

SOLIGENIX, INC.  
Form 10-Q  
November 12, 2010

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, 2010

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  
(Issuer'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 Exchange Act during the past 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,

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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 November 11, 2010, 215,892,360 shares of the registrant's common stock (par value, \$.001 per share) were outstanding.

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SOLIGENIX, INC.

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## PART I - FINANCIAL INFORMATION

## ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc.  
Consolidated Balance Sheets

	September 30, 2010 (Unaudited)	December 31, 2009
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$9,028,228	\$7,692,011
Grants receivable	214,191	23,632
Inventory, net	-	42,865
Prepaid expenses	224,771	141,313
<b>Total current assets</b>	<b>9,467,190</b>	<b>7,899,821</b>
Office furniture and equipment, net	22,529	21,172
Intangible assets, net	1,212,020	1,463,289
<b>Total assets</b>	<b>\$10,701,739</b>	<b>\$9,384,282</b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$1,491,538	\$844,857
Accrued compensation	38,759	365,199
<b>Total current liabilities</b>	<b>1,530,297</b>	<b>1,210,056</b>
<b>Commitments and contingencies</b>		
<b>Shareholders' equity:</b>		
Preferred stock; 5,000,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 400,000,000 shares authorized; 215,892,360 shares and 185,655,720 shares issued and outstanding in 2010 and 2009, respectively	215,892	185,656
Additional paid-in capital	122,755,042	116,340,770
Accumulated deficit	(113,799,492 )	(108,352,200 )
<b>Total shareholders' equity</b>	<b>9,171,442</b>	<b>8,174,226</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$10,701,739</b>	<b>\$9,384,282</b>

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

Soligenix, Inc.

Consolidated Statements of Operations  
For the Three and Nine Months Ended September 30, 2010 and 2009  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues, principally from grants	\$860,517	\$766,645	\$1,640,955	\$1,629,277
Cost of revenues	( 779,396 )	( 584,329 )	( 1,402,262 )	( 1,255,503 )
Gross profit	81,121	182,316	238,693	373,774
Operating expenses:				
Research and development	1,122,144	1,109,333	3,791,145	3,835,246
General and administrative	356,448	617,735	1,439,051	1,728,400
Stock-based compensation – research and development	154,406	25,314	234,558	157,391
Stock-based compensation – general and administrative	186,638	90,922	229,351	261,331
Total operating expenses	1,819,636	1,843,304	5,694,105	5,982,368
Loss from operations	( 1,738,515 )	( 1,660,988 )	( 5,455,412 )	( 5,608,594 )
Other income:				
Interest income, net	4,775	611	8,120	18,217
Net loss	\$( 1,733,740 )	\$( 1,660,377 )	\$( 5,447,292 )	\$( 5,590,377 )
Basic and diluted net loss per share	\$( 0.01 )	\$( 0.01 )	\$( 0.03 )	\$( 0.03 )
Basic and diluted weighted average common shares outstanding	215,869,026	168,093,600	197,818,925	161,446,898

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

Soligenix, Inc.  
Consolidated Statements of Changes in Shareholders' Equity  
For the Nine Months Ended September 30, 2010  
(Unaudited)

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Deficit	Total
Balance, December 31, 2009	185,655,720	\$ 185,656	\$ 116,340,770	\$(108,352,200 )	\$ 8,174,226
Issuance of common stock pursuant to private placement, net of issuance costs	28,801,351	28,801	5,651,055	-	5,679,856
Issuance of common stock pursuant to equity line agreement – Fusion	294,091	294	69,706	-	70,000
Issuance of common stock to vendors	403,225	403	104,435	-	104,838
Issuance of common stock warrants to vendors	-	-	67,052	-	67,052
Issuance of common stock for option and warrant exercises	780,875	781	58,072	-	58,853
Shares retired	(42,902 )	(43 )	43	-	-
Stock-based compensation expense	-	-	463,909	-	463,909
Net loss	-	-	-	(5,447,292 )	(5,447,292 )
Balance, September 30, 2010	215,892,360	\$ 215,892	\$ 122,755,042	\$(113,799,492 )	\$ 9,171,442

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

Soligenix, Inc.

Consolidated Statements of Cash Flows  
For the Nine Months Ended September 30,  
(Unaudited)

	2010	2009
<b>Operating activities:</b>		
Net loss	\$(5,447,292 )	\$(5,590,377 )
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Amortization and depreciation	135,270	126,411
Stock or warrants issued in exchange for services	171,890	427,712
Stock-based compensation	463,909	418,722
Capitalized patent write-off	378,501	-
Stock issued to former employee	-	119,579
<b>Change in operating assets and liabilities:</b>		
Grants receivable	(190,559 )	(483,930 )
Inventory	42,865	(26,861 )
Prepaid expenses	(83,458 )	(74,657 )
Accounts payable	646,682	476,003
Accrued compensation	(326,440 )	(147,778 )
Total adjustments	1,238,660	835,201
Net cash used in operating activities	(4,208,632 )	(4,755,176 )
<b>Investing activities:</b>		
Acquisition of intangible assets	(257,598 )	(132,754 )
Purchase of office equipment	(6,261 )	(10,981 )
Net cash used in investing activities	(263,859 )	(143,735 )
<b>Financing activities:</b>		
Net proceeds from sale of common stock	5,679,856	10,825,762
Proceeds from sale of common stock pursuant to equity line	70,000	85,000
Proceeds from exercise of options and warrants	58,852	-
Net cash provided by financing activities	5,808,708	10,910,762
Net increase in cash and cash equivalents	1,336,217	6,011,851
Cash and cash equivalents at beginning of period	7,692,011	1,475,466
Cash and cash equivalents at end of period	\$9,028,228	\$7,487,317

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

Soligenix, Inc.  
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the “Company”) 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, including LPMTM Leuprolide, while Soligenix’s collaboration partner, Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) will commercialize orBec® in North America once approved. Soligenix’s BioDefense business segment intends to convert its ricin toxin vaccine and radiation injury programs from early stage development to advanced development and manufacturing.

The Company generates revenues primarily from the National Institutes of Health under three active grants and Sigma-Tau.

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, 2009. 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 September 30, 2010, the Company had cash and cash equivalents of \$9,028,228 as compared to \$7,692,011 as of December 31, 2009, representing an increase of \$1,336,217 or 17%. As of September 30, 2010, the Company had working capital of \$7,936,893 as compared to working capital of \$6,689,765 as of December 31, 2009, representing an increase of \$1,247,128 or 19%. The increase was the result of the private placement of common stock and warrants completed in June 2010, offset by cash used in operating activities over the period. For the nine months ended September 30, 2010, the Company’s cash used in operating activities was \$4,208,632 as compared to \$4,755,176 for the same period in 2009. This decrease in spending was primarily attributable to a June 2010 modification in the monthly payments to Numoda Corporation as a result of reduced services required, with regard to conduct of the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”).





Management's business strategy can be outlined as follows:

- complete the pivotal Phase 3 confirmatory clinical trial for orBec® in the treatment of acute GI GVHD;
- identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico;
- evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as acute radiation enteritis, radiation injury, irritable bowel syndrome ("IBS"), and Crohn's disease;
- reinitiate development of LPM™ Leuprolide;
- continue to secure additional government funding for each of our BioTherapeutics and BioDefense programs through grants, contracts and/or procurements;
- convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area;
- acquire or in-license new clinical-stage compounds for development; and
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