 2010, resulting in a spending decrease of $105,816 or 4%. This was partially due to the one time patent write-off cost of $378,501 in 2010 in connection to the return of the botulinum toxin vaccine license to Thomas Jefferson University. During the three and six months ended June 30, 2011, we incurred expenses of $926,615 and $1,713,192, respectively, in connection with the conduct of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD and related studies.

General and administrative expenses decreased by $94,327, or 17%, to $450,179 for the three months ended June 30, 2011, as compared to $544,506 for the same period in 2010. This decrease is primarily attributable to investor relation activities associated with our equity financing in June 2010. For the six months ended June 30, 2011, general and administrative expenses was $1,014,091 representing a decrease of $68,512, or 6% compared to $1,082,603 for the same period in 2010.

Stock-based compensation expenses related to research and development increased $166,723 or 417%, to $206,671 for the three months ended June 30, 2011, as compared to $39,948 for the same period in 2010. Stock-based compensation expenses related to research and development increased $243,188 or 303%, to $323,340 for the six months ended June 30, 2011, as compared to $80,152 for the same period in 2010. Stock-based compensation expenses related to general and administrative increased $4,544, or 22%, to $25,198 for the three months ended June 30, 2011, as compared to $20,654 for the same period in 2010. Stock-based compensation expenses related to general and administrative increased $22,583, or 53%, to $65,296 for the six months ended June 30, 2011, as compared to $42,713 for the same period in 2010. These increases result from a large grant in January 2011 to a new employee, 25% of which vested at issuance and was immediately recognized into costs.

Financial Condition

Cash and Working Capital

As of June 30, 2011, we had cash and cash equivalents of $4,156,749 as compared to $7,451,714 as of December 31, 2010, representing a decrease of $3,294,965 or 44%. As of June 30, 2011, we had working capital of $3,165,990 as compared to working capital of $6,101,103 as of December 31, 2010, representing a decrease of $2,935,113 or 48%. The decrease in cash and working capital was the result of cash used in operating activities over the period, offset by $255,000 in proceeds from issuances of common stock under the Fusion Equity line and stock option exercises. For the six months ended June 30, 2011, our cash used in operating activities was $3,506,317 as compared to $2,506,355 for the same period in 2010, representing an increase of $999,962, or 40%.

Based on our current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, recently announced European territory license with Sigma-Tau, which provided a $5,000,000 up front payment, proceeds from our grant-funded programs, and potential proceeds from the Fusion Capital transaction, we believe that our current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter of 2013.

Our plans with respect to our liquidity management include the following:

- We have approximately $8.4 million in active grant funding still available to support our research programs through 2011 and beyond. Additionally, we have submitted additional grant applications for further support of our programs with various funding agencies, and have received encouraging feedback to date on the likelihood of additional funding.
    - We have approximately $7.4 million in available capacity under its Fusion Capital equity facility through October 2011. Although we have historically drawn down modest amounts under this agreement, we could draw more within certain contractual parameters.
- We will seek non-dilutive funding through completion of partnerships for our orBec®/oral BDP programs in territories outside North America and Europe;
- 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 Net Operating Losses (“NOL”) sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $245,810 in proceeds pursuant to NOL sales in 2010 and assuming our application is accepted, we expect to participate in the expanded program during 2011 and beyond; and
- We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

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 $7.7 million before any grant reimbursements, of which $4.6 million relates to the BioTherapeutics business and $3.1 million relates to the BioDefense business. We anticipate grant revenues in the next 12 months to completely offset research and development expenses for the development of our thermostable vaccine technology. We anticipate grant revenues in the next 12 months to partially offset research and development

expenses for the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD and the development of SGX201 in acute radiation enteritis.

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

| | 2011 | 2010 |
|---|---|---|
| Research & Development Expenses | | |
| orBec® | $1,713,193 | $1,488,492 |
| RiVax™ and thermostable vaccines | 845,916 | 796,432 |
| BT-VACC™ (program terminated) | - | 378,501 |
| Oraprine™ | 1,500 | 3,000 |
| LPM™-Leuprolide | 2,577 | 2,577 |
| Total | $2,563,186 | $2,669,002 |
| | | |
| Reimbursed under Grants | | |
| orBec® | $328,503 | $133,717 |
| RiVax™ and thermostable vaccines | 575,045 | 381,149 |
| BT-VACC™ (program terminated) | - | 108,000 |
| Total | 903,548 | $622,866 |
| | | |
| Grand Total | $3,466,734 | $3,291,868 |

Commitments

The Company has commitments of approximately $505,000 as of June 30, 2011 pursuant to its agreement with Numoda Corporation for electronic data capture in connection with the confirmatory Phase 3 clinical trial of orBec® that began in September 2009 and is expected to complete in second half of 2011.

The Company has several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

On April 1, 2009, the Company entered into a sub-lease agreement through March 31, 2012 for office space in Princeton, New Jersey. The Company was required to provide four months of rent as a security deposit. The rent for the first 18 months will be approximately $7,500 per month, or $17.00 per square foot. This rent increased to approximately $7,650 per month, or $17.50 per square foot, for the remaining 18 months.

In February 2007, the Company’s Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, upon the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of its assets are transferred from us and/or our stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 450,000 common shares to employees and a consultant shall be issued.

Employees with employment contracts have severance agreements that may provide separation benefits from the Company if they are involuntarily separated from employment.

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

| Year | Research and Development | Property and Other Leases | Total |
|---|---|---|---|
| 2011 | $ 365,000 | $48,834 | $413,834 |
| 2012 | 355,000 | 28,761 | 383,761 |
| 2013 | 75,000 | 5,793 | 80,793 |
| 2014 | 75,000 | 1,448 | 76,448 |
| 2015 | 75,000 | - | 75,000 |
| Total | $ 945,000 | $84,836 | $1,029,836 |

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

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report (the "Evaluation Date"). Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective.

Changes in Internal Controls

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal controls that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, such controls. However, effective as of April 26, 2011, our Controller resigned and our Chief Financial Officer, on an interim basis, assumed substantially all of the responsibilities and duties of the Controller function. On June 2, 2011, the Company announced the appointment of Joseph Warusz as Vice President of Administration and Controller.

PART II - OTHER INFORMATION.

ITEM 1A – RISK FACTORS

We have identified no additional risk factors other than those included in Part I, Item 1A of our Form 10-K for the fiscal year ended December 31, 2010. Readers are urged to carefully review our risk factors because they may cause our results to differ from the "forward-looking" statements made in this Report. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements except as required by law.

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

In thirteen separate transactions during the six months ended June 30, 2011, the Company issued an aggregate of 1,422,807 shares of common stock under the common stock purchase agreement with Fusion Capital Fund II, LLC (“Fusion Capital”). The purchase price was calculated in accordance with the formula set forth in the purchase agreement. The Company received an aggregate of $255,000 in proceeds which approximated the shares’ fair market value on the dates of issuance. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

ITEM 6 - EXHIBITS

| 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. |

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOLIGENIX, INC.

| | |
|---|---|
| August 12, 2011 | by /s/ Christopher J. Schaber<br>Christopher J. Schaber, PhD<br>President and Chief Executive Officer<br>(Principal Executive Officer) |
| August 12, 2011 | by /s/ Evan Myrianthopoulos<br>Evan Myrianthopoulos<br>Chief Financial Officer<br>(Principal Financial Officer) |
| August 12, 2011 | by /s/ Joseph Warusz<br>Joseph Warusz<br>Vice President of Administration and Controller<br>(Principal Accounting Officer) |

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