

SOLIGENIX, INC.
Form 10-Q
August 11, 2016

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended June 30, 2016

or

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

For the transition period from _____ to _____

Commission File No. 000-16929

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

41-1505029

(I.R.S. Employer
Identification Number)

29 EMMONS DRIVE, SUITE C-10

08540

PRINCETON, NJ

(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 and posted on its corporate Web Site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of August 8, 2016, 33,577,522 shares of the registrant's common stock (par value, \$.001 per share) were outstanding.

SOLIGENIX, INC.

Index

Description	Page
Part I FINANCIAL INFORMATION	
Item 1 Consolidated Financial Statements	3
Consolidated Balance Sheets as of June 30, 2016 (unaudited) and December 31, 2015	3
Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2016 and 2015 (unaudited)	4
Consolidated Statement of Changes in Shareholders' Equity (Deficiency) for the Six Months Ended June 30, 2016 (unaudited)	5
Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2016 and 2015 (unaudited)	6
Notes to Consolidated Financial Statements (unaudited)	7
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	21
Item 3 Quantitative and Qualitative Disclosures About Market Risk	39
Item 4 Controls and Procedures	39
Part II OTHER INFORMATION	
Item 1A Risk Factors	40
Item 2 Unregistered Sales of Equity Securities and Use of Proceeds	40
Item 6 Exhibits	42
SIGNATURES	41
2	

PART I - FINANCIAL INFORMATION**ITEM 1 - Financial Statements****Soligenix, Inc. and Subsidiaries****Consolidated Balance Sheets**

	June 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$3,183,289	\$4,921,545
Contracts and grants receivable	1,805,871	1,985,212
Prepaid expenses	229,064	244,267
Total current assets	5,218,224	7,151,024
Office furniture and equipment, net	39,927	47,366
Intangible assets, net	157,896	188,732
Total assets	\$5,416,047	\$7,387,122
Liabilities and shareholders' equity (deficiency)		
Current liabilities:		
Accounts payable	\$4,177,376	\$4,379,936
Notes payable	-	292,719
Warrant liability	1,148,616	2,434,101
Accrued compensation	56,169	298,675
Total current liabilities	5,382,161	7,405,431
Commitments and contingencies		
Shareholders' equity (deficiency):		
Preferred stock, 350,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 100,000,000 shares and 50,000,000 shares authorized at June 30, 2016 and December 31, 2015 respectively; 32,859,631 shares and 31,269,522 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	32,860	31,270
Additional paid-in capital	148,120,813	146,828,000
Accumulated deficit	(148,119,787)	(146,877,579)
Total shareholders' equity (deficiency)	33,886	(18,309)
Total liabilities and shareholders' equity (deficiency)	\$5,416,047	\$7,387,122

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

Soligenix, Inc. and Subsidiaries**Consolidated Statements of Operations****For the Three and Six Months Ended June 30, 2016 and 2015****(Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues				
Contract revenue	\$3,160,050	\$1,082,141	\$5,791,037	\$1,794,547
Grant revenue	-	17,686	-	121,566
Total revenues	3,160,050	1,099,827	5,791,037	1,916,113
Cost of revenues	(2,342,539)	(816,702)	(4,574,874)	(1,344,101)
Gross profit	817,511	283,125	1,216,163	572,012
Operating expenses:				
Research and development	827,832	1,442,914	2,256,332	2,472,798
General and administrative	999,637	874,962	1,875,494	1,692,232
Total operating expenses	1,827,469	2,317,876	4,131,826	4,165,030
Loss from operations	(1,009,958)	(2,034,751)	(2,915,663)	(3,593,018)
Other income (expense):				
Change in fair value of warrant liability	525,328	(1,943,494)	1,285,485	(4,955,110)
Other income	390,599	-	390,599	-
Interest income (expense)	1,256	551	(2,629)	1,112
Total other income (expense)	917,183	(1,942,943)	1,673,455	(4,953,998)
Net loss	\$(92,775)	\$(3,977,694)	\$(1,242,208)	\$(8,547,016)
Basic net loss per share	\$(0.00)	\$(0.15)	\$(0.04)	\$(0.34)
Diluted net loss per share	\$(0.02)	\$(0.15)	\$(0.08)	\$(0.34)
Basic weighted average common shares outstanding	31,769,369	25,726,264	31,524,391	25,066,038
Diluted weighted average common shares outstanding	32,733,781	25,726,264	32,679,813	25,066,038

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

Soligenix, Inc. and Subsidiaries**Consolidated Statement of Changes in Shareholders' Equity / (Deficiency)****For the Six Months Ended June 30, 2016****(Unaudited)**

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2015	31,269,522	\$31,270	\$146,828,000	\$(146,877,579)	\$(18,309)
Issuance of common stock pursuant to Lincoln Park Equity Line	1,540,109	1,540	961,060	-	962,600
Costs associated with Lincoln Park Equity Line	-	-	(41,381)	-	(41,381)
Issuance of common stock to vendors	50,000	50	36,450	-	36,500
Share-based compensation expense	-	-	336,684	-	336,684
Net loss	-	-	-	(1,242,208)	(1,242,208)
Balance, June 30, 2016	32,859,631	\$32,860	\$148,120,813	\$(148,119,787)	\$33,886

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

Soligenix, Inc. and Subsidiaries**Consolidated Statements of Cash Flows****For the Six Months Ended June 30,****(Unaudited)**

	2016	2015
Operating activities:		
Net loss	\$(1,242,208)	\$(8,547,016)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	45,436	121,657
Amortization of discount on debt	7,281	-
Share-based compensation	336,684	279,188
Gain on settlement liability	(390,599)	-
Issuance of common stock for services	36,500	118,761
Change in fair value of warrant liability	(1,285,485)	4,955,110
Change in operating assets and liabilities:		
Contracts and grants receivable	179,341	61,202
Prepaid expenses	15,203	(70,610)
Accounts payable	188,039	(367,098)
Accrued compensation	(242,506)	(266,943)
Total adjustments	(1,110,106)	4,831,267
Net cash used in operating activities	(2,352,314)	(3,715,749)
Investing activities:		
Purchases of office furniture and equipment	(7,161)	(13,706)
Net cash used in investing activities	(7,161)	(13,706)
Financing activities:		
Proceeds from issuance of common stock pursuant to the equity line	962,600	1,115,025
Stock issuance costs associated with equity line purchase agreement	(41,381)	-
Repayment of notes payable	(300,000)	-
Proceeds from exercise of warrants	-	1,113,164
Proceeds from exercise of stock options	-	11,750
Net cash provided by financing activities	621,219	2,239,939
Net decrease in cash and cash equivalents	(1,738,256)	(1,489,516)
Cash and cash equivalents at beginning of period	4,921,545	5,525,094
Cash and cash equivalents at end of period	\$3,183,289	\$4,035,578
Supplemental disclosure of non cash financing activities:		
Reclassification of warrant liability to additional paid in capital upon partial exercise of warrants issued in unit offering	\$-	\$2,543,117

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 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 melioidosis therapeutic candidate. The development of the vaccine programs is currently supported by the heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases (“NIAID”), the Company will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. The Company plans to use the funds received under the government contracts with the Biomedical Advanced Research and Development Authority (“BARDA”) and NIAID to advance the development of OrbeShield® for the treatment of GI ARS.

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

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with the United States Food and Drug Administration ("FDA") regulations, litigation, and product liability. Results for the three and six months ended June 30, 2016 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of June 30, 2016, the Company had cash and cash equivalents of \$3,183,289 as compared to \$4,921,545 as of December 31, 2015, representing a decrease of \$1,738,256 or 35%. As of June 30, 2016, the Company had working capital of \$984,679, which excludes a non-cash warrant liability of \$1,148,616, as compared to working capital of \$2,179,694, which excludes a non-cash warrant liability of \$2,434,101, as of December 31, 2015, representing a decrease of \$1,195,015 or 55%. The decrease is primarily related to expenditures to support the collection of long-term follow-up safety data from the Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer and to support the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL.

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

Management's business strategy can be outlined as follows:

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

Continue to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study for the treatment of oral mucositis in head and neck cancer patients and publish the findings from this study;

Obtain agreement from the FDA on a pivotal Phase 2b/3 protocol of SGX942 in the treatment of oral mucositis in head and neck cancer patients;

Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease;

Continue development of RiVax™ in combination with the Company's ThermoVax® technology, to develop new heat stable vaccines in biodefense, with NIAID funding support;

Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS under the BARDA contract and 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;