DOR BIOPHARMA INC
Form 10-Q
August 14, 2008

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 June 30, 2008

( ) 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)
850 Bear Tavern Road, Suite 201 Ewing, NJ (Address of principal executive offices)	08628 (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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer" and "accelerated filer" and "smaller reporting company" in Rule 12b-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 August 4, 2008, 101,805,497 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

	June 30, 2008	December 31, 2007
	(Unaudited)	
Assets		
Current assets:		
Cash	$ 1,077,570	$ 2,220,128
Grants receivable	99,929	97,845
Prepaid expenses	175,805	119,178
Total current assets	1,353,304	2,437,151
Office and laboratory equipment, net	24,214	25,941
Intangible assets, net	1,387,507	1,320,787
Total assets	$ 2,765,025	$ 3,783,879
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,306,904	$ 847,610
Accrued compensation	224,754	345,903
Total current liabilities	1,531,658	1,193,513
Shareholders' equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 101,256,776 and 94,996,547, respectively issued and outstanding	101,256	94,996
Additional paid-in capital	102,655,708	101,391,090
Accumulated deficit	(101,523,597)	(98,895,720)
Total shareholders' equity	1,233,367	2,590,366
Total liabilities and shareholders' equity	$ 2,765,025	3,783,879

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 June 30,
(Unaudited)

	2008	2007
Revenues	$ 488,244	$ 279,481
Cost of revenues	(391,845)	(107,418)
Gross profit	96,399	172,063
Operating expenses:		
Research and development	743,601	1,031,015
General and administrative	554,526	654,481
Stock based compensation research and development	39,583	31,195
Stock based compensation general and administrative	36,793	82,126
Total operating expenses	1,374,503	1,798,817
Loss from operations	(1,278,104)	(1,626,754)
Other income (expense):		
Interest income	6,821	71,694
Interest (expense)	(423)	(607)
Total other income (expense)	6,398	71,087
Net loss	$(1,271,706)	$(1,555,667)
BasicBBasic and diluted net loss per share	$ (0.01)	$ (0.02)
Basic Basic and diluted weighted average common shares outstanding	100,877,708	92,585,933

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

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DOR BioPharma, Inc.
Consolidated Statements of Operations
For the six months ended June 30,
(Unaudited)

	2008	2007
Revenues	$ 1,165,884	$ 514,652
Cost of revenues	(921,024)	(185,489)
Gross profit	244,860	329,163
Operating expenses:		
Research and development	1,343,603	2,073,773
General and administrative	1,402,637	1,862,938
Stock based compensation research and development	79,166	87,529
Stock based compensation general and administrative	73,586	157,710
Total operating expenses	2,898,992	4,181,950
Loss from operations	(2,654,132)	(3,852,787)
Other income (expense):		
Interest income	26,857	133,941
Interest (expense)	(603)	(1,020)
Total other income (expense)	26,254	132,921
Net loss	$(2,627,878)	$(3,719,866)
Basic and diluted net loss per share	$ (0.03)	$ (0.04)
Basic and diluted weighted average common shares outstanding	99,328,191	88,071,875

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 six months ended June 30,
(Unaudited)

	2008	2007
Operating activities		
Net loss	$ (2,627,878)	$ (3,719,866)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	70,049	54,423
Non-cash stock compensation	537,278	893,216
Change in operating assets and liabilities:		
Grants receivable	(2,084)	5,022
Prepaid expenses	(56,627)	(100,125)
Accounts payable	458,795	(1,010,854)
Proceeds sale of equipment	500	-
Accrued compensation	(121,149)	(279,306)
Total adjustments	886,762	(437,624)
Net cash used by operating activities	(1,741,116)	(4,157,490)
Investing activities:		
Acquisition of intangible assets	(131,142)	(171,948)
Purchase of office equipment	(3,900)	(2,405)
Net cash used by investing activities	(135,042)	(174,353)
Financing activities:		
Proceeds from sale of common stock	658,600	6,235,404
Proceeds from equity line	75,000	-
Proceeds from exercise of warrants	-	1,530,763
Proceeds from exercise of stock options	-	117,000
Net cash provided by financing activities	733,600	7,883,167
Net increase (decrease) in cash and cash equivalents	(1,142,558)	3,551,324
Cash and cash equivalents at beginning of period	2,220,128	119,636
Cash and cash equivalents at end of period	$ 1,077,570	$ 3,670,960
Supplemental disclosure of cash flow:		
Cash paid for interest	$ 180	$ 413
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

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 BDP, and other biotherapeutic products namely LPMTM-Leuprolide, OraprineTM, and LPETM and PLPTM Systems for Delivery of Water-Insoluble Drugs. 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 six months ended June 30, 2008, the Company had one customer, the U.S. Federal Government. All revenues were generated from two active U.S. Federal Government Grants. As of June 30, 2008 all outstanding receivables were from the U.S. Federal Government, National Institute of Health and The U.S. Food and Drug Administration.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma, Inc., and its wholly owned subsidiaries ("DOR" or the "Company"). All significant intercompany accounts and transactions have been eliminated in 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 U.S. Federal Government and the National Institute of Health. The amounts were billed in the month subsequent to period end. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful accounts has been established. If accounts become uncollectible, they are charged to operations when that determination is made.

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". Based on this consideration, all outside legal and filing costs incurred in the procurement and defense of patents are capitalized.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. 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.

The Company capitalizes and amortizes intangibles over a period of 11 to 16 years. 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. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, DOR capitalizes these costs and amortizes them over the remaining useful life of the patents. DOR capitalizes intangible assets based on alternative future use.

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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 or six months ended June 30, 2008 and 2007, respectively.

Fair Value of Financial Instruments

Accounting principles generally accepted in the United States of America 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

All of the Company's revenues are from government grants which are based upon subcontractor costs and internal costs covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when DOR incurs internal expenses that are related to the grant.

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 (IPR&D) 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.

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Stock Based Compensation

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, "Share-Based Payment," effective January 1, 2006, which requires companies to record compensation expense for stock options issued to employees or non-employee directors at an amount determined by the fair value of options. SFAS No. 123R is effective for annual periods beginning after December 15, 2005.

The Company adopted SFAS No. 123R using the "modified prospective application" and therefore, financial statements from periods ending prior to January 1, 2006 have not been restated. The Company's net loss for the three months ended June 30, 2008 and 2007 pertaining to share-based compensation was $76,376 and $113,321 respectively; higher than if it had continued to account for share-based compensation under APB No. 25. For the six months ended June 30, 2008 and 2007, the net loss was higher by $152,753 and $245,239 respectively. For the three months ended June 30, 2008, $39,583 of the $76,376 was for Research and Development personnel and $36,793 was for General and Administrative personnel. For the same period in 2007, $31,195 of the $113,321was for Research and Development personnel and $82,126 was for General and Administrative personnel. For the six months ended June 30, 2008 and 2007, $79,167 of the $152,753 was for Research and Development personnel and the other $73,586 was for General and Administrative personnel. For the same period in 2007, $87,529 of the $245,239 was for Research and Development personnel and the other $157,710 was for General and Administrative personnel. 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. At June 30, 2008, the total compensation cost for stock options not yet recognized was approximately $450,000.

The fair value of each option grant at the three and six months ended June 30, 2008 and June 30, 2007 were estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. The Company did not award any stock options for the three and six months ended June 30, 2008 while 150,000 and 450,000 stock options were granted during the three and six months ended June 30, 2007. The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.23 and $0.27 for the three and six months ended June 30, 2007, respectively.

The fair value of options in accordance with SFAS 123 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 120% and 90% in 2008 and 2007, respectively, and average risk-free interest rates of 3.7% and 4.45% in 2008 and 2007, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 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.

As stock options are exercised, common stock share certificates are issued via electronic transfer or physical share certificates by the Company's transfer agent. Shares are issued from the 2005 stock option plan and increase the number of shares the Company has outstanding.

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Shares repurchased

The Company from time to time evaluates whether to repurchase existing common stock shares in the marketplace. This repurchased stock would be reflected as Treasury Stock. At this time we have no plans to repurchase the Company stock.

Income Taxes

The Company files a consolidated federal income tax return and utilizing asset and liability method of accounting for income taxes. Under this method, 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 June 30, 2008 because of the net operating losses incurred by the Company since its inception.

Net Loss Per Share

In accordance with accounting principles generally accepted in the United States of America, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the respective periods (excluding shares that are not yet issued). The effect of stock options and warrants are antidilutive for all periods presented.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

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3. Going Concern and Management's Plan

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. At June 30, 2008, the Company had a working capital deficit of $178,354 and a net loss of $2,627,878 for the six months ended June 30, 2008. The Company also expects to sustain substantial losses over the next twelve months. Since its inception in 1987, the Company has incurred significant and recurring operating losses and negative cash flow from operations which raises substantial doubt about its ability to continue as a going concern. The Company's ability to continue its operations are dependent upon its ability to raise sufficient capital.

Management's plan is as follows:

- The Company is and will continue to seek capital in the private and/or public equity markets to continue its operations.
    - The Company will also seek capital through licensing of orBec.
- The Company has implemented an austerity budget plan including suspension of its programs not supported by grant funding, reduction of office personnel, reduction in overhead expenses, and payment in stock in lieu of salary to two employees.
- The Company is continuing to seek grant funds and to respond to requests for proposals from governmental sources.
- The Company will utilize Names Patient Sales wherever possible in countries outside the United States to generate revenues from orBec.
- The Company is exploring outlicensing opportunities for LPM-Leuprolide and BioDefense programs in the United States and in Europe.
    - The Company has engaged investment bankers to assist in exploring merger and acquisition opportunities.

There is no assurance that the Company will be able to successfully implement its plan or will be able to generate positive cash flows from either operations, partnerships, or from equity financings.

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4. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
June 30, 2008				
Licenses	12.2	$ 462,234	$ 129,263	$ 332,971
Patents	9.4	1,764,632	710,096	1,054,536
Total	10.0	$ 2,226,866	$ 839,359	$ 1,387,507
December 31, 2007				
Licenses	12.7	$ 462,234	$ 115,681	$ 346,553
Patents	9.7	1,633,490	659,256	974,234
Total	10.4	$ 2,095,724	$ 774,937	$ 1,320,787

Amortization expense was $33,243 and $27,000 for the three months ended June 30, 2008 and 2007, respectively. Amortization expense was $64,422 and $48,300 for six months ended June 30, 2008 and 2007, respectively.

Based on the balance of licenses and patents at June 30, 2008, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Amount
2008	$ 130,000
2009	138,000
2010	140,000
2011	142,000
2012	145,000

License fees and royalty payments are expensed annually.

5. Grants Receivable

In the second quarter of 2008, the Company recorded grant revenues from its three U.S. Government Grants in the amount of $488,244. For the six months ended June 30, 2008 recorded grant revenues were $1,165,884. Outstanding receivables at quarter end were $99,929. This receivable has since been collected.

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6. Shareholders' Equity

During the three months ended June 30, 2008, the Company issued 415,002 shares of common stock as payment to vendors for consulting services. An expense of $73,000 was recorded which approximated the shares' fair market value on the date of issuance, respectively. The Company also issued 542,396 shares of common stock under its existing Fusion Capital Equity facility. The Company received $75,000 in proceeds and recorded $1,589 expense for the pro-rated commitment share expense which approximated the shares' fair market value on the date of issuance. During the six months ended June 30, 2008, the Company issued 518,027 and 115,917 shares of common stock as payment to vendors for consulting services and as severance for employees, respectively. An expense of $92,313 and $20,625 was recorded which approximated the shares' fair market value on the date of issuance, respectively. During the six month period ended June 30, 2007, the Company issued 815,357 shares of common stock as payment to vendors for consulting services. An expense of $327,000 was recorded which approximated the shares' fair market value on the date of issuance. These shares of common stock were included in the Company's Form SB-2 Registration Statement filed with the SEC on March 9, 2007. Also during the six months ended June 30, 2007, 6,208,287 warrants were exercised to purchase shares of common stock which provided proceeds of $1,530,763, 260,000 stock options were exercised to purchase shares of common stock which provided proceeds of $117,000, and 23,866 common stock shares were issued to employees as payment for payroll in lieu of cash in the amount of $7,500.

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 $20,000 and $1.0 million every two business days, depending on certain conditions, of the Company's common stock up to an aggregate of $8.0 million over approximately a 25-month period. 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 purchased 2,777,778 common shares and 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. At this time the Company is unable to draw on Fusion because the Company's stock price is near or below $0.10 per share.

On February 14, 2008, the Company completed the sale of 881,111 shares of its common stock to institutional and other accredited investors for an aggregate purchase price of approximately $158,600. The investors received four year warrants to purchase an aggregate of 440,556 shares of our common stock at an exercise price of $0.22 per share.

On February 9, 2007, the Company completed the sale of 11,680,850 shares of DOR's common stock to institutional investors and certain of the Company's officers and directors for a purchase price of $5,490,000.

On January 3, 2007, in consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,000,000 of the Company's common stock at the market price of $0.246 per share, representing 4,065,041 shares of common stock, and contributed an additional $2 million in cash. The $2 million contribution was to be considered an advance payment to be deducted from future payments due to the Company by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this transaction's dilutive nature, all investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders in that placement who still held shares of the Company's common stock were issued additional shares as a cost basis adjustment from $0.277 to $0.246 per share of the Company's common stock. Neither these investors, nor any others for that matter, hold any further anti-dilution rights. Because no agreement was reached by March 1, 2007, DOR was obligated to return the $2 million to Sigma-Tau by April 30, 2007. On June 1, 2007, the Company returned

the $2 million to Sigma Tau.

7. Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, litigation, product liability, development of new technological innovations, dependence on key personnel, protections of proprietary technology, and compliance with FDA regulations.

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8. Business Segments

The Company had two active segments for the three and six months ended June 30, 2008 and 2007, respectively: BioDefense and BioTherapeutics. Summary data:

FOR THE THREE MONTHS ENDED

	June 30,	
	2008	2007
Net Revenues		
BioDefense	$ 488,244	$ 279,481
Total	$ 488,244	$ 279,481
Loss from Operations		
BioDefense	$ (70,268)	$ 72,716
BioTherapeutics	(645,378)	(878,684)
Corporate	(562,459)	(820,785)
Total	$ (1,278,105)	$ (1,626,753)
Identifiable Assets		
BioDefense	$ 1,221,901	$ 1,363,124
BioTherapeutics	310,535	362,397
Corporate	1,232,589	2,178,384
Total	$ 2,765,025	$ 3,903,905
Amortization and Depreciation Expense		
BioDefense	$ 15,381	$ 37,069
BioTherapeutics	19,224	10,069
Corporate	1,361	2,138
Total	$ 35,966	$ 49,276
Interest Income		
Corporate	$ 6,398	$ 71,694
Total	$ 6,398	$ 71,694
Stock Option Compensation		
BioDefense	$ 19,517	$ 14,680
BioTherapeutic	20,066	16,515
Corporate	36,793	82,126
Total	$ 76,376	$ 113,321

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FOR THE SIX MONTHS ENDED

	June 30,	
	2008	2007
Net Revenues		
BioDefense	$ 677,640	$ 514,652
Total	$ 677,640	$ 514,652
Loss from Operations		
BioDefense	$ (104,383)	$ 106,394
BioTherapeutics	(1,077,623)	(1,576,691)
Corporate	(1,472,126)	(2,382,490)
Total	$ (2,564,132)	$ (3,852,787)
Amortization and Depreciation Expense		
BioDefense	$ 29,598	$ 39,931
BioTherapeutics	37,637	8,131
Corporate	2,814	3,062
Total	$ 70,049	$ 51,124
Interest Income		
Corporate	$ 26,254	$ 133,941
Total	$ 26,254	$ 133,941
Stock Option Compensation		
BioDefense	$ 39,034	$ 29,361
BioTherapeutic	40,132	58,168
Corporate	73,586	157,710
Total	$ 152,752	$ 245,239

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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-KSB for the year ended December 31, 2007. 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 the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines.

We maintain two active business segments: BioTherapeutics and BioDefense. Our business strategy is to: (a) work with the FDA on the design of a new confirmatory Phase 3 clinical trial in GI GVHD; (b) seek a development and marketing partner for orBec® for territories both inside and outside of the U.S.; (c) conduct a prophylactic use clinical trial of orBec® for the prevention of GI 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 tract such as radiation enteritis and Crohn's disease; (e) reinitiate development including manufacturing of LPMTM-Leuprolide; (f) secure additional government funding for each of our biodefense programs, RiVaxTM, BT-VACCTM, and our new anthrax vaccine, through grants, contracts, and procurements; (g) explore acquisition strategies under which the Company may be acquired by another company with oncologic or gastrointestinal symmetry; (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; and (i) acquire or in-license new clinical-stage compounds for development.

On September 21, 2006, we filed a new drug application ("NDA") for our lead product orBec® (oral beclomethasone dipropionate) with the FDA for the treatment of GI GVHD. On November 3, 2006, we also filed a Marketing Authorization Application ("MAA") for orBec® with the European Central Authority, European Medicines Evaluation Agency (the "EMEA") which was subsequently withdrawn in May 2008. We reached this decision after consultation with the EMEA and determining that confirmatory evidence of clinical efficacy will be required for approval this is consistent with the request made by the FDA. The withdrawal of an MAA application does not prejudice the possibility of making a new application at a later stage.

On October 18, 2007, we received a not approvable letter from the U.S. Food and Drug Administration (the "FDA") in response to our NDA for orBec® (oral beclomethasone dipropionate) for the treatment of 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. On October 19, 2007, we requested an end of review conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting: (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's special protocol assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in the second half of 2008. Completion of this clinical trial will require further funding from financings or partnerships.

During 2008, we entered into several collaborative agreements for Named Patient Access Programs ("NPAP"). These programs have the potential to generate significant revenues. We were successful in entering into NPAP agreements in Europe, South Korea, Singapore and Malaysia. These territories were added to our Named Patient programs already established during 2007 in Australia, New Zealand, and South Africa.

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BioTherapeutics Overview

Through our BioTherapeutics Division, we are developing oral therapeutic products to treat unmet medical needs. Our lead product, orBec®, has been evaluated in a randomized, multi-center, double-blind, placebo-controlled pivotal Phase 3 clinical trial for the treatment of GI GVHD, a serious and life-threatening gastrointestinal inflammation associated with allogeneic hematopoietic cell transplantation ("HCT"). While orBec® did not achieve statistical significance in time to treatment failure through Day 50 (p-value 0.1177), the primary endpoint of its pivotal Phase 3 trial, there was a positive trend observed and it did achieve statistical significance in other key outcomes such as median time to treatment failure through Day 80 (p-value 0.0226). Most importantly, it demonstrated a statistically significant survival advantage in comparison to placebo at 200 days post-transplantation (p-value 0.0139) and at one year post-randomization (p-value 0.04).

We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006. We also filed an MAA with the EMEA on November 3, 2006, which was validated on November 28, 2006 and subsequently withdrawn in May 2008. On October 18, 2007, we received a not approvable letter from the FDA for orBec®. 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 & controls information as part of the not approvable letter. On October 19, 2007, we requested an end of review conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting; (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's special protocol assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in the second half of 2008. Completion of this clinical trial will require further funding from financings or partnerships.

On June 30, 2008, we announced that we had entered into a collaboration 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 comprehensive scope of services including using their robust industry benchmarking capabilities to develop an accurate operational and financial plan including the use of an extensive and proprietary management and oversight capabilities process. Most importantly, Numoda's highly accelerated and efficient data lock at the end of the clinical trial expedites completion of the study while also increasing quality. 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 will also take an equity position in DOR common stock in exchange for a portion of its services in connection with the conduct of the upcoming confirmatory Phase 3 clinical trial. Working with Numoda, we will be also able to take full advantage of early reporting of results to potential licensing partners and others. In order to completely execute the collaboration we will require further funding from financings or partnerships.

On July 18, 2008, we announced that we entered into collaboration with Steward Cross Pte Ltd ("Steward Cross"), a specialty pharmaceutical company based in Singapore, under which Steward Cross will act as DOR's Sponsor with regard to the administration of a NPAP for patients suffering from acute GI GVHD in Singapore and Malaysia. We will manufacture and supply orBec® to Steward Cross, while Steward Cross will be responsible for all distribution costs in Singapore and Malaysia.

On July 15, 2008, we announced that we entered into a definitive collaborative agreement with IDIS Limited, for the supply and distribution within the European Union of orBec® via a NPAP GI GVHD. IDIS is the leading specialist in the management of NPPs in Europe. We are allowed to supply orBec® for a fee to clinicians seeking to obtain investigational therapies.

On February 15, 2008, we announced that we entered into a Letter of Intent with BL&H Co. Ltd. ("BL&H"), a specialty pharmaceutical company based in Seoul, Korea, pursuant to which BL&H will act as our Sponsor with regard to the administration of a NPAP for orBec® to patients suffering from acute GI GVHD in South Korea.

On November 28, 2007, we announced that we entered into a Letter of Intent with Orphan Australia Pty Ltd. ("Orphan Australia"), a specialty pharmaceutical company based in Melbourne, Australia, pursuant to which Orphan Australia will act as our sponsor with regard to the administration of an NPAP for orBec® to GI GVHD patients in Australia, New Zealand and South Africa.

On September 12, 2007, we announced that our academic partner, the Fred Hutchinson Cancer Research Center ("FHCRC"), received a $1 million grant from the National Institute of Health ("NIH") to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of gastrointestinal (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 GI 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. 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.

In April 2007, we initiated our next pipeline development program in the biotherapeutics area: our LPM™ (Lipid Polymer Micelle) drug delivery system to enhance the intestinal absorption of water-soluble drugs/peptides which are ordinarily poorly absorbed. We recommenced preclinical formulation work on LPM™ in 2007 after a period of approximately four years. This system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides that are not readily absorbed in the GI tract. Preclinical animal pharmacokinetic ("PK") data have demonstrated high relative bioavailability of the therapeutic peptide drug leuprolide in the 20-40% range. Leuprolide is both a candidate drug for further development in several indications, such as prostate cancer and endometriosis as well as a prototype for development of other similar non-absorbable, but water soluble drugs. The mechanism for absorption by LPM™ is thought to involve passive uptake through the opening of paracellular channels in intestinal epithelial tissue. This program is

currently suspended pending further funding from financing or partnerships.

BioDefense Overview

In collaboration with the University of Texas Southwest Medical Center, Thomas Jefferson University, and the President and Fellows of Harvard College, we are developing vaccines to combat the threat posed by the potent biological toxins; ricin toxin, botulinum toxin and anthrax. Our ricin toxin and botulinum toxin vaccines under development are recombinant products in bacterial hosts and both consist of nontoxic subunits of the native toxins. These subunits induce antibodies that neutralize the toxins from which they are derived. Through exclusive licenses with the universities, we have secured important intellectual property rights related to these vaccines. All of these are considered bioterrorism threats by the U.S. Department of Homeland Security, the National Institute of Allergy and Infectious Diseases ("NIAID"), Department of Defense ("DOD") and Centers for Disease Control and Prevention ("CDC"). In fact, the threat of ricin toxin as a biological weapon of mass destruction has been highlighted along with anthrax in a recent Federal Bureau of Investigation ("FBI") Bioterror report released in November 2007, which says, "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations." We are developing our biodefense countermeasures for potential U.S. government procurement pursuant to the Project BioShield Act of 2004, which provides incentives to industry to supply biodefense countermeasures to the Strategic National Stockpile. To our knowledge, we are now the only company in the world developing vaccines against the top two Bioterror threats, as recently identified by the FBI.

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RiVax™

Ricin toxin is a heat stable toxin that is easily isolated and purified from the bean of the castor plant. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The 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.

The development of RiVaxTM, our ricin toxin vaccine, 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. The 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.

On January 29, 2008, we announced that we have 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. RiVax™ is intended to protect against exposure to ricin toxin that might result from the purposeful release of ricin in an aerosolized form or as a poisonous contaminant in food or water. 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.

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 the University of Texas Southwestern Medical Center 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 the University of Texas Southwestern. 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. We have recently initiated a non-human primate study and have begun a human clinical trial with RiVaxTM in August of 2008.

During January 2008, we submitted an application for RiVax™ pursuant to an Request for Procurement (“RFP”), entitled "Biodefense Vaccine Enhancement from Biomedical Advanced Research and Development Authority (“BARDA”) for vaccines to be included in the Strategic National Stockpile. BARDA is a new agency within the U.S. Department of Health and Human Services (“HHS”) established to implement acquisition under the Project BioShield Act and to foster

the development of vaccines and countermeasures such as RiVax™ that have achieved milestone hurdles, and are candidates for continued development. We recently received notification that we will not be awarded any funds pursuant to this particular grant. We regularly apply for biodefense grants, as well as RFPs, when appropriate, from NIH and other applicable governmental bodies that support biodefense.

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.

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BT-VACC™

Our botulinum toxin vaccine, called BT-VACC™, stems 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 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 route provides a self administration option, which will bypass the requirement for needles and personnel to administer the vaccine.

In July 2007, we announced that the first results from testing of a multivalent form of BT-VACCTM have been published in the journal Infection and Immunity (Ravichandran et al., 2007, Infection and Immunity, v. 75, p. 3043). These results are the first that 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. Further, the combination vaccine can induce protection when given mucosally as a booster to animals that have been given a primary vaccine injection.

ADDITIONAL PROGRAMS

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 the proper 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 unless we receive grant funding.

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orBec®

Our lead therapeutic product, orBec®, is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006, and in accordance with the Prescription Drug User Fee Act ("PDUFA"), the FDA was to complete its review of all materials related to orBec® by July 21, 2007. Additionally, on May 9, 2007, the Oncologic Drugs Advisory Committee ("ODAC") appointed by the FDA voted that the data supporting orBec® did not show substantial evidence of efficacy by a margin of 7 to 2 for the treatment of GI GVHD. The FDA was not bound by ODAC's recommendations, but it took the panel's advice into consideration when reviewing the NDA for orBec®.

On July 18, 2007, we received notification from the FDA that the PDUFA date for the FDA's review of the NDA for orBec® was extended to October 21, 2007. The extension was the result of our July 13, 2007 provision of supplemental information to the orBec® NDA. This information was requested by the FDA at a June 13, 2007 NDA review meeting. According to FDA policy, the submission of this supplemental information was classified as a major amendment, extending the new PDUFA date for the orBec® NDA to October 21, 2007.

On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec®. 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. On October 19, 2007, we requested an end of review conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting: (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well-designed, well-executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's special protocol assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in the second half of 2008. Completion of this clinical trial will require further funding from financings or partnerships.

We also filed an MAA with the EMEA on November 3, 2006, which was validated on November 28, 2006 and voluntarily withdrawn in May 2008. We reached this decision after consultation with the EMEA and determining that confirmatory evidence of clinical efficacy will be required for approval this is consistent with the request made by the FDA. The withdrawal of an MAA application does not prejudice the possibility of making a new application at a later stage.

We anticipate the market potential for orBec® for the treatment of GI GVHD to be approximately 60 percent of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We are evaluating partnering opportunities in the U.S. and abroad in an effort to seek support for future clinical development of orBec® for the treatment of GI GVHD. We also intend to seek a partner for the other potential indications of orBec® and oral BDP.

On July 12, 2007, we announced that patient enrollment had 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 Phase 2 clinical trial is supported in part by an NIH grant awarded to the FHCRC. We will not receive any monetary benefit from this grant. The protocol is entitled "A Phase 2 study to evaluate the efficacy of oral beclomethasone dipropionate for prevention of acute GVHD after hematopoietic cell

transplantation with myeloablative conditioning regimens." The study will enroll a total of 138 patients with 92 subjects in the orBec® arm and 46 subjects in the placebo arm. The principal investigator of the trial is Paul Martin, M.D., of the FHCRC and a Professor of Medicine at Washington University. Patients will be treated with orBec® or placebo at the start of their conditioning regimen and will continue to be treated for 75 days after transplantation. The objective of the trial is to test the hypotheses that prophylactic administration of orBec® can prevent the incidence and/or reduce the severity of acute GVHD, therefore, decreasing the need for use of high dose systemic steroid treatment after allogeneic HCT. Completion of patient enrollment in this trial is targeted for the second half of 2009.

On September 12, 2007, we announced that our academic partner, FHCRC, received a $1 million grant from the NIH to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of gastrointestinal (GI) radiation injury. While we will not receive any monetary benefit from this grant, we will benefit if this study is successful as it would 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 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 infections that are often the primary cause of death in acute radiation injury. This type of therapy, if successful, will benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism.

In addition to the preclinical studies in radiation exposure being conducted at FHCRC, we plan to begin a Phase 1/2 clinical trial in radiation enteritis patients in the second half of 2008.

We also plan to initiate a Phase 2 clinical trial in chronic GVHD in the first half of 2009. Chronic GVHD can begin anytime during or after the third month post-transplantation. About 60 percent of patients who receive an allogeneic transplant and are alive at day 100 post-transplantation will develop chronic GVHD. Chronic GVHD can range from mild to life-threatening. Some transplantation survivors suffer from chronic GVHD for many years.

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LPMTM - Leuprolide

In April 2007, we announced the initiation of a development program with our Lipid Polymer Micelle ("LPM™") oral drug delivery technology. The LPM™ system is a 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. This program is currently suspended pending further funding from financing or partnerships.

In preclinical studies, our 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 (GnRh), 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 2008 to confirm these findings.

The LPM™ system is a proprietary oral delivery platform technology that 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.

We expect to validate the LPM platform technology using leuprolide as the target peptide. We intend to perform a Phase 1 PK study with a version of LPM that prolongs the absorption of leuprolide and results in high relative bioavailability. An oral version of leuprolide may also 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 United States 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. This program is suspended pending further funding from financing or partnerships.

LPETM and PLPTM Systems for Delivery of Water-Insoluble Drugs

We may develop two lipid-based systems, LPETM and PLPTM, to support the oral delivery of small molecules of water insoluble drugs. Such drugs include most kinds of cancer chemotherapeutics currently delivered intravenously. The LPETM system is in the form of an emulsion or an emulsion pre-concentrate incorporating lipids, polymers and co-solvents. We have filed for patent applications on the use of perillyl alcohol as a solvent, surfactant and absorption enhancer for lipophilic compounds. The polymers used in these formulations can either be commercially available or proprietary polymerized lipids and lipid analogs. 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 United States. 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. 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 payments made to legal firms that are engaged in filing and protecting our rights to our intellectual property and rights for our current products in both the domestic and international markets.

We capitalize intangible assets that have alternative future uses. 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.

We capitalize legal costs associated with the protection and maintenance of our patents. As a development stage company with drug and vaccine products in an often lengthy basic and 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 capitalized $131,142 in patent related costs during the six months ended June 30, 2008. This amount is represented in the cash flow statements, in the section for investing activities presented in the financial statements. On the balance sheet as of June 30, 2008 and December 31, 2007, these amounts are presented on the line intangible assets, net in the amount of $1,387,507 and $1,320,787, respectively.

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 ("IPR&D") 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

All of our revenues are from government grants which are based upon subcontractor costs and internal costs covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant.

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Material Changes in Results of Operations

We are a research and development company. The first and second quarter 2008 revenues and associated expenses were from NIH Grants awarded in September 2004 and September 2006. The NIH grants are associated with our ricin and botulinum vaccines.

For the three months ended June 30, 2008, we had a net loss of $1,271,707 as compared to a net loss of $1,555,668 for the three months ended June 30, 2007, for a decrease of $283,961 or 18%. For the six months ended June 30, 2008, we had a $2,627,878 net loss as compared to $3,719,866 in the six months ended June 30, 2007, for a decrease of $1,091,988 or 29%. This decrease is primarily attributed to lower research and development costs, lower public and investor relation expenses, a reduction in employee, travel and consultant expenses, and the dilution expense taken for stock issued to investors from the April 2006 PIPE in the amount of $308,743 in 2007.

For the three months ended June 30, 2008, we had grant revenues of $488,244 as compared to $279,481 in the three months ended June 30, 2007, for an increase of $208,763 or 75%. For the six months ended June 30, 2008, we had grant revenues of $1,165,884 as compared to $514,652 in the six months ended June 30, 2007, for an increase of $651,232 or 127%. During the first and second quarter of 2008 we achieved certain milestones with our subcontractors and made drawdowns from our NIH grants. We also incurred expenses related to that revenue in the three months ended June 30, 2008 and 2007 of $391,845 and $107,418, respectively, for an increase of $284,427 or 265%. For the six months ended June 30, 2008 and 2007, we incurred expenses to that revenue of $921,024 and $185,489, respectively. This difference consisted of a reclassification error for $182,600 in expenses recorded to research and development costs instead of cost of revenues. Costs of revenues relate to payments made to subcontractors and universities in connection with the grants.

The gross profit for the three months ended June 30, 2008 was $96,399 as compared to $172,063 in the three months ended June 30, 2007, for a decrease of $75,664 or 44%. For the six months ended June 30, 2008, we had a gross profit of $244,860 as compared to $329,163 in the six months ended June 30, 2007, for a decrease of $84,303 or 26%. Again this difference relates to the reclassification error.

Research and development spending decreased by $287,414, or 28%, to $743,601, for the three months ended June 30, 2008 as compared to $1,031,015 for the corresponding period ended June 30, 2007. For the six months ended June 30, 2008 we had $1,343,603 of research and development spending as compared to $2,073,773 in the six months ended June 30, 2007, for a decrease of $730,170 or 35%. During the first and second quarter of 2008, we incurred expenses for FDA and European regulatory matters, for clinical preparation for orBec® and LPM formulation work. The majority of research and development expenses in 2007 were related to preparation of FDA and European regulatory matters.

General and administrative expenses decreased $99,955, or 15%, to $554,526 for the three months ended June 30, 2008, as compared to $654,481 for the corresponding period ended June 30, 2007. For the six months ended June 30, 2008 we had $1,402,637 of general and administrative expenses as compared to $1,862,938 in the six months ended June 30, 2007, for a decrease of $460,301 or 25%. The decrease was primarily due to the dilution expense taken in the first quarter of 2007 for stock issued to investors in the April 2006 PIPE in the amount of $308,743. Additionally, the decrease was due to a reduction in employee and consultant expenses, travel expenses and expenses for public and investor relations of approximately $230,000. During the first quarter of 2008, commitment shares were issued and an expense of $270,000 was recorded as a result of the Fusion Capital equity transaction.

Stock based compensation expenses for research and development increased $8,388, or 27%, to $39,583 for the three months ended June 30, 2008, as compared to $31,195 for the corresponding period ended June 30, 2007. For the six months ended June 30, 2008 we had $79,166 in stock based compensation expenses for research and development as

compared to $87,529 in the six months ended June 30, 2007, for a decrease of $8,363 or 10%.

Stock based compensation expenses for general and administrative decreased $45,333, or 55%, to $36,793 for the three months ended June 30, 2008, as compared to $82,126 for the corresponding period ended June 30, 2007. For the six months ended June 30, 2008 we had $73,586 in stock based compensation expenses for research and development as compared to $157,710 in the six months ended June 30, 2007, for a decrease of $84,124 or 53%.

Interest income for the three months ended June 30, 2008 was $6,821 as compared to $71,694 for the three months ended June 30, 2007, representing a decrease of $64,874 or 90%. For the six months ended June 30, 2008 we had $26,857 of interest income as compared to $133,941 in the six months ended June 30, 2007, for a decrease of $107,084 or 80%. This decrease is due to a lower cash balance in 2008 as compared to 2007.

Interest expense for the three months ended June 30, 2008 was $423 as compared to $607 for the three months ended June 30, 2007, for a decrease of $184 or 30%. For the six months ended June 30, 2008 we had $603 of interest expense as compared to $1,020 in the six months ended June 30, 2007, for a decrease of $417 or 41%. This decrease was the result of lower balances that were short-term financed for insurance premiums due and therefore less interest was accrued and paid.

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Financial Condition

Cash and Working Capital

The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. As of June 30, 2008, we had cash of $1,077,570 as compared to $2,220,128 as of December 31, 2007. As of August 4, 2008, we had cash of approximately $950,000. As of June 30, 2008, we had working capital deficit of $178,354 as compared to working capital of $1,243,638 as of December 31, 2007, representing a decrease of $1,421,992. For the six months ended June 30, 2008, our cash used in operating activities was approximately $1,700,000, compared to $4,200,000 for the corresponding period ended June 30, 2007. Our ability to continue operations is dependent upon our ability to raise sufficient capital.

Management's plan is as follows:

- We will continue to seek capital in the private and/or public equity markets to continue our operations.
- We will also seek capital through licensing of orBec.
- We have implemented an austerity budget plan including suspension of our programs not supported by grant funding, reduction of office personnel, reduction in overhead expenses, and payment in stock in lieu of salary to two employees.
- We will continue to seek grant funds and to respond to requests for proposals from governmental sources.
- We will utilize Names Patient Sales wherever possible in countries outside the United States to generate revenues from orBec.
- We are exploring outlicensing opportunities for LPM-Leuprolide and BioDefense programs in the United States and in Europe.
- We have engaged investment bankers to assist in exploring merger and acquisition opportunities.

As stated above we are operating under an austerity budget plan. We need to seek additional capital to begin the Phase 3 clinical trial for orBec® for the treatment of GI GVHD. We may obtain capital pursuant to one or more corporate partnerships relating to orBec®. 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 or 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.

Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

Expenditures

Under our austerity budget and based upon our 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 $1,200,000, not inclusive of BioDefense programs, or programs covered under existing NIH or orphan grants, and not including a new confirmatory Phase 3 clinical trial for orBec® for the treatment of GI GVHD. In order to fund a portion of these expenditures we will need funding from financings and partnerships. 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 $700,000 contributing towards our overhead expenses.

The table below details our costs for by program for the six months ended June 30:

	2008	2007
Program - Research & Development Expenses		
orBec®	$ 941,302	$ 1,611,579
RiVax™	183,710	234,876
BT-VACC™	106,663	197,514
Oraprine™	3,500	3,400
LPMTM-Leuprolide	108,428	26,404
Research & Development Expense	$ 1,343,603	$ 2,073,773
Program - Reimbursed under Grants		
orBec®	$ -	$ -
RiVax™	865,802	161,586
BT-VACC™	55,222	23,903
Oraprine™	-	-
LPMTM-Leuprolide	-	-
Reimbursed under Grant	$ 921,024	$ 185,489
TOTAL	$ 2,264,627	$ 2,259,262

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Income Taxes

Deferred tax assets:

	June 30, 2008	December 31, 2007
Deferred tax assets:		
Net operating loss carry forwards	$ 27,000,000	$25,000,000
Orphan drug and research and development credit carry forwards	1,800,000	2,000,000
Other	3,000,000	3,000,000
Total	31,800,000	30,000,000
Valuation allowance	(31,800,000)	(30,000,000)
Net deferred tax assets	$ -	$ -

At December 31, 2007, the Company had net operating loss carry forwards of approximately $73,000,000 for Federal and state tax purposes, portions of which are currently expiring each year until 2026.

The following is the approximate amount of the Company's tax credits and net operating losses that expire over the next five years:

2008	$ 910,000
2009	1,330,000
2010	1,410,000
2011	870,000
2012	3,870,000

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, 2007 and 2006 was as follows:

	2008	2007
Income tax loss at federal statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(4.00)	(4.29)
Valuation allowance	38.00	38.29
Provision for income taxes (benefit)	- %	- %

Due to the move of the corporate offices to New Jersey, the Florida net operating loss is suspended.

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 ("IRS") and state authorities for purposes of determining the amount of net operating losses to reduce taxable income generated in a given tax year.

Leases

The following summarizes our contractual obligations at June 30, 2008, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligation	Year 2008	Year 2009	Year 2010
Non-cancelable obligation (1)(2)	$ 21,000	$ 4,500	$ 4,500
TOTALS	$ 21,000	$ 4,500	$ 4,500

(1) On October 1, 2007, we signed a one year lease to occupy office space in Ewing, New Jersey.

(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.

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PART II - OTHER INFORMATION.

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.

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.

August 14, 2008 by /s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

August 14, 2008 by /s/ Evan Myrianthopoulos
Evan Myrianthopoulos
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
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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