SOLIGENIX, INC.
Form 424B3
November 23, 2009

Prospectus Supplement dated
November 13, 2009

Filed Pursuant to Rule
424(b)(3)
File No. 333-157322

SOLIGENIX, INC.

This prospectus supplement supplements:

- the prospectus dated April 17, 2009 relating to the offer and sale by the selling stockholders identified in the prospectus of up to 44,491,610 shares of our common stock.

This prospectus supplement contains the Form 10-Q we filed with the Securities and Exchange Commission on November 13, 2009. This prospectus supplement should be read in conjunction with, and may not be utilized without, the relevant Prospectus, which is to be delivered with this prospectus supplement. This prospectus supplement is qualified by reference to the relevant Prospectus except to the extent that the information in this prospectus supplement updates and supersedes the information contained in such Prospectus, including any supplements or amendments thereto.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2009

( ) 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 C-10 Princeton, NJ	08540
(Address of principal executive offices)	(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 x No o

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 o No o

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 o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

At November 10, 2009, 185,501,158 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

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PART I. - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc.
Consolidated Balance Sheets

	September 30, 2009 (Unaudited)	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 7,487,317	$ 1,475,466
Grants receivable	762,246	278,316
Inventory, net	109,043	82,182
Prepaid expenses	162,994	86,837
Total current assets	8,521,600	1,922,801
Office and laboratory equipment, net	25,609	21,217
Intangible assets, net	1,431,648	1,418,717
Total assets	$ 9,978,857	$ 3,362,735
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,491,008	$ 1,015,005
Accrued compensation	222,835	370,614
Total current liabilities	1,713,843	1,385,619
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; 185,501,158 shares and 118,610,704 shares issued and outstanding in 2009 and 2008, respectively	185,501	118,610
Additional paid-in capital	115,987,637	104,176,253
Accumulated deficit	(107,908,124)	(102,317,747)
Total shareholders' equity	8,265,014	1,977,116
Total liabilities and shareholders' equity	$ 9,978,857	$ 3,362,735

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

Soligenix, Inc.
Consolidated Statements of Operations
For the Three Months Ended September 30,
(Unaudited)

	2009	2008
Revenues, principally from grants	$ 766,645	$ 605,736
Cost of revenues	(584,329)	(538,182)
Gross profit	182,316	67,554
Operating expenses:		
Research and development	1,109,333	60,238
General and administrative	617,735	410,336
Stock-based compensation - research and development	25,314	39,584
Stock-based compensation - general and administrative	90,922	36,792
Total operating expenses	1,843,304	546,950
Loss from operations	(1,660,988)	(479,396)
Other income:		
Interest income, net	611	3,695
Net loss	$ (1,660,377)	$ (475,701)
Basic and diluted net loss per share	$ (0.01)	$ -
Basic Basic and diluted weighted average common shares outstanding	168,093,600	102,767,174

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

Soligenix, Inc.
Consolidated Statements of Operations
For the Nine Months Ended September 30,
(Unaudited)

	2009	2008
Revenues, principally from grants	$ 1,629,277	$ 1,771,620
Cost of revenues	(1,255,503)	(1,459,206)
Gross profit	373,774	312,414
Operating expenses:		
Research and development	3,835,246	1,403,841
General and administrative	1,728,400	1,812,972
Stock based compensation - research and development	157,391	118,750
Stock based compensation - general and administrative	261,331	110,378
Total operating expenses	5,982,368	3,445,941
Loss from operations	(5,608,594)	(3,133,527)
Other income:		
Interest income, net	18,217	29,948
Net loss	$ (5,590,377)	$ (3,103,579)
Basic and diluted net loss per share	$ (0.03)	$ (0.03)
Basic Basic and diluted weighted average common shares outstanding	161,446,898	100,478,733

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

Soligenix, Inc.
Consolidated Statements of Changes in Shareholders' Equity
For the Nine Months Ended September 30, 2009
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2008	118,610,704	$118,610	$104,176,253	($102,317,747)	$1,977,116
Issuance of common stock from private placements, net of expenses of $347,000	38,266,602	38,267	6,388,995		6,427,262
Issuance of common stock for collaboration and supply agreement to Sigma Tau	25,000,000	25,000	4,375,000		4,400,000
Issuance of common stock pursuant to equity line agreement	554,427	554	84,446		85,000
Issuance of common stock to vendors	2,500,000	2,500	297,500		300,000
Issuance of common stock warrants to vendors			127,712		127,712
Issuance of common stock to former employee	569,425	570	119,009		119,579
Stock-based compensation expense			418,722		418,722
Net loss				(5,590,377)	(5,590,377)
Balance, September 30, 2009	185,501,158	$185,501	$115,987,637	($107,908,124)	$8,265,014

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

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

	2009	2008
Operating activities:		
Net loss	$ (5,590,377)	$ (3,103,579)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	126,411	107,804
Stock or warrants issued in exchange for services	427,712	394,161
Stock-based compensation	418,722	229,128
Stock issued to former employee	119,579	-
Change in operating assets and liabilities:		
Grants receivable	(483,930)	(106,810)
Inventory	(26,861)	(83,182)
Prepaid expenses	(74,657)	(9,452)
Accounts payable	476,003	514,452
Accrued compensation	(147,778)	(67,784)
Total adjustments	835,201	978,317
Net cash used in operating activities	(4,755,176)	(2,125,262)
Investing activities:		
Acquisition of intangible assets	(132,754)	(191,350)
Proceeds from sale of equipment	-	500
Purchase of office equipment	(10,981)	(3,900)
Net cash used in investing activities	(143,735)	(194,750)
Financing activities:		
Net proceeds from sale of common stock	10,825,762	658,600
Proceeds from sale of common stock pursuant to equity line	85,000	127,500
Net cash provided by financing activities	10,910,762	786,100
Net increase (decrease) in cash and cash equivalents	6,011,851	(1,533,912)
Cash and cash equivalents at beginning of period	1,475,466	2,220,128
Cash and cash equivalents at end of period	$ 7,487,317	$ 686,216
Non-cash transactions:		
Non-cash stock payment to an institutional investor	$ -	$ 270,000

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

Soligenix, Inc.
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the "Company"), formerly known as DOR BioPharma, Inc., 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. 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. Soligenix's BioDefense business segment intends to convert its ricin toxin and botulinum toxin vaccine programs from early stage development to advanced development and manufacturing.

The Company generates revenues from the National Institutes of Health under three active BioDefense grants and its Named Patient Access Program ("NPAP") partners for orBec®.

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, 2008. 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, 2009, the Company had cash and cash equivalents of $7,487,317 as compared to $1,475,466 as of December 31, 2008, representing an increase of $6,011,851. This total was augmented in October 2009 by the receipt of $1 million from our North American collaboration partner Sigma-Tau Pharmaceuticals, inc. in connection with the initiation of our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD"). As of September 30, 2009, the Company had working capital of $6,807,757 as compared to working capital of $537,182 as of December 31, 2008, representing an increase of $6,270,575. The increase was the result of the execution of our collaboration agreement and ensuing sale of our common stock to our commercialization partner Sigma-Tau of $4.5 million, plus the $10.8 million in proceeds from the sale of our common stock and warrants to accredited investors, less the cash used in operating activities over the period.

For the nine months ended September 30, 2009, the Company's cash used in operating activities was $4,755,176, as compared to $2,125,262 for the same period in 2008. The increase in spending was attributable to the preparation and conduct of the confirmatory Phase 3 clinical trial of orBec® in the treatment of 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; Sigma-Tau will pay us a 35% royalty (inclusive of drug supply) on net sales in these territories as well as pay for commercialization expenses, including launch activities;
- conduct a Phase 2 clinical trial of orBec® for the prevention of acute GVHD;
- 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 radiation enteritis, radiation injury and Crohn's disease;
- reinitiate development of our other BioTherapeutics products, including LPM™ Leuprolide;
- continue to secure additional government funding for each of our BioDefense programs, RiVax™ and BT-VACC™, through grants, contracts and 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;
- make orBec® available worldwide through NPAP for the treatment of acute GI GVHD;
- acquire or in-license new clinical-stage compounds for development; and
- explore other business development and acquisition strategies under which we may be considered to be an attractive acquisition candidate by another company.

Based on the Company's current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, proceeds from our grant programs, and potential minimal proceeds from the Fusion Capital transaction, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter of 2011.

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

- The Company has $9.7 million in active grant funding still available to support its ricin and botulinum toxin vaccine programs in 2009 and beyond. Additionally, the Company has submitted additional grant applications for further support of these programs and others with various funding agencies, and received encouraging feedback to date on the likelihood of funding.
- 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.
- As discussed further in Note 5, the Company has approximately $7.8 million in available capacity under its Fusion Capital equity facility. Although the Company has historically drawn amounts in modest amounts under this agreement, the Company could draw more within certain contractual parameters.
- 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.

Segment Information

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.

Grants Receivable

Receivables consist of unbilled amounts due from grants from the National Institutes of Health of the U.S. Federal Government for costs incurred prior to the period end.

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 our 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 industrial 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 designed to protect, preserve, maintain and perhaps extend the lives of the patents. The Company capitalizes such costs and amortizes intangibles over a period of 11 to 16 years.

The Company capitalized $132,754 and $191,350 in patent related costs during the nine months ended September 30, 2009 and 2008, respectively.

Impairment of Long-Lived Assets

Office and laboratory equipment and intangible assets 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 intangible assets for the nine months ended September 30, 2009 or 2008.

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Inventory

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method and includes the cost of materials and overhead. All inventory for this period is finished goods and consists of orBec® treatments. The Company records an allowance as needed for excess inventory. During the year ended December 31, 2008 an allowance of $100,000 was provided. This allowance will be evaluated on a quarterly basis and adjustments will be made as required. The Company did not make an adjustment to this allowance during the nine months ended September 30, 2009.

Fair Value of Financial Instruments

Accounting principles generally accepted in the U.S. require that fair values be disclosed for the Company's financial instruments. The carrying amounts of the Company's financial instruments, which include grants receivable and current liabilities, are considered to be representative of their respective fair values.

Revenue Recognition

The Company's revenues are generated from NIH grants and NPAP sales of orBec®. The revenue from NIH grants are based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant. Revenue from NPAP sales of orBec® are recognized when the product is shipped. The NPAP revenues are recorded when the product is shipped.

Research and Development Costs

Research and development costs are charged to expense when incurred. 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 and 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.

Stock-Based Compensation

The fair value of options in accordance with FASB ASC 718, Stock Compensation, was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions:

- a dividend yield of 0%;
- an expected life of 4 years;
- volatilities of 125% and 120% for 2009 and 2008, respectively;
- and average risk-free interest rates of 3.8% and 3.7% in 2009 and 2008, respectively.

The Company estimates these values based on the assumptions that have been historically available. The fair value of each option grant made during 2009 and 2008 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods, which approximates the service period. The Company awarded 750,000 and 2,812,500 stock options for the three and nine months ended September 30, 2009, respectively, while 50,000 stock options were granted during the nine months ended September 30, 2008. No stock options were were granted during the three months ended September 30, 2008..

Stock compensation expense for options granted to non-employees has been determined in accordance with FASB ASC 718, Stock Compensation, and 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 option's price is re-measured using the Black-Scholes model at the end of each three month reporting period.

Upon exercise, shares are issued from the amended 2005 equity incentive plan and increase the number of shares the Company has outstanding. There were no stock option exercises during the nine months ended September 30, 2009 or during the year ended December 31, 2008. There were forfeitures or expirations of 210,000 stock options during the nine months ended September 30, 2009 and forfeitures of 779,800 stock options during the year ended December 31, 2008. The intrinsic value of the stock options outstanding at September 30, 2009 was zero.

From time to time, the Company issues common stock to vendors, consultants, and employees as compensation for services performed. These shares are typically issued as restricted stock, unless issued to non-affiliates under the 2005 Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrictive legend removed if the shares underlying the certificate are sold pursuant to an effective registration statement, which the Company must file and have approved by the SEC, if the shares underlying the certificate are sold pursuant to Rule 144, provided certain conditions are satisfied, or if the shares are sold pursuant to another exemption from the registration requirements of the Securities Act of 1933, as amended.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

Stock options are issued with an exercise price equal to the market price on the date of issuance. Stock options issued to directors are fully vested upon issuance. Stock options issued to employees generally vest 25% upfront, then 25% each year for a period of three years. Stock options vest over each three month period from the date of issuance to the end of the three year period. 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 six months, unless otherwise extended by the Board.

The intrinsic value was calculated as the difference between the Company's common stock closing price on the OTC BB at September 30, 2009 and the exercise price of the stock option issued multiplied by the number of shares underlying the stock options. The Company's common stock price at September 30, 2009 was $0.28.

Income Taxes

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 bases. 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 recognized through September 30, 2009 due to the net operating losses incurred by the Company since its inception. Additionally, the Company has not recorded a liability for unrecognized tax benefits or uncertain tax positions at September 30, 2009 or 2008.

Earnings Per Share

Basic earnings per share (EPS) excludes dilution and is computed by dividing income 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 large number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

	Three Months Ended September 30, 2009			Three Months Ended September 30, 2008		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	($1,660,377)	168,093,600	($0.01)	($475,701)	102,767,174	-

	Nine Months Ended September 30, 2009			Nine Months Ended September 30, 2008		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	($5,590,377)	161,446,898	($0.03)	($3,103,579)	100,478,733	($0.03)

Options and warrants outstanding at September 30, 2009 and 2008 were 19,047,539 and 9,620,039 of options, and 42,097,874 and 20,657,219 of warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at September 30, 2009 were $0.25 and $0.24, respectively. No options and warrants were included in the 2009 and 2008 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

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 that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Recently Issued Accounting Standards

In June 2009, the FASB issued ASC 105, Generally Accepted Accounting Principles, which establishes the FASB Accounting Standards Codification as the sole source of authoritative generally accepted accounting principles. The Codification supersedes existing GAAP for nongovernmental entities. Pursuant to the provisions of FASB ASC 105, the Company has updated references to GAAP in its financial statements issued for the period ended September 30, 2009 and thereafter. The implementation of these standards did not have any effect on the Company's consolidated financial statements.

In June 2009, the FASB issued SFAS No. 167, Amendments to FASB Interpretation No. 46(R). SFAS No. 167 is a revision to FASB Interpretation No. 46 (Revised December 2003), Consolidation of Variable Interest Entities, and changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity's purpose and design and the reporting entity's ability to direct the activities of the other entity that most significantly impact the other entity's economic performance. SFAS No. 167 will require a reporting entity to provide additional disclosures about its involvement with variable interest entities and any significant changes in risk exposure due to that involvement. A reporting entity will be required to disclose how its involvement with a variable interest entity affects the reporting entity's financial statements. SFAS No. 167 will be effective at the start of a reporting entity's first fiscal year beginning after November 15, 2009, or January 1, 2010, for a calendar year-end entity. Early application is not permitted. The Company is evaluating if the adoption of this standard will have a material impact on its financial statements.

Effective April 1, 2009, the Company adopted FASB ASC 855-10, Subsequent Events - Overall. FASB ASC 855-10 incorporates into authoritative accounting literature certain guidance that already existed within generally accepted auditing standards, but the rules concerning recognition and disclosure of subsequent events will remain essentially unchanged. Subsequent events guidance addresses events which occur after the balance sheet date but before the issuance of financial statements. Under FASB ASC 855-10, an entity must record the effects of subsequent events that provide evidence about conditions that existed at the balance sheet date and must disclose but not record the effects of subsequent events which provide evidence about conditions that did not exist at the balance sheet date. The Company adopted FASB ASC 855-10 and it did not have an impact on the Company's consolidated financial statements. There were no recognized or non-recognized subsequent events occurring after September 30, 2009 that required accounting or disclosure in accordance with FASB ASC 855-10. Subsequent events were evaluated to November 13, 2009, the date the financial statements of the Company were issued.

Note 3. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

	Weighted Average Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
September 30, 2009				
Licenses	11.5	$ 462,234	$ 154,710	$ 307,524
Patents	8.8	2,003,355	879,231	1,124,124
Total	9.3	$2,465,589	$1,033,941	$1,431,648
December 31, 2008				
Licenses	11.7	$ 462,234	$ 142,994	$ 319,240
Patents	9.0	1,870,603	771,126	1,099,477
Total	9.5	$2,332,837	$914,120	$1,418,717

Amortization expense was $44,000 and $119,824 for the three and nine months ended September 30, 2009, respectively. Amortization expense was $35,437 and $99,859 for the three and nine months ended September 30, 2008, respectively.

Based on the balance of licenses and patents at September 30, 2009, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2010	$ 165,000
2011	170,000
2012	175,000
2013	180,000
2014	185,000

License fees and royalty payments are expensed annually as incurred as the Company does not attribute any future benefits to them other than within that period.

Note 4. Income Taxes

Deferred tax assets consist of the following:

	September 30, 2009	December 31, 2008
Net operating loss carry forwards	$ 32,025,000	$ 26,300,000
Orphan drug and research and development credit carry forwards	2,000,000	2,000,000
Other	3,300,000	3,300,000
Total	37,325,000	31,600,000
Valuation allowance	(37,325,000)	(31,600,000)
Net deferred tax assets	$ -	$ -

At December 31, 2008, the Company had net operating loss carry forwards (NOLs) of approximately $76,000,000 for Federal and state tax purposes, portions of which are currently expiring each year until 2028. In addition, the Company had $2,000,000 of various tax credits that start expiring from December 2009 to December 2028. 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 carryforwards 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 possible that the utilization of the NOLs may be limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to income tax assessment for years before 2004. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service and state authorities for purposes of determining the amount of net operating loss carryforward that can be used to reduce taxable income.

The net changes in the valuation allowance for nine months ended September 30, 2009 and the year ended December 31, 2008 were an increase of approximately $5,725,000 and $1,600,000, respectively, resulting primarily from net operating losses generated. As a result of the Company’s continuing tax losses, it has recorded a full valuation allowance against its net deferred tax assets.

The Company has no tax provision for the periods ended September 30, 2009 and 2008 due to losses and full valuation allowances against deferred tax assets.

Note 5. Shareholders' Equity

Preferred Stock

The Company has 5,000,000 shares of preferred stock authorized, none of which are issued or outstanding.

Common Stock

The following items represent transactions in the Company's common stock for the nine months ended September 30, 2009:

- In eight separate transactions during the nine months ended September 30, 2009, the Company issued an aggregate of 554,427 shares of common stock under its existing Fusion Capital equity facility. The Company received an aggregate of $85,000 in proceeds which approximated the shares' fair market value on the date of issuance.

- On September 28, 2009, the Company received $4,390,200 from the completed private placement of common stock and warrants to accredited investors. Under the terms of the agreements, the Company sold 17,352,567 common shares together with five year warrants to purchase up to 8,676,284 shares of the Company's common stock at $0.278 per share, for an aggregate price of $4,390,200, or $0.253 per share, representing the market price as determined by the five-day average closing price of the Company's common stock prior to the date of the agreements. The expiration date of the warrants can be accelerated if the Company's common stock meets certain price thresholds and the Company would receive additional gross proceeds of approximately $2,412,000 if they are all exercised. The Company's North American collaboration partner, Sigma-Tau Pharmaceuticals, Inc., led this offering with an investment of $1 million.

    - In August 2009, 569,425 shares of the Company's common stock were issued to the former controller, treasurer and secretary of the Company in partial settlement of certain compensation and severance liabilities pursuant to the employee's employment agreement. The aggregate number of shares is subject to future adjustment for a six month period following the separation date should the market price fall below the original issuance price. The former employee was granted standard piggyback registration rights with respect to those shares. Compensation expense of $119,579 was recorded in General & Administrative Expense for the three and nine months ended September 30, 2009 related to this issuance, representing the fair market value of the shares at the date of issuance.

- On March 6, 2009, the Company issued 2,500,000 shares of common stock pursuant to the $400,000 ($300,000 of which was issued on this date) common stock equity investment agreement with its clinical trials management partner, Numoda Corporation ("Numoda"). These shares were priced at the then current market price of $0.12 per share. The remaining $100,000 investment will be completed in January 2010 and will either be paid in cash or in 833,334 shares of common if the market price falls below $0.12. The investment follows the collaboration between the Company and Numoda announced on June 30, 2008 and represents partial payment by the Company under its collaboration agreement. The Company recognized $400,000 of research and development costs during March 2009 as a result of this transaction.

· On February 11, 2009, the Company entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®.In connection with the execution of the collaboration agreement, the Company entered into a common stock purchase agreement with Sigma-Tau pursuant to which the Company sold 25,000,000 shares of common stock to Sigma-Tau for $0.18 per share, representing an aggregate price of $4,500,000. The purchase price was equal to one hundred fifty percent (150%) of the average trading price of the Company's common stock over the five trading days prior to February 11, 2009. As part of the transaction, the Company granted Sigma-Tau certain demand and piggy-back registration rights.

- On January 20, 2009, the Company received $2,384,200 from the completed private placement of common stock and warrants to accredited investors. Under the terms of the agreement, the Company sold 20,914,035 common shares together with five year warrants to purchase up to 20,914,035 shares of the Company's common stock at $0.14 per share, for an aggregate price of $2,384,200, or $0.114 per share, representing a premium to the Company's common stock market price on the date of the agreements. The expiration date of the warrants can be accelerated if the Company's common stock meets certain price thresholds and the Company would receive additional gross proceeds of approximately $2,900,000 if they are all exercised.

In February 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The Fusion Capital equity facility allows the Company to require Fusion Capital to purchase between $80,000 and $1.0 million of the Company's common stock every two business days, up to an aggregate of $8.0 million over approximately a 25-month period depending on certain conditions, including the quoted market price of the Company's common stock on such date. As part of the agreement, the Company issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital made an initial purchase of 2,777,778 common shares and received a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, representing an aggregate price of $500,000. The Company issued an additional 75,000 shares of common stock as a commitment fee in connection with this $500,000 purchase.

If the Company's stock price exceeds $0.15, then the amount required to be purchased may be increased under certain conditions as the price of the Company's common stock increases. The Company cannot require Fusion Capital to purchase any shares of the Company's common stock on any trading days that the market price of the Company's common stock is less than $0.10 per share. Furthermore, for each additional purchase by Fusion, additional commitment shares in commensurate amounts up to a total of 1,275,000 shares will be issued based upon the relative proportion of purchases compared to the total commitment maximum of 18.5 million shares. The total issuance of common stock related to commitment shares for 2008 was 1,369,125 shares, which were issued to Fusion Capital and consisted of 1,275,000 shares as a commitment fee, 75,000 shares as a commitment fee for the $500,000 invested, and 19,125 shares for the commitment fee shares on the equity line draws totaling $127,500.

During the year ended December 31, 2008, the Company issued 993,084 shares of common stock under the Fusion Capital equity facility. In connection with these issuances the Company received $127,500 in proceeds which approximated the shares' fair market value on the dates of issuance.

Warrants

During 2009, the Company issued 1,200,000 warrants to purchase common stock shares to consultants in exchange for their services. In January 2009, 50,000 warrants were issued to Strategic Outsourcing Solutions, LLC which had an exercise price of $0.10. In February 2009, 1,000,000 warrants were issued to George B. McDonald, M.D. which had an exercise price of $0.11. In June 2009, 150,000 warrants were issued to Griffin Securities Inc. which had an exercise price of $0.198. Expense charges of $127,712 were recorded during the nine months ended September 30, 2009.

Note 6. Commitments and Contingencies

The Company has commitments of approximately $3.3 million at September 30, 2009 in connection with a collaboration agreement with Numoda for the execution of our upcoming confirmatory Phase 3 clinical trial of orBec® that began in September 2009 and is expected to complete in the first half of 2011.

The Company has several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However,

there can be no assurance that clinical or commercialization success will occur.

On March 4, 2007, the Company entered into an investment banking agreement with RBC Capital Markets ("RBC"). As a result of the Company's transactions with Sigma-Tau, RBC claims that it is entitled to certain compensation under such agreement up to $1.6 million. The Company disputes that RBC is entitled to any compensation for the Sigma-Tau transactions and will vigorously defend any lawsuit filed by RBC.

In February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, upon the completion of a transaction, or series or a combination of related transactions negotiated by the Company's Board of Directors whereby, directly or indirectly, a majority of the Company's capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 450,000 common shares to employees and a consultant shall be issued.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment.

Note 7. Business Segments

The Company maintains two active business segments: BioTherapeutics and 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,	
	2009	2008
Revenues, Principally from Grants		
BioDefense	$ 742,645	$ 565,118
BioTherapeutics	24,000	40,618
Total	$ 766,645	$ 605,736
Loss from Operations		
BioDefense	$ 66,348	$ 23,403
BioTherapeutics	(1,113,629)	(305,920)
Corporate	(613,707)	(196,879)
Total	$ (1,660,988)	$ (479,396)
Amortization and Depreciation Expense		
BioDefense	$ 24,594	$ 17,462
BioTherapeutics	20,594	14,679
Corporate	1,188	1,159
Total	$ 46,376	$ 33,300
Interest Income, Net		
Corporate	$ 611	$ 3,695
Stock-Based Compensation		
BioDefense	$ 7,484	$ 19,517
BioTherapeutics	17,830	20,067
Corporate	90,922	36,792
Total	$ 116,236	$ 76,376

	Nine Months Ended September 30,	
	2009	2008
Revenues, Principally from Grants		
BioDefense	$ 1,577,277	$ 1,731,002
BioTherapeutics	52,000	40,618
Total	$ 1,629,277	$ 1,771,620
Loss from Operations		
BioDefense	$ (50,824)	$ (151,938)
BioTherapeutics	(3,740,515)	(1,353,831)
Corporate	(1,817,255)	(1,627,758)
Total	$ (5,608,594)	$ (3,133,527)
Amortization and Depreciation Expense		
BioDefense	$ 69,159	$ 61,160
BioTherapeutics	53,957	42,671
Corporate	3,295	3,973
Total	$ 126,411	$ 107,804
Interest Income, Net		
Corporate	$ 18,217	$ 29,948
Stock-Based Compensation		
BioDefense	$ 58,898	$ 58,550
BioTherapeutics	98,493	60,200
Corporate	261,331	110,378
Total	$ 418,722	$ 229,128

	As of September 30, 2009	As of December 31, 2008
Identifiable Assets		
BioDefense	$ 1,552,802	$ 1,221,901
BioTherapeutics	671,092	310,535
Corporate	7,754,963	1,830,299
Total	$ 9,978,857	$ 3,362,735

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL AND RESULTS OF OPERATIONS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes and other information included in our Annual Report on Form 10-K for the year ended December 31, 2008. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expression, however, these words are not the exclusive means identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the SEC or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Overview:

Business Overview and Strategy

Soligenix, Inc., formerly known as DOR BioPharma, Inc., was incorporated in Delaware in 1987. We are a late-stage research and development biopharmaceutical company focused on developing products to treat the life-threatening side effects of cancer treatment and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines. We maintain two active business segments: BioTherapeutics and BioDefense. Our BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, including LPMTM-Leuprolide. Our BioDefense business segment intends to convert its ricin toxin, botulinum toxin, and anthrax vaccine programs from early stage development to advanced development and manufacturing.

Our business strategy can be outlined as follows:

- complete the pivotal Phase 3 confirmatory 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, as we have granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico; Sigma-Tau will pay us a 35% royalty (inclusive of drug supply) on net sales in these territories as well as pay for commercialization expenses, including launch activities;
    - conduct and complete a Phase 2 clinical trial of orBec® for the prevention of acute GVHD;
- evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract such as radiation enteritis, radiation injury and Crohn's disease;
    - reinitiate development of our other biotherapeutics products, including LPMTM Leuprolide;
- continue to secure additional government funding for each of our BioDefense programs, RiVaxTM and BT-VACCTM, through grants, contracts and 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;

- make orBec® available worldwide through the NPAP for the treatment of acute GI GVHD;
- acquire or in-license new clinical-stage compounds for development; and
- explore other business development and acquisition strategies under which we may be considered to be an attractive acquisition candidate by another company.

Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08550 and our telephone number is (609) 538-8200.

BioTherapeutics Overview

orBec® and Oral BDP

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GI GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs to treat acute GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970's as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. orBec® is specifically formulated for oral administration as a single product consisting of two tablets; one tablet is intended to release BDP in the upper sections of the GI tract, and the other tablet is intended to release BDP in the lower sections of the GI tract.

Based on data from the prior Phase 3 study of orBec®, the current confirmatory Phase 3 study is a highly powered, double-blind, randomized, placebo-controlled, multi-center trial and will seek to enroll an estimated 166 patients. The primary endpoint is the treatment failure rate at Study Day 80. This endpoint was successfully measured as a secondary endpoint (p-value 0.005) in the previous Phase 3 study as a key measure of durability following a 50-day course of treatment with orBec® (i.e., 30 days following cessation of treatment).

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec® also benefits from orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD, as well as an orphan drug designation in the U.S for the treatment of chronic GI GVHD. Orphan drug designations provide for 7 and 10 years of post-approval market exclusivity in the U.S and Europe, respectively.

Historical Background

Two prior randomized, double-blind, placebo-controlled Phase 2 and 3 clinical trials support orBec®'s ability to provide clinically meaningful outcomes when compared with the current standard of care, including a lowered exposure to systemic corticosteroids following allogeneic transplantation. Currently, there are no approved products to treat GI GVHD. The first trial was a 60-patient Phase 2 single-center clinical trial conducted at the Fred Hutchinson Cancer Research Center. The second trial was a 129-patient pivotal Phase 3 multi-center clinical trial of orBec® conducted at 16 leading bone marrow/stem cell transplantation centers in the US and France. Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely median time-to-treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in other key secondary endpoints such as the proportion of patients free of GVHD at Day 50 (p-value 0.05) and Day 80 (p-value 0.005) and the median time-to-treatment failure through Day 80 (p-value 0.0226), as well as a 66% reduction in mortality among patients randomized to orBec® at 200 days post-transplant with only 5 patient (8%) deaths in the orBec® group compared to 16 patient (24%) deaths in the placebo group (p-value 0.0139). Within one year after randomization in the pivotal Phase 3 trial, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died (46% reduction in mortality, p-value 0.04).

In the Phase 2 study, the primary endpoint was the clinically relevant determination of whether GI GVHD patients at Day 30 (the end of treatment) had a durable GVHD treatment response as measured by whether or not they were able to consume at least 70% of their estimated caloric requirement. The GVHD treatment response at Day 30 was 22 of 31 (71%) vs. 12 of 29 (41%) in the orBec® and placebo groups, respectively (p-value 0.02). Additionally, the GVHD treatment response at Day 40 (10 days post cessation of therapy) was 16 of 31 (52%) vs. 5 of 29 (17%) in the orBec® and placebo groups, respectively (p-value 0.007).

Based on the data from Phase 2 and the Phase 3 studies, on September 21, 2006, we filed a new drug application ("NDA") for our lead product orBec® with the U.S. Food and Drug Administration ("FDA") for the treatment of acute GI GVHD. On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of acute GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of this letter.

We recently reached agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating our lead product orBec® for the treatment of acute GI GVHD. The agreement was made under the FDA's Special Protocol Assessment ("SPA") procedure. An agreement via the SPA procedure is an agreement with the FDA that a Phase 3 clinical trial design (e.g., endpoints, sample size, control group and statistical analyses) is acceptable to support a regulatory submission seeking new drug approval. After the study begins, the FDA can only change a SPA for very limited reasons. If and/or when the confirmatory Phase 3 trial is successful, we will file a complete response to the FDA action letter. This response is expected to be designated a class II response with a corresponding FDA review time frame of 6 months.

Further, in June 2009, we received Protocol Assistance feedback from the European Medicines Agency (EMEA) on the design of the Phase 3 clinical trial for orBec®. The EMEA agreed that should the new confirmatory Phase 3 study produce positive results, the data would be sufficient to support a marketing authorization in all 27 European Union member states. In doing so, the EMEA agreed to the primary endpoint and the other principal design features of the new study.

We have entered into a collaboration agreement with Numoda Corporation for the execution of our upcoming confirmatory Phase 3 clinical trial of orBec®. Collaborating with Numoda will allow us to take advantage of a scope of services including using their industry benchmarking capabilities to develop an operational and financial plan including the use of a proprietary management and oversight capabilities process. Barring any unforeseen modifications to the Phase 3 clinical program, Numoda will guarantee the agreed clinical trial budget against cost overruns. As part of the collaboration, Numoda has agreed to accept payment in our common stock in exchange for a portion of its services in connection with the conduct of the confirmatory Phase 3 clinical trial. To date, we have issued 2,847,222 shares of common stock to Numoda in partial payment for its services. Working with Numoda, we also will be able to take full advantage of early reporting of results to potential licensing partners and others. The confirmatory Phase 3 trial has been initiated and is expected to complete in the first half of 2011.

On July 12, 2007, we announced that patient enrollment commenced in a randomized, double blind, placebo-controlled, Phase 2 clinical trial of orBec® for the prevention of acute GVHD after allogeneic HCT with myeloablative conditioning regimens. The trial is being conducted by Paul Martin, M.D., at the FHCRC in Seattle, Washington and is being supported, in large part, by an NIH grant. We will not receive any direct monetary benefit from this grant, but if successful, this funded trial could serve to increase the value of our orBec®/oral BDP program. The Phase 2 trial will seek to enroll up to 138 (92 orBec® and 46 placebo) patients. The primary endpoint of the trial is the proportion of subjects who develop acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. Patients in this study will begin dosing at the start of the conditioning regimen and continue through day 75 following HCT. This trial is expected to complete in the first half of 2010.

Mortality Results

	Phase 3 Trial		Phase 2 Trial	
	orBec®	Placebo	orBec®	Placebo
Number of patients randomized	62	67	31	29
Number (%) who died	5 (8%)	16 (24%)	3 (10%)	6 (21%)
Hazard ratio (95% confidence interval)	0.33 (0.12, 0.89)		0.47 (0.12, 1.87)	
Death with infection*	3 (5%)	9 (13%)	2 (6%)	5 (17%)
Death with relapse*	3 (5%)	9 (13%)	1 (3%)	4 (14%)

*Some patients died with both infection and relapse of their underlying malignancy.

In this Phase 3 clinical trial, survival at the pre-specified endpoint of 200 days post-transplantation showed a clinically meaningful and statistically significant result. According to the manuscript, “the risk of mortality during the 200-day post-transplantation period was 67% lower with orBec® treatment compared to placebo treatment (hazard ratio 0.33;

95% CI: 0.12, 0.89; p-value 0.03, Wald chi-square test).” The most common proximate causes of death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying hematologic malignancy had contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 (4.8%) in the BDP arm. Acute or chronic GVHD was the proximate cause of death in 3/67 patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

A retrospective analysis of survival at 200 days post-transplantation in the supportive Phase 2 clinical trial showed consistent response rates with the Phase 3 trial; three patients (10%) who had been randomized to orBec® had died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduced hazard of day-200 mortality, although not statistically significantly different. Detailed analysis of the likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy were both reduced in the same proportion after treatment with orBec® compared to placebo. By transplantation day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in the orBec® arm and 4 of 29 patients (14%) in the placebo arm. Infection contributed to the deaths of 2 of 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

In this Phase 3 trial, orBec® achieved these mortality results despite the fact that there were more “high risk of underlying cancer relapse” patients in the orBec® group than in the placebo group: 40, or 65%, versus 29, or 43%, respectively. There was also an imbalance of non-myeloablative patients in the orBec® treatment group, 26, or 42%, in the orBec® group versus 15, or 22%, in the placebo group, putting the orBec® group at a further disadvantage. In addition, a subgroup analysis also revealed that patients dosed with orBec® who had received stem cells from unrelated donors had a 94% reduction in the risk of mortality 200 days post-transplantation.

Among the data reported in the January 2007 issue of Blood, the peer-reviewed Journal of the American Society of Hematology, orBec® showed continued survival benefit when compared to placebo one year after randomization in the pivotal Phase 3 clinical trial. Overall, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died within one year of randomization (46% reduction in mortality, p-value 0.04). Results from the Phase 2 trial also demonstrated enhanced long-term survival benefit with orBec® versus placebo. In that study, at one year after randomization, 6 of 31 patients (19%) in the orBec® group had died while 9 of 29 patients (31%) in the placebo group had died (45% reduction in mortality, p-value 0.26). Pooling the survival data from both trials demonstrated that the survival benefit of orBec® treatment was sustained long after orBec® was discontinued and extended well beyond 3 years after the transplantation. As of September 25, 2005, median follow-up of patients in the two trials was 3.5 years (placebo patients) and 3.6 years (orBec® patients), with a range of 10.6 months to 11.1 years. The risk of mortality was 37% lower for patients randomized to orBec® compared with placebo (p-value 0.03).

Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in study drug discontinuation were all comparable to that of the placebo group in both trials. Patients who remained on orBec® until Day 50 in the Phase 3 study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo. This effect was far less pronounced than those seen in patients on high dose prednisone.

Commercialization and Market

We anticipate the market potential for orBec® for the treatment of acute GI GVHD to be approximately 50 percent of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. Sigma-Tau is a pharmaceutical company that develops novel therapies for the unmet

needs of patients with rare diseases. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec® in the U.S., Canada and Mexico (the "Territory"). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment of $1 million was made in connection with the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD. Total additional milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $9 million. Sigma-Tau will pay us a 35% royalty (inclusive of drug supply) on net sales in the Territory as well as pay for commercialization expenses, including launch activities. In connection with the execution of the collaboration and supply agreement, we entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 25 million shares of our common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price is equal to one hundred fifty percent (150%) of the average trading price of our common stock over the five trading days prior to February 11, 2009. On November 26, 2008, prior to entering the collaboration agreement, we sold Sigma-Tau 16,666,667 common shares at $0.09 per share (the market price at the time) for proceeds of $1,500,000 in exchange for the exclusive right to negotiate a collaboration deal with us until March 1, 2009.