SOLIGENIX, INC.
Form 10-Q
November 09, 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 September 30, 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	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

29 EMMONS DRIVE, SUITE B-10

PRINCETON, NJ	**08540**
(Address of principal executive offices)	(Zip Code)

(609) 538-8200
(Registrant's telephone number, including area code)

Indicate by check whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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	Accelerated filer
Non-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 November 3, 2018, 17,682,839 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

	September 30, 2018 (Unaudited)	**December 31, 2017**
Assets		
Current assets:		
Cash and cash equivalents	$11,720,085	$7,809,487
Contract and grants receivable	998,609	926,251
Prepaid expenses	420,963	263,254
Income tax receivable	-	416,810
Total current assets	13,139,657	9,415,802
Security deposit	22,734	22,734
Office furniture and equipment, net	25,993	37,163
Deferred issuance costs	47,352	-
Intangible assets, net	53,653	73,952
Total assets	$13,289,389	$9,549,651
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$1,713,632	$1,753,614
Accrued expenses	1,984,407	1,143,306
Deferred revenue	259,862	-
Accrued compensation	63,019	333,019
Total current liabilities	4,020,920	3,229,939
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, 350,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 50,000,000 and 25,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 17,682,839 shares and 8,730,640 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	17,683	8,731
Additional paid-in capital	172,317,754	163,581,026
Accumulated other comprehensive loss	(1,767)	-
Accumulated deficit	(163,065,201)	(157,270,045)

Total shareholders' equity	9,268,469	6,319,712
Total liabilities and shareholders' equity	$13,289,389	$9,549,651

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

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Operations

For the Three and Nine Months Ended September 30, 2018 and 2017

(Unaudited)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2018	2017	2018	2017
Revenues				
Contract revenue	$1,064,398	$1,395,234	$3,209,256	$3,717,089
Grant revenue	316,955	426,832	1,017,414	426,832
Total revenues	1,381,353	1,822,066	4,226,670	4,143,921
Cost of revenues	(1,237,230)	(1,474,151)	(3,709,827)	(3,238,633)
Gross profit	144,123	347,915	516,843	905,288
Operating expenses:				
Research and development	1,394,913	605,719	4,377,483	3,606,973
General and administrative	667,799	711,819	2,041,340	2,322,957
Total operating expenses	2,062,712	1,317,538	6,418,823	5,929,930
Loss from operations	(1,918,589)	(969,623)	(5,901,980)	(5,024,642)
Interest income, net	56,981	6,529	106,824	16,513
Net loss	$(1,861,608)	$(963,094)	$(5,795,156)	$(5,008,129)
Basic net loss per share	$(0.11)	$(0.17)	$(0.50)	$(0.89)
Diluted net loss per share	$(0.11)	$(0.17)	$(0.50)	$(0.89)
Basic weighted average common shares outstanding	17,495,066	5,757,973	11,660,091	5,610,767
Diluted weighted average common shares outstanding	17,495,066	5,757,973	11,660,091	5,610,767

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

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Comprehensive Loss

For the Three and Nine Months Ended September 30, 2018 and 2017

(Unaudited)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2018	2017	2018	2017
Net loss	$(1,861,608)	$(963,094)	$(5,795,156)	$(5,008,129)
Other comprehensive loss:				
Foreign currency translation adjustments	(1,767)	-	(1,767)	-
Comprehensive loss	$(1,863,375)	$(963,094)	$(5,796,923)	$(5,008,129)

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 Nine Months Ended September 30, 2018

(Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Par Value	Deficit	Loss	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	20,161	20	38,380	-	-	38,400
Issuance of common stock in public financing, net of underwriting discount	8,932,038	8,932	8,682,014	-	-	8,636,946
Issuance costs associated with public financing	-	-	(192,130)	-	-	(192,130)
Share-based compensation expense	-	-	262,464	-	-	262,464
Foreign currency translation adjustment	-	-	-	(1,767)	-	(1,767)
Net loss	-	-	-	-	(5,795,156)	(5,795,156)
Balance, September 30, 2018	17,682,839	$17,683	$172,317,754	$ (1,767)	$(163,065,201)	$9,268,469

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

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

For the Nine Months Ended September 30,

(Unaudited)

	2018	**2017**
Operating activities:		
Net loss	**$(5,795,156)**	$(5,008,129)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	**33,392**	57,647
Share-based compensation	**262,464**	328,756
Issuance of common stock for services	**-**	5,925
Change in operating assets and liabilities:		
Contract and grants receivable	**(72,358)**	571,906
Prepaid expenses	**(157,709)**	13,838
Income tax receivable	**416,810**	-
Accounts payable and accrued expenses	**753,768**	54,714
Accrued compensation	**(270,000)**	(216,961)
Deferred revenue	**259,862**	-
Total adjustments	**1,226,229**	815,825
Net cash used in operating activities	**(4,568,927)**	(4,192,304)
Investing activities:		
Purchases of office furniture and equipment	**(1,924)**	(2,132)
Net cash used in investing activities	**(1,924)**	(2,132)
Financing activities:		
Proceeds from issuance of common stock pursuant to the equity line	**38,400**	115,930
Net proceeds from issuance of common stock pursuant to public financing	**8,636,946**	451,970
Costs associated with public financing	**(192,130)**	(146,878)
Net cash provided by financing activities	**8,483,216**	421,022
Effect of exchange rate changes on cash and cash equivalents	**(1,767)**	-
Net increase (decrease) in cash and cash equivalents	**3,910,598**	(3,773,414)
Cash and cash equivalents at beginning of period	**7,809,487**	8,772,567
Cash and cash equivalents at end of period	**$11,720,085**	$4,999,153
Supplemental disclosure of non cash financing activity:		
Accrued deferred issuance costs	$47,352	-

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

Soligenix, Inc.

Notes to Consolidated Financial Statements

(Unaudited)

Note 1. Nature of Business

Basis of Presentation

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

The Company's BioTherapeutics business segment is developing a 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®, its ricin toxin vaccine candidate, OrbeShield®, 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®, 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 has advanced the development of OrbeShield® 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® 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® and the base period of the BARDA contract for the development of OrbeShield® were completed during the first quarter of 2017. 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 ("FDA") regulations, and other regulatory authorities, litigation, and product liability. Results for the nine months ended September 30, 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 September 30, 2018, the Company had an accumulated deficit of $163,065,201. During the nine months ended September 30, 2018, the Company incurred a net loss of $5,795,156 and used $4,568,927 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"), proceeds available from the at-the-market ("ATM") sales agreement with B. Riley FBR, Inc. ("FBR"), 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 September 30, 2018, the Company had cash and cash equivalents of $11,720,085 as compared to $7,809,487 as of December 31, 2017, representing an increase of $3,910,598 or 50%. As of September 30, 2018, the Company had working capital of $9,118,737 as compared to working capital of $6,185,863 as of December 31, 2017, representing an increase of $2,932,874 or 47%. The increase is primarily related to the proceeds received from the Company's July 2018 public offering offset by the expenditures incurred to support the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL and 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:

Following positive interim analysis, complete enrollment and report final 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;

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 $15.2 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 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 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 pipeline programs. However, there can be no assurances that we can consummate such transactions;

The Company has up to $9.0 million remaining from the ATM agreement with FBR under the prospectus supplement updated October 3, 2018;

The Company has up to $10.1 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.

Contract and Grants Receivable

Contract and grants receivable consist of amounts due from various grants from the NIH and a contract 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 nine months ended September 30, 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 nine months ended September 30, 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 September 30, 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, contract and grants receivable, accounts payable, accrued expenses, and accrued compensation approximate their fair value based on the short-term maturity of these instruments.

Deferred Issuance Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred issuance costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in shareholders' equity as a reduction of additional paid-in capital generated as a result of the offering.

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.

For the nine months ended September 30, 2018 and 2017, the Company issued stock options at a weighted average exercise price of $1.66 and $2.55 per share, respectively. The fair value of options issued during the nine months ended September 30, 2018 and 2017 were estimated using the Black-Scholes option-pricing model and the following assumptions:

- a dividend yield of 0%;
- an expected term of 4 years;
- volatility of 91% - 93% for 2018 and 90% - 93% for 2017;
- forfeitures at a rate of 12%; and
- risk-free interest rates ranging from 2.68% - 2.93% for 2018 and 1.60% - 1.81% for 2017.

The fair value of each option grant made during 2018 and 2017 was estimated on the date of each grant using the Black-Scholes option pricing model and is amortized 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 September 30, 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 income tax expense. There were no tax related interest and penalties recorded for the periods ended September 30, 2018 or 2017. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at September 30, 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.

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2018	2017	2018	2017
Common stock purchase warrants	6,304,143	2,603,575	6,304,143	2,603,575
Stock options	783,175	510,055	783,175	510,055
Total	7,087,318	3,113,630	7.087,318	3,113,630

The weighted average exercise price of the Company's stock options and warrants outstanding at September 30, 2018 were $7.02 and $3.09 per share, respectively, and at September 30, 2017 were $9.93 and $4.45 per share, respectively.

Use of Estimates and Assumptions

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

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 requiring substantially all leases be recognized by the lessee on its balance sheet as a right-of-use asset and a corresponding lease liability, including leases currently accounted for as operating leases, 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 plans to adopt the new standard on January 1, 2019 and is evaluating the impact of the adoption of this update on its 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.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The FASB issued this update with the intention of reducing cost and complexity and to improve financial reporting for share-based payments issued to nonemployees. The ASU expands the scope of Topic 718, which currently only includes share-based payments issued to employees, to also include share-based payments issued to nonemployees for goods and services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is 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
September 30, 2018			
Licenses	$462,234	$ 408,581	$53,653
Patents	1,893,185	1,893,185	-
Total	$2,355,419	$ 2,301,766	$53,653
December 31, 2017			
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 $6,791 and $14,963 for the three months ended September 30, 2018 and 2017, respectively, and $20,299 and $45,810 for the nine months ended September 30, 2018 and 2017, respectively.

Based on the balance of licenses and patents at September 30, 2018, future amortization expense is expected to be as follows:

	Amortization Expense
October 1 thru December 31, 2018	$ 6,791
2019	$ 27,164
2020	$ 19,698

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:

	September 30, 2018	December 31, 2017
Clinical trials	$ 1,863,103	$ 1,011,666
Other	121,304	131,640
Total	$ 1,984,407	$ 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 and one or more of its subsidiaries file income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. During the year ended December 31, 2017, 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 NOL carry forwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey NOL carry forwards, resulting in the recognition of $416,810 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 and nine month periods ended September 30, 2018 and 2017 due to losses incurred and the recognition of full valuation allowances recorded against net deferred tax assets.

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 nine months ended September 30, 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.

On April 6, 2018 the Company issued 10,078 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 12 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 September 30, 2018, the Company has $10.1 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 to sell shares of the Company's common stock 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 sets the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales may be 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 provides that FBR is 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 Company has no obligation to sell any shares under the sales agreement, and may suspend solicitation and offers under the sales agreement at any time.

Sales of common stock made pursuant to the sales agreement, if any, will be made pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-217738) filed on May 5, 2017 with the SEC, the base prospectus filed as part of such registration statement, and any prospectus supplements. The shares sold pursuant to the sales agreement have been and will be 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.

On August 11, 2017, the Company filed a prospectus supplement for the sale of up to $4.8 million of shares of common stock pursuant to the sales agreement, and the Company sold an aggregate of approximately $1 million of shares thereunder. The offering costs incurred to register the shares pursuant to the prospectus supplement dated August 11, 2017 were $164,825. On October 3, 2018, the Company filed an updated prospectus supplement with the SEC and may offer and sell shares of the Company's common stock pursuant to the sales agreement having an aggregate offering price of up to $9.0 million, from time to time. The prospectus supplement filed on October 3, 2018, supersedes the prospectus supplement dated August 11, 2017, and no additional shares will be offered or sold pursuant to the prospectus supplement dated August 11, 2017.

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.

On July 2, 2018, the Company closed an underwritten public offering of 7,766,990 shares of its common stock and warrants to purchase up to an aggregate of 3,106,796 shares of its common stock at a combined offering price of $1.03. In addition, at the closing the underwriters exercised the over-allotment option to purchase additional warrants to purchase up to 466,019 shares of common stock. The warrants have a per share exercise price of $2.25 and will expire forty-two months from the date of issuance. On July 9, 2018, the underwriters exercised the over-allotment option to purchase 1,165,048 additional shares of common stock. The total gross proceeds to the Company from the offering were approximately $9.2 million before deducting underwriting discounts and commissions and other estimated offering expenses. In connection with the public offering, warrants to purchase 155,340 shares of the Company’s common stock were issued to representatives of the underwriters of the offering. The warrants are exercisable at a per share price of $1.13 and are exercisable twelve months from the effective date of the offering and will expire forty-two months from the effective date of the offering.

Note 7. Commitments and Contingencies

The Company has commitments of approximately $425,000 as of September 30, 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. During the nine months ended September 30, 2018, approximately $197,000 was paid to the University of British Columbia as a milestone payment, which was accrued for at December 31, 2017.

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 September 30, 2018, no milestones 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:

Year	Research and Development	Property and Other Leases	Total
October 1 through December 31, 2018	$ 25,000	$ 36,753	$61,753
2019	100,000	145,713	245,713
2020	100,000	118,833	218,833
2021	100,000	-	100,000
2022	100,000	-	100,000
Total	$ 425,000	$ 301,299	$726,299

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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 September 30,	
	2018	**2017**
Contract/Grant Revenue		
Vaccines/BioDefense	$1,101,222	$1,395,234
BioTherapeutics	280,131	426,832
Total	$1,381,353	$1,822,066
Income (Loss) from Operations		
Vaccines/BioDefense	$(29,743)	$48,840
BioTherapeutics	(1,066,152)	(161,463)
Corporate	(822,694)	(857,000)
Total	$(1,918,589)	$(969,623)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$4,496	$9,279
BioTherapeutics	5,247	7,792
Corporate	1,265	905
Total	$11,008	$17,976
Other Income (Expense), Net		
Corporate	$56,981	$6,529
Share-Based Compensation		
Vaccines/BioDefense	$12,818	$11,303
BioTherapeutics	28,109	22,827
Corporate	23,142	53,952
Total	$64,069	$88,082

	Nine Months Ended September 30,	
	2018	**2017**
Contract/Grant Revenue		
Vaccines/BioDefense	$3,359,521	$3,717,089
BioTherapeutics	867,149	426,832
Total	4,226,670	$4,143,921
Income (Loss) from Operations		
Vaccines/BioDefense	$(85,649)	$382,710
BioTherapeutics	(3,511,460)	(2,763,279)
Corporate	(2,304,871)	(2,644,073)
Total	$(5,901,980)	$(5,024,642)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$13,488	$28,659
BioTherapeutics	15,976	25,436
Corporate	3,928	3,552
Total	$33,392	$57,647
Other Income, Net		
Corporate	$106,824	$16,513
Share-Based Compensation		
Vaccines/BioDefense	$41,304	$44,274
BioTherapeutics	78,325	95,424
Corporate	142,835	189,058
Total	$262,464	$328,756

	As of September 30, 2018	**As of December 31, 2017**
Identifiable Assets		
Vaccines/BioDefense	$ 956,638	$ 906,416
BioTherapeutics	111,342	116,344
Corporate	12,221,409	8,526,891
Total	$ 13,289,389	$ 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®, our ricin toxin vaccine candidate, OrbeShield®, 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 ricin vaccine program currently is supported by our 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"), we will attempt to advance the development of RiVax® to protect against exposure to ricin toxin. We have advanced the development of OrbeShield® 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:

Following positive interim analysis, complete enrollment and report final 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;

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.

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

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
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 positive interim analysis received in October 2018, and final results expected in the first quarter of 2020
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial initiated July 2017, with interim analysis anticipated in the first half of 2019 and final results expected in the second half of 2019
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed; efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial initiation contingent upon additional funding, such as through partnership
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial completed; safety profile and preliminary efficacy demonstrated; further clinical development contingent upon additional funding, such as through partnership

Vaccine Thermostability Platform**

Soligenix Product Candidate	Indication	Stage of Development
ThermoVax®	Thermostability of aluminum adjuvanted vaccine for ricin	Pre-clinical

BioDefense Products**

Soligenix Product Candidate	Indication	Stage of Development
RiVax®	Vaccine against Ricin Toxin Poisoning	Phase 1a and 1b trials completed, safety and neutralizing antibodies for protection demonstrated; Phase 2 trial planned for the first half of 2019
OrbeShield®	Therapeutic against GI ARS	Pre-clinical
SGX943	Therapeutic against Emerging Infectious Diseases	Pre-clinical

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

BioTherapeutics Overview

SGX301 – for Treating Cutaneous T-Cell Lymphoma

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

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

Hypericin is one of the most efficient known generators of singlet oxygen, the key component for phototherapy. The generation of singlet oxygen induces necrosis and apoptosis in adjacent cells. The use of topical synthetic hypericin coupled with directed visible light results in generation of singlet oxygen only at the treated site. We believe that the use of visible light (as opposed to cancer-causing ultraviolet light) is a major advance in photodynamic therapy. In a published Phase 2 clinical study in CTCL, after six weeks of twice weekly therapy, a majority of patients experienced a statistically significant ($p \leq 0.04$) improvement with SGX301 whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively.

SGX301 has received Orphan Drug designation as well as Fast Track designation from the FDA. The Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven-year term of market exclusivity for SGX301 upon final FDA approval, Orphan Drug designation also positions us to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of FDA user fees for the potential submission of a New Drug Application ("NDA") for SGX301, and certain tax credits. In addition, Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a NDA for SGX301 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review. SGX301 for the treatment of CTCL also was granted Orphan Drug designation in the European Union ("EU") from the European Medicines Agency ("EMA") Committee for Orphan Medical Products and Promising Innovative Medicine ("PIM") designation from the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom ("UK").

We initiated our pivotal Phase 3 clinical study of SGX301 for the treatment of CTCL during December 2015. This trial, referred to as the "FLASH" study (Fluorescent Light Activated Synthetic Hypericin), aims to evaluate the response to SGX301 as a skin directed therapy to treat early stage CTCL. We are actively enrolling patients with approximately thirty CTCL centers across the U.S. participating in this pivotal trial. The Phase 3 protocol is a highly powered, double-blind, randomized, placebo-controlled, multicenter trial and will seek to enroll approximately 120 evaluable subjects. The trial will consist of three treatment cycles, each of eight weeks duration. Treatments will be administered twice weekly for the first six weeks and treatment response will be determined at the end of the eighth week. In the first treatment cycle, approximately 80 subjects will receive SGX301 and 40 will receive placebo treatment of their index lesions. In the second cycle, all subjects will receive SGX301 treatment of their index lesions, and in the third cycle all subjects will receive SGX301 treatment of all of their lesions. The majority of subjects enrolled to date have elected to continue into the third optional, open-label cycle of the study. We continue to work closely with the Cutaneous Lymphoma Foundation, as well as the National Organization for Rare Disorders. Subjects will be followed for an additional six months after their last evaluation visit. The primary efficacy endpoint will be assessed on the percentage of patients in each of the two treatment groups (i.e., SGX301 and placebo) achieving a partial or complete response of the treated lesions, defined as a ≥ 50% reduction in the total Composite Assessment of Index Lesion Disease Severity ("CAILS") score for three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline. Other secondary measures will assess treatment response including duration, degree of improvement, time to relapse and safety.

During September 2017, the National Cancer Institute ("NCI"), part of the National Institutes of Health ("NIH") awarded us a Small Business Innovation Research ("SBIR") grant of approximately $1.5 million over two years to support the conduct of our pivotal, Phase 3, randomized, double-blind, placebo-controlled study evaluating SGX301 (synthetic hypericin) as a treatment for CTCL.

During October 2018, an Independent Data Monitoring Committee ("DMC") completed an unblinded interim analysis with data from approximately 100 subjects, including an assessment of the Phase 3 FLASH study's primary efficacy endpoint. The DMC provided a positive recommendation to randomize approximately 40 additional subjects into the trial to maintain the rigorous assumption of 90% statistical power for the primary efficacy endpoint. No safety concerns were reported by the DMC based on the interim analysis.

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

Cutaneous T-Cell Lymphoma

CTCL is a class of non-Hodgkin's lymphoma ("NHL"), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs, which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These skin-trafficking malignant T-cells migrate to the skin, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. Mycosis fungoides ("MF") is the most common form of CTCL. It generally presents with skin involvement only, manifested as scaly, erythematous patches. Advanced disease with diffuse lymph node and visceral organ involvement is usually associated with a poorer response rate to standard therapies. A relatively uncommon sub-group of CTCL patients present with extensive skin involvement and circulating malignant cerebriform T-cells, referred to as Sézary syndrome. These patients have substantially graver prognoses (expected five-year survival rate of 24%), than those with MF (expected five-year survival rate of 88%).

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

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

Dusquetide

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

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

Dusquetide has demonstrated efficacy in numerous animal disease models including mucositis, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. Dusquetide was shown to have a good safety profile and be well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. We believe that market opportunities for dusquetide include, but are not limited to, oral and gastrointestinal mucositis, acute Gram-positive bacterial infections (e.g., methicillin resistant *Staphylococcus aureus* (MRSA)), acute Gram-negative infections (e.g., acinetobacter, melioidosis), and acute radiation syndrome.

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is our product candidate containing our IDR technology, dusquetide, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA. In addition, dusquetide has been granted PIM designation in the UK by the MHRA for the treatment of severe oral mucositis in head and neck cancer patients receiving chemoradiation therapy. The U.S. Patent and Trademark Office has granted the patent titled “Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis”. The newly issued patent claims therapeutic use of dusquetide and related IDR analogs, and adds to composition of matter claims for dusquetide and related analogs that have been granted in the U.S. and worldwide.

We initiated a Phase 2 clinical study of SGX942 for the treatment of oral mucositis in head and neck cancer patients in December of 2013. We completed enrollment in this trial in the second half of 2015, and in December 2015 released positive preliminary results. In this Phase 2 proof-of-concept clinical study that enrolled 111 patients, SGX942, at a dose of 1.5 mg/kg, successfully reduced the median duration of severe oral mucositis by 50%, from 18 days to 9 days ($p=0.099$) in all patients and by 67%, from 30 days to 10 days ($p=0.040$) in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. The p-values met the prospectively defined statistical threshold of $p<0.1$ in the study protocol. A less severe occurrence of oral mucositis, ulcerative oral mucositis (defined as oral mucositis with a WHO score ≥2 corresponding to the occurrence of overt ulceration in the mouth), was also monitored during the study. In the patients receiving the most aggressive chemoradiation therapy, the median duration of oral mucositis was found to decrease from 65 days in the placebo treated patients to 51 days in the patients treated with SGX942 1.5 mg/kg ($p=0.099$).

In addition to identifying the best dose of 1.5 mg/kg, this study achieved all objectives, including increased incidence of “complete response” of tumor at the one month follow-up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and decreases in infection rate were also observed with SGX942 treatment, consistent with the preclinical results observed in animal models.

SGX942 was found to be generally safe and well tolerated, consistent with the safety profile observed in the prior Phase 1 study conducted in 84 healthy volunteers. The long-term (12 month) follow-up data was consistent with the preliminary positive safety and efficacy findings. While the placebo population experienced the expected 12-month survival rate of approximately 80%, as defined in the Surveillance, Epidemiology, and End Results statistics 1975-2012 from the National Cancer Institute, the SGX942 1.5 mg/kg treatment group reported a 12-month survival rate of 93% (7% mortality in the SGX942 1.5 mg/kg group compared to 19% in the placebo group). Similarly, tumor resolution (complete response) at 12 months was better in the SGX942 1.5 mg/kg treatment group relative to the placebo population (80% in the 1.5 mg/kg group compared to 74% in the placebo group). Moreover, in the patients receiving chemotherapy every third week, the SGX942 1.5 mg/kg treatment group had a tumor resolution rate (complete response) of 82% throughout the 12 months following chemoradiation therapy, while the placebo group experienced a 64% complete response rate. The long-term follow-up results from the Phase 2 study are reviewed in "Dusquetide: Reduction in Oral Mucositis associated with Enduring Ancillary Benefits in Tumor Resolution and Decreased Mortality in Head and Neck Cancer Patients" published online in Biotechnology Reports and available at the following link: https://doi.org/10.1016/j.btre.2017.05.002. In addition to safety, evaluations of other secondary efficacy endpoints, such as the utilization of opioid pain medication, indicated that the SGX942 1.5mg/kg treatment group had a 40% decrease in the use of opioids at the later stage of the treatment phase of the trial, when oral mucositis is usually most severe and expected to increase pain medication use. This was in contrast to the placebo group, which demonstrated a 10% increase in use of opioids over this same period. Data from this Phase 2 trial was published online in the Journal of Biotechnology. The publication also delineates the supportive nonclinical data in this indication, demonstrating consistency in the qualitative and quantitative biological response, including dose response, across the nonclinical and clinical data sets. The results are available at the following link: http://authors.elservier.com/sd/article/S01681656116315668.

On September 9, 2016, we and SciClone Pharmaceuticals, Inc. ("SciClone") entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in defined territories. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territories, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

We have received clearance from the FDA to advance the pivotal Phase 3 protocol for SGX942 in the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. Additionally, we have received positive Scientific Advice from the EMA for the development of SGX942 as a treatment for oral mucositis in patients with head and neck cancer. The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, multinational, Phase 3 pivotal study, if successful, in conjunction with the Phase 2 dose-ranging study, is generally considered sufficient to support a marketing authorization application ("MAA") to the EMA for potential licensure in Europe. The advice also provided several suggestions to strengthen the study design and data collection that were integrated into the final protocol. Scientific Advice is offered by the EMA to stakeholders for clarification of questions arising during development of medicinal products. The scope of Scientific Advice is limited to scientific issues and focuses on development strategies rather than pre-evaluation of data to support an MAA. Scientific Advice is legally non-binding and is based on the current scientific knowledge which may be subject to future changes.

We had been working with leading oncology centers, a number of which participated in the Phase 2 study, to advance this Phase 3 clinical trial referred to as the "DOM–INNATE" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity). Based on the positive and previously published Phase 2 results (Study IDR-OM-01), the pivotal Phase 3 clinical trial (Study IDR-OM-02) is a highly powered, double-blind, randomized, placebo-controlled, multinational trial that will seek to enroll approximately 190 subjects with squamous cell carcinoma of the oral cavity and oropharynx who are scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m^2 every third week. Subjects will be randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for two weeks following completion of chemoradiation therapy ("CRT"). The primary endpoint for the study will be the median duration of severe oral mucositis, which will be assessed by oral examination at each treatment visit and then through six weeks following completion of CRT. Oral mucositis will be evaluated using the WHO Grading system. Severe oral mucositis is defined as a WHO Grade of ≥3. Subjects will be followed for an additional 12 months after the completion of treatment.

During July 2017, we initiated our pivotal Phase 3 study with a controlled roll-out of U.S. study sites, followed by the addition of European centers in 2018. We anticipate that approximately fifty U.S. and European oncology centers will be participating in this pivotal Phase 3 study.

During September 2017, the National Institute of Dental and Craniofacial Research ("NIDCR"), part of the NIH, awarded us a SBIR grant of approximately $1.5 million over two years to support the conduct of our Phase 3, multinational, randomized, double-blind, placebo-controlled study evaluating SGX942 (dusquetide) as a treatment for severe oral mucositis in patients with head and neck cancer receiving CRT.

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

Oral Mucositis

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

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

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

Oral BDP

Oral BDP (beclomethasone 17,21-dipropionate) represents a first-of-its-kind oral, locally acting therapy tailored to treat GI inflammation. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. Oral BDP is specifically formulated for oral administration as a single product consisting of two tablets. One tablet is intended to release BDP in the upper sections of the GI tract and the other tablet is intended to release BDP in the lower sections of the GI tract.

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

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

SGX203 – for Treating Pediatric Crohn's Disease

SGX203 is a two tablet delivery system of BDP specifically designed for oral use that allows for administration of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has given SGX203 Orphan Drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease. A pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease will be contingent upon additional funding, such as through partnership funding support.

Pediatric Crohn's Disease

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

Crohn's disease can appear at any age, but it is most often diagnosed in adults in their 20s and 30s. However, approximately 30% of people with Crohn's disease develop symptoms before 20 years of age. We estimate, based upon our review of historic published studies and reports, and an interpolation of data on the incidence of pediatric Crohn's disease, that pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the U.S. with a comparable number in Europe. Crohn's disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (approximately 40%) of pediatric Crohn's patients have involvement of their upper gastrointestinal tract.

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

SGX201 – for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. In 2012, we completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study were to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. The study demonstrated that oral administration of SGX201 was safe and well tolerated across all four dose groups. There was also evidence of a potential dose response with respect to diarrhea, nausea and vomiting and the assessment of enteritis according to National Cancer Institute Common Terminology Criteria for Adverse Events for selected gastrointestinal events. In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population. This program was supported in part by a $500,000 two-year SBIR grant awarded by the NIH. We continue to work with our Radiation Enteritis medical advisors to identify additional funding opportunities to support the clinical development program. Further clinical development of SGX201 will be contingent upon additional funding, such as through partnership.

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

Acute Radiation Enteritis

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

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

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

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

Vaccines/BioDefense Overview

ThermoVax® – Thermostability Technology

ThermoVax® is a novel method of rendering aluminum salt, (known colloquially as Alum), adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax® lies in its potential ability to eliminate the need for cold chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve the high costs of producing and maintaining vaccines under

refrigerated conditions. Based on historical reports from the World Health Organization and other scientific reports, we believe that a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius ("C") and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. ThermoVax® has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines for ricin exposure in emergency settings.

ThermoVax® development was supported pursuant to our $9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax®) and anthrax (VeloThrax®) vaccines. Proof-of-concept preclinical studies with ThermoVax® indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our aluminum-adjuvanted ricin toxin vaccine, RiVax® and our aluminum-adjuvanted anthrax vaccine, VeloThrax®. Each vaccine was manufactured under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax® was kept at 40 degrees C (104 degrees Fahrenheit) for up to one year, all of the animals vaccinated with the lyophilized RiVax® vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax® vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C. When VeloThrax® was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we also have demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists.

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

During September 2017, we announced we will be participating in a NIAID Research Project (R01) grant awarded to UH Manoa for the development of a trivalent thermostabilized Ebola vaccine, with our awarded funding of approximately $700,000 over five years. Previous collaborations demonstrated the feasibility of developing a heat stable subunit Ebola vaccine. Under the terms of the subaward, we will continue to support vaccine formulation development with our proprietary vaccine thermostabilization technology, ThermoVax®. Ultimately, the objective is to produce a thermostable trivalent filovirus vaccine for protection against Ebola and related diseases, allowing worldwide distribution without the need for cold storage.

On December 21, 2010, we executed a worldwide exclusive license agreement with the UC for certain patents relating to ThermoVax® in all fields of use. In April 2018, the UC delivered a notice of termination of our license agreement based upon our failure to achieve one of the development milestones: initiation of the Phase 1 clinical trial of the heat stabilization technology by March 31, 2018. After negotiating with the UC, we and the UC agreed to extend the termination date to October 31, 2018 in order to allow us time to agree upon a potential agreement that would allow us to keep the rights to, and to continue to develop, the heat stabilization technology or a product candidate containing the heat stabilization technology in our field of use.

On October 31, 2018, in a series of related transactions, (a) we and the UC agreed to terminate the original license agreement; (b) the UC and VitriVax, Inc. ("VitriVax") executed a worldwide exclusive license agreement for the heat stabilization technology for all fields of use, and (c) we and VitriVax executed a worldwide exclusive sublicense agreement for the heat stabilization technology for use in the fields of ricin and Ebola vaccines.

RiVax® – Ricin Toxin Vaccine

RiVax® is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin and if approved, would be the first ricin vaccine. The immunogen in RiVax® induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated ricin A chain subunit that is enzymatically inactive and lacks residual toxicity of the holotoxin. RiVax® has demonstrated statistically significant ($p < 0.0001$) preclinical survival results, providing 100% protection against acute lethality in an aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS USA 112:3782-3787), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax® established that the immunogen was safe and induced antibodies that we believe may protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial which was completed in September 2012 and was sponsored by University of Texas Southwestern Medical Center ("UTSW"), evaluated a more potent formulation of RiVax® that contained an aluminum adjuvant (Alum). The results of the Phase 1b study indicated that Alum-adjuvanted RiVax® was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax®. The outcomes of this second study were published in the Clinical and Vaccine Immunology (Vitetta et al., 2012, Recombinant Ricin Vaccine Phase 1b Clinical Trial, Clin. Vaccine Immunol. 10:1697-1699). We have adapted the original manufacturing process for the immunogen contained in RiVax® for thermostability and large scale manufacturing and recent studies have confirmed that the thermostabilized RiVax® formulation enhances the stability of the RiVax® antigen, enabling storage for at least 1 year at temperatures up to 40°C (104 °F). The program will pursue approval via the FDA "Animal Rule" since it is not possible to test the efficacy of the vaccine in a clinical study which would expose humans to ricin. Uniform, easily measured and species-neutral immune correlates of protection that can be measured in humans and animals, and are indicative of animal survival to subsequent ricin challenge, are central to the application of the "Animal Rule". Recent work has identified such potential correlates of immune protection in animals and work to qualify and validate these approaches is continuing, with the goal of utilizing these assays in a planned Phase 1/2 clinical trial with the thermostable RiVax® formulation. We have entered into a collaboration with IDT Biologika GmbH to scale-up the formulation/filling process and continue development and validation of analytical methods established at IDT to advance the program. We also have initiated a development agreement with Emergent BioSolutions, Inc. to implement a commercially viable, scalable production technology for the RiVax® drug substance protein antigen.

The development of RiVax® has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to us and to UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately $25 million in grant funding from the NIH for the development of RiVax®. In September 2014, we entered into a contract with the NIH for the development of RiVax® that would provide up to an additional $24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH. The development agreements with Emergent BioSolutions and IDT are specifically funded under this NIH contract.

During June 2017, NIAID exercised an option for the evaluation of RiVax® to fund additional animal efficacy studies. The exercised option will provide us with approximately $2.0 million in additional funding. Additionally, during August 2017 NIAID exercised an option to fund good manufacturing practices compliant RiVax® bulk drug substance and finished drug product manufacturing, which is required for the conduct of future preclinical and clinical safety and efficacy studies. The exercised option will provide us with approximately $2.5 million in additional non-dilutive funding, bringing the total amount awarded to date under this contract to $21.2 million, of which $16.2 million is still available. If all contract options are exercised, the total award of up to $24.7 million will support the preclinical, manufacturing and clinical development activities necessary to advance heat stable RiVax® with the FDA. In addition, biomarkers for RiVax® testing have been successfully identified, facilitating potential approval under the FDA Animal Rule.

RiVax® has been granted Orphan Drug designation by the FDA for the prevention of ricin intoxication. In addition, RiVax® has also been granted Orphan Drug designation in the EU from the EMA Committee for Orphan Medical Products.

Assuming development efforts are successful for RiVax®, we believe potential government procurement contract(s) could reach as much as $200 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements and Industry Data and Market Information.”

As a new chemical entity, an FDA approved RiVax® vaccine has the potential to qualify for a biodefense Priority Review Voucher (“PRV”). Approved under the 21st Century Cures Act in late 2016, the biodefense PRV is awarded upon approval as a medical countermeasure when the active ingredient(s) have not been otherwise approved for use in any context. PRVs are transferable and can be sold, with sales in recent years of up to $350 million. When redeemed, PRVs entitle the user to an accelerated review period of nine months, saving a median of seven months review time as calculated in 2009. However, FDA must be advised 90 days in advance of the use of the PRV and the use of a PRV is associated with an additional user fee ($2.7 million in 2017).

Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigation Bioterror report released in November 2007 titled Terrorism 2002-2005, which states that “Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations” (http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf). In recent years, Al Qaeda in the Arabian Peninsula has threatened the use of ricin toxin to poison food and water supplies and in connection with explosive devices. Domestically, the threat from ricin remains a concern for security agencies. In April 2013, letters addressed to the President of the United States, a U.S. Senator and a judge tested positive for ricin. As recently as October 2018, an envelope addressed to President Trump was suspected to contain this potent and potentially lethal toxin.

The Centers for Disease Control and Prevention has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. The recent ricin threat to government officials has heightened the awareness of this toxic threat. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield nor is there a known antidote for ricin toxin exposure.

OrbeShield® – for Treating GI Acute Radiation Syndrome

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

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

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. We are seeking to treat the same type of toxicity in our acute radiation enteritis clinical program with SGX201. As a result, we believe that OrbeShield® has the potential to be a "dual use" compound, a desirable characteristic which is a specific priority for ARS and other medical countermeasure indications.

In September 2013, we received two government contracts from BARDA and NIAID for the advanced preclinical and manufacturing development of OrbeShield® leading to FDA approval to treat GI ARS. The BARDA contract contained a two-year base period with two contract options, exercisable by BARDA, for a total of five years and up to $26.3 million. The NIAID contract consisted of a one-year base period and two contract options, exercisable by NIAID, for a total of three years and up to $6.4 million. We received a combined approximate $18 million in contract funding from both BARDA and NIAID which includes combined supplemental funding of $634,000, extending the programs through the first quarter of 2017. The NIAID contract was completed during the first quarter of 2017 along with the expiration of the base period of the BARDA contract for the development of OrbeShield®, with BARDA electing not to extend the current contract beyond the base period. We intend to continue to apply for additional government funding, as opportunities to do so become available. Previously, development of OrbeShield® had been largely supported by a $1 million NIH grant to our academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, we received an SBIR grant from NIAID of approximately $600,000 to support further preclinical development of OrbeShield® for the treatment of acute GI ARS. The FDA has given OrbeShield® Orphan Drug designation and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

Assuming development efforts are successful for OrbeShield®, we believe potential government procurement contracts could reach as much as $450 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information."

GI Acute Radiation Syndrome

ARS occurs after toxic radiation exposure and involves several organ systems, notably the bone marrow, the GI tract and later the lungs. In the event of a nuclear disaster or terrorist detonation of a nuclear bomb, casualties exposed to greater than 2 grays ("Gy") of absorbed radiation are at high risk for development of clinically significant ARS. Exposure to high doses of radiation exceeding 10-12 Gy causes acute GI injury which can result in death. The GI tract is highly sensitive due to the continuous need for crypt stem cells and production of mucosal epithelium. The extent of injury to the bone marrow and the GI tract are the principal determinants of survival after exposure to TBI. Although

the hematopoietic syndrome can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. As a result, we believe there is an urgent medical need for specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

SGX943 – for Treating Emerging and/or Antibiotic-Resistant Infectious Diseases

SGX943 is an IDR, containing the same active ingredient as SGX942. Dusquetide is a fully synthetic, 5-amino acid peptide with high aqueous solubility and stability. Extensive *in vivo* preclinical studies have demonstrated enhanced clearance of bacterial infection with SGX943 administration. SGX943 has shown efficacy against both Gram-negative and Gram-positive bacterial infections in preclinical models, independent of whether the bacteria is antibiotic-resistant or antibiotic-sensitive.

The innate immune system is responsible for rapid and non-specific responses to combat bacterial infection. Augmenting these responses represents an alternative approach to treating bacterial infections. In animal models, IDRs are efficacious against both antibiotic-sensitive and antibiotic-resistant infections, both Gram-positive and Gram-negative bacteria, and are active irrespective of whether the bacteria occupies a primarily extracellular or intracellular niche. IDRs are also effective as stand-alone agents or in conjunction with antibiotics. An IDR for the treatment of serious bacterial infections encompasses a number of clinical advantages including:

Treatment when antibiotics are contraindicated, such as:

before the infectious organism and/or its antibiotic susceptibility is known; or

in at-risk populations prior to infection.

An ability to be used as an additive, complementary treatment with antibiotics, thereby:

enhancing efficacy of sub-optimal antibiotic regimens (e.g., partially antibiotic-resistant infections);

enhancing clearance of infection, thereby minimizing the generation of antibiotic resistance; and

reducing the required antibiotic dose, again potentially minimizing the generation of antibiotic resistance.

An ability to modulate the deleterious consequences of inflammation in response to the infection, including the inflammation caused by antibiotic-driven bacterial lysis; and

Being unlikely to generate bacterial resistance since the IDR acts on the host, and not the pathogen.

Importantly, systemic inflammation and multi-organ failure is the ultimate common outcome of not only emerging and/or antibiotic-resistant infectious diseases, but also of most biothreat agents (e.g., *Burkholderia pseudomallei*), indicating that dusquetide would be applicable not only to antibiotic-resistant infection, but also to biothreat agents, especially where the pathogen is not known and/or has been engineered for enhanced antibiotic resistance.

Critical Accounting Policies

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

Revenue Recognition

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

From time to time, we issue restricted shares of 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 fair value of each option grant made during 2018 and 2017 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

On December 22, 2017, the 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. We do not anticipate any impact to tax expense due to the full valuation allowance on our deferred tax assets and believe that the most significant impact on our 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 our 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 we refine our estimates or complete our 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 our current and past performance, the market environment in which we operate, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through June 30, 2018 due to the net operating losses incurred by us since our inception. We recognize 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 2018 or 2017. Additionally, we have not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at June 30, 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.

Use of Estimates and Assumptions

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

Material Changes in Results of Operations

Three and Nine Months Ended September 30, 2018 Compared to September 30, 2017

For the three months ended September 30, 2018, we had a net loss of $1,861,608 as compared to a net loss of $963,094 for the same period in the prior year, representing an increase in the net loss of $898,514 or 93%. For the nine months ended September 30, 2018, we had a net loss of $5,795,156 as compared to a net loss of $5,008,129 for the same period in the prior year, representing an increase in the net loss of $787,027 or 16%. The increase in net loss for the three and nine months ended September 30, 2018 is primarily due to increased expenditures incurred to support both the pivotal Phase 3 trial of SGX301 in the treatment of cutaneous T-cell lymphoma and the pivotal Phase 3 trial of SGX942 in the treatment of oral mucositis in head and neck cancer.

For the three and nine months ended September 30, 2018, revenues related to government contracts awarded in support of our development of RiVax®, our ricin toxin vaccine program, as well as grants awarded in support of our pivotal Phase 3 clinical trials of SGX301 and SGX942. For the three months ended September 30, 2018, we had revenues of $1,381,353 as compared to $1,822,066 for the same period in the prior year, representing a decrease of $440,713 or 24%. For the nine months ended September 30, 2018, we had revenues of $4,226,670 as compared to $4,143,921 for the same period in the prior year, representing an increase of $82,749 or 2%. The decrease in revenues for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was a result of a RiVax® milestone payment received during the three months ended September 30, 2017 and decreased reimbursable employee costs incurred during the three months ended September 30, 2018.

We incurred costs related to those revenues for the three months ended September 30, 2018 and 2017 of $1,237,230 and $1,474,151, respectively, representing a decrease of $236,921 or 16%. For the nine months ended September 30, 2018, costs related to revenues were $3,709,827 as compared to $3,238,633 for the same period in the prior year, representing an increase of $471,194 or 15%. The increase in costs during the nine months ended September 30, 2018 as compared to September 30, 2017 was primarily the result of the increased manufacturing costs incurred in the scale up of the manufacturing process for RiVax®.

Our gross profit for the three months ended September 30, 2018 was $144,123 or 10% of revenues, as compared to $347,915 or 19% of revenues for the same period in 2017, representing a decrease of $203,792 or 9% of revenues. For the nine months ended September 30, 2018, gross profit was $516,843 or 12% of revenues, as compared to $905,288 or 22% of revenues for the same period in 2017, representing a decrease of $388,445 or 10% of revenues. The decrease in gross profit percentage for the three and nine months ended September 30, 2018, as compared to the same periods in 2017, was primarily attributable to higher amounts of reimbursement in 2017 for certain contractor and employee expenses from contracts. The decrease in gross profit for the three and nine months ended September 30, 2018 is attributable to a smaller share of reimbursable costs that were available for contracted fixed overhead reimbursement compared to the same period of the prior year. Additionally, we received a milestone fee in the third quarter of 2017 under our RiVax® contract with NIAID. There was no similar milestone received for the three months ended September 30, 2018.

Research and development expenses were $1,394,913 for the three months ended September 30, 2018 as compared to $605,719 for the same period in 2017, representing an increase of $789,194 or 130%. For the nine months ended September 30, 2018, research and development expenses were $4,377,483 compared to $3,606,973 for the same period in 2017, representing an increase of $770,510 or 21%. The increase in research and development spending for the three and nine months ended September 30, 2018 was primarily due to the expenditures incurred in the Phase 3 clinical trial of SGX942, including the expansion of the trial to select countries in Europe, as well as the ongoing Phase 3 clinical trial of SGX301.

General and administrative expenses were $667,799 for the three months ended September 30, 2018 as compared to $711,819 for the same period in 2017, representing a decrease of $44,020 or 6%. For the nine months ended September 30, 2018, general and administrative expenses were $2,041,340 compared to $2,322,957, representing a decrease of $281,617 or 12%. The decrease in general and administrative expenses for the three and nine months ended September 30, 2018 is primarily related to a decrease in professional consulting fees and to a decrease in our compensation expenses, including share-based compensation expense.

Interest income for the three months ended September 30, 2018 was $56,981 as compared to $6,529 for the same period in 2017, representing an increase of $50,452 or 773%. Interest income for the nine months ended September 30, 2018 was $106,824 as compared to $16,513 for the same period in 2017, representing an increase of $90,311 or 547%. The increase is due to larger cash investments in dividend-producing accounts for the three and nine months ended September 30, 2018 as compared to the same periods in 2017.

Financial Condition

Cash and Working Capital

As of September 30, 2018, we had cash and cash equivalents of $11,720,085 as compared to $7,809,487 as of December 31, 2017, representing an increase of $3,910,598 or 50%. As of September 30, 2018, we had working capital of $9,118,737 as compared to working capital of $6,185,863 as of December 31, 2017, representing an increase of $2,932,874 or 47%. The increase in cash and working capital was primarily related to the net proceeds from our July 2018 public offering of approximately $8.4 million offset by the increased 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, as well as the ongoing Phase 3 clinical trial of SGX301.

Based on our 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, proceeds available from the at-the-market ("ATM") sales agreement with B. Riley FBR, Inc. ("FBR"), 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 included in this Quarterly Report on Form 10-Q.

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

We have up to $15.2 million in active government contract funding still available to support our associated research programs through 2018 and beyond, provided the federal agencies exercise all options and do not elect to terminate the contracts for convenience. We plan to submit additional contract and grant applications for further support of our programs with various funding agencies;

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

We will pursue 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 $416,810 in proceeds from the sale of NJ NOL in 2017, we expect to participate in the program for the year ending December 31, 2018 and beyond if the program is available;

We plan to pursue potential partnerships for pipeline programs. However, there can be no assurances that we can consummate such transactions;

We have up to $9.0 million remaining from the ATM sales agreement with FBR under the prospectus supplement updated October 3, 2018;

We have up to $10.1 million available from an equity facility expiring in March 2019; and

We may seek additional capital in the private and/or public equity markets, pursue government contracts and grants as well as business development activities, to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately $13.4 million before any contract reimbursements, of which $9.3 million relates to the BioTherapeutics business and $4.1 million relates to the Vaccines/BioDefense business. We anticipate contract and grants revenues in the next 12 months of approximately $6.1 million to offset research and development expenses of the Vaccines/BioDefense and BioTherapeutics business segments.

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

	2018	**2017**
Research & Development Expenses		
RiVax® and ThermoVax® Vaccines	**$ 313,735**	$339,609
Dusquetide (SGX942)	**2,332,590**	1,710,973
SGX943	**-**	115
SGX301	**1,451,349**	1,213,268
Other	**279,809**	343,008
Total	**$ 4,377,483**	$3,606,973
Reimbursed under Government Contracts and Grants		
OrbeShield®	**$ -**	$171,618
RiVax® and ThermoVax® Vaccines	**3,125,027**	2,779,728
SGX942	**271,011**	128,186
SGX301	**313,789**	159,101
Total	**$ 3,709,827**	$3,238,633
Grand Total	**$ 8,087,310**	$6,845,606

Contractual Obligations

We have commitments of approximately $425,000 as of September 30, 2018 relating to several licensing agreements with consultants and universities. Additionally, we have collaboration and license agreements, which upon clinical or commercialization success may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur. During the nine months ended September 30, 2018, approximately $197,000 was paid to the University of British Columbia as a milestone payment, which was accrued for at December 31, 2017.

We currently lease 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 our 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, we entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which we 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, we paid $275,000 in cash and issued 184,912 shares of common stock with a fair value of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in our research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the U.S. Provided all future success-oriented milestones are attained, we will be required to make payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company not to exceed 19.9% ownership of our outstanding stock. As of September 30, 2018, no milestone payments have been made or accrued.

In February 2007, our Board of Directors authorized the issuance of 5,000 shares of our common stock to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party. Dr. Schaber’s amended employment agreement includes our obligation to issue such shares if such event occurs.

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

Year	Research and Development	Property and Other Leases	Total
October 1 through December 31, 2018	$ 25,000	$ 36,753	$61,753
2019	100,000	145,713	245,713
2020	100,000	118,833	218,833
2021	100,000	-	100,000
2022	100,000	-	100,000
Total	$ 425,000	$ 301,299	$726,299

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ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are the Company's controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the U.S. Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the possible controls and procedures.

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

Changes in Internal Controls

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

materially affect, the Company’s internal control over financial reporting.

PART II – OTHER INFORMATION.

ITEM 1A – RISK FACTORS

Our business faces significant risks. These risks include those disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. If any of the events or circumstances described in the referenced risks actually occur, our business, financial condition or results of operations could be materially adversely affected and such events or circumstances could cause our actual results to differ materially from the results contemplated by the "forward-looking" statements contained in this report. These risks should be read in conjunction with the other information set forth in this Quarterly Report as well as in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in our periodic reports on Form 10-Q and Form 8-K. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements, except as required by law.

SIGNATURES

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

SOLIGENIX, INC.

November 9, 2018 by /s/ Christopher J. Schaber
Christopher J. Schaber, PhD
President and Chief Executive Officer
(Principal Executive Officer)

November 9, 2018 by /s/ Karen Krumeich
Karen Krumeich
Senior Vice President & Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
31.1	Certification of Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
31.2	Certification of Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.