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

(State or other jurisdiction of incorporation or organization)

41-1505029

(I.R.S. Employer Identification Number)

29 EMMONS DRIVE, SUITE B-10PRINCETON, NJ08540(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.

Index

	Description	Page
Part I	FINANCIAL INFORMATION	1
Item 1	Consolidated Financial Statements Consolidated Balance Sheets as of September 30, 2018 (unaudited) and December 31, 2017 Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017 (unaudited) Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017 (unaudited) Consolidated Statement of Changes in Shareholders' Equity for the Nine Months Ended September 30, 2018 (unaudited) Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 (unaudited) Notes to Consolidated Financial Statements (unaudited)	1 1 2 3 4 5 6
Item 3 Item 4	Management's Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures About Market Risk Controls and Procedures	19 39 39 40
Item 1A	Risk Factors	40

Item 6 Exhibits

PART I - FINANCIAL INFORMATION

ITEM 1 - Financial Statements

Soligenix, Inc. and Subsidiaries

Consolidated Balance Sheets

Assets	September 30, 2018 (Unaudited)	December 31, 2017
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.

1

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	· · · ·	· · · · · ·	\$(0.50)	\$(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.

Consolidated Statements of Comprehensive Loss

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

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 3	0,
	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.

3

Consolidated Statement of Changes in Shareholders' Equity

For the Nine Months Ended September 30, 2018

(Unaudited)

	Common Stock		Additional Accumulated Paid-In Comprehensive		Accumulated	
	Shares	Par Value	Deficit	Loss	Deficit	Total
Balance, December 31, 2017 Issuance of common stock	8,730,640	\$8,731	\$163,581,026	\$ -	\$(157,270,045)	\$6,319,712
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 Balance, September 30, 2018	- 17,682,839	- \$17,683	- \$172,317,754	- \$ (1,767)	(5,795,156)) \$(163,065,201)	(5,795,156) \$9,268,469

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

Consolidated Statements of Cash Flows

For the Nine Months Ended September 30,

(Unaudited)

	2018	2017
Operating activities: Net loss	\$ (5 705 156)	\$(5,008,129)
Adjustments to reconcile net loss to net cash used in operating activities:	\$(3,733,130)	\$(3,000,129)
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)	
Income tax receivable	416,810	-
Accounts payable and accrued expenses	753,768	54,714
Accrued compensation	(270,000)	
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.

5

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 developmen