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

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, 2010

or

o 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

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

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
Assets		
Current assets:		
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
Total current assets	9,467,190	7,899,821
Office furniture and equipment, net	22,529	21,172
Intangible assets, net	1,212,020	1,463,289
Total assets	$10,701,739	$9,384,282
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$1,491,538	$844,857
Accrued compensation	38,759	365,199
Total current liabilities	1,530,297	1,210,056
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; 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)
Total shareholders' equity	9,171,442	8,174,226
Total liabilities and shareholders' equity	$10,701,739	$9,384,282

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		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	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
Operating activities:		
Net loss	$(5,447,292)	$(5,590,377)
Adjustments to reconcile net loss to net cash used in operating activities:		
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
Change in operating assets and liabilities:		
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)
Investing activities:		
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)
Financing activities:		
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").

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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
- explore other business development and acquisition strategies.

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 second quarter of 2012.

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

- The Company has approximately $9.9 million in active grant funding still available to support its research programs through 2010 and beyond. Additionally, the Company has submitted additional grant applications for further support of these programs and others with various funding agencies.
- 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 has approximately $7.7 million in available capacity under its 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 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

The following list includes only updates to the Company's significant accounting policies. 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.

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 their expected useful life – generally a period of 11 to 16 years.

During the nine months ended September 30, 2010, the Company incurred $378,501 in expense as a result of a one-time patent write off related to its return of the botulinum toxin vaccine license and abandonment of related patents. This expense is reflected in research and development expense in the consolidated statement of operations.

The Company capitalized $257,598 and $132,754 in patent related costs during the nine months ended September 30, 2010 and 2009, respectively.

Impairment of Long-Lived Assets

Office furniture and 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 long-lived assets for the nine months ended September 30, 2010 or 2009.

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. Inventory consists of finished goods related to the orBec® Named Patient Access Program ("NPAP"). The Company records an allowance as needed for excess inventory. During the year ended December 31, 2009 an allowance of $150,000 was provided. This allowance will be evaluated on a quarterly basis and adjustments will be made as required. During the nine months ended September 30, 2010, the Company disposed of its remaining inventory valued at $30,211 due to product expiration dates and expects to manufacture more product for the NPAP during early 2011.

Revenue Recognition

Substantially all of the Company's revenues are generated from NIH grants. The Company also generates revenues from the achievement of licensing milestones (in prior periods), and from sales of orBec® under the NPAP. The

revenue from NIH grants is 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. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant. Licensing milestone revenues are recorded when earned. Revenue from NPAP sales of orBec® are recognized when the product is shipped.

Stock-Based Compensation

From time to time, the Company issues restricted shares of common stock to vendors, consultants, and employees as compensation for services performed. 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 vest 25% upfront, then 25% each subsequent 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 nine months, unless otherwise extended by the Board.

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.

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 ranging from 127% to 129% and 126% to 130% for 2010 and 2009, respectively; and
- risk-free interest rates ranging from 1.0% to 1.9% and 1.5% to 2.2% in 2010 and 2009, respectively.

The Company estimates these values based on the assumptions that have been historically available. The fair value of each option grant made during 2010 and 2009 was estimated on the date of each grant using the Black-Scholes option pricing model and is then amortized ratably over the option's vesting periods, which approximates the service period. The Company awarded 8,442,500 and 2,812,500 stock options to new employees and new and existing Board members during the nine months ended September 30, 2010 and 2009, respectively. Of the 2010 grants, 7,335,000 stock options were issued to employees on July 1, 2010 subject to shareholder approval of an increase to the number of available shares under the 2005 Equity Incentive Plan at the Company's annual meeting of stockholders. Expense reductions of $126,171 and $59,015 are included in Stock-based Compensation - Research & Development and - General & Administrative, respectively, for the three and nine months ended September 30, 2010, which represent the decrease in the fair value of the options between their grant date (and the original expense recorded using that date) and fair value of the options at the date of the shareholder approval of the increase to the number of shares available under the equity plan.

There were 680,875 shares of stock options exercised and 87,125 shares of stock options that expired or were forfeited during the nine months ended September 30, 2010.

The intrinsic value of the stock options outstanding at September 30, 2010 was zero. The intrinsic value was calculated as the difference between the Company's common stock closing price on the Over-the-Counter Bulletin Board at September 30, 2010 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, 2010 was $0.18.

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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 provided through September 30, 2010 due to the net operating losses incurred by the Company since its inception. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at September 30, 2010 or 2009.

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,					
	2010			2009		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$(1,773,740)	215,869,026	$(0.01)	$(1,660,377)	168,093,600	$(0.01)

	Nine Months Ended September 30,					
	2010			2009		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$(5,447,292)	197,818,925	$(0.03)	$(5,590,377)	161,446,898	$(0.03)

Share issuable upon the exercise of options and warrants outstanding at September 30, 2010 and 2009 were 26,986,039 and 19,047,539 shares issuable upon the exercise of options, and 54,431,373 and 42,097,874 shares issuable upon the exercise of warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at September 30, 2010 were $0.24 and $0.22 per share, 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 per share, respectively. No options and warrants were included in the 2010 and 2009 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

Note 3. Office Furniture and Equipment

Office furniture and equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. Office and laboratory equipment consisted of the following:

	September 30, 2010	December 31, 2009
Office equipment	$37,828	$31,567
Office furniture	2,889	2,889
	40,717	34,456
Less: Accumulated depreciation	(18,188)	(13,284)
Office furniture and equipment, net	$22,529	$21,172

Depreciation expense was $1,621 and $2,376 for the three months ended September 30, 2010 and 2009, respectively, and $4,904 and $6,589 for the nine months ended September 30, 2010 and 2009, respectively.

Note 4. 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, 2010				
Licenses	10.0	$ 462,233	$ 190,605	$ 271,628
Patents	4.3	1,840,220	899,828	940,392
Total	5.46	$ 2,302,453	$ 1,090,433	$ 1,212,020
December 31, 2009				
Licenses	10.7	$ 462,234	$ 170,231	$ 292,003
Patents	6.2	2,077,401	906,115	1,171,286
Total	7.0	$ 2,539,635	$1,076,346	$1,463,289

Amortization expense was $47,870 and $44,000 for the three months ended September 30, 2010 and 2009, respectively, and $130,366 and $119,824 for the nine months ended September 30, 2010 and 2009, respectively. In addition, during the nine months ended September 30, 2010, the Company incurred $378,501 in a one-time patent write off cost related to its return of the botulinum toxin vaccine license and abandonment of related patents. This cost is reflected in research and development expense in the consolidated statement of operations.

Based on the balance of licenses and patents at September 30, 2010, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2010	$ 187,000
2011	$ 187,000
2012	$ 187,000
2013	$ 187,000
2014	$ 187,000

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 5. Income Taxes

Deferred tax assets consist of the following:

	September 30, 2010	December 31, 2009
Net operating loss carry forwards	$29,697,000	$24,249,000
Orphan drug and research and development credit carry forwards	3,339,000	3,339,000
Other	2,312,000	2,312,000
Total	35,348,000	29,900,000
Valuation allowance	(35,348,000)	(29,900,000)
Net deferred tax assets	$-	$-

At December 31, 2009, the Company had net operating loss carry forwards ("NOLs") of approximately $82,000,000 for federal and state tax purposes, portions of which are currently expiring each year until 2029. In addition, the Company had $3,600,000 of various tax credits that start expiring from December 2009 to December 2029. 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 likely that the utilization of the NOLs may be substantially 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 Company's policy is to recognize interest and penalties related to uncertain tax positions in income tax expense when assessed. No liability was recorded for interest or penalties related to uncertain tax positions at September 30, 2010. The Company believes that it has appropriate support for the income tax positions it has taken and expects to be taken on its tax returns.

As a result of the Company's continuing tax losses, it has recorded a full valuation allowance against a net deferred tax asset. The Company has no tax provision for the periods ended September 30, 2010 and 2009 due to losses and full valuation allowances against net deferred tax assets.

Note 6. 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, 2010:

In five separate transactions during the nine months ended September 30, 2010, the Company issued an aggregate of 294,091 shares of common stock under its existing Fusion Capital equity facility. The Company received an aggregate

of $70,000 in proceeds which approximated the shares' fair market value on the date of issuance.

In January 2010, the Company issued 403,225 shares of common stock pursuant to the $400,000 ($300,000 of which was issued in 2009) common stock equity investment agreement with its clinical trials management partner, Numoda Corporation ("Numoda"). These shares were priced at the then current 5-day average market price of $0.25 per share. The Company recognized $104,838 of research and development expense during the nine months ended September 30, 2010 as a result of this transaction.

On June 15, 2010, the Company entered into a Securities Purchase Agreement totaling $5,904,277 (before expenses of the offering) with accredited investors, including members of the Company's Board of Directors and Sigma-Tau. Pursuant to the Purchase Agreement, on June 18, 2010, the Company completed the private placement to the investors of 28,801,351 shares of the Company's common stock and warrants to purchase up to 17,280,810 shares of the Company's common stock. The warrants are exercisable at a price of $0.28 per share for a period of five years commencing on June 18, 2010. The expiration date of the warrants is subject to acceleration if the closing sales price of the Company's common stock attains certain per share values. The Company paid an aggregate placement agent/finder's fee to three different entities of $162,977 in cash and issued warrants to purchase 941,348 shares of common stock having the same terms as the warrants issued to the investors in the private placement. Net proceeds to the Company of the offering were $5,679,856.

As a result of stock option and warrant exercises, 680,875 and 100,000 shares, respectively, were issued during the nine months ended September 30, 2010.

Warrants

During 2010, in addition to warrants issued above in the June private placement, the Company issued 540,000 warrants to purchase common stock shares to consultants in exchange for their services. Expense charges of $49,693 and $67,052 were recorded during the three and nine months ended September 30, 2010, respectively, as a result of these issuances.

Note 7. Commitments and Contingencies

The Company has commitments of approximately $932,000 at September 30, 2010 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 second 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.

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.

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Note 8. 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,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues, Principally from Grants				
BioDefense	$781,894	$742,645	$1,383,788	