DOR BIOPHARMA INC
Form 10-Q
May 15, 2009

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 March 31, 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

DOR BIOPHARMA, 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 (Address of principal executive offices)	08540 (Zip Code)

(609) 538-8200
(Issuer's telephone number, including area code)

Indicate by check whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes 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 filerAccelerated filer o Non-accelerated filer o Smaller reporting company x
o

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 May 10, 2009, 167,070,944 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

DOR BioPharma, Inc.
Consolidated Balance Sheets

	March 31, 2009 (Unaudited)	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 6,513,368	$ 1,475,466
Grants receivable	149,128	278,316
Inventory, net	79,370	82,182
Prepaid expenses	76,072	86,837
Total current assets	6,817,938	1,922,801
Office and laboratory equipment, net	23,175	21,217
Intangible assets, net	1,427,517	1,418,717
Total assets	$ 8,268,630	$ 3,362,735
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,038,013	$ 1,015,005
Accrued compensation	167,327	370,614
Total current liabilities	1,205,340	1,385,619
Commitments and contingencies		
Shareholders' equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 167,070,944 and 118,610,704 shares, respectively issued and outstanding	167,071	118,610
Additional paid-in capital	111,359,061	104,176,253
	( )	()
Accumulated deficit	104,462,842	102,317,747
Total shareholders' equity	7,063,290	1,977,116
Total liabilities and shareholders' equity	$ 8,268,630	$ 3,362,735

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

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DOR BioPharma, Inc.
Consolidated Statements of Operations
For the three months ended March 31,
(Unaudited)

	2009	2008
Revenues, primarily from grants	$ 530,317	$ 677,640
Cost of revenues	(417,309)	(529,179)
Gross profit	113,008	148,461
Operating expenses:		
Research and development	1,590,999	600,001
General and administrative	532,137	848,111
Stock based compensation-research and development	73,390	39,583
Stock based compensation-general and administrative	72,450	36,793
Total operating expenses	2,268,976	1,524,488
Loss from operations	(2,155,968)	(1,376,027)
Other income:		
Interest income, net	10,872	19,856
Net loss	$ (2,145,096)	$ (1,356,171)
BasicnBasic and diluted net loss per share	$ (0.01)	$ (0.01)
Basic Basic and diluted weighted average common shares outstanding	148,911,114	97,761,457

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

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DOR BioPharma, Inc.
Consolidated Statements of Changes in Shareholders' Equity
For the three months ended March 31, 2009
(Unaudited)

	Common Stock		Additional Paid-In capital	Accumulated Deficit
	Shares	Par Value		
Balance, January 1, 2009	118,610,7044	$118,610	$104,176,253	($102,317,746)
Issuance of common stock from private placement, net of $144,000	20,914,035	20,915	2,219,287	-
Issuance of common stock for collaboration and supply agreement	25,000,000	25,000	4,425,000	-
Issuance of common stock for equity line	46,205	46	4,954	-
Issuance of common stock to vendors	2,500,000	2,500	297,500	-
Issuance of common stock warrants to vendors	-	-	90,227	-
Stock option expense	-	-	145,840	-
Net loss	-	-	-	(2,145,096)
Balance, March 31, 2009	167,070,944	$167,071	$111,359,061	($104,462,842)

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

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DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the three months ended March 31,
(Unaduited)

	2009	2008
Operating activities		
Net loss	$ (2,145,096)	$ (1,356,171)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	39,934	34,084
Non-cash stock compensation	490,227	309,938
Stock option compensation	145,840	76,376
Change in operating assets and liabilities:		
Grants receivable	129,188	32,222
Inventory	2,812	40,047
Prepaid expenses	10,765	137,456
Accounts payable	(76,992)	-
Accrued compensation	(203,286)	(228,688)
Total adjustments	538,488	401,435
Net cash used by operating activities	(1,606,608)	(954,736)
Investing activities:		
Acquisition of intangible assets	(46,622)	(41,481)
Proceeds from sale of equipment	-	500
Purchases of office and laboratory equipment	(4,069)	(2,151)
Net cash used by investing activities	(50,691)	(43,132)
Financing activities:		
Net proceeds from sale of common stock	6,690,200	658,600
Proceeds from sale of common stock pursuant to equity line	5,001	-
Net cash provided by financing activities	6,695,201	658,600
Net increase (decrease) in cash and cash equivalents	5,037,902	(339,268)
Cash and cash equivalents at beginning of period	1,475,466	2,220,128
Cash and cash equivalents at end of period	$ 6,513,368	$ 1,880,860
Non-cash transactions:		
Non-cash stock payment to an institutional investor	$ -	$ 270,000

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

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DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Basus of Presentations

The Company is a late-stage biopharmaceutical company incorporated in 1987, focused on the development of biotherapeutic products and biodefense vaccines intended for areas of unmet medical need. DOR's biotherapeutic business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products namely LPMTM-Leuprolide. DOR's biodefense business segment intends to convert its ricin toxin, botulinum toxin, and anthrax vaccine programs from early stage development to advanced development and manufacturing.

During the three months ended March 31, 2009, the Company generated revenues from the U.S. Federal Government and Named Patient Access Program ("NPAP") partners for orBec®. Revenues from the U.S. Federal Government were generated from three active grants for the Company's biodefense programs. As of March 31, 2009, outstanding receivables were from the U.S. Federal Government, the National Institutes of Health and Orphan Australia.

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

Liquidity

As of March 31, 2009, the Company had cash of $6,513,368 as compared to $1,475,466 as of December 31, 2008, representing an increase of $5,037,902. As of March 31, 2009, the Company had working capital of $5,612,598 as compared to working capital of $537,183 as of December 31, 2008, representing an increase of $5,075,415.

For the 3 months ended March 31, 2009, the Company's cash used in operating activities was approximately $1,606,608, compared to $954,236 for the corresponding period ended March 31, 2008, an increase in spending attributable to clinical trial preparation for the upcoming confirmatory Phase 3 clinical trial of orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD"). The Company continues to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners, and expect to continue to do so in the future.

Based on the Company's current rate of cash outflows and cash in the bank, the Company believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the third quarter of 2010. The Company has $1.3 million in grant funding still available to support its programs in 2009 and beyond. Additionally, the Company has submitted several grant applications for further support of its programs that have been submitted for government funding.

Management's plan is as follows:

> The Company is exploring out-licensing opportunities for orBec® and oral BDP in territories outside North America, and for LPMTM-Leuprolide and BioDefense programs in the United States and in Europe.
>
> The Company entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. 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, a $1 million payment, will be made upon the enrollment of the first patient in the Company's confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD, which is expected to occur in the second half of 2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay the Company a 35% royalty (inclusive of drug supply) on net sales in the Territory, as well as pay for commercialization expense, including launch activities. In connection with the execution of the collaboration and supply agreement, the Company entered into a common stock purchase agreement with Sigma-Tau pursuant to which the Company sold 25 million shares of common stock to Sigma-Tau for $0.18 per share, for 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.

The Company has and will utilize Named Patient Access Programs wherever possible in countries outside the United States to generate revenues from orBec®.

The Company intends to utilize its existing $8 million equity line of credit with Fusion Capital (approximately $7.8 million of which is still available to the Company through June 2010) if and when it deems market conditions to be appropriate.

The Company expects to receive new government grants intended to support existing and new research and development over the next twelve months. In addition to research and development funding, these grants would provide additional support for its overhead expenditures as well as defray certain costs intended to cover portions of its upcoming confirmatory Phase 3 trial of its lead product orBec® in acute GI GVHD. These grants would therefore have the effect of extending its cash resources. The Company routinely files for government grants which support its biotherapeutic and biodefense programs. There is no assurance these programs will continue to be available or that the Company will be successful in receiving grant awards.

The Company may obtain additional funds through the issuance of equity or equity-linked securities through private placements or rights offerings.

It is possible that the Company will seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, and 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.

In the event that such growth is less than forecasted in our 2009-2010 operating plan, management has developed contingency plans to reduce the Company operating expenses.

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2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma, Inc., and it's wholly and majority owned subsidiaries ("DOR" or the "Company"). 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 Institute of Health of the U.S. Federal Government for costs incurred prior to the period end. The amounts were billed in the month subsequent to period end and collected shortly thereafter. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, the bad debt expense is charged to operations.

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 SFAS 2, "Accounting for Research and Development Costs".

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 DOR'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 $46,622 and $41,481 in patent related costs during the quarter ended March 31, 2009 and the quarter ended March 31, 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 an impairment of intangible assets for the three months ended March 31, 2009 or 2008.

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 quarter ended March 31, 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 from government grants and NPAP sales of orBec®. The revenue from government 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 the NPAP sales of orBec® are recognized when the product is shipped. NPAP sales are FOB shipping.

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.

Stock Based Compensation

The fair value of options in accordance with SFAS 123R was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 125% for 2009 and 121% for 2008, and average risk-free interest rates of 3.7% and 3.8% 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 at the three months ended March 31, 2009 and March 31, 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 1,500,000 stock options for the three months ended March 31, 2009 while 50,000 stock options were granted during the three months ended March 31, 2008. The weighted average fair value of options granted, with an exercise price equal to the fair market value of the stock, was $0.08, and $0.16 for the three months ended March 31, 2009 and 2008, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123R and Emerging Issues Task Force ("EITF") 96-18, 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.

As stock options are exercised, common stock share certificates are issued via electronic transfer or physical share certificates by the Company's transfer agent. 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 three months ended March 31, 2009 or during the year ended December 31, 2008. There were no forfeitures during the three months ended March 31, 2009 and forfeitures of 779,800 stock options during the year ended December 31, 2008. The Intrinsic value of the stock options 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 at 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 are employees or directors. In general when an employee or director terminates employment the options will expire within six months.

The intrinsic value was calculated as the difference between the Company's common stock closing price on the OTC BB at December 31, 2008 and the exercise price of the stock option issued multiplied by the number of stock options. The Company's common stock price at March 31, 2009 was $0.10.

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, 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 March 31, 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 for March 31, 2009 and 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.

	Quarter Ended March 31, 2009			Quarter Ended March 31, 2008		
	Loss	Shares	EPS	Loss	Shares	EPS
Basic and Diluted EPS	($2.14)	148.91	($0.01)	($1.36)	97.76	($0.01)

Options and warrants outstanding at March 31, 2009 and 2008 were 17,860,039 and 10,289,849 options, and 41,233,755 and 30,274,074 warrants, respectively. No options and warrants were included in the 2009 and 2008 computations of diluted earnings because the effect would be anti-dilutive due to losses in the respective years. The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2009 are $0.25 and $0.16, respectively.

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.

New Accounting Pronouncements

Effective January 1, 2009, the Company adopted EITF Issue No. 07-05, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock ("EITF Issue No. 07-05"). EITF Issue No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133. The adoption of EITF Issue No. 07-05 did not have a material effect on the Company's financial statements.

Effective January 1, 2009, the Company adopted FAS No. 141 (revised 2007), Business Combinations (FAS 141(R)), which replaces FAS No. 141, Business Combinations. FAS 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. This statement also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. FAS 141(R) applies prospectively to the Company's business combinations for which the acquisition date is on or after January 1, 2009.

Effective January 1, 2009, the Company adopted FSP No. FAS 142-3, Determination of the Useful Life of Intangible Assets ("FSP No. FAS 142-3"). FSP No. FAS 142-3 amends the factors that should be considered in developing assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets, to improve consistency between the useful life of a recognized intangible asset and the period of expected cash flows used to measure the fair value of the asset. FSP No. FAS 142-3 is applied prospectively to intangible assets acquired after the effective date. The adoption of FSP No. FAS 142-3 did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP SFAS No. 107-1 and Accounting Principles Board ("APB") Opinion 28-1, Interim Disclosures About Fair Value of Financial Instruments ("FSP SFAS No. 107-1 and APB No. 28-1"). FSP SFAS No. 107-1 and APB No. 28-1 amend SFAS No. 107, Disclosures About Fair Value of Financial Instruments, to require disclosures about the fair value of financials in interim as well as in annual financial statements, and APB No. 28, Interim Financial Reporting, to require those disclosures in all interim financial statements. FSP SFAS No. 107-1 and APB No. 28-1 are effective for periods ending after June 15, 2009. The Company is evaluating if the adoption of FSP SFAS No. 107-1 and APB No. 28-1 will have a material impact on its financial statements.

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
March 31, 2009				
Licenses	11.5	$ 462,234	$ 149,710	$ 312,524
Patents	8.8	1,917,225	802,231	1,114,993
Total	9.3	$ 2,379,459	$ 951,941	$ 1,427,517
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 $37,822 and $31,179 for the quarters ended March 31, 2009 and 2008, respectively.

Based on the balance of licenses and patents at March 31, 2009, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
2010	$ 160,000
2011	165,000
2012	170,000
2013	175,000
2014	180,000

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

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4. Income Taxes

Deferred tax assets as of:

	March 31, 2009	December 31, 2008
Deferred tax assets:		
Net operating loss carry forwards	$ 28,400,000	$ 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	33,700,000	31,600,000
Valuation allowance	(33,700,000)	(31,600,000)
Net deferred tax assets	$ -	$ -

At December 31, 2008, the Company had net operating loss carry forwards 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 change in the valuation allowance for three months ended March 31, 2009 and the year ended December 31, 2008 was an increase of approximately $2,100,000 and decrease of $1,600,000 respectively, resulting primarily from net operating losses generated. As a result of the Company’s continuing tax losses, the Company has recorded a full valuation allowance against a net differed tax asset.

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2009 and 2008 was as follows:

	2009	2008
Income tax loss at federal statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(6.50)	(6.50)
Valuation allowance	40.50	40.50
Provision for income taxes (benefit)	- %	- %

Effective January 1, 2007, the Company adopted Financial Interpretation ("FIN") No. 48, Accounting for Uncertainty in Income Taxes – An Interpretation of FASB Statement No. 109. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The adoption did not have an effect on the consolidated financial statements.

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5. Shareholders' Equity

Preferred Stock

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

Common Stock

Transactions for the quarter ended March 31, 2009 and the year ended December 31, 2008

On March 19, 2009, the Company issued 46,205 shares of common stock under its existing Fusion Capital Equity facility. The Company received $5,000 in proceeds which approximated the shares' fair market value on 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. These shares were priced at the then current market price of $0.12 per share. $100,000 of this investment will be completed in January 2010 and it will either be paid in cash or 833,334 common stock shares if price falls below $0.12. The investment follows and enhances 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 for the three months ended March 31, 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®. 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, a $1 million payment, will be made upon the enrollment of the first patient in the Company's confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD, which is expected to occur in the second half of 2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay the Company a 35% royalty (inclusive of drug supply) on net sales in the Territory, as well as pay for commercialization expense, including launch activities. In connection with the execution of the collaboration and supply agreement, the Company entered into a common stock purchase agreement with Sigma-Tau pursuant to which the Company sold 25 million shares of common stock to Sigma-Tau for $0.18 per share, for 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 representing the market price of $0.114 per share 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 $2.9 million if they are all exercised.

During the 12 months ended December 31, 2008, the Company issued 758,082 shares of common stock as payment to vendors for consulting services. An expense of $111,500 was recorded which approximated the shares' fair market value on the date of issuance, respectively.

During the 12 months ended December 31, 2008, the Company also issued 993,084 shares of common stock under its existing 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 date of issuance.

During the 12 months ended December 31, 2008, the Company issued 168,309 shares of common stock as compensation or severance for employees. An expense of $26,000 was recorded which approximated the shares' fair market value on the date of issuance.

On December 1, 2008, the Company entered into a non-binding letter of intent with Sigma-Tau, which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other pipeline compounds until March 1, 2009. Under the terms of the letter of intent, Sigma-Tau purchased $1.5 million of the Company's common stock at the then market price of $0.09 per share, representing 16,666,667 shares.

On February 14, 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The Fusion Capital facility allows the Company to require Fusion Capital to purchase between $80,000 and $1.0 million every two business days, of the Company's common stock 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, for 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 for commitment shares for 2008 was 1,369,125; which were issued to Fusion Capital and consisted of 1,275,000 as a commitment fee, 75,000 as a commitment fee for the $500,000 invested, and 19,125 for the commitment fee shares on the equity line draws of $127,500.

Warrants

During 2009, the Company issued 1,050,000 warrants to purchase common stock shares to consultants for services. One million of the common stock warrants were issued to George B. McDonald, M.D. which had an exercise price of $0.10 and 50,000 warrants to Strategic Outsourcing Solutions, LLC which had an exercise price of $0.14. An expenses charge of $90,227 was recorded for the quarter ended March 31, 2009.

6. Commitments and Contingencies

The Company has commitments of approximately $5.6 million at March 31, 2009 in connection with a collaboration agreement with Numoda for the execution of our upcoming confirmatory, Phase 3 clinical trial of orBec® that will begin in second half of 2009 and is expected to continue through second half of 2010.

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.

Certain operating leases for office and warehouse space maintained by the Company resulted in rent expense for the quarter ended March 31, 2009 and 2008 of $19,533 and $17,836, respectively.

The Company has approximate future obligations over the next five years as follows:

Year	Research and Development	Property and Other Leases	Public and Investor Relations	Total
2009	$ 2,300,000	$ 74,000	$ 43,000	$ 2,417,000
2010	2,900,000	95,000	-	2,995,000
2011	200,000	96,000	-	296,000
2012	200,000	105,000	-	305,000
2013	200,000	115,000	-	315,000
Total	$ 5,800,000	$ 485,000	$ 43,000	$ 6,328,000

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.

On 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 750,000 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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7. Business Segments

The Company had two active segments for the quarter ended March 31, 2009 and March 31, 2008: BioDefense and BioTherapeutics. Each segment includes an element of overhead costs specifically associated with its operations with its corporate shares services group responsible for support functions generic to both operating segments.

	March 31,	
	2009	2008
Net Revenues		
BioDefense	$ 514,317	$ 677,640
BioTherapeutics	16,000	
Total	$ 530,317	$ 677,640
Loss from Operations		
BioDefense	$ (65,938)	$ (96,390)
BioTherapeutics	(1,537,772)	(406,763)
Corporate	(552,258)	(872,874)
Total	$ (2,155,968)	$ (1,376,027)
Identifiable Assets		
BioDefense	$ 947,666	$ 864,161
BioTherapeutics	658,979	562,551
Corporate	6,661,985	1,955,178
Total	$ 8,268,630	$ 3,381,890
Amortization and Depreciation Expense		
BioDefense	$ 22,040	$ 19,635
BioTherapeutics	16,838	12,997
Corporate	1,056	1,452
Total	$ 39,934	$ 34,084
Interest Income		
Corporate	$ 11,190	$ 20,036
Total	$ 11,190	$ 20,036
Stock Option Compensation		
BioDefense	$ 26,531	$ 19,517
BioTherapeutic	46,859	20,066
Corporate	72,450	36,793
Total	$ 145,840	$ 76,376

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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 the 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 within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe-harbor created by that Section. 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 wo not the exclusive means of 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

We were incorporated in Delaware in 1987. We are a late-stage research and development biopharmaceutical company focused on developing products to treat 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. We maintain two active business segments: BioTherapeutics and BioDefense.

Our business strategy is to:

(a) initiate and execute the pivotal Phase 3 confirmatory clinical trial for orBec® in the treatment of acute GI GVHD;
(b) 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;
(c) conduct and complete a Phase 2 clinical trial of orBec® for the prevention of acute GVHD;
(d) 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;
(e) make orBec® available worldwide through NPAP for the treatment of acute GI GVHD;
(f) reinitiate development of our other biotherapeutics products, namely LPMTM Leuprolide;
(g) continue to secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts and procurements;
(h) 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;
(i) acquire or in-license new clinical-stage compounds for development; and
(j) 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®

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 proximal portions of the GI tract, and the other tablet is intended to release BDP in the distal portions of the GI tract.

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, which provide for seven and 10 years of post-approval market exclusivity, respectively.

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Clinical and Regulatory History

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=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 the not approvable 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 an SPA for very limited reasons. Based on data from the prior Phase 3 study of orBec®, the upcoming confirmatory Phase 3 protocol will be 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).

We have entered into a collaboration agreement with Numoda Corporation ("Numoda"), 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 upcoming 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. We expect to begin enrollment in the confirmatory Phase 3 trial in the second half of 2009.

On December 1, 2008, we received $1.5 million under a non-binding letter of intent with Sigma-Tau, which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other pipeline compounds until March 1, 2009. Sigma-Tau is a pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. Sigma-Tau has both prescription and consumer products in the metabolic, oncology, and renal markets.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. 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 will be made upon the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD, which is expected to occur in the second half of 2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 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 $0.90 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.

On September 12, 2007, we announced that our academic partner, the Fred Hutchinson Cancer Research Center ("FHCRC"), received a $1 million grant from NIH to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of GI radiation injury. While we will not receive any monetary benefit from this grant, we will benefit if this work is successful and it will enhance the value of our orBec®/oral BDP program. The purpose of the studies funded by the grant, entitled "Improving Gastrointestinal Recovery after Radiation," is to evaluate the ability of three promising clinical-grade drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This type of therapy, if successful, would benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism. In most radiation scenarios, injury to the hematopoietic (blood) system and gastrointestinal tract are the main determinants of survival. The studies will compare overall survival and markers of intestinal cell regeneration when the drug regimens are added to supportive care intended to boost proliferation of blood cells. The principal investigator of the study is George E. Georges, M.D., Associate Member of the FHCRC.

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. Enrollment in this trial is expected to be completed in the second half of 2009.

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orBec® Survival Results at 200 Days Post Transplantation

	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=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.

orBec® Comprehensive Long-Term Mortality Results

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=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=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=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 Beclomethasone Dipropionate (orBec®). Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec® in the U.S., Canada and Mexico. For more information relating to this agreement, see “Clinical and Regulatory History” commencing on page 19.

BioDefense Overview

RiVax™

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first and only ricin toxin vaccine to be clinically tested in humans. Ricin is a potent glycoprotein toxin derived from the beans of castor plants. It can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The Centers for Disease Control ("CDC") has classified ricin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

We have announced positive Phase 1 clinical trial results for RiVax™ which demonstrated that the vaccine is well tolerated and induces antibodies in humans that neutralize the ricin toxin. The functional activity of the antibodies was confirmed by animal challenge studies in mice which survived exposure to ricin toxin after being injected with serum samples from the volunteers. The outcome of the study was published in the Proceedings of the National Academy of Sciences. A second Phase 1 trial is currently underway, utilizing an adjuvanted formulation.

The initial Phase 1 clinical trial was conducted by Dr. Ellen Vitetta at the University of Texas Southwestern Medical Center ("UTSW") at Dallas, DOR's academic partner on the RiVax™ program. The National Institutes of Health ("NIH") has awarded us two grants one for $6.4 million and one for $5.2 million for a total of $11.6 million for the development of RiVax™ covering process development, scale-up and cGMP manufacturing, and preclinical toxicology testing pursuant to the FDA's "animal rule."

The development of RiVaxTM has progressed significantly. In September 2006, we received a grant of approximately $5.2 million from NIAID, a division of the NIH, for the continued development of RiVax™, a recombinant vaccine against ricin toxin. This RiVax™ grant will provide approximately $5.2 million over a three year period to fund the development of animal models which will be used to correlate human immune response to the vaccine with protective efficacy in animals. This is necessary for ultimate licensure by the FDA, when human efficacy vaccine trials are not possible. This new grant also supports the further biophysical characterization of the vaccine containing a well-characterized adjuvant that is needed to enhance the immune response to recombinant proteins. These studies will be required to assure that the vaccine is stable and potent over a period of years. A prototype version of RiVax™ has been evaluated in a Phase 1 clinical trial and was shown to be safe and effective, while also inducing ricin neutralizing antibodies as confirmed in subsequent animal studies.

On April 29, 2008, we announced the initiation of a comprehensive program to evaluate the efficacy of RiVax™, in non-human primates. This study is taking place at the Tulane University Health Sciences Center and will provide data that will further aid in the interpretation of immunogenicity data obtained in the human vaccination trials. The study was initiated in the second quarter of 2008.

On January 29, 2008, we announced that we successfully achieved a two-year milestone in the long-term stability program of the key ingredient of RiVax™, a recombinant subunit vaccine against ricin toxin. The results of the two-year analysis, undertaken as part of the formal stability program, demonstrate that the immunogen component of RiVax™, a recombinant derivative of the ricin A chain, is stable under storage conditions for at least two years without loss of its natural configuration or the appearance of any detectable degradation products. A vaccine is considered by many to be the best way to prospectively protect populations at risk of exposure against ricin toxin. As this vaccine would potentially be added to the Strategic National Stockpile and dispensed in the event of a terrorist attack, the activity of the vaccine must be maintained over a period of years under stockpile storage conditions.

On November 15, 2007, we announced that we entered into a Cooperative Research and Development Agreement with the Walter Reed Army Institute of Research (“WRAIR”) to provide additional means to characterize the immunogenic protein subunit component of RiVax™, our preventive vaccine against ricin toxin. The agreement will be carried out at the Division of Biochemistry at WRAIR and will encompass basic studies to reveal the underlying protein structure that is important in inducing human immune responses to ricin toxin. Ricin toxin is an easy to manufacture toxin that poses a serious threat as a bioweapon, primarily by inhalation. Some of the features that are critical to induce protective immune responses by vaccination with RiVax™ include structural determinants in the core and the surface of the protein. The purpose of the agreement is to obtain data to correlate protein structure with induction of protective immunity and long-term stability of the protein. These studies will involve comparison to structures of similar natural and recombinant proteins. RiVax™ induces antibodies that appear primarily in the blood of animals and humans. Some of these antibodies recognize determinants on the protein that are dependent on the conformation of the protein and may be involved in biological activity. Overall, antibodies in the blood are correlated to protection against exposure when the toxin enters the circulatory system or when it comes into contact with lung surfaces, where the major effects lead to severe inflammation, tissue necrosis and death. RiVax™ induces such antibodies in humans as well as other animal species. Lieutenant Colonel Charles B. Millard, Ph.D., Director of the Division of Biochemistry at WRAIR, will lead the studies to be conducted at WRAIR, which will include X-ray crystal analysis to determine the structural parameters of the RiVax™ vaccine. We will not receive any monetary benefits from this agreement. We will take part in evaluating the data that is found by WRAIR’s studies, which they are funding. If successful, this will enhance the value of our RiVax™ product and assist with continuing the progression of the program.

In July 2007, we announced that the Office of Orphan Products Development ("OOPD") of the FDA has awarded a development grant for the further clinical evaluation of RiVaxTM. The grant was awarded to UTSW to further the development of RiVaxTM. We will not receive any monetary benefits from this grant; however, the successful completion of this work will enhance the value of our RiVaxTM program and continue to move it forward. The principal investigator for the project is Dr. Vitetta, Director of the Cancer Immunobiology Center at UTSW. The award totals approximately $940,000 for three years and is to be used for the evaluation of an adjuvant for use with the vaccine. Typically, awards made by the OOPD are to support clinical trials for development of products that address rare diseases or medicines that would be used in numerically small populations. UTSW began a second Phase 1 human clinical trial with an adjuvanted formulation of RiVaxTM in August of 2008.

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BT-VACC™

Our botulinum toxin vaccine, called BT-VACC™, originated from the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania. The vaccine is being developed as an oral or intranasal formulation to be given as a primary immunization series or as oral or nasal booster to individuals who have been primed with an injected vaccine. Botulinum toxin is the product of the bacteria Clostridium botulinum. Botulinum toxin is the most poisonous natural substance known to man. Botulinum toxin causes acute, symmetric, descending flaccid paralysis due to its action on peripheral cholinergic nerves. Paralysis typically presents 12 to 72 hours after exposure. Death results from paralysis of the respiratory muscles. Current treatments include respiratory support and passive immunization with antibodies which must be administered before symptoms occur, which leaves little time post-exposure for effective treatment.

In the context of oral and nasal formulations, we are developing a multivalent vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. We have identified lead antigens against Serotypes A, B and E consisting of the Hc50 fragment of the botulinum toxin. Typically, vaccines given by mucosal routes are not immunogenic because they do not attach to immune inductive sites. In the case of the combination BT-VACCTM, both the A and the B antigens were capable of attaching to cells in the mucosal epithelium and inducing an immune response with similar magnitude to the injected vaccine. Our preclinical data suggests that a bivalent formulation of serotypes A and B is completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in animal models. The animals were given a small quantity of the bivalent combination vaccine containing each of the type A and type B antigens (10 micrograms) three times a day at two week intervals. All of the animals developed equivalent immune responses to A and B types in the serum. Importantly, they were then protected against exposure to each of the native toxin molecules given at 1000 fold the dose that causes lethality. The immune responses were also comparable to the same vaccines when given by intramuscular injection.

In July 2007, we announced that the first results from testing of a multivalent form of BT-VACCTM were published in the journal Infection and Immunity (Ravichandran et al., 2007, Infection and Immunity, v. 75, p. 3043). These results are the first to describe the protective immunity elicited by a multivalent vaccine that is active by the mucosal route. The vaccine consists of a combination of three non-toxic subunits of botulinum toxin that induced protection against the corresponding versions of the natural toxins. The results published in Infection and Immunity show that non-toxic subunits (protein components of the natural toxin) of three of the serotypes of botulinum toxin that cause almost all instances of human disease, namely serotypes A, B, and E, can be combined and delivered via nasal administration. The combination vaccine induced antibodies in the serum of mice and protected against subsequent exposure to high doses of a combination of the natural A, B, and E serotype neurotoxins. The combination vaccine also can induce protection when given mucosally as a booster to animals that have been given a primary vaccine injection.

In September 2006, we were awarded a NIAID Phase 1 SBIR grant totaling approximately $500,000 to conduct further work to combine antigens from different serotypes of botulinum toxin for a prototype multivalent vaccine. This program is currently ongoing and the grant funding has supported further work in characterizing antigen formulations that induce protective immunity to the three most common botulinum toxin types that may be encountered naturally or in the form of a bioweapon. This work will continue the research conducted by Dr. Lance Simpson and colleagues who originally showed that recombinant non-toxic segments of the botulinum toxin can be given by the oral as well as the intranasal route to induce a strong protective immune response in animals. This observation forms the basis for development of an oral or intranasal vaccine for botulinum toxin that can be used in humans. Currently, the recombinant vaccines under development are given by intramuscular injections. The alternate oral or intranasal route that we are developing potentially provides a self administration option, which would offer the distinct advantage of bypassing the requirement for needles and personnel to administer the vaccine.

Anthrax Vaccine Option

On May 8, 2008, we entered into a one-year exclusive option with the President and Fellows of Harvard College to license analogues of anthrax toxin for prospective use in vaccines against anthrax, a potentially fatal disease caused by the spore-forming, gram-positive bacterium Bacillus anthracis. The option, which was obtained through negotiation with Harvard University's Office of Technology Development, encompasses an issued U.S. patent that covers engineered variants of protective antigen ("PA") developed in the Harvard Medical School laboratory of Dr. John Collier. PA is the principal determinant of protective immunity to anthrax and is being developed for second- and third-generation anthrax vaccines. There has been a major effort on the part of the federal government to develop vaccines for use both pre- and post-exposure to improve upon the vaccine currently in use. This vaccine, known as AVA (for anthrax vaccine adsorbed), consists of a defined, but impure mixture of bacterial components. AVA is FDA approved, but requires multiple injections followed by annual boosters. Vaccines such as AVA or those based on the purified, recombinant anthrax toxin component PA ("rPA") induce antibodies that neutralize anthrax holotoxin and can strongly protect animals from inhaled anthrax spores. Several of the protein variants developed by Dr. Collier have been shown to be more immunogenic than native rPA, perhaps because they are processed more efficiently by cellular antigen processing pathways. We believe that with government funding we will be able to develop the Collier anthrax vaccine into one with an improved stability profile, an issue that has proven challenging in the development of other anthrax vaccines. We do not intend to conduct any new research and development or commit any funds to this program until we receive grant funding.

Additional Programs

LPMTM - Leuprolide

Our Lipid Polymer Micelle ("LPM™") oral drug delivery system is a proprietary platform technology designed to allow for the oral administration of peptide drugs that are water-soluble but poorly permeable through the gastrointestinal tract. We have previously demonstrated in preclinical animal models that the LPM™ technology is adaptable to oral delivery of peptide drugs and that high systemic levels after intestinal absorption can be achieved with the peptide hormone drug leuprolide. The LPM™ system utilizes a lipid based delivery system that can incorporate the peptide of interest in a thermodynamically stable configuration called a "reverse micelle" that, through oral administration, can promote intestinal absorption. Reverse micelles are structures that form when certain classes of lipids come in contact with small amounts of water. This results in a drug delivery system in which a stable clear dispersion of the water soluble drug can be evenly dispersed within the lipid phase. LPM™ is thought to promote intestinal absorption due to the ability of the micelles to open up small channels through the epithelial layer of the intestines that allow only molecules of a certain dimension to pass through while excluding extremely large molecules such as bacteria and viruses. The reverse micelles also structurally prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inhibition by surfactant(s) in the formulation.

In preclinical studies, the LPM™ delivery technology significantly enhanced the ability of leuprolide to pass through the intestinal epithelium in comparison to leuprolide alone. Leuprolide is a synthetic peptide agonist of gonadotropin releasing hormone, which is used in the treatment of prostate cancer in men and endometriosis in women. Leuprolide exhibits poor intestinal absorption from an aqueous solution with the oral bioavailability being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2.2% for the control oral solution. Based on these promising preclinical data, we anticipate preparing for a Phase 1 study in humans in first half of 2010 to confirm these findings.

An oral version of leuprolide may provide a significant advantage over the currently marketed "depot" formulations. Leuprolide is one of the most widely used anti-cancer agents for advanced prostate cancer in men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide sales of approximately $1.8 billion in 2006. Injectable leuprolide is also widely used in non-cancer indications, such as endometriosis in women (a common condition in which cells normally found in the uterus become implanted in other areas of the body), uterine fibroids in women (noncancerous growths in the uterus) and central precocious puberty in children (a condition

causing children to enter puberty too soon). Leuprolide is currently available only in injectable, injectable depot and subcutaneous implant routes of delivery which limits its use and utility.

OraprineTM

We anticipate that an orally administered version of the immunosuppressant drug azathioprine may have a significant role in treating inflammatory diseases of the oral cavity. Further, an orally administered drug may provide a niche in the current transplant medicine market for an alternative to solid dosage forms of azathioprine that would have utility in elderly patients. OraprineTM is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the U.S. as Imuran®. We conducted a Phase 1 bioequivalence trial following a trial conducted by Dr. Joel Epstein at the University of Washington that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from GVHD. Oral GVHD can occur in up to 70% of patients who have undergone bone marrow/stem cell transplantation despite treatment with other immunosuppressive drugs such as prednisone, methotrexate, tacrolimus, and cyclosporine. Azathioprine is one of the most widely used immunosuppressive medications in clinical medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mechanisms to foreign bodies (such as the transplanted organ). The decrease in the patient's immune system increases the chances of preventing rejection of the transplanted organ in the patient.

On September 25, 2007, we announced a Notice of Allowance of patent claims based on U.S. Patent Application #09/433,418 entitled "Topical Azathioprine for the Treatment of Oral Autoimmune Diseases." Concurrently, the patent has also been issued by the European Patent Office with the serial number EP 1 212 063 B1. This patent family specifically includes claims for treatment and prevention of oral GVHD with locally or topically applied azathioprine. We anticipate filing an ANDA; however this program is suspended pending further funding from financing or partnerships.

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Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. We evaluate these estimates and judgments on an on-going basis.

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in SFAS 2, “Accounting for Research and Development Costs”. Based on this consideration, we capitalized all outside legal and filing costs incurred in the procurement and defense of patents.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. 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.

We capitalize and amortize intangibles over a period of 11 to 16 years. We capitalize legal costs associated with the protection and maintenance of our patents and rights for our current products in both the domestic and international markets. As a late stage research and development company with drug and vaccine products in an often lengthy clinical research process, we believe that patent rights are one of our most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at each stage of development. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, our policy is to capitalize these costs and amortize them over the remaining useful life of the patents. We capitalize intangible assets’ alternative future use as referred to in SFAS No.142 and in paragraph 11 c. of SFAS No. 2.

We capitalize intangible assets that have alternative future uses as this is common practice in the pharmaceutical development industry. Of our intangible asset balance, our purchase of the RiVaxTM vaccine license from the University of Texas Southwestern Medical Center for $462,234 was for up-front license costs. We capitalize license costs because they have alternative future use as referred to in paragraph 11 c. of SFAS No.2. We believe that both of these intangible assets purchased have alternative future uses.

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.

Revenue Recognition

Our revenues are generated from U.S. government grants and from NPAP sales of orBec®. The government grants are based upon subcontractor costs and internal costs covered by the grant, 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 we incur internal expenses that are related to the grant. The NPAP revenues are recorded when orBec® is shipped.

Stock Based Compensation

The fair value of options in accordance with SFAS 123R was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 125% for 2009 and 121% for 2008, and average risk-free interest rates of 3.7% and 3.8% in 2009 and 2008, respectively. We estimate these values based on the assumptions that have been historically available. The fair value of each option grant at the three months ended March 31, 2009 and March 31, 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. We awarded 1,500,000 stock options for the three months ended March 31, 2009 while 50,000 stock options were granted during the three months ended March 31, 2008. The weighted average fair value of options granted, with an exercise price equal to the fair market value of the stock, was $0.08, and $0.16 for the three months ended March 31, 2009 and 2008, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123R and Emerging Issues Task Force ("EITF") 96-18, 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.

As stock options are exercised, common stock share certificates are issued via electronic transfer or physical share certificates by our transfer agent. Upon exercise, shares are issued from the amended 2005 equity incentive plan and increase the number of shares we have outstanding. There were no stock option exercises during the three months ended March 31, 2009 or during the year ended December 31, 2008. There were no forfeitures during the three months ended March 31, 2009 and forfeitures of 779,800 stock options during the year ended December 31, 2008. The Intrinsic value of the stock options was zero.

From time to time, we issue 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 we 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 at 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 are employees or directors. In general when an employee or director terminates employment the options will expire within six months.

The intrinsic value was calculated as the difference between our common stock closing price on the OTC BB at December 31, 2008 and the exercise price of the stock option issued multiplied by the number of stock options. Our common stock price at March 31, 2009 was $0.10.

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Material Changes in Results of Operations

Quarter and Year Ended March 31, 2009 Compared to Quarter and Year Ended March 31, 2008.

For the three months ended March 31, 2009, we had a net loss of $2,145,096 as compared to a net loss of $1,356,171 for the three months ended March 31, 2008, representing an increase of $788,925, or 58%. This increase is primarily attributed to increased spending of $968,996 in research and development for the initiation of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD. For the three months ended March 31, 2009, there was a decrease in general and administrative expenses that were related to the commitment shares that were issued in connection with the Fusion Capital equity transaction during the three months ended March 31, 2008 and a resultant expense of $270,000 was recorded.

For the three months ended March 31, 2009 revenues and associated expenses relate to NIH Grants awarded in September 2004 and September 2006 and from NPAP sales of orBec®. The NIH grants support the research and development of our ricin and botulinum vaccines.

For the three months ended March 31, 2009, we had revenues of $530,317 as compared to $677,640 in the three months ended March 31, 2008, for a decrease of $147,323, or 22%. During 2009, we recorded $16,000 from our NPAP sales of orBec®. Our overall revenue was slightly lower during the first three months of 2009 due to lower draw-downs from our NIH grants. We also incurred expenses related to that revenue in the three months ended March 31, 2009 and 2008 of $417,309 and $529,179, respectively, a decrease of $111,870, or 21%. These costs relate to payments made to subcontractors and universities in connection with research performed in support of the grants.

Our gross profit for the three months ended March 31, 2009 was $113,008 as compared to $148,461 in the 12 months ended March 31, 2008, representing a decrease of $35,453, or 24%. The decrease was primarily due to decreased subcontracted reimbursed costs for the grants.

Research and development spending increased by $990,998, or 165%, to $1,590,999, for the three months ended March 31, 2009 as compared to $600,001 for the corresponding period ended March 31, 2008. During the first three months of 2009, we incurred expenses of $968,996 in connection with clinical preparation for the confirmatory Phase 3 clinical trial of orBec® for the treatment of GI GVHD. The Company's primary vendor was Numoda which accumulated $938,200 of these expenses.

General and administrative expenses decreased $315,974, or 37%, to $532,137 for the three months ended March 31, 2009, as compared to $848,111 for the corresponding period ended March 31, 2008. The decrease was primarily due to the commitment shares that were issued in connection with the Fusion Capital equity transaction during the three months ended March 31, 2008 and a resultant expense of $270,000 was recorded.

Stock based compensation expenses for research and development increased $33,807, or 85%, to $73,390 for the three months ended March 31, 2009, as compared to $39,583 for the corresponding period ended March 31, 2008. This increase was related to stock options that were issued to newly hired employees and for options issued in the three months ended December 31, 2008 that began vesting in the first three months of March 31, 2009.

Stock based compensation expenses for general and administrative increased $35,657, or 97%, to $72,450 for the three months ended March 31, 2009, as compared to $36,793 for the corresponding period ended March 31, 2008. This increase was related to stock options that were issued to a new director and for options issued in the three months ended December 31, 2008 that began vesting in the first three months of March 31, 2009.

Interest income for the three months ended March 31, 2009 was $11,190 as compared to $20,036 for the three months ended March 31, 2008, representing a decrease of $8,846 or 44%. This decrease is due to lower prevailing interest rates available on our cash balances in 2009 as compared to 2008. Interest expense for the three months ended March

31, 2009 was $318 as compared to $180 for the three months ended March 31, 2008, representing an increase of $138 or 76%. This increase was the result of higher balances that were short-term financed for insurance premiums due and therefore more interest was accrued and paid.

Financial Condition

Cash and Working Capital

As of March 31, 2009, we had cash of $6,513,368 as compared to $1,475,466 as of December 31, 2008. As of March 31, 2009, we had working capital of $5,612,598 as compared to working capital of $537,183 as of December 31, 2008, representing an increase of $5,075,415. The increase was the result of the sale of our common stock to our commercialization partner Sigma-Tau of $4.5 million and approximately $2.3 million from the sale of our common stock and warrants to accredited investors. We continue to use equity instruments to provide a portion of the compensation due to our employees, vendors and collaboration partners, and expect to continue to do so in the future.

For the three months ended March 31, 2009, our cash used in operating activities was approximately $1,606,600, compared to $954,000 for the corresponding period ended March 31, 2008.

Based on our current rate of cash outflows, cash in the bank, and potential proceeds from the Fusion Capital transaction, we believe that our cash will be sufficient to meet our anticipated needs for working capital and capital expenditures into the third quarter of 2010.

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Management's plan is as follows:

We are exploring out-licensing opportunities for orBec® and oral BDP in territories outside North America, and for LPMTM -Leuprolide and BioDefense programs in the U.S. and in Europe.

We entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. 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, a $1 million payment, will be made upon the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD, which is expected to occur in the second half of 2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay us 35% royalty (inclusive of drug supply) on net sales in the Territory, as well as pay for commercialization expense, 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 common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price was 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. As part of the transaction, we granted Sigma-Tau certain demand and piggy-back registration rights.

We have and will utilize NPAPs wherever possible in countries outside the U.S. to generate revenues from orBec®.

We intend to utilize our existing $8 million equity line of credit with Fusion Capital (approximately $7.8 million of which is still available to us through June 2010) if and when we deem market conditions to be appropriate.

We expect to receive new government grants intended to support existing and new research and development over the next twelve months. In addition to research and development funding, these grants would provide additional support for our overhead expenditures as well as defray certain costs intended to cover portions of our upcoming confirmatory Phase 3 trial of our lead product orBec® in acute GI GVHD. These grants would therefore have the effect of extending our cash resources. We routinely file for government grants which support our biotherapeutic and biodefense programs. There is no assurance these programs will continue to be available or that we will be successful in receiving grant awards.

We may obtain additional funds through the issuance of equity or equity-linked securities through private placements or rights offerings.

If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to pursue certain courses of action. We may not be able to obtain such financing on acceptable terms if at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations. We

are currently evaluating additional equity financing opportunities and may execute them when appropriate.

In the event that we exceed our anticipated 2009-2010 operating plan, management has developed contingency plans to reduce operating expenses. However, in any case, there can be no assurance that we will be able to maintain adequate liquidity to allow us to continue to operate the business or prevent the possible impairment of our assets.

Since December 31, 2008, we have sold a total of 45,960,240 shares of common stock and warrants to purchase 20,914,035 shares of common stock for gross proceeds of $6,889,200.

Expenditures

Under existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our expenditures for the next 12 months to be approximately $4,400,000, not inclusive of BioDefense programs, or programs covered under existing NIH or orphan grants. We anticipate grant revenues in the next 12 months to offset research and development expenses for the development of our ricin toxin vaccine and botulinum toxin vaccine in the amount of approximately $2,400,000 with $800,000 of that total amount contributing towards our overhead expenses.

The table below details our costs for by program for the three months ended March 31:

	2009	2008
Program - Research & Development Expenses		
orBec®	$ 1,309,732	$ 351,675
RiVax™	224,500	120,287
BT-VACC™	52,690	60,261
Oraprine™	1,500	3,000
LPMTM-Leuprolide	2,577	64,778
Research & Development Expense	$ 1,590,999	$ 600,001
Program - Reimbursed under Grants		
orBec®	$ 19,784	$ -
RiVax™	397,525	515,190
BT-VACC™	-	13,989
Reimbursed under Grant	$ 417,309	$ 529,179
TOTAL	$ 2,008,308	$ 1,129,180

Leases

The following summarizes our lease obligations at March 31, 2009, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligation	Year 2009	Year 2010	Year 2011
Non-cancelable obligation (1)(2)	$ 74,000	$ 95,000	$ 96,000
TOTALS	$ 74,000	$ 95,000	$ 96,000

(1) On April 1, 2009, we entered into a sub-lease agreement thru March 31, 2012 to occupy office space in Princeton, New Jersey. We are required to provide 4 months of rent as a security deposit, the rent for the first 18 months will be approximately $7,500 per month, or $17.00 per square foot. This increases to approximately $7,650 per month

of rent, or $17.50 per square foot for the remaining 18 months.

(2) On April 24, 2008, we signed a three year lease for a copier.

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ITEM 3 -_QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

ITEM 4 -_CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report (the "Evaluation Date"). Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective.

Changes in Internal Controls

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal controls that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, such controls.

PART II - OTHER INFORMATION.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On March 6, 2009, we issued 2,500,000 shares of common stock pursuant to the common stock equity investment agreement with our clinical trials management partner, Numoda. These shares were priced at the then current market price of $0.12 per share. The Company's private sale of common stock to Numoda was made in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended (the "Act"), and Rule 506 promulgated thereunder. The Company's reliance on the exemption was based, in part, on Numoda's representation that it is an "accredited investor" as defined in Rule 501(a) under the Act.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. In connection with the execution of the collaboration and supply agreement, we also entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 25 million shares of common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price was 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. The Company's private sale of securities to Sigma-Tau was made in reliance upon an exemption from registration pursuant to Section 4(2) of the Act and Rule 506 promulgated thereunder. The Company's reliance of the exemption was based, in part, on Sigma-Tau's representations that it is an "accredited investor" as defined in Rule 501(a) under the Act.

ITEM 5 - EXHIBITS

31.1 Certification of Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).

31.2 Certification of Principal Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).

32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DOR BIOPHARMA, INC.

May 14, 2009	by /s/ Christopher J. Schaber Christopher J. Schaber, Ph.D. President and Chief Executive Officer (Principal Executive Officer)
May 14, 2009	by /s/ Evan Myrianthopoulos Evan Myrianthopoulos Chief Financial Officer (Principal Financial and Accounting Officer)

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