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

The accompanying notes are an integral part of these financial statements

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.