DOR BIOPHARMA INC
Form 10QSB
August 15, 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 June 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)
1101 Brickell Ave., Suite 701-S Miami, FL	**33131**
(Address of principal executive offices)	(Zip Code)

(786) 425-3848
(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 August 14, 2007, 92,930,574 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
June 30, 2007
(Unaudited)

Assets		
Current assets:		
Cash and cash equivalents	**$**	**3,670,960**
Grants receivable		**84,911**
Prepaid expenses		**194,595**
Total current assets		**3,950,466**
Office and laboratory equipment, net		**25,974**
Intangible assets, net		**1,196,887**
Total assets	$	**5,173,327**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$	**1,101,623**
Accrued compensation		**123,641**
Total current liabilities		**1,225,264**
Shareholders' equity:		
Common stock, $.001 par value. Authorized 250,000,000		
shares; 92,905,142 issued and outstanding		**91,905**
Additional paid-in capital		**100,306,100**
Accumulated deficit		**(96,450,942)**
Total shareholders' equity		**3,948,063**
Total liabilities and shareholders' equity	$	**5,173,327**

The accompanying notes are an integral part of these financial statements

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

		2007		2006
Revenues:	**$**	**279,481**	$	138,779
Cost of revenues		**(107,418)**		(88,852)
Gross profit		**172,063**		49,927
Operating expenses:				
Research and development		**1,031,015**		1,834,554
Purchased in-process research and development		**-**		981,819
General and administrative		**767,802**		606,330
Total operating expenses		**1,798,817**		3,422,703
Loss from operations		**(1,626,754)**		(3,372,776)
Other income (expense):				
Interest income		**71,694**		25,690
Interest expense		**(607)**		-
Total other income (expense)		**71,087**		25,690
Net loss	$	**(1,555,667)**	$	(3,347,086)
Basic and diluted net loss per share	$	**(0.02)**	$	(0.05)
Basic and diluted weighted average common shares outstanding		**92,585,933**		66,978,207

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

		2007		2006
Revenues:	**$**	**514,652**	$	1,526,411
Cost of revenues		**(185,489)**		(1,128,257)
Gross profit		**329,163**		398,154
Operating expenses:				
Research and development		**2,073,773**		3,059,979
Purchased in-process research and development		**-**		981,819
General and administrative		**2,108,177**		1,439,522
Total operating expenses		**4,181,950**		5,481,320
Loss from operations		**(3,852,787)**		(5,083,166)
Other income (expense):				
Interest income		**133,941**		29,178
Interest expense		**(1,020)**		-
Total other income (expense)		**132,921**		29,178
Net loss	$	**(3,719,866)**	$	(5,053,988)
Basic and diluted net loss per share	$	**(0.04)**	$	(0.09)
Basic and diluted weighted average common shares outstanding		**88,071,875**		59,100,048

The accompanying notes are an integral part of these financial statements

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

		2007		2006
Operating activities:				
Net loss	**$**	**(3,719,866)**	$	(5,053,988)
Adjustments to reconcile net loss to net cash used by operating activities:				
Amortization and depreciation		**54,424**		99,907
Non-cash stock compensation		**893,216**		393,779
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		**5,022**		(214,909)
Prepaid expenses		**(100,125)**		18,890
Accounts payable		**(1,010,855)**		680,729
Accrued royalties		**-**		(60,000)
Accrued compensation		**(279,306)**		(59,324)
Total adjustments		**(437,624)**		2,657,191
Net cash used by operating activities		**(4,157,490)**		(2,396,797)
Investing activities:				
Acquisition of intangible assets		**(171,948)**		(170,035)
Purchases of equipment		**(2,405)**		-
Net cash used by investing activities		**(174,353)**		(170,035)
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		**3,551,324**		1,081,517
Cash and cash equivalents at beginning of period		**119,636**		821,702
Cash and cash equivalents at end of period	**$**	**3,670,960**	$	1,903,219
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 and biodefense vaccines. DOR has filed a new drug application ("NDA") for the Company's lead product orBec® (oral beclomethasone dipropionate) with the U.S. Food and Drug Administration (the "FDA") for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"), and had originally received a Prescription Drug User Fee Act ("PDUFA") date for the FDA to complete its review of the orBec® NDA by July 21, 2007. On July 18, 2007 the Company 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 DOR's July 13, 2007 provision of supplemental information to the orBec® NDA. This information was requested by the FDA in 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.

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 is not bound by ODAC's recommendations, but it will take the panel's advice into consideration when reviewing the NDA for orBec®.

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

During the quarter ended June 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 June 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.

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 six months ended June 30, 2007 was $118,055 and $249,973, 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 June 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 150,000 stock options granted in the quarter ended June 30, 2007 and 450,000 stock options were granted during the 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 $0.33 and $0.46 for the quarter ended June 30, 2007 and June 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 90% and 126% in 2007 and 2006, respectively and average risk-free interest rates in 2007 and 2006 of 4.45% and 3.6%, 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 11.8 million and 12.1 million shares of the Company's common stock outstanding at June 30, 2007, and 2006, respectively.

3. Management's Plan

The Company has incurred continuing losses since its inception in 1987. At June 30, 2007, the Company had working capital of $2,725,202, and a net loss of $3,719,866. In the six months ended June 30, 2007, the Company has raised approximately $6,500,000 through equity financing and approximately $1,647,000 in warrant and stock option exercises. The Company expects to sustain additional losses over the next 12 months. The Company's ability to raise additional funding may be more difficult should the Food and Drug Administration deny marketing approval of orBec® in the United States.

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

- The Company plans on calling existing warrants for exercise in cash when its stock price achieves appropriate levels enabling the call provisions of the warrants to take affect.
- The Company is exploring outlicensing opportunities for orBec® both in the US and Europe and for its BioDefense programs.
- The Company plans to continue seeking grant funds from governmental sources. In September 2006, the Company received two grants totaling approximately $5,300,000 to support the development of its BioDefense vaccine programs.
- The Company believes that its current cash position will allow it to operate over the next 12 months. However, several factors could affect this including the outcome of the Company's NDA and MAA filings. Therefore, 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 eight quarters at a reduced level and only continue with the 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
June 30, 2007	10.0	$ 1,911,510	$ 714,452	$ 1,197,058
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 June 30, 2007 and 2006, respectively. Amortization expense was $48,300 and $90,000 for the six months ended June 30, 2007 and June 30, 2006, respectively.

At June 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	$ 106,000
2008	106,000
2009	106,000
2010	106,000
2011	106,000

License fees and royalty payments are expensed annually.

5. Grants Receivable

In the second quarter of 2007, the Company recorded grant revenues from the three U.S. Government Grants in the amount of $279,481. For the six months ended June 30, 2007 the Company recorded $514,652 in grant revenues. Outstanding receivables at quarter end were $84,911. This receivable has since been collected.

6. Shareholders' Equity

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, 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 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 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 of 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 16, 2007, the Company issued 995,947 common shares to investors in the April 2006 private investment placement ("PIPE"), which was a result of the January 3, 2007 purchase of $1,000,000 of the Company's common stock at $0.246 per share by Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"). The common stock issued to the remaining April 2006 PIPE investors was the result of the re-pricing of their investment to $0.246 per share as compared to the $0.2771 per share price of the April 2006 PIPE. The securities purchase agreement of the April 2006 PIPE called for the repricing of stock to the $0.246 per share price and thus causing a dilutive event to occur. Due to this dilutive event, the Company recorded an expense of $308,743.

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, all other terms of the letter of intent remained in effect, and the Company and Sigma-Tau are currently engaged in discussions for a European collaboration relating to orBec®. 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, 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 not 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. No potential loss is estimable at this time. As of the date of this report, no claim or complaint has been filed by Gastrotech Pharma A/S (“Gastrotech”) as to the obligation to pay a break-up fee of $1,000,000. The Company’s position is that it does not owe Gastrotech any break-up fee pursuant to not renewing its letter of intent to acquire Gastrotech. There is no additional information to report as of the date of this report.

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8. Business Segments

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

	For the three months ended June 30,	
	2007	2006
Revenues		
BioDefense	**$ 279,481**	$ 92,678
BioTherapeutics	**-**	46,101
Total	**$ 279,481**	$ 138,779
Income (Loss) from Operations		
BioDefense	**$ 72,716**	$ (943,963)
BioTherapeutics	**(878,684)**	(1,829,015)
Corporate	**(820,785)**	(599,798)
Total	**$ (1,626,753)**	$ (3,372,776)
Amortization and Depreciation Expense		
BioDefense	**$ 24,426**	$ 37,069
BioTherapeutics	**4,026**	10,069
Corporate	**1,453**	2,138
Total	**$ 29,905**	$ 49,276
Identifiable Assets		
BioDefense	**$ 895,564**	$ 1,363,124
BioTherapeutics	**416,234**	362,397
Corporate	**3,861,529**	2,178,384
Total	**$ 5,173,327**	$ 3,903,905

	For the six months ended June 30,	
	2007	2006
Revenues		
BioDefense	**$ 514,652**	$ 1,434,211
BioTherapeutics	**-**	92,200
Total	**$ 514,652**	$ 1,526,411
Income (Loss) from Operations		
BioDefense	**$ 106,394**	$ (826,686)
BioTherapeutics	**(1,576,691)**	(2,843,346)
Corporate	**(2,382,490)**	(1,413,134)
Total	**$ (3,852,787)**	$ (5,083,166)
Amortization and Depreciation Expense		
BioDefense	**$ 39,931**	$ 74,477
BioTherapeutics	**8,131**	20,477
Corporate	**3,062**	4,953
Total	**$ 51,124**	$ 99,907

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. We have filed a new drug application ("NDA") for our lead product orBec® (oral beclomethasone dipropionate) with the U.S. Food and Drug Administration (the "FDA") for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"), and had originally received a Prescription Drug User Fee Act ("PDUFA") date for the FDA to complete its review of the orBec® NDA 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® would be 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 in 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.

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 is not bound by ODAC's recommendations, but it will take the panel's advice into consideration when reviewing the NDA for orBec®.

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

Until the FDA responds to our NDA our business strategy is to: (a) prepare for the potential marketing approval of orBec® by the FDA and the EMEA; (b) conduct a prophylactic use clinical trial of orBec® for the prevention of GI GVHD; (c) 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; (d) reinitiate development

including manufacturing of our other biotherapeutics products namely LPM™-Leuprolide, and Oraprine™; (e) explore acquisition strategies under which the Company may be acquired by another company with oncologic or GI symmetry; (f) identify a sales and marketing partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (g) secure additional government funding for each of our biodefense programs through grants, contracts, and procurements; (h) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area; 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. They have 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 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 is not bound by ODAC's recommendations, but it will take the panel's advice into consideration when reviewing the NDA for orBec®.

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 U.S. and abroad in anticipation of commercialization of orBec®. We also intend to seek a partner for the other potential indications of orBec®. We are also actively considering a strategy of a commercial launch of orBec® by ourselves in the U.S.

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 graft-versus-host disease ("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, which is being reviewed by the Institutional Review Board of FHCRC, 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 the second quarter of 2008.

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 I 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 to 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.

BT-VACC™

Our botulinum toxin vaccine, called BT-VACC™, was developed through the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania. 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. 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 one year NIAID Phase I 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.

LPM™ - Leuprolide

In April 2007, we announced plans to initiate a clinical development program in humans 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 drugs such as leuprolide 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.

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.

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.

In re-initiating the LPM™ technology, we have enlisted the assistance of experienced drug delivery, formulation and clinical consultants who have been intimately involved with the development of the LPM™ technology. We anticipate preparing for a Phase 1 safety, tolerability and pharmacokinetic study with LPM-leuprolide in 2007.

Oraprine™

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 acquired the azathioprine drug (Oraprine™) as a result of the merger of Endorex and CTD in November 2001. Also acquired were patent applications licensed from Dr. Joel Epstein of the University of Washington. 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 graft versus host disease. 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. Oraprine™ may provide a convenient

dosage form for patients who have difficulty swallowing pills or tablets, such as children.

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 $172,119 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 $1,196,887.

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 were associated with our ricin and botulinum vaccines. The original amount of the first NIH grant was $5,173,298. This was increased on May 6, 2005, to $6,433,316. The increase of $1,260,018 was awarded based on a renegotiated F&A (facilities and administrative) rate with the NIH. This rate provided a fixed rate for facilities and administrative costs (overhead expenditures) that is applied against all costs associated with the grant awarded. The rate is determined primarily on a year by year basis. The rate for 2006 and 2007 was a provisional rate and the final rate has not yet been determined but the expectations are that the rate will be lower than it was previously. In 2006 in anticipation of the final rate we recorded an estimate of $390,000. The second NIH grant was received for ricin in September 2006 for $5,203,405. The NIH SBIR grant for botulinum was received in September 2006 for $465,191. We were awarded a one year FDA grant on September 23, 2005 for the “Oral BDP for the Treatment of GI GVHD” in the amount of $318,750.

For the three months ended June 30, 2007, we had grant revenues of $279,481 as compared to $138,779 in the three months ended June 30, 2006, an increase of $140,702, or 101%. For the six months ended June 30, 2007, we had grant revenues of $514,652, a decrease of $1,011,759, or 66%, as compared to revenues of $1,526,411 for the same period in 2006. In 2006 compared to 2007, our progress on the grant had exceeded the original schedule, accelerating 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 June 30, 2007 and 2006 of $107,418 and $88,852, respectively, an increase of $18,566, or 21%. For the six months ended June 30, 2007, we had incurred expenses of $185,489, a decrease of $942,768, or 84%, as compared to expenses of $1,128,257. 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 higher and more comprehensive F&A rate and the FDA grant. The gross profit for the three months ended June 30, 2007 was $172,063 as compared to $49,927 in the three months ended June 30, 2006, an increase of $122,136, or 245%. The gross profit for the six months ended June 30, 2007 was $329,163 as compared to $398,154 in the six months ended June 30, 2006, a decrease of $68,991, or 17%. 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 $803,539, or 44%, to $1,031,015, for the three months ended June 30, 2007 as compared to $1,834,554 for the corresponding period ended June 30, 2006. Research and development spending decreased $986,206, or 32%, to $2,073,773, for the six months ended June 30, 2007 as compared to $3,059,979 for the corresponding period ended June 30, 2006. In the second quarter of 2007, a majority of expenses were related to preparation for ODAC and FDA meetings 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.

In-process research and development expenditures were $981,819 for the three months and six months ended June 30, 2006, a decrease of 100% as compared to zero for the same periods ended June 30, 2007. 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 $161,472, or 27%, to $767,802 for the three months ended June 30, 2007, as compared to $606,330 for the corresponding period ended June 30, 2006. General and administrative expenses increased $668,655, or 46%, to $2,108,177 for the six months ended June 30, 2007, as compared to $1,439,522 for the corresponding period ended June 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. Our expenses for public and investor relations increased by approximately, $188,000. Other expenses such as salary and travel also contributed to the increase in 2007.

Interest income for the three months ended June 30, 2007 was $71,694 as compared to $25,690 for the three months ended June 30, 2006, representing an increase of $46,004 or 179%. Interest income for the six months ended June 30, 2007 was $133,941 as compared to $29,178 for the six months ended June 30, 2006, representing an increase of $104,763 or 359%. This increase is due to a higher cash balance in 2007 as compared to 2006.

Interest expense for the three months ended June 30, 2007 was $607 as compared to $0 for the three months ended June 30, 2006, a decrease of $607 or 100%. Interest expense for the six months ended June 30, 2007 was $1,020 as compared to zero for the six months ended June 30, 2006, an increase of $1,020 or 100%. This increase was due to interest paid for financing insurance premiums.

For the three months ended June 30, 2007, we had a net loss of $1,555,667 as compared to a $3,347,086 net loss for the three months ended June 30, 2006, a decrease of $1,791,419, or 54%. For the six months ended June 30, 2007, we had a net loss of $3,719,866 as compared to a $5,053,988 net loss for the six months ended June 30, 2006, a decrease of $1,334,122, or 26%. This decrease in the net loss is primarily attributed to the increases 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 June 30, 2007, we had cash and cash equivalents of $3,670,960 as compared to $119,636 as of December 31, 2006, and working capital of $2,725,201 as compared to negative working capital of $2,211,386 as of December 31, 2006 representing an increase of $4,936,587. For the six months ended June 30, 2007, our cash used in operating activities was $4,157,490, compared to $2,396,797 for the six months ended June 30, 2006.

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 $3,000,000. 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 $3,900,000 with $800,000 contributing towards our overhead expenses.

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

	2007	2006
Projects-Research & Development Expenses		
orBec®	$ 1,611,579	$ 1,670,841
RiVax™	234,876	1,155,803
BT-VACC™	197,514	226,335
Oraprine™	3,400	3,400
LPM™-Leuprolide	26,404	3,600
Research & Development Expense	$ 2,073,773	$ 3,059,979
Projects-Reimbursed under Grants		
orBec®	$ -	$ 46,099
RiVax™	161,586	1,082,158
BT-VACC™	23,903	-
Oraprine™	-	-
LPM™-Leuprolide	-	-
Reimbursed under Grant	$ 185,489	$ 1,128,257
TOTAL	$ 2,259,262	$ 4,188,236

Leases

The following summarizes our contractual obligations at June 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)	$ 6,267	$ -	-
TOTALS	**$ 6,267**	**$ -**	**$ -**

(1) Currently we occupy the same office space since August 2006, but are under a month to month lease.

Equity Transactions

On February 9, 2007, we completed the sale of 11,680,850 shares of our common stock to institutional investors and certain of our officers and directors for a purchase price of $5,490,000. We filed a registration statement with the Securities and Exchange Commission covering the shares of common stock issued and issuable pursuant to the exercise of certain placement agent warrants, and it 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 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, $0.246.

On February 21, 2007, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") relinquished its exclusive rights granted to it on January 3, 2007, under a letter of intent with regard to acquisition discussions. However, all other terms of the letter of intent remained in effect, and we are still engaged in discussions with Sigma-Tau for a European collaboration relating to orBec®. In accordance with the letter of intent, Sigma-Tau purchased $1,000,000 of our common stock at the market price of $0.246 per share, representing 4,065,041 shares of common stock, and paid us 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 from Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because no definitive 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). We returned the $2 million on June 1, 2007 and satisfied the obligation.

On February 28, 2007, our Board of Directors approved the issuance of 2,700,000 shares of our common stock to certain employees and a consultant. Such shares will be issued immediately prior to the completion of a transaction, or series or combination of related transactions, negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party (an "Acquisition Event"). Of the shares of common stock to be issued upon an Acquisition Event, 1,000,000 shares will be issued to Christopher J. Schaber, a director and our Chief Executive Officer and President; 750,000 shares will be issued to Evan Myrianthopoulos, a director and our Chief Financial Officer; and 300,000 shares will be issued to James Clavijo, our Controller, Treasurer, and Corporate Secretary. We expect to enter into agreements with Dr. Schaber, Mr. Myrianthopoulos and Mr. Clavijo with regard to the arrangement described above. We expect that such agreements will include terms and conditions customary to agreements of such type.

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 into the second quarter of 2008. 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 including a possible launch of orBec®, 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.

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ITEM 3 - CONTROLS AND PROCEDURES

Our Chief Executive Officer and our Chief Financial Officer (the "Certifying Officers") are responsible for establishing and maintaining disclosure controls and procedures. Such officers have concluded (based upon their evaluations of these controls and procedures as of the end of the period covered by this report) that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in this report is accumulated and communicated to management, including the Certifying Officers as appropriate, to allow timely decisions regarding required disclosure.

The Certifying Officers have also indicated that there were no changes in our internal controls over financial reporting or other factors that occurred during the period cover by this report that has materially affected, or is likely to materially affect, such controls, and there were no significant deficiencies and material weaknesses.

Our management, including the Certifying Officers, does not expect that our disclosure controls or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any systems of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of these inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

PART II - OTHER INFORMATION.

ITEM 4 - 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
32.1 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1 Risk Factors

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SIGNATURES

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

DOR BIOPHARMA, INC.

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

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