

SOLIGENIX, INC.  
Form 10-Q  
May 11, 2018

**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, 2018**

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 B-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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 7, 2018, 8,750,801 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**

	March 31, 2018 (Unaudited)	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$6,368,057	\$7,809,487
Contracts and grants receivable	826,994	926,251
Prepaid expenses	159,189	263,254
Income tax receivable	-	416,810
Total current assets	7,354,240	9,415,802
Security deposit	22,734	22,734
Office furniture and equipment, net	34,589	37,163
Intangible assets, net	<b>67,236</b>	73,952
Total assets	<b>\$7,478,799</b>	<b>\$9,549,651</b>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$1,753,603	\$1,753,614
Accrued expenses	1,606,826	1,143,306
Accrued compensation	48,094	333,019
Total current liabilities	<b>3,408,523</b>	3,229,939
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, 350,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 25,000,000 shares authorized; 8,740,723 shares and 8,730,640 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	8,741	8,731
Additional paid-in capital	163,708,786	163,581,026
Accumulated deficit	<b>(159,647,251)</b>	(157,270,045)
Total shareholders' equity	4,070,276	6,319,712
Total liabilities and shareholders' equity	<b>\$7,478,799</b>	<b>\$9,549,651</b>

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

**Soligenix, Inc. and Subsidiaries****Consolidated Statements of Operations****For the Three Months Ended March 31, 2018 and 2017****(Unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	2018	2017
Revenues:		
Contract revenue	\$777,284	\$1,330,884
Grant revenue	342,489	-
Total revenues	1,119,773	1,330,884
Cost of revenues	(978,921 )	(1,087,315)
Gross profit	140,852	243,569
Operating expenses:		
Research and development	1,803,360	1,217,540
General and administrative	731,593	764,219
Total operating expenses	2,534,953	1,981,759
Loss from operations	(2,394,101)	(1,738,190)
Interest income, net	16,895	4,753
Net loss	\$(2,377,206)	\$(1,733,437)
Basic net loss per share	\$(0.27 )	\$(0.32 )
Diluted net loss per share	\$(0.27 )	\$(0.32 )
Basic weighted average common shares outstanding	8,734,897	5,472,449
Diluted weighted average common shares outstanding	8,734,897	5,472,449

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

**Soligenix, Inc. and Subsidiaries****Consolidated Statement of Changes in Shareholders' Equity****For the Three Months Ended March 31, 2018****(Unaudited)**

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2017	8,730,640	\$8,731	\$163,581,026	\$(157,270,045)	\$6,319,712
Issuance of common stock pursuant to Lincoln Park Equity Line	10,083	10	19,790		19,800
Share-based compensation expense			107,970		107,970
Net loss				(2,377,206)	(2,377,206)
Balance, March 31, 2018	8,740,723	\$8,741	\$163,708,786	\$(159,647,251)	\$4,070,276

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)**

	2018	2017
Operating activities:		
Net loss	\$(2,377,206)	\$(1,733,437)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	11,214	21,050
Share-based compensation	107,970	146,627
Issuance of common stock for services	-	5,925
Change in operating assets and liabilities:		
Contracts and grants receivable	99,257	213,287
Income tax receivable	416,810	-
Prepaid expenses	104,065	(3,056 )
Accounts payable and accrued expenses	463,509	(94,251 )
Accrued compensation	(284,925 )	(182,760 )
Total adjustments	917,900	106,822
Net cash used in operating activities	(1,459,306)	(1,626,615)
Investing activities		
Purchases of office furniture and equipment	(1,924 )	(2,131 )
Net cash used in investing activities	(1,924 )	(2,131 )
<b>Financing Activities:</b>		
Proceeds from issuance of common stock pursuant to the equity line	19,800	-
Net cash provided by financing activities	19,800	-
Net decrease in cash and cash equivalents	(1,441,430)	(1,628,746)
Cash and cash equivalents at beginning of period	7,809,487	8,772,567
Cash and cash equivalents at end of period	\$6,368,057	\$7,143,821

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

**Soligenix, Inc.**

**Notes to Consolidated Financial Statements**

**Note 1. Nature of Business**

Basis of Presentation

Soligenix, Inc. (the “Company”) 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 novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible fluorescent light for the treatment of cutaneous T-cell lymphoma (“CTCL”), its first-in-class innate defense regulator (“IDR”) technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and 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).

The Company’s Vaccines/BioDefense business segment includes active development programs for RiVax<sup>®</sup>, its ricin toxin vaccine candidate, OrbeShield<sup>®</sup>, a GI acute radiation syndrome (“GI ARS”) therapeutic candidate and SGX943, a therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of the vaccine program is currently supported by the heat stabilization technology, known as ThermoVax<sup>®</sup>, 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<sup>®</sup> to protect against exposure to ricin toxin. The Company has advanced the development of OrbeShield<sup>®</sup> for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority (“BARDA”) and NIAID. The Company will continue to pursue additional government funding support.

The Company generates revenues under government grants primarily from the National Institutes of Health (“NIH”) and government contracts from BARDA and NIAID. The Company is currently developing RiVax<sup>®</sup> under a NIH contract of up to \$24.7 million, and SGX301 and SGX942 under two separate NIH grants of approximately \$1.5 million each over two years. The NIAID contract for the development of OrbeShield<sup>®</sup> was completed during the first quarter of 2017, and the base period of the BARDA contract for the development of OrbeShield<sup>®</sup> completed, with BARDA

electing not to extend the current contract beyond the base period. The Company will continue to apply for additional government funding.

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 regulations, and other regulatory authorities, litigation, and product liability. Results for the three months ended March 31, 2018 are not necessarily indicative of results that may be expected for the full year.

### Liquidity

In accordance with Accounting Standards Codification 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of March 31, 2018, the Company had an accumulated deficit of \$159,647,251. During the three months ended March 31, 2018, the Company incurred a net loss of \$2,377,206 and used \$1,459,306 of cash in operations. The Company expects to continue to generate losses in the foreseeable future. The Company's liquidity needs will be largely determined by the budgeted operational expenditures incurred in regards to the progression of its product candidates. The Company's plans to meet its liquidity needs primarily include its ability to control the timing and spending on its research and development programs and raising additional funds through potential partnership and/or financings. Based on the Company's operating budget, current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the equity line with Lincoln Park Capital Fund, LLC ("Lincoln Park"), 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 12 months from issuance of the financial statements.

As of March 31, 2018, the Company had cash and cash equivalents of \$6,368,057 as compared to \$7,809,487 as of December 31, 2017, representing a decrease of \$1,441,430 or 18%. As of March 31, 2018, the Company had working capital of \$3,945,717 as compared to working capital of \$6,185,863 as of December 31, 2017, representing a decrease of \$2,240,146 or 36%. The decrease in cash and working capital was primarily related to expenditures to support the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL and expenditures incurred in the pivotal Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer, including the expansion of the Phase 3 trial of SGX942 to select European study sites.

Management's business strategy can be outlined as follows:

- Complete enrollment and report preliminary results in the Company's pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;
- Continue enrollment of the pivotal Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer, including the expansion of the Phase 3 trial of SGX942 to select European study sites;
- Continue development of RiVax® in combination with the Company's ThermoVax® technology to develop a new heat stable vaccine in biodefense with NIAID funding support;
- Continue to apply for and secure additional government funding for each of the Company's 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 \$18.4 million in active government contract and grant funding still available to support its associated research programs through 2018 and beyond, provided the federal agencies exercise all options and do not elect to terminate the contracts or grants for convenience. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies;
- The Company will continue to explore the use of 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;
- 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 in 2018 of \$416,810 in proceeds from the sale of NJ NOL in 2017, the Company expects to participate in the program for the year ending December 31, 2018 and beyond as long as the program is available;
- The Company plans to pursue potential partnerships for its pipeline programs. However, there can be no assurances that the Company can consummate such transactions;
- The Company has \$10.2 million available from an equity facility 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 evaluating additional equity/debt 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 amounts due from various grants from the NIH and contracts from 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.

The Company did not capitalize any patent related costs during the three months ended March 31, 2018 and 2017.

#### Impairment of Long-Lived Assets

Office furniture and equipment and intangible assets with finite lives 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, 2018 and 2017.

#### 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, 2018. 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, accrued expenses, 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.

#### 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.

#### 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 generally vest 25% on the grant date, then 25% each subsequent year for a period of three years. 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 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.

The Company did not issue any stock options during the three months ended March 31, 2018. During the three months ended March 31, 2017, the Company issued stock options at a weighted average exercise price of \$2.67 per share. The fair value of options issued during the three months ended March 31, 2017 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 84%  
forfeitures at a rate of 12%; and  
risk free interest rates ranging 1.72% - 1.81%

The fair value of each option grant made during 2017 was estimated on the date of each grant using the Black-Scholes option pricing model and recognized as share-based compensation expense ratably over the option vesting periods, which approximates the service period.

### Income Taxes

On December 22, 2017, the United States ("U.S.") government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act significantly revises U.S. corporate income taxation by, among other things, lowering the U.S. corporate income tax rate from 35.0% to 21.0% effective January 1, 2018. The Company does not anticipate any impact to the tax provision due to the full valuation allowance on its deferred tax assets and believes that the most significant impact on its consolidated financial statements was the reduction of approximately \$14 million for the deferred tax assets related to net operating losses and other assets. Such reduction was fully offset by changes to the Company's valuation allowance.

In December 2017, the U.S. Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin 118, which allows a measurement period, not to exceed one year, to finalize the accounting for the income tax impacts of the Tax Act. Until the accounting for the income tax impacts of the Tax Act is complete, the reported amounts are based on reasonable estimates, are disclosed as provisional and reflect any adjustments in subsequent periods as the Company refines its estimates or completes its accounting of such tax effects.

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 basis. 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, 2018 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 the income tax provision. There were no tax related interest and penalties recorded for the periods ended March 31, 2018 or 2017. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2018 and December 31, 2017.

### 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.

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, 2018	For the Quarter Ended March 31, 2017
Common stock purchase warrants	2,577,238	2,853,575
Stock options	782,155	464,355
Total	3,359,393	3,317,930

The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2018 were \$7.16 and \$4.38 per share, respectively, and at March 31, 2017 were \$12.70 and \$4.13 per share, respectively.

#### Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of warrants and, stock options and 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 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 the Company's consolidated financial statements and related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *(Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*.

The new standard applies to issuers of financial instruments with down-round features. A down-round provision is a term in an equity-linked financial instrument (i.e. a freestanding warrant contract or an equity conversion feature embedded within a host debt or equity contract) that triggers a downward adjustment to the instrument's strike price (or conversion price) if equity shares are issued at a lower price (or equity-linked financial instruments are issued at a lower strike price) than the instrument's then-current strike price. The purpose of the feature is typically to protect the instrument's counterparty from future issuances of equity shares at a more favorable price. The ASU amends (1) the classification of such instruments as liabilities or equity by revising the certain guidance relative to evaluating if they must be accounted for as derivative instruments and (2) the guidance on recognition and measurement of freestanding equity-classified instruments. For the Company, this ASU is effective January 1, 2019, with early adoption permitted. The Company is evaluating the impact of the adoption of this update on its consolidated financial statements and related disclosures.

**Note 3. Intangible Assets**

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

	Cost	Accumulated Amortization	Net Book Value
<b><u>March 31, 2018</u></b>			
Licenses	\$462,234	\$ 394,998	\$67,236
Patents	1,893,185	1,893,185	-
Total	\$2,355,419	\$ 2,288,183	\$67,236
<b><u>December 31, 2017</u></b>			
Licenses	\$462,234	\$ 388,282	\$73,952
Patents	1,893,185	1,893,185	-
Total	\$2,355,419	\$ 2,281,467	\$73,952

Amortization expense was \$6,716 and \$15,338 for the three months ended March 31, 2018 and 2017, respectively.

Based on the balance of licenses and patents at March 31, 2018, future annual amortization expense is expected to be as follows:

	Amortization Expense
April 1 through December 31, 2018	\$ 30,584
2019	\$ 36,652

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

**Note 4. Accrued Expenses**



The following is a summary of the Company's accrued expenses:

	<b>March 31,</b>	December 31,
	<b>2018</b>	2017
Clinical trial expenses	\$ 1,271,888	\$ 1,011,666
Other	334,938	131,640
Total	\$ 1,606,826	\$ 1,143,306

**Note 5. Income Taxes**

The Company had gross NOLs at December 31, 2017 of approximately \$99,402,000 for federal tax purposes and approximately \$5,766,000 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 \$8,000,000 of various tax credits which expire from 2018 to 2035. 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 has no tax provision for the three month periods ended March 31, 2018 and 2017 due to losses incurred and the recognition of full valuation allowances recorded against net deferred tax assets.

On December 22, 2017, the U.S. government enacted the Tax Act. The Tax Act significantly revises U.S. corporate income taxation by, among other things, lowering the U.S. corporate income tax rate from 35.0% to 21.0% effective January 1, 2018. The Company does not anticipate any impact to the tax provision due to the full valuation allowance on its deferred tax assets and believes that the most significant impact on its consolidated financial statements was the reduction of approximately \$14 million for the deferred tax assets related to net operating losses and other assets. Such reduction was fully offset by changes to the Company's valuation allowance.

In December 2017, the SEC issued Staff Accounting Bulletin 118, which allows a measurement period, not to exceed one year, to finalize the accounting for the income tax impacts of the Tax Act. Until the accounting for the income tax impacts of the Tax Act is complete, the reported amounts are based on reasonable estimates, are disclosed as provisional and reflect any adjustments in subsequent periods as the Company refines its estimates or completes its accounting of such tax effects.

## **Note 6. Shareholders' Equity**

### 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, 2018, the Company issued the following shares of common stock:

On February 21, 2018, the Company issued 10,083 shares of common stock pursuant to the equity line with Lincoln Park.

In March 2016, the Company entered into a common stock purchase agreement with Lincoln Park. The 2016 Lincoln Park equity facility allows the Company to require Lincoln Park to purchase up to 10,000 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 15,000 shares of common stock if the closing price of the common shares is not below \$10.00, up to 20,000 shares of common stock if the closing price of the common shares is not below \$15.00 and up to 25,000 shares of common stock if the closing price of the common shares is not below \$20.00. 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 50,000 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 \$7.50 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. At March 31, 2018, the Company had \$10.2 million available from this equity line which expires in March 2019.

### FBR Agreement and Common Stock Offerings

On August 11, 2017, the Company entered into an At Market Issuance Sales Agreement with FBR Capital Markets & Co. (“FBR”) to sell shares of the Company’s common stock, with aggregate gross proceeds of up to \$4,800,000, from time to time, through an “at-the-market” equity offering program under which FBR acts as sales agent. Under the Sales Agreement, the Company set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales were requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. The Sales Agreement provided that FBR was entitled to compensation for its services in an amount equal to 3% of the gross proceeds from the sale of shares sold under the Sales Agreement. The offering costs incurred to register the shares pursuant to the Sales Agreement were \$164,825. The Company had no obligation to sell any shares under the Sales Agreement, and could suspend solicitation and offers under the Sales Agreement. The shares were issued pursuant to the Company’s shelf registration statement on Form S-3 and the Prospectus Supplement filed August 11, 2017 with the SEC in connection with the offer and sale of the shares pursuant to the Sales Agreement. The shares were issued pursuant to General Instruction I.B.6 of Form S-3, which permits the Company to sell shelf securities in a public primary offering with a value not exceeding one-third of the average market value of the Company’s voting and non-voting common equity held by non-affiliates in any 12-month period as long as the aggregate market value of the Company’s outstanding voting and non-voting common equity held by non-affiliates is less than \$75 million. Currently no more shares may be sold under the Prospectus Supplement filed on August 11, 2017 because the Company has issued the maximum amount of shares permitted to be sold under General Instruction I.B.6 of Form S-3. With the passage of time or the fluctuation of the aggregate market value of the Company’s voting and non-voting common equity held by non-affiliates, the Company anticipates that it will again be permitted to issue shares in reliance on General Instruction I.B.6 of Form S-3.

On November 3, 2017, the Company issued 1,575,500 shares of common stock at a purchase price of \$2.00 per share in a registered direct offering and 982,000 shares of common stock at a purchase price of \$2.00 per share in a concurrent private placement. In connection with the concurrent registered public offering and the private placement, warrants to purchase 51,151 shares of the Company’s common stock were issued to representatives of the underwriters of the offering. The warrants are exercisable at \$2.50 per share of common stock underlying the warrants for a four-year period commencing six months from the effective date of the offering. Gross proceeds to the Company from these offerings were approximately \$5,115,000 before deducting placement agent fees and other estimated offering expenses payable by the Company.

### **Note 7. Commitments and Contingencies**

The Company has commitments of approximately \$475,000 as of March 31, 2018 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, 2018, the Company has accrued for approximately \$197,000

in milestone payments.

The Company currently leases approximately 6,200 square feet of office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey pursuant to a lease that was amended in October 2017 and expires in October 2020. This office space currently serves as the Company's corporate headquarters. The rent for the first 12 months is approximately \$11,367 per month, or approximately \$22.00 per square foot. The rent will increase to approximately \$11,625 per month, or approximately \$22.50 per square foot, for the next 12 months and increase to approximately \$11,883 per month, or approximately \$23.00 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 \$275,000 in cash and issued 184,912 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 U.S. 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 provided they do not exceed 19.9% ownership of the Company’s outstanding stock. As of March 31, 2018, no milestone or royalty payments have been paid or accrued.

In February 2007, the Company’s Board of Directors authorized the issuance of 5,000 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:

<b>Year</b>	<b>Research and Development</b>	<b>Property and Other Leases</b>	<b>Total</b>
April 1 through December 31, 2018	\$ 75,000	\$145,461	\$220,461
2019	100,000	148,561	248,561
2020	100,000	127,377	227,377
2021	100,000	5,696	105,696
2022	100,000	-	100,000
<b>Total</b>	<b>\$ 475,000</b>	<b>\$427,095</b>	<b>\$902,095</b>

**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.

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	2018	2017
Revenues		
Vaccines/BioDefense	<b>\$809,256</b>	\$1,330,884
BioTherapeutics	<b>310,517</b>	-
Total	<b>\$1,119,773</b>	\$1,330,884
Income/(Loss) from Operations		
Vaccines/BioDefense	<b>\$(86,205)</b>	\$136,600
BioTherapeutics	<b>(1,521,348)</b>	(1,027,555)
Corporate	<b>(786,548)</b>	(847,235)
Total	<b>\$(2,394,101)</b>	\$(1,738,190)
<b>Amortization and Depreciation Expense</b>		
Vaccines/BioDefense	<b>\$4,480</b>	\$9,769
BioTherapeutics	<b>5,384</b>	9,567
Corporate	<b>1,350</b>	1,714
Total	<b>\$11,214</b>	\$21,050
<b>Interest Income, Net</b>		
Corporate	<b>\$16,895</b>	\$4,753
Share-Based Compensation		
Vaccines/BioDefense	<b>\$15,668</b>	\$17,998
BioTherapeutics	<b>28,318</b>	49,770
Corporate	<b>63,984</b>	78,859
Total	<b>\$107,970</b>	\$146,627
	<b>As of</b>	As of
	<b>March 31,</b>	December 31,
	<b>2018</b>	2017
Identifiable Assets		
Vaccines/BioDefense	<b>\$768,868</b>	\$906,416
BioTherapeutics	<b>146,404</b>	116,344

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Corporate	<b>6,563,527</b>	8,526,891
Total	<b>\$7,478,799</b>	\$ 9,549,651



## **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, 2017. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as “believes,” “anticipates,” “expects,” “intends,” “may,” “will” “plans” and other similar expressions, however, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the U.S. Securities and Exchange Commission or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the U.S. Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business. We provide addresses to internet sites solely for the information to investors. We do not intend any addresses to be active links or to otherwise incorporate the contents of any website into this report.*

### **Our Business Overview**

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

Our BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible fluorescent light for the treatment of cutaneous T-cell lymphoma (“CTCL”), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and 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).

Our Vaccines/BioDefense business segment includes active development programs for RiVax<sup>®</sup>, our ricin toxin vaccine candidate, OrbeShield<sup>®</sup>, our GI acute radiation syndrome (“GI ARS”) therapeutic candidate and SGX943, our

therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax<sup>®</sup>, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases (“NIAID”), we will attempt to advance the development of RiVax<sup>®</sup> to protect against exposure to ricin toxin. We have advanced the development of OrbeShield<sup>®</sup> for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority (“BARDA”) and grants from NIAID.

An outline of our business strategy follows:

Complete enrollment and report preliminary results in our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;

Continue enrollment of our pivotal Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer, including the expansion of the Phase 3 trial of SGX942 to select European study sites;

Continue development of RiVax® in combination with our ThermoVax® technology to develop a new heat stable vaccine in biodefense with NIAID funding support;  
 Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;  
 Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies; and  
 Acquire or in-license new clinical-stage compounds for development.

**Corporate Information**

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

**Our Product Candidates in Development**

The following tables summarize our product candidates under development:

**BioTherapeutic Product Candidates**

<b>Soligenix Product Candidate</b>	<b>Therapeutic Indication</b>	<b>Stage of Development</b>
SGX301	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 clinical trial initiated in December 2015, with an interim analysis anticipated in the second half of 2018 and final results expected in the first half of 2019
SGX942	&nbs	