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	