SOLIGENIX, INC.
Form 10-Q
May 12, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2016

or

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

For the transition period from _____ to _____

Commission File No. 000-16929

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation or organization)	**41-1505029** (I.R.S. Employer Identification Number)
29 EMMONS DRIVE, SUITE C-10 **PRINCETON, NJ** (Address of principal executive offices)	**08540** (Zip Code)

(609) 538-8200
(Registrant’s telephone number,

including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of “accelerated filer” and “large accelerated filer” in Rule 112b-2 of the Exchange Act.

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

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

As of May 6, 2016, 31,472,522 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

SOLIGENIX, INC.

Index

PART I - FINANCIAL INFORMATION

ITEM 1 - Financial Statements

Soligenix, Inc. and Subsidiaries

Consolidated Balance Sheets

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$4,260,440	$4,921,545
Contracts and grants receivable	1,023,301	1,985,212
Prepaid expenses	89,525	244,267
Total current assets	5,373,266	7,151,024
Office furniture and equipment, net	44,440	47,366
Intangible assets, net	173,314	188,732
Total assets	$5,591,020	$7,387,122
Liabilities and shareholders' deficiency		
Current liabilities:		
Accounts payable	$4,632,771	$4,379,936
Notes payable	298,970	292,719
Warrant liability	1,673,944	2,434,101
Accrued compensation	35,669	298,675
Total current liabilities	6,641,354	7,405,431
Commitments and contingencies		
Shareholders' deficiency:		
Preferred stock, 350,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 50,000,000 shares authorized; 31,369,522 shares and 31,269,522 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	31,370	31,270
Additional paid-in capital	146,945,308	146,828,000
Accumulated deficit	(148,027,012)	(146,877,579)
Total shareholders' deficiency	(1,050,334)	(18,309)
Total liabilities and shareholders' deficiency	$5,591,020	$7,387,122

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

1

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Operations

For the Three Months Ended March 31, 2016 and 2015

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Contract revenue	$2,630,986	$712,406
Grant revenue	-	103,880
Total revenues	2,630,986	816,286
Cost of revenues	(2,232,335)	(527,399)
Gross profit	398,651	288,887
Operating expenses:		
Research and development	1,428,499	1,029,884
General and administrative	875,857	817,270
Total operating expenses	2,304,356	1,847,154
Loss from operations	(1,905,705)	(1,558,267)
Other income (expense):		
Change in fair value of warrant liability	760,157	(3,011,616)
Interest income (expense), net	(3,885)	561
Total other income (expense)	756,272	(3,011,055)
Net loss	$(1,149,433)	$(4,569,322)
Basic net loss per share	$(0.04)	$(0.19)
Diluted net loss per share	$(0.06)	$(0.19)
Basic weighted average common shares outstanding	31,279,412	24,405,813
Diluted weighted average common shares outstanding	32,600,727	24,405,813

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

2

Soligenix, Inc. and Subsidiaries

Consolidated Statement of Changes in Shareholders' Deficiency

For the Three Months Ended March 31, 2016

(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2015	31,269,522	$31,270	$146,828,000	$(146,877,579)	$(18,309)
Issuance of common stock pursuant to Lincoln Park Equity Line	100,000	100	(100)	-	-
Costs associated with Lincoln Park Equity Line	-	-	(19,003)	-	(19,003)
Share-based compensation expense	-	-	136,411	-	136,411
Net loss	-	-	-	(1,149,433)	(1,149,433)
Balance, March 31, 2016	31,369,522	$31,370	$146,945,308	$(148,027,012)	$(1,050,334)

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

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

For the Three Months Ended March 31,

(Unaudited)

	2016	2015
Operating activities:		
Net loss	$(1,149,433)	$(4,569,322)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	22,607	59,926
Common stock issued to vendors	-	101,360
Share-based compensation	136,411	142,025
Amortization of discount on debt	6,251	-
Change in fair value of warrant liability	(760,157)	3,011,616
Change in operating assets and liabilities:		
Contracts and grants receivable	961,911	449,347
Prepaid expenses	154,742	41,382
Accounts payable	252,835	(459,603)
Accrued compensation	(263,006)	(282,841)
Total adjustments	511,594	3,063,212
Net cash used in operating activities	(637,839)	(1,506,110)
Investing activities		
Purchases of office furniture and equipment	(4,263)	(11,553)
Net cash used in investing activities	(4,263)	(11,553)
Financing Activities:		
Net proceeds from issuance of common stock pursuant to the equity lines	-	246,525
Stock issuance cost associated with equity line purchase agreement	(19,003)	-
Proceeds from exercises of options and warrants	-	758,649
Net cash (used in) provided by financing activities	(19,003)	1,005,174
Net decrease in cash and cash equivalents	(661,105)	(512,489)
Cash and cash equivalents at beginning of period	4,921,545	5,525,094
Cash and cash equivalents at end of period	$4,260,440	$5,012,605
Supplemental disclosure of non cash investing and financing activities:		
Reclassification of warrant liability to additional paid in capital upon partial exercises of warrants issued in unit offering	$-	$1,648,811

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

4

Soligenix, Inc.

Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

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

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

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

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

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology,

compliance with the United States Food and Drug Administration (the U.S. “FDA”) regulations, litigation, and product liability. Results for the three months ended March 31, 2016 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of March 31, 2016, the Company had cash and cash equivalents of $4,260,440 as compared to $4,921,545 as of December 31, 2015, representing a decrease of $661,105 or 13%. The decrease in cash was primarily due to net cash used in operations of $637,839. As of March 31, 2016, the Company had working capital of $405,856 which excludes a non-cash warrant liability of $1,673,944, as compared to working capital of $2,179,694 as of December 31, 2015, which excludes a non-cash warrant liability of $2,434,101, representing a decrease of $1,773,838 or 81% in working capital. This decrease is primarily related to expenditures to support the Phase 2 clinical trial of SGX942 and the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL.

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

Management's business strategy can be outlined as follows:

Complete enrollment and report preliminary results in the pivotal Phase 3 clinical trial with SGX301 for the treatment of CTCL;
Initiate a pivotal Phase 3 clinical trial of oral BDP, known as SGX203, for the treatment of pediatric Crohn's disease;
Continue to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study in the treatment of oral mucositis in head and neck cancer patients and publish the findings from this study;
Obtain FDA agreement on a pivotal Phase 2b/3 protocol of SGX942 in the treatment of oral mucositis in head and neck cancer patients;
Continue development of RiVax™ in combination with ThermoVax® technology, to develop new heat stable vaccines in biodefense;
Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS;
Continue to apply for and secure additional government funding for each of the other BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
Pursue business development opportunities for the Company's pipeline programs, as well as explore merger/acquisition strategies; and
Acquire or in-license new clinical-stage compounds for development.

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

The Company has up to $40.3 million in active government funding still available to support its associated research programs through 2016 and beyond. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies.
The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.
The Company will pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $488,933 in proceeds of the sale of NJ NOL in 2015, the Company expects to participate in the program during 2016 and beyond.
The Company plans to pursue potential partnerships for pipeline programs. However, there can be no assurances that we can consummate such a transaction.
The Company has $8.2 million available from equity facilities expiring in November 2016 and $12.0 million from equity facilities expiring in March 2019; 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 on an ongoing basis and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment. The Company divides its operations into two operating segments: BioTherapeutics and Vaccines/BioDefense.

Cash and cash equivalents

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

Contracts and Grants Receivable

Contracts and grants receivable consist of unbilled amounts due from various grants from the NIH and contracts from BARDA and NIAID, an institute of NIH, for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the respective governmental agencies in the month subsequent to period end and collected shortly thereafter. Accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

Intangible Assets

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

Company's rights, and perhaps extend the lives of the patents. The Company capitalizes such costs and amortizes intangibles on a straight-line basis over their expected useful life – generally a period of 11 to 16 years.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the related asset or group of assets. No such write downs have occurred during the three months ended March 31, 2016 and 2015.

The Company did not capitalize any patent related costs during the three months ended March 31, 2016 and 2015.

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.

The Company did not record any impairment of long-lived assets for the three months ended March 31, 2016 and 2015.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on March 31, 2016. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

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

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

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

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, contracts and grants receivable, accounts payable, notes payable and accrued compensation approximate their fair value based on the short-term maturity of these instruments. The Company recognizes all derivative financial instruments as assets or liabilities in the financial statements and measures them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with the Company’s June 2013 registered public offering were accounted for as derivatives. See Note 5, *Warrant Liability*.

8

Revenue Recognition

The Company's revenues are primarily generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs reimbursable internal expenses that are related to the government contracts and grants.

Research and Development Costs

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

Accounting for Warrants

The Company considered FASB ASC 815, *Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock*, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and, therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. The Company evaluated the provisions and determined that warrants issued in connection with the Company's June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of the Company's common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants are recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. All other warrants issued were indexed to the Company's stock and therefore are accounted for as equity instruments for 2016 and 2015.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon

issuance). Stock options issued to employees vest 25% on the grant date, then 25% each subsequent year for a period of three years. Stock options vest over each three-month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

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

Share-based compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, *Stock Compensation*, and FASB ASC 505-50, *Equity-Based Payments to Non-Employees*, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The fair value is remeasured each reporting period until performance is complete.

For the three months ended March 31, 2016 and 2015, the Company issued stock options at a weighted average exercise price of $0.89 and $1.10 per share, respectively. The fair value of options issued during the three months ended March 31, 2016 and 2015 were estimated using the Black-Scholes option-pricing model and the following assumptions:

a dividend yield of 0%;
an expected life of 4 years;
volatility of 121% for 2016 and ranging from 139% - 141% for 2015
forfeitures at a rate of 12%; and
risk free interest rates ranging from 1.19% - 1.52% and .99 - 1.33% for 2016 and 2015 respectively.

The fair value of each option grant made during 2016 and 2015 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option vesting periods, which approximates the service period.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through March 31, 2016 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 2016 and 2015. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2016 and December 31, 2015.

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.

	For the Quarter Ended March 31, 2016	**For the Quarter Ended** March 31, 2015
Numerator:		
Net loss for basic earnings per share	$(1,149,433)	$(4,569,322)
Less change in fair value of warrant liability	760,157	-
Net loss for diluted earnings per share	$(1,909,590)	$(4,569,322)
Denominator:		
Weighted-average basic common shares outstanding	31,279,412	24,405,813
Assumed conversion of dilutive securities:		
Common stock purchase warrants	1,321,315	-
Denominator for diluted earnings per share – adjusted weighted-average shares	32,600,727	24,405,813
Basic net loss per share	$(0.04)	$(0.19)
Diluted net loss per share	$(0.06)	$(0.19)

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

	For the Quarter Ended March 31, 2016	For the Quarter Ended March 31, 2015
Common stock purchase warrants	1,889,191	6,085,714
Stock options	2,824,737	2,272,022
Total	4,713,928	8,357,736

The weighted average exercise price of the Company’s stock options and warrants outstanding at March 31, 2016 were $2.10 and $0.74 per share, respectively, and at March 31, 2015 were $2.34 and $1.25 per share, respectively.

Use of Estimates and Assumptions

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

Recently Issued Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” The amendments in this ASU are intended to define management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Specifically, this ASU provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact the adoption of this standard will have on the Company's consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases” (topic 842). The FASB issued this update to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The updated guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption of the update is permitted. The Company is evaluating the impact of the adoption of this update on our consolidated financial statements and related disclosures.

Note 3. Intangible Assets

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

	Weighted Average Remaining Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
March 31, 2016				
Licenses	3.5	$462,234	$ 340,524	$121,710
Patents	0.8	1,893,185	1,841,581	51,604
Total		$2,355,419	$ 2,182,105	$173,314
December 31, 2015				
Licenses	3.8	$462,234	$ 333,732	$128,502
Patents	1.1	1,893,185	1,832,955	60,230
Total		$2,355,419	$ 2,166,687	$188,732

Amortization expense was $15,418 and $54,039 for the three months ended March 31, 2016 and 2015, respectively.

Based on the balance of licenses and patents at March 31, 2016, the annual amortization expense for each of the succeeding four years is estimated to be as follows:

	Amortization Expense
April 1 through December 31,2016	$ 46,382
2017	$ 61,800
2018	$ 37,300
2019	$ 27,832

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

Note 4. Notes Payable

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

In consideration for entering into the Equity Line Purchase Agreements, the Company issued to the investors promissory notes having an aggregate principal amount of $300,000, which were recorded as stock issuance costs. The promissory notes were paid on April 15, 2016, and had an issuance date present value of $282,071. The promissory notes did not include terms for interest, therefore the interest was imputed at 9%. Total discount amortization of $6,251 was recorded as interest expense for the three months ended March 31, 2016. The discount is being accreted over the term of the promissory notes using the effective interest rate method.

Note 5. Warrant Liability

Warrants issued in connection with the Company's June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of its common stock (or "down-round" provision) and contain net settlement provisions. As a result, the Company accounts for these warrants as liabilities instead of equity instruments. Down-round provisions reduce the exercise or conversion price of a warrant if the Company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed for fixed" option. As a result of the Company's December 2014 registered public unit offering, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to $0.61 per share. As a result of the Company's December 2015 drawdown on the Equity Line Purchase Agreement, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to $0.51 per share.

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

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013 totaling $4,827,788, which was based on the June 25, 2013 closing price of a share of the Company's common stock as reported on OTC Markets of $0.96. On March 31, 2016, the closing price of the Company's common stock as reported on OTC Markets was $0.84. Due to the fluctuations in the market value of the Company's common stock from December 31, 2015 through March 31, 2016, the Company recognized non-cash income of $760,157 for the change in the fair value of the warrant liability for the three months ended March 31, 2016.

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

	December 31, 2015	March 31, 2016
Number of shares underlying the warrants	3,036,928	3,036,928
Exercise price	$ 0.51	$0.51
Volatility	98 %	98 %
Risk-free interest rate	1.19 %	0.80 %

Expected dividend yield	0	0
Expected warrant life (years)	2.48	2.24
Stock Price	$ 1.13	$0.84

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3). The table reflects gains for the three months ended March 31, 2016 for the financial liability categorized as Level 3 as of March 31, 2016**.**

Fair Value Measurements Using Significant Unobservable Inputs (Level 3):

	December 31, 2015	Decrease from Warrants Exercised in 2016	Decrease in Fair Value	March 31, 2016
Warrant liability	$ 2,434,101	-	$760,157	$1,673,944

Note 6. Income Taxes

The Company had gross NOLs at December 31, 2015 of approximately $90,891,000 for federal tax purposes and approximately $5,273,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which will begin to expire in 2018. In addition, the Company has $4,909,000 of various tax credits which expire from 2018 to 2034. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carry forwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. During the year ended December 31, 2015 , in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused net operating loss carryforwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey net operating loss carryforwards, resulting in the recognition of $488,933 of income tax benefit, net of transaction costs. There can be no assurance as to the continuation or magnitude of this program in the future.

The Company has no tax provision for the three month periods ended March 31, 2016 and 2015 due to losses incurred and the recognition of full valuation allowances recorded against net deferred tax assets.

Note 7. Shareholders' Deficiency

Preferred Stock

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

Common Stock

During the three months ended March 31, 2016, the Company issued the following shares of common stock:

the Company issued Lincoln Park Capital 100,000 shares of common stock as consideration for entering into an equity line purchase agreement.

Equity Line Purchase Agreements

In March 2016, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). The Lincoln Park equity facility allows the Company to require Lincoln Park to purchase up to 100,000 shares ("Regular Purchase") of the Company's common stock every two business days, up to an aggregate of $12.0 million over approximately a 36-month period with such amounts increasing as the quoted stock price increases. The Regular Purchase may be increased up to 150,000 shares of common stock if the closing price of the common shares is not below $1.00, up to 200,000 shares of common stock if the closing price of the common shares is not below $1.50 and up to 250,000 shares of common stock if the closing price of the common shares is not below $2.00. The purchase price for the Regular Purchase shall be equal to the lesser of (i) the lowest sale price of the common shares during the purchase date, or (ii) the average of the three lowest closing sale prices of the common shares during the twelve business days prior to the purchase date. Each Regular Purchase shall not exceed $750,000. Furthermore, for each purchase by Lincoln Park, additional commitment shares in commensurate amounts up to a total of 500,000 shares will be issued based upon the relative proportion of the aggregate amount of $12.0 million. In addition to the Regular Purchase and provided that the closing price of the common shares is not below $0.75 on the purchase date, the Company in its sole discretion may direct Lincoln Park on each purchase date to purchase on the next stock trading day (Accelerated Purchase Date") additional shares of Company stock up to the lesser of (i) three times the number of shares purchased following a Regular Purchase or (ii) 30% of the trading volume of shares traded on the Accelerated Purchase Date at a price equal to the lesser of the closing sale price on the Accelerated Purchase Date or 95% of the Accelerated Purchase Date's volume weighted average price.

As part of the agreement, the Company issued 100,000 shares of common stock as consideration for its commitment to purchase shares of our common stock under the purchase agreement. The value of these shares on the date granted was $81,000.

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

From the date that the SEC declared the registration statement effective, in August 2015, until December 31, 2016, the Company had the right to sell up to $5 million, $4 million and $1 million worth of shares of common stock to Kodiak Capital, Kingsbrook and River North, respectively.

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

The initial drawdown under the Equity Line Purchase Agreements was $500,000 offset by issuance cost of $453,162, which was included in the Consolidated Statements of Changes in Shareholders' Deficiency for the year ended December 31, 2015. Issuance costs included professional fees, 3% commitment fee (promissory notes payable by April 15, 2016) and SEC filing fees.

In December 2015, a second drawdown was made, whereby under the Equity Line Purchase Agreements, the Company issued 3,936,235 shares of common stock receiving proceeds of $2,000,000.

On March 7, 2016, in accordance with the terms of the Equity Line Purchase Agreements, the Company exercised its right to terminate the Purchase Agreements upon written notice to the Investors. The Company did not incur any penalties as a result of this termination.

Note 8. Commitments and Contingencies

The Company has commitments of approximately $450,000 as of March 31, 2016 for several licensing agreements with consultants and universities. Additionally, the Company has collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur. As of March 31, 2016, no milestone or royalty payments have been paid or accrued.

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

On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma’s synthetic hypericin product. As consideration for the assets acquired, the Company paid $250,000 in cash and issued 1,849,113 shares of common stock with a fair value based on the Company’s stock price on the date of grant of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company’s research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, the Company will be required to make additional payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company not to exceed 19.9% ownership of Company’s outstanding stock. As of March 31, 2016, no milestone payments have been paid or accrued.

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

As a result of 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**
April 1 through December 31, 2016	$ 50,000	$ 118,000	$168,000
2017	100,000	151,000	251,000
2018	100,000	52,000	152,000
2019	100,000	-	100,000
2020	100,000	-	100,000
Total	$ 450,000	$ 321,000	$771,000

16

Note 8. Operating Segments

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

	Three Months Ended March 31,	
	2016	2015
Contract/Grant Revenue		
Vaccines/BioDefense	$2,630,986	$802,314
BioTherapeutics	-	13,972
Total	$2,630,986	$816,286
Income/(Loss) from Operations		
Vaccines/BioDefense	$317,991	$84,681
BioTherapeutics	(1,245,585)	(764,876)
Corporate	(978,111)	(878,072)
Total	$(1,905,705)	$(1,558,267)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$10,019	$9,786
BioTherapeutics	10,433	48,374
Corporate	2,155	1,766
Total	$22,607	$59,926
Interest Income/(Expense)		
Corporate	$(3,885)	$561
Share-Based Compensation		
Vaccines/BioDefense	$28,006	$24,592
BioTherapeutics	34,832	29,256
Corporate	73,573	88,177
Total	$136,411	$142,025

As of March 31,	As of December 31, 2015

	2016	
Identifiable Assets		
Vaccines/BioDefense	$1,150,768	$2,123,676
BioTherapeutics	70,274	76,183
Corporate	4,369,978	5,187,263
Total	$5,591,020	$7,387,122

17

ITEM 2 – Management's Discussion and Analysis OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes, Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2015. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are