

SOLIGENIX, INC.
Form 10-Q
August 12, 2011

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, 2011

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 PRINCETON, NJ

(Address of principal executive
offices)

08540

(Zip Code)

(609) 538-8200

(Registrant's telephone number,
including area code)

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

Yes No

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

Yes No

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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 9, 2011, 220,791,077 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, 2011 and December 31, 2010	3
	Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2011 and 2010	4
	Consolidated Statements of Changes in Shareholders' Equity for the Six Months Ended June 30, 2011	5
	Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2011 and 2010	6
	Notes to Consolidated Financial Statements	7
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3	Quantitative and Qualitative Disclosures About Market Risk	33
Item 4	Controls and Procedures	33
Part II	OTHER INFORMATION	
Item 1A	Risk Factors	34
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	34
Item 6	Exhibits	34
	SIGNATURES	35

PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets
(Unaudited)

	June 30, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	\$4,156,749	\$7,451,714
Grants receivable	336,560	120,787
Other receivable	4,322	251,864
Prepaid expenses	91,635	187,494
Total current assets	4,589,266	8,011,859
Office furniture and equipment, net	17,100	20,699
Intangible assets, net	1,246,543	1,235,989
Total assets	\$5,852,909	\$9,268,547
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$1,373,974	\$1,674,175
Accrued compensation	49,302	236,581
Total current liabilities	1,423,276	1,910,756
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 5,000,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 400,000,000 shares authorized; 218,240,167 shares and 216,192,360 shares issued and outstanding in 2011 and 2010, respectively	218,240	216,192
Additional paid-in capital	123,601,900	122,880,378
Accumulated deficit	(119,390,507)	(115,738,779)
Total shareholders' equity	4,429,633	7,357,791
Total liabilities and shareholders' equity	\$5,852,909	\$9,268,547

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, 2011 and 2010
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues, principally from grants	\$405,820	\$444,642	\$1,213,825	\$780,438
Cost of revenues	(349,511)	(349,093)	(903,548)	(622,866)
Gross profit	56,309	95,549	310,277	157,572
Operating expenses:				
Research and development	1,307,051	1,070,711	2,563,186	2,669,002
General and administrative	450,179	544,506	1,014,091	1,082,603
Stock-based compensation – research and development	206,671	39,948	323,340	80,152
Stock-based compensation – general and administrative	25,198	20,654	65,296	42,713
Total operating expenses	1,989,099	1,675,819	3,965,913	3,874,470
Loss from operations	(1,932,790)	(1,580,270)	(3,655,636)	(3,716,898)
Other income:				
Interest income, net	1,473	2,977	3,908	3,345
Net loss	\$(1,931,317)	\$(1,577,293)	\$(3,651,728)	\$(3,713,553)
Basic and diluted net loss per share	\$(0.01)	\$(0.01)	\$(0.02)	\$(0.02)
Basic and diluted weighted average common shares outstanding	217,998,049	190,751,511	217,424,979	188,644,289

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

Soligenix, Inc. and Subsidiaries
 Consolidated Statements of Changes in Shareholders' Equity
 For the Six Months Ended June 30, 2011
 (Unaudited)

	Common Stock Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Total
Balance, December 31, 2010	216,192,360	\$216,192	\$122,880,378	\$(115,738,779)	\$7,357,791
Issuance of common stock pursuant to equity line agreement – Fusion	1,422,807	1,423	253,577	-	255,000
Issuance of common stock for stock option and warrant exercises	625,000	625	68,125	-	68,750
Fair value of common stock warrants to vendors	-	-	11,184	-	11,184
Stock-based compensation expense	-	-	388,636	-	388,636
Net loss	-	-	-	(3,651,728)	(3,651,728)
Balance, June 30, 2011	218,240,167	\$218,240	\$123,601,900	\$(119,390,507)	\$4,429,633

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)

	2011	2010
Operating activities:		
Net loss	\$(3,651,728)	\$(3,713,553)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	105,443	85,779
Common stock or warrants issued in exchange for services	11,184	122,197
Stock-based compensation	388,636	122,865
Capitalized patent write-off	-	378,501
Change in operating assets and liabilities:		
Grants receivable	(215,773)	(87,665)
Other receivable	247,542	(8,000)
Inventory	-	7,733
Prepaid expenses	95,859	(18,228)
Accounts payable	(300,201)	923,946
Accrued compensation	(187,279)	(319,930)
Total adjustments	145,411	1,207,198
Net cash used in operating activities	(3,506,317)	(2,506,355)
Investing activities:		
Acquisition of intangible assets	(112,398)	(168,102)
Purchase of office equipment	-	(947)
Net cash used in investing activities	(112,398)	(169,049)
Financing activities:		
Net proceeds from sale of common stock	-	5,679,856
Proceeds from sale of common stock pursuant to equity line	255,000	70,000
Proceeds from exercise of options and warrants	68,750	45,540
Net cash provided by financing activities	323,750	5,795,396
Net increase/(decrease) in cash and cash equivalents	(3,294,965)	3,119,992
Cash and cash equivalents at beginning of period	7,451,714	7,692,011
Cash and cash equivalents at end of period	\$4,156,749	\$10,812,003

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

Soligenix, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (“Soligenix,” the “Company,” “we” or “us”) is a late-stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. The Company maintains two active business segments: BioTherapeutics and BioDefense. Soligenix’s BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, while the Company’s collaboration partner, Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) will commercialize orBec® in North America and Europe, once approved. Soligenix’s BioDefense business segment intends to use RiVax™, its ricin toxin vaccine, to support development efforts with its heat stabilization technology, and SGX202, its radiation injury program, to convert from early stage development to advanced development with the assistance of ongoing government grant funding.

The Company currently generates revenues primarily from the National Institutes of Health (the “NIH”) under three active grants and from its license with Sigma-Tau, once milestones are achieved.

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 FDA regulations, litigation, and product liability.

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States of America. The accompanying consolidated financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements have been condensed or omitted from this report, as is permitted by such rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The unaudited consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2010. Results for interim periods are not necessarily indicative of results for the full year. The Company has experienced significant quarterly fluctuations in operating results and it expects those fluctuations will continue.

Liquidity

As of June 30, 2011, the Company had cash and cash equivalents of \$4,156,749 as compared to \$7,451,714 as of December 31, 2010, representing a decrease of \$3,294,965. As of June 30, 2011, the Company had working capital of \$3,165,990 as compared to working capital of \$6,101,103 as of December 31, 2010, representing a decrease of \$2,935,113 or 48%. The decrease in cash and working capital was the result of cash used in operating activities over the six month period, offset by \$255,000 in proceeds from issuances of common stock under the common stock purchase agreement with Fusion Capital Fund II, LLC (“Fusion Capital”). For the six months ended June 30, 2011, the Company’s cash used in operating activities was \$3,506,317 as compared to \$2,506,355 for the same period in 2010, representing an increase of \$999,962. Based on our current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, recently announced European territory license with

Sigma-Tau, which provided a \$5,000,000 up front payment, proceeds from our grant-funded programs, and potential proceeds from the Fusion Capital transaction, we believe that our current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter of 2013.

Management's business strategy can be outlined as follows:

- complete the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD");
- Identify a development and marketing partner for orBec® for territories outside of North America and Europe;
- complete and report data from the Phase 1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute GVHD, treatment of chronic GI GVHD, radiation injury, and Crohn's disease;
- continue to secure additional government funding for each of our BioTherapeutics and BioDefense programs through grants, contracts and/or procurements;
- use RiVax™ to support development efforts with our heat stabilization technology to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
 - acquire or in-license new clinical-stage compounds for development; and
 - explore other business development and acquisition strategies.

The Company's plans with respect to its liquidity management include the following:

- The Company has approximately \$8.4 million in active grant funding still available to support its research programs through 2011 and beyond. The Company has also submitted additional grant applications for further support of its programs with various funding agencies, and has received encouraging feedback to date on the likelihood of additional funding.
- The Company has approximately \$7.4 million in available capacity under the Company's Fusion Capital equity facility through October 2011. Although the Company has historically drawn down modest amounts under this agreement, the Company could draw more within certain contractual parameters;
- The Company will seek non-dilutive funding through completion of partnerships for its orBec®/oral BDP programs in territories outside North America and Europe;
- 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 Losses ("NOL") sales in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$245,810 in proceeds pursuant to NOL sales in 2010 and assuming its application is accepted, the Company expects to participate in the expanded program during 2011 and beyond; 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 currently evaluating additional equity financing opportunities 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