DOR BIOPHARMA INC
Form 10QSB
November 14, 2007

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

FORM 10-QSB

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

For the Quarterly Period Ended September 30, 2007

( ) 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. 1-14778

DOR BIOPHARMA, INC.
(Exact name of small business issuer 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	**08628**
(Address of principal executive offices)	(Zip Code)

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

Check whether the issuer (1) has 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 shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

At November 7, 2007, 94,774,187 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

Transitional Small Business Disclosure Format (check one): Yes [ ] No [X]

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PART I. - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

DOR BioPharma, Inc.
Consolidated Balance Sheet
September 30, 2007
(Unaudited)

Assets		
Current assets:		
Cash and cash equivalents	**$**	**2,544,784**
Grants receivable		**173,634**
Prepaid expenses		**147,650**
Total current assets		**2,866,068**
Office and laboratory equipment, net		**30,701**
Intangible assets, net		**1,292,342**
Total assets	$	**4,189,111**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$	**1,046,636**
Accrued compensation		**133,305**
Total current liabilities		**1,179,941**
Shareholders' equity:		
Common stock, $.001 par value. Authorized 250,000,000		
shares; 92,997,331 issued and outstanding		**92,997**
Additional paid-in capital		**100,614,098**
Accumulated deficit		**(97,697,925)**
Total shareholders' equity		**3,009,170**
Total liabilities and shareholders' equity	$	**4,189,111**

The accompanying notes are an integral part of these financial statements

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

		2007		2006
Revenues:	**$**	**429,445**	$	117,982
Cost of revenues		**(301,672)**		(70,147)
Gross profit		**127,773**		47,835
Operating expenses:				
Research and development		**601,668**		761,276
General and administrative		**783,208**		660,085
Total operating expenses		**1,384,876**		1,421,361
Loss from operations		**(1,257,103)**		(1,373,526)
Other income (expense):				
Interest income		**10,121**		10,104
Interest expense		**-**		(2,106)
Total other income (expense)		**10,121**		7,998
Net loss	$	**(1,246,982)**	$	(1,365,528)
Basic and diluted net loss per share	$	**(0.01)**	$	(0.02)
Basic and diluted weighted average common shares outstanding		**92,938,838**		68,533,689

The accompanying notes are an integral part of these financial statements

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

		2007		2006
Revenues:	**$**	**943,737**	$	1,644,393
Cost of revenues		**(669,882)**		(1,198,403)
Gross profit		**273,855**		445,990
Operating expenses:				
Research and development		**2,611,220**		3,821,255
Purchased in-process research and development		**-**		981,819
General and administrative		**2,772,525**		2,099,608
Total operating expenses		**5,383,745**		6,902,682
Loss from operations		**(5,109,890)**		(6,456,692)
Other income (expense):				
Interest income		**144,062**		39,282
Interest expense		**(1,020)**		(2,106)
Total other income (expense)		**143,042**		37,176
Net loss	$	**(4,966,848)**	$	(6,419,516)
Basic and diluted net loss per share	$	**(0.06)**	$	(0.10)
Basic and diluted weighted average common shares outstanding		**89,389,416**		62,062,667

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the nine months ended September 30,
(Unaudited)

	2007	2006
Operating activities:		
Net loss	**$ (4,966,848)**	$ (6,419,516)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	**84,475**	148,913
Non-cash stock compensation	**1,201,306**	655,552
Non-cash stock purchase of in-process research and development	**-**	981,819
Impairment expense for intangibles	**-**	816,300
Change in operating assets and liabilities:		
Grants receivable	**(83,701)**	156,766
Prepaid expenses	**(53,180)**	41,926
Accounts payable	**(1,064,096)**	77,545
Accrued royalties	**-**	(60,000)
Accrued compensation	**(271,389)**	(48,535)
Total adjustments	**(186,585)**	2,770,286
Net cash used by operating activities	**(5,153,433)**	(3,649,230)
Investing activities:		
Acquisition of intangible assets	**(294,404)**	(228,668)
Purchases of equipment	**(10,182)**	(2,552)
Net cash used by investing activities	**(304,586)**	(231,220)
Financing activities:		
Net proceeds from sale of common stock	**6,235,404**	3,535,029
Proceeds from exercise of warrants	**1,530,763**	-
Proceeds from exercise of stock options	**117,000**	113,320
Net cash provided by financing activities	**7,883,167**	3,648,349
Net increase (decrease) in cash and cash equivalents	**2,425,148**	(232,101)
Cash and cash equivalents at beginning of period	**119,636**	821,702
Cash and cash equivalents at end of period	**$ 2,544,784**	$ 589,601
Non-cash transactions:		
Non-cash stock payment to an institutional investor	**$ -**	$ 220,374
Cash paid for interest	**$ 1,020**	$ -

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

DOR BioPharma, Inc. ("DOR" or the "Company") is a research and development biopharmaceutical company incorporated in 1987, focused on the development of oral therapeutic products intended for areas of unmet medical need as well as therapeutic and vaccine products that are to be used as biodefense countermeasures.

On October 18, 2007, the Company received a not approvable letter from the U.S. Food and Drug Administration (the "FDA") in response to its new drug application ("NDA") for orBec® (oral beclomethasone dipropionate) for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"). The FDA has requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. Additionally, the FDA has requested information with respect to other sections of the NDA. The Company has requested a meeting with the FDA to further understand the letter and gain clarity as to the next steps.

DOR has also filed a Marketing Authorization Application ("MAA") with the European Medicines Evaluation Agency ("EMEA") for orBec®, which has been validated for review.

On October 1, 2007, the Company relocated its corporate offices to Ewing, New Jersey.

During the quarter ended September 30, 2007, the Company had one customer, the U.S. Federal Government. All revenues were generated from three U.S. Federal Government Grants. As of September 30, 2007, all outstanding receivables were from the U.S. Federal Government, National Institute of Allergy and Infectious Diseases ("NIAID"), a division of the National Institutes of Health ("NIH"), and the Orphan Products Division of the FDA ("Government").

2. Summary of Significant Accounting Policies

Basis of Presentation

These unaudited interim consolidated financial statements of the Company were prepared under the rules and regulations for reporting on Form 10-QSB. Accordingly, the Company omitted some information and note disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with the audited consolidated financial statements and their notes included in the Company's annual report on Form 10-KSB for the year ended December 31, 2006. In the Company's opinion, the consolidated financial statements include all adjustments necessary for a fair statement of the results of operations, financial position and cash flows for the interim periods. All adjustments were of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results for the full fiscal year.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments, with an original maturity of three months or less.

Grants Receivable

Receivables consist of unbilled amounts due from grants from the U.S. Federal Government, and the NIAID. The amounts were billed in the month subsequent to quarter 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

Currently, the most significant estimate or judgment that DOR 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, DOR 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.

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 its 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 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.

Impairment of Long-Lived Assets

Office and laboratory equipment and intangible assets are evaluated and reviewed for impairment at least annually or 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 or the business to which such assets relate. 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.

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 has 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. As a result of adopting SFAS No. 123R, the Company's net loss for the quarter ended and nine months ended September 30, 2007 was $279,340 and $529,313, respectively, higher than if it had continued to account for share-based compensation under APB No. 25.

The fair value of each option grant at the quarter ended September 30, 2007 is estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. There were 2,925,000 stock options granted in the quarter ended September 30, 2007 and 3,375,000 stock options were granted during the nine months ended September 30, 2007.

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.18 and $0.27 for the quarter ended September 30, 2007 and September 30, 2006, 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 100% and 116% in 2007 and 2006, respectively and average risk-free interest rates in 2007 and 2006 of 4.5% and 4.0%, 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.

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.

There were options to purchase approximately 13.7 million and 12.8 million shares of the Company's common stock outstanding at September 30, 2007, and 2006, respectively.

3. Management's Plan

The Company has incurred continuing losses since its inception in 1987. At September 30, 2007, the Company had working capital of $1,687,127, and a net loss of $4,966,848. In the nine months ended September 30, 2007, the Company has raised approximately $6,500,000 through equity financing and approximately $1,647,000 in warrant and stock option exercises. Subsequent to September 2007, the Company had exercises of warrant and stock options of approximately $577,000. The Company expects to sustain additional losses over the next 12 months. The Company's ability to raise additional funding may be more difficult due to the Food and Drug Administration not approving orBec® for marketing in the United States.

Management's plan to generate positive cash flows either from operations or financing includes the following:

- The Company is exploring outlicensing opportunities for orBec® both in the US and Europe and for its BioDefense programs.
- The Company has engaged RBC Capital Markets as its advisor in exploring mergers and acquisitions and the various opportunities presented.
- The Company plans to continue seeking grant funds from governmental sources. In September 2006, the Company received two grants totaling approximately $5,500,000 to support the development of its BioDefense vaccine programs. An additional $1 million grant from the Orphan Products division of the FDA was awarded in September 2007 to its academic collaborators at the University of Texas Southwestern Medical Center to fund a supplemental trial of ricin vaccine (RiVax™) to support its ricin toxin vaccine program. Additionally, the Company's development partner, the Fred Hutchinson Cancer Research Center, has received NIH grants that support the preclinical and clinical development of orBec®/Oral BDP for the treatment of radiation injury and the prevention of GVHD.
- The Company believes that its current cash position will allow it to operate over the next 12 months. If there were no other sources of financing, reductions or discontinuation of operations of several of the Company's programs may be required. If this should occur, the Company believes it could continue to operate over the next four quarters at a reduced level and continue with its existing grant projects.

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

4. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
September 30, 2007	10.0	$ 2,033,794	$ 714,452	$ 1,292,342
December 31, 2006	10.1	$ 1,739,391	$ 666,152	$ 1,073,239

Amortization expense was $27,000 and $45,000 for the quarters ended September 30, 2007 and 2006, respectively. Amortization expense was $75,300 and $135,000 for the nine months ended September 30, 2007 and September 30, 2006, respectively.

At September 30, 2007, based on the balance of the intangibles the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
2007	$ 105,000
2008	105,000
2009	105,000
2010	105,000
2011	105,000

License fees and royalty payments are expensed annually.

5. Grants Receivable

In the third quarter of 2007, the Company recorded grant revenues from the three U.S. Government Grants in the amount of $429,455. For the nine months ended September 30, 2007 the Company recorded $943,737 in grant revenues. Outstanding receivables at quarter end were $173,634. This receivable has since been collected.

6. Shareholders' Equity

During the nine month period ended September 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, 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 116,055 common stock shares were issued to employees as payment for payroll in lieu of cash in the amount of $36,250.

On February 9, 2007, the Company completed the sale of 11,680,850 shares of DOR common stock to institutional investors and certain of our officers and directors for a gross purchase price of $5,490,000 (less $259,950 in placement agent fees). The common shares purchased were priced at $0.47 per share which represented a 6% discount to the then current market price. The placement agents received warrants to purchase 560,106 shares of common stock at an

exercise price of $0.59 per share. The warrants are exercisable for a period of five years commencing on February 9, 2007. The Company filed a registration statement with the Securities and Exchange Commission which was declared effective on April 18, 2007.

The securities purchase agreement of the April 2006 private investment placement ("PIPE") stipulated that if subsequent shares were sold at a lower price per share, the investors in that transaction were entitled to receive additional shares to compensate for the difference in price. The purchase in January 2007 by Sigma-Tau of $1,000,000 of DOR's common stock at $0.246 per share created a dilutive event which triggered the issuance of additional shares. Therefore, on February 16, 2007, 995,947 shares of common stock were issued to the remaining April 2006 PIPE investors at the same price as those issued to Sigma-Tau. This transaction resulted in a charge of $308,743 to account for the difference between the original price of $0.2771 and the $0.246.

On February 21, 2007, Sigma-Tau relinquished its exclusive rights granted to it on January 3, 2007, under a letter of intent with regard to acquisition discussions. However at that time, all other terms of the letter of intent remained in effect. 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 then market price of $0.246 per share, representing 4,065,041 shares of common stock, and paid an additional $2,000,000 in cash. The $2,000,000 payment 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 no agreement was reached by March 1, 2007, the Company was obligated to return the $2 million to Sigma-Tau by May 31, 2007 (as amended by mutual consent in a letter dated May 3, 2007 and filed on Form 8-K). The Company returned the $2 million on June 1, 2007 and thus satisfied the obligation.

7. Contingencies

The October 28, 2005, letter of intent with Gastrotech Pharma A/S ("Gastrotech"), as amended on December 29, 2005, expired in accordance with its terms on January 15, 2005 without being extended or renewed. Additionally, on January 15, 2006 the Company notified Gastrotech Pharma that it would not be renewing the letter of intent. The breakup fee of $1,000,000 is only payable if a party breaches the terms of the letter of intent or terminates the letter of intent. In accordance with SFAS No. 5, the Company disclosed a potential liability in that Gastrotech advised the Company that if it were not willing to comply with the terms of the letter of intent, DOR would be in material breach of its obligations and would be obligated to pay Gastrotech the break up fee of $1,000,000. However, pursuant to SFAS No. 5, paragraph 33b, the Company has not recorded a loss provision because it does not believe there will be any monetary damages since there is no pending litigation, the Company cannot reasonably determine the amount of loss, and does not believe it has any liability to Gastrotech for allowing the letter of intent to expire. In addition, the Company has not recorded an accrual for the potential loss, because it does not believe, as described in item 8(a) and 8(b) of SFAS No. 5, that any loss has been confirmed, nor has any outcome or judgment occurred. Moreover, the Company does not feel that it is probable that a liability has been incurred. Perhaps more importantly, Gastrotech has not brought any legal action against the Company. As of the date of this report, no claim or complaint has been filed by Gastrotech as to the obligation to pay a break-up fee of $1,000,000.

8. Business Segments

The Company had two active segments for the nine months ended September 30, 2007 and 2006: BioDefense and BioTherapeutics.

	For the three months ended September 30,	
	2007	2006
Revenues		
BioDefense	**$ 429,445**	$ 71,881
BioTherapeutics	**-**	46,101
Total	**$ 429,445**	$ 117,982
Income (Loss) from Operations		
BioDefense	**$ 25,676**	$ (99,395)
BioTherapeutics	**(581,363)**	(624,952)
Corporate	**(701,416)**	(649,179)
Total	**$ (1,257,103)**	$ (1,373,526)
Amortization and Depreciation Expense		
BioDefense	**$ 31,062**	$ 38,001
BioTherapeutics	**3,462**	9,001
Corporate	**1,525**	2,002
Total	**$ 36,049**	$ 49,004
Identifiable Assets		
BioDefense	**$ 984,287**	$ 1,140,106
BioTherapeutics	**511,690**	377,812
Corporate	**2,693,135**	689,838
Total	**$ 4,189,111**	$ 2,207,756

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	For the nine months ended September 30,	
	2007	2006
Revenues		
BioDefense	**$ 943,737**	$ 1,506,092
BioTherapeutics	**-**	138,301
Total	**$ 943,737**	$ 1,644,393
Income (Loss) from Operations		
BioDefense	**$ (51,010)**	$ (1,907,899)
BioTherapeutics	**(2,276,555)**	(3,468,298)
Corporate	**(2,782,325)**	(1,080,495)
Total	**$ (5,109,890)**	$ (6,456,692)
Amortization and Depreciation Expense		
BioDefense	**$ 68,293**	$ 112,477
BioTherapeutics	**11,593**	29,478
Corporate	**4,587**	6,955
Total	**$ 84,473**	$ 148,910

ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS

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-QSB, 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, 2006. 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-QSB are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expression, however, these words are not the exclusive means 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, including those identified in Exhibit 99.1 "Risk Factors" filed with this Form 10-QSB, 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-QSB 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 are a research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines.

On October 18, 2007, we received a not approvable letter from the U.S. Food and Drug Administration (the "FDA") in response to our new drug application ("NDA") for orBec® (oral beclomethasone dipropionate) for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"). The FDA has requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. Additionally, the FDA has requested information with respect to other sections of the new drug application NDA. We have requested a meeting with the FDA to further understand the letter and gain clarity as to the next steps. Once we have agreement on a new protocol with the FDA, we will endeavor to begin a new Phase 3 clinical program for the treatment of GI GVHD in 2008.

We also have filed a Marketing Authorization Application ("MAA") with the European Medicines Evaluation Agency ("EMEA") for orBec®, which has been validated for review. We expect a response on our MAA from the EMEA in the first half of 2008.

Our business strategy is to: (a) work with the FDA on the design of new clinical trials in GI GVHD; (b) explore acquisition strategies under which the Company may be acquired by another company with oncologic or GI symmetry; (c) seek a development and marketing partner for orBec® for territories both inside and outside of the US; (d) prepare for the potential marketing approval of orBec® by EMEA; (e) conduct a prophylactic use clinical trial of orBec® for the prevention of GI GVHD; (f) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract such as chronic GVHD, radiation enteritis, and Crohn's disease; (g) reinitiate development including manufacturing of

our other biotherapeutics products namely LPM™-Leuprolide, and Oraprine™; (h) secure additional government funding for each of our biodefense programs, RiVax™ and BT-VACC™, through grants, contracts, and procurements; (i) 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. We were incorporated in 1987. We maintain two active segments: BioTherapeutics and BioDefense.

On January 3, 2007, we received $3 million under a non-binding letter of intent with Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”), which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other DOR compounds until March 1, 2007. Sigma-Tau is a pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. Sigma-Tau has both prescription and consumer products in metabolic, oncology, renal and supplements. Under the terms of the letter of intent, Sigma-Tau purchased $1 million of our common stock at the market price of $0.246 per share, representing approximately four million shares. Sigma-Tau paid an additional $2 million, which was to be considered an advance payment to be deducted from upfront monies due to us by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because no agreement was reached by March 1, 2007, we were obligated to return the $2 million to Sigma-Tau by May 31, 2007 (as amended by mutual consent in a letter dated May 3, 2007 and filed on Form 8-K). We returned the $2 million on June 1, 2007 and satisfied the obligation.

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. 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 is 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, putting the new action date for the orBec® NDA at October 21, 2007. Additionally, on May 9, 2007, the Oncologic Drugs Advisory Committee ("ODAC") appointed by the FDA voted that the data supporting orBec® (oral beclomethasone dipropionate) 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 October 18, 2007, we received a not approvable letter from the FDA for orBec®. The FDA has requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. Additionally, the FDA has requested information with respect to other sections of the NDA. We have requested a meeting with the FDA to further understand the letter and gain clarity as to the next steps. Once we have agreement on a new protocol with the FDA, we will endeavor to begin a new Phase 3 clinical program for the treatment of GI GVHD in 2008, we will require additional funding to conduct this program.

We also filed an MAA with the EMEA on November 3, 2006, which was validated for review on November 28, 2006. We have assembled an experienced team of consultants and contractors who worked on all aspects of the NDA and MAA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of gastrointestinal GI GVHD to be approximately 60 percent of the more than 10,000 bone marrow and stem cell transplants 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 US and abroad in an effort to seek support for future clinical development of orBec® for the treatment of intestinal GI GVHD. We also intend to seek a partner for the other potential indications of oral Beclomethasone Dipropionate/orBec®.

On July 12, 2007, we announced that patient enrollment commenced in a randomized, double blinded, placebo controlled Phase 2 clinical trial of orBec® for the prevention of acute GVHD after allogeneic hematopoietic cell transplantation ("HCST") with myeloablative conditioning regimens. The Phase 2 clinical trial is supported in part by a National Institute of Health ("NIH") grant awarded to the Fred Hutchinson Cancer Research Center ("FHCRC"). The protocol, 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," is a randomized, double-blinded, placebo-controlled trial. 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, MD, of the Fred Hutchinson Cancer Research Center 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 transplant. The objectives of the trial are 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 HCST. Completion of patient enrollment in this trial is targeted for mid year 2008,

with results announced in the second half of 2008.

On September 12, 2007, we announced that our academic partner, the Fred Hutchinson Cancer Research Center (FHCRC), has 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. 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, will benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism.

In addition to preclinical work on radiation exposure being conducted at FHCRC, we will endeavor tobegin preclinical studies in radiation exposure, as well as 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 2008. Chronic GVHD can begin anytime during or after the third month post-transplant. About 60 percent of patients who receive an allogeneic transplant and are alive at day 100 post transplant will develop chronic GVHD. Chronic GVHD can range from mild to life-threatening. Some transplant survivors have problems with chronic GVHD for many years.

RiVax™

The development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. In September of 2006 we received a grant of approximately $5.2 million from the National Institute of Allergy and Infectious Diseases ("NIAID"), a division of the National Institute of Health ("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 last year and was shown to be safe and effective, while also inducing ricin neutralizing antibodies as confirmed in subsequent animal studies.

We also announced in March 2007 that we have successfully completed a 1 year interim analysis in the long-term stability program of the key ingredient of RiVax™, a recombinant subunit vaccine against ricin toxin intended to protect against exposure to ricin that might result from purposeful release of toxin in an aerosolized form or as a poisonous contaminant in food or water. The results of interim analysis in the formal stability program demonstrate that the immunogen component of RiVax™, a recombinant derivative of ricin A chain, is stable under storage conditions for at least one year without loss of its natural configuration or the appearance of any detectable degradation products. A vaccine for ricin is considered by many the best way to prospectively protect certain human populations who are at risk of exposure. Since this vaccine would presumably be added to the Strategic National Stockpile and dispensed in the case of a terrorist attack, the activity of the vaccine must be maintained over a period of years under potential stockpile storage conditions.

Our academic partner, The University of Texas Southwestern led by Dr. Ellen Vitetta, completed a Phase 1 safety and immunogenicity trial of RiVax™ in human volunteers. The results of the Phase 1 safety and immunogenicity dose-escalation study indicate that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. Despite the absence of an adjuvant, antibodies were present in the blood of several volunteers for as long as 127 days after their last vaccination. The functional activity of the antibodies was confirmed by transferring serum globulins from the vaccinated individuals along with active ricin toxin into sensitive mice, which then survived subsequent exposure to ricin toxin. The outcome of the study was published in the *Proceedings of the National Academy of Sciences*. In January of 2005, we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. In July of 2006, we announced the successful completion of the current Good Manufacturing Practices ("cGMP") milestone for the production of RiVax™.

In July of 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 RiVax™. The grant has been awarded to UT Southwestern Medical Center, in the development of RiVax™. The Principal Investigator for the project is Dr. Vitetta, Director of the Cancer Immunobiology Center at UT 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 plan on initiating a non-human primate study and endeavor to begin a human clinical trial with RiVax™ in the first half of 2008.

The Company believes that RiVax is at a sufficiently advanced state of development for the awarding of further development contracts from other agencies and branches of the government. For example, the Department of Health and Human Services has created during 2006 a separate agency, BARDA ("BioDefense Advanced Research and Development Authority") within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services. BARDA manages Project BioShield to procure countermeasures and

vaccines and is the agency now responsible for advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents. The purpose of BARDA is to take over where NIH has left off in the transition from research and development to advanced development and clinical testing. In addition, BARDA is responsible for establishing priorities for civilian biodefense. The company expects to continue to respond to requests for proposals ("RFP") that may arise within BARDA and other branches of the government.

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 one of the most poisonous natural substances known. 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-VACC™ 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 to date 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 of 2006, we were also awarded a NIAID Phase 1 SBIR grant totaling approximately $0.5 million to conduct further work to combine antigens from different serotypes of botulinum toxin for a prototype multivalent vaccine. The grant funding will support 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 of 2007, we announced that the first results from testing of a multivalent form of BT-VACC™, 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.

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LPM™ - 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.

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 expect to perform Phase 1 bioavailability studies 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 depo and subcutaneous implant routes of delivery which limits its use and utility.

Oraprine™

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 given drug may provide a niche in the current transplant medicine market for an alternative to solid dosage forms of azathioprine that would have a use in elderly patients. Oraprine™ 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. Epstein 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.

LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs

We may develop two lipid-based systems, LPE™ and PLP™, to support the oral delivery of small molecules of water insoluble drugs. Such drugs include most kinds of cancer chemotherapeutics currently delivered intravenously. The LPE™ 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.

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. On an on-going basis, we evaluate these estimates and judgments.

Intangible Assets

Currently, the most significant estimate or judgment 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 in the pharmaceutical development industry. Of the intangible asset balance, $425,000 is for up-front license costs. We purchased a license from the University of Texas Southwestern Medical Center, for the license to the RiVax™ vaccine for $425,000. 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. For a development stage company with drug and vaccine products in an often lengthy basic and clinical research process, we believe that patent rights form 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.

During 2007, we capitalized $294,574 in patent related costs. This amount is represented in the cash flow statement, in the section for investing activities presented in the 2007 10-QSB financial statements. On the balance sheet this amount is presented on the line intangible assets, net in the amount of $1,292,342.

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 partial funding of our overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant.

Material Changes in Results of Operations

We are a research and development company. The 2007 revenues and associated expenses were from NIH Grants received in September 2004 and September 2006. The NIH grants are associated with our ricin and botulinum vaccines. In addition, we were awarded a one year FDA grant on September 23, 2005 for the "Oral BDP for the Treatment of GI GVHD."

For the three months ended September 30, 2007, we had grant revenues of $429,445 as compared to $117,982 in the three months ended September 30, 2006, an increase of $311,463, or 264%. For the nine months ended September 30, 2007, we had grant revenues of $943,737, a decrease of $700,656, or 43%, as compared to revenues of $1,644,393 for the same period in 2006. In 2006 compared to 2007, our progress on the grant had exceeded the original schedule, which accelerated the milestone revenues that were recorded in the first quarter of 2006. We also incurred expenses related to that revenue in the three months ended September 30, 2007 and 2006 of $301,672 and $70,147, respectively, an increase of $231,525, or 330%. For the nine months ended September 30, 2007, we had incurred expenses of $669,882, a decrease of $528,521, or 44%, as compared to expenses of $1,198,403. These costs relate to payments made to subcontractors and universities in connection with the grants.

Although we have a gross profit, it is a result of the increase in the NIH award for a more comprehensive facilities and administrative rate or overhead rate ('F&A rate") and the FDA grant. The gross profit for the three months ended September 30, 2007 was $127,773 as compared to $47,835 in the three months ended September 30, 2006, an increase of $79,938, or 167%. The gross profit for the nine months ended September 30, 2007 was $273,855 as compared to $445,990 in the nine months ended September 30, 2006, a decrease of $172,135, or 39%. This was due to the decreased grant revenues in the first quarter ended 2007 that were eligible for the F&A rate as well as the expected decrease in the final F&A rate.

Research and development spending decreased $159,608, or 21%, to $601,668, for the three months ended September 30, 2007 as compared to $761,276 for the corresponding period ended September 30, 2006. Research and development spending decreased $1,210,035, or 32%, to $2,611,220, for the nine months ended September 30, 2007 as compared to $3,821,255 for the corresponding period ended September 30, 2006. In the third quarter of 2007, a majority of expenses were related to preparation of FDA and European regulatory matters. The decrease for research and development spending was primarily the result of the impairment expense for intangibles of $816,300 in 2006 and a reduction in estimated patent expenses of $50,000.

In-process research and development expenditures were $0 for the three months and nine months ended September 30, 2007, a decrease of 0% and 100% as compared to $0 and $981,819 for the same periods ended September 30, 2006. This decrease is due to the purchase acquisition of all of the outstanding common stock of Enteron that the Company did not already own.

General and administrative expenses increased $123,122, or 19%, to $783,208 for the three months ended September 30, 2007, as compared to $660,085 for the corresponding period ended September 30, 2006. General and administrative expenses increased $672,917, or 32%, to $2,772,525 for the nine months ended September 30, 2007, as compared to $2,099,608 for the corresponding period ended September 30, 2006. The increase was primarily due to the dilution expense taken for stock issued to investors from the April 2006 PIPE in the amount of $308,743. In addition, we had expenses for public and investor relations which increased by approximately, $175,000. During the 9 months ended September 30, 2007 we also had accounted for $529,313 in stock option expense.

Interest income for the three months ended September 30, 2007 was $10,121 as compared to $10,104 for the three months ended September 30, 2006, representing an increase of $17 or 0%. Interest income for the nine months ended September 30, 2007 was $144,062 as compared to $39,282 for the nine months ended September 30, 2006, representing an increase of $104,780 or 267%. This increase is due to a higher cash balance in 2007 as compared to

2006. During the third quarter of 2007 we had cash in a floating rate fund that decreased in value over the period and therefore decreased our earnings for the quarter 2007 by $42,442.

Interest expense for the three months ended September 30, 2007 was $0 as compared to $2,106 for the three months ended September 30, 2006, a decrease of $2,106 or 100%. Interest expense for the nine months ended September 30, 2007 was $1,020 as compared to $2,106 for the nine months ended September 30, 2006, an increase of $1,086 or 52%. This decrease was due to interest paid for financing insurance premiums.

For the three months ended September 30, 2007, we had a net loss of $1,064,261 as compared to a $1,365,528 net loss for the three months ended September 30, 2006, a decrease of $301,267, or 22%. For the nine months ended September 30, 2007, we had a net loss of $4,966,848 as compared to a $6,419,516 net loss for the nine months ended September 30, 2006, a decrease of $1,452,668, or 23%. This decrease in the net loss is primarily attributed to higher costs in 2006 for: regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®, the in-process research and development expense of $981,819 for acquiring all of the outstanding common stock of Enteron that the Company did not already own, and the impairment expense for intangibles of $816,300.

Financial Condition

Cash and Working Capital

As of September 30, 2007, we had cash and cash equivalents of $2,544,784 as compared to $119,636 as of December 31, 2006, and working capital of $1,686,127 as compared to negative working capital of $2,211,386 as of December 31, 2006 representing an increase of $3,897,513. For the nine months ended September 30, 2007, our cash used in operating activities was $5,153,433, compared to $3,649,230 for the six months ended September 30, 2006.

As of October 31, 2007, we had cash and cash equivalents of approximately $2,650,000. During October 2007, we had option and warrant exercises for common stock resulting in cash proceeds of approximately $577,000.

Based on our current rate of cash outflows, we believe that our cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the fourth quarter of 2008. This does not include trials outside the existing awarded grants, included but not limited to a new Phase 3 clinical trial of orBec® for the treatment of GI GVHD. It is possible that within the upcoming twelve months we will seek additional capital in the private and/or public equity markets to expand our operations to conduct clinical programs, to respond to competitive pressures, to develop new products and services and to support new strategic partnerships. 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.

Expenditures

Under existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our expenditures for the next twelve months to approximate $500,000 not inclusive of BioDefense programs, nor programs covered under existing NIH or orphan grants and not including a new Phase 3 clinical trial for orBec® for the treatment of GI GVHD. We anticipate grant revenues in the next twelve months to offset research and development expenses for the development of our ricin toxin vaccine and botulinum toxin vaccine in the amount of approximately $2,800,000 with $650,000 contributing towards our overhead expenses.

The table below details our costs for the nine months ended September 30, 2007 and 2006 by project.

	2007	2006
Projects-Research & Development Expenses		
orBec®	$ 1,999,563	$ 3,333,783
RiVax™	317,390	247,637
BT-VACC™	256,914	229,335
Oraprine™	5,100	5,100
LPM™-Leuprolide	32,254	5,400
Research & Development Expense	$ 2,611,220	$ 3,821,255
Projects-Reimbursed under Grants		
orBec®	$ -	$ 46,099
RiVax™	636,979	1,152,304
BT-VACC™	32,903	-

Oraprine™	-	-
LPM™-Leuprolide	-	-
Reimbursed under Grant	$ 669,882	$ 1,198,403
TOTAL	$ 3,281,102	$ 5,019,658

Leases

The following summarizes our contractual obligations at September 30, 2007, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligation	**Year 2007**	**Year 2008**	**Year 2009**
Non-cancelable obligation (1)	$ 18,000	$ 54,000	-
TOTALS	**$ 18,000**	**$ 54,000**	**$ -**

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

ITEM 3 - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Controls

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

PART II - OTHER INFORMATION.

ITEM 4 - SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

(a) The Annual Meeting of the Company's stockholders was held on September 27, 2007. Of the 92,930,574 shares of outstanding common stock on the record date of August 7, 2007, a total of 74,133,166 shares were represented in person or by proxy.

(b) The following directors were re-elected effective September 27, 2007:

	Votes Cast	
	For	**Against**
James S. Kuo, M.D.	70,624,423	3,508,743
Christopher J. Schaber, Ph.D.	70,624,073	3,509,093
Evan Myrianthopoulos	70,626,837	3,506,329
Cyrille F. Buhrman	71,622,921	2,510,245

(c)(i) The vote to approve the grant of discretionary authority to the board of directors for a 24 month period (a) to amend the Company's Amended and Restated Certificate of Incorporation to change the name of the Company or (b) to determine not to proceed with the name change was: 68,490,910 for, 5,480,152 against and 162,101 abstain.

(ii) The vote to approve the grant of discretionary authority to the board of directors for a 24 month period (a) to amend the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock at a ratio within the range from 1-4-2 to 1-4-10, determine the effective of the reverse stock split, and to proportionately reduce the number of shares of the Company's common stock authorized for issuance or (b) to determine not to proceed with the reverse stock split and proportionate reduction of the number shares of the Company's common stock authorized for issuance was: 61,377,624 for, 11,745,856 against and 1,009,683 abstain.

(iii) The vote to amend the Company's 2005 Equity Incentive Plan to increase the maximum number of shares of the Company's common stock available for issuance under the plan by 10,000,000 shares, bringing the total shares reserved for issuance under the plan to 20,000,000 was: 14,076,714 for, 6,311,175 against and 1,106,046 abstain. On this proposal there where 52,639,231 broker held non-votes.

(iv) The vote to approve Sweeney Gates & Co. as the Company's independent auditors for the year ending December 31, 2007 was: 73,124,310 for, 802,611 against and 206,245 abstain.

ITEM 6 - 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

99.1 Risk Factors

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.

November 14, 2007 by: /s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

November 14, 2007 by: /s/ Evan Myrianthopoulos
Evan Myrianthopoulos
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)