DOR BIOPHARMA INC
Form 10QSB
May 12, 2006

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 March 31, 2006

( ) 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)
1691 Michigan Ave., Suite 435 Miami, FL	**33139**
(Address of principal executive offices)	(Zip Code)

(305) 534-3383
(Issuer's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 May 8, 2006, 65,395,814 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

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

Table of Contents

PART I. - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

DOR BioPharma, Inc.
Consolidated Balance Sheet
March 31, 2006
(Unaudited)

Assets		
Current assets:		
Cash and cash equivalents	**$**	**328,109**
Grants receivable		**1,105,480**
Prepaid expenses		**135,043**
Total current assets		**1,568,632**
Office and laboratory equipment, net		**39,097**
Intangible assets, net		**1,849,990**
Total assets	$	**3,457,719**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$	**3,011,554**
Accrued compensation		**192,958**
Total current liabilities		**3,204,512**
Shareholders' equity:		
Common stock, $.001 par value. Authorized 150,000,000		
shares; 52,195,327 issued and outstanding		**52,195**
Additional paid-in capital		**86,475,645**
Accumulated deficit		**(86,274,633)**
Total shareholders' equity		**253,207**
Total liabilities and shareholders' equity	$	**3,457,719**

The accompanying notes are an integral part of these financial statements

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

		2006		2005
Revenues:	**$**	**1,387,632**	$	113,540
Cost of revenues		**(1,039,404)**		(90,213)
Gross profit		**348,228**		23,327
Operating expenses:				
Research and development		**1,225,425**		729,985
General and administrative		**833,193**		341,935
Total operating expenses		**2,058,618**		1,071,920
Loss from operations		**(1,710,390)**		(1,048,593)
Other income (expense):				
Interest and other income		**3,489**		21,596
Interest expense		**-**		(2,3718)
Total other income (expense)		**3,489**		19,278
Net loss	$	**(1,706,901)**	$	(1,029,315)
Basic and diluted net loss per share	$	**(0.03)**	$	(0.02)
Basic and diluted weighted average common shares outstanding		**51,221,889**		46,974,194

The accompanying notes are an integral part of these financial statements

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

		2006		2005
Operating activities:				
Net loss	**$**	**(1,706,901)**	$	(1,029,315)
Adjustments to reconcile net loss to net cash used by operating activities:				
Amortization and depreciation		**50,631**		65,517
Non-cash stock option compensation		**(193,749)**		(284,855)
Change in operating assets and liabilities:				
Grants receivable		**(541,150)**		682,590
Prepaid expenses		**3,751**		(34,676)
Accounts payable		**1,375,654**		(563,776)
Accrued royalties		**(60,000)**		-
Accrued compensation		**44,358**		-
Total adjustments		**1,066,993**		(135,200)
Net cash used by operating activities		**(639,908)**		(1,164,515)
Investing activities:				
Acquisition of intangible assets		**(92,005)**		(182,349)
Purchases of equipment		**-**		(2,856)
Net cash used by investing activities		**(92,005)**		(185,205)
Financing activities:				
Net proceeds from sale of common stock		**125,000**		3,552,157
Proceeds from exercise of stock options		**113,320**		-
Net cash provided by financing activities		**238,320**		3,552,157
Net increase (decrease) in cash and cash equivalents		**(493,593)**		2,202,437
Cash and cash equivalents at beginning of period		**821,702**		2,332,190
Cash and cash equivalents at end of period	**$**	**328,109**	$	4,534,627
Non-cash transactions:				
Non-cash stock payment to an institutional investor	**$**	**220,374**	$	-

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 "Company") is a research and development biopharmaceutical company incorporated in 1987, focused on the development of biotherapeutic products and biodefense vaccines and intended for areas of unmet medical need. DOR's biotherapeutic business segment focuses on the development and regulatory approval of orBec®, which is intended to treat gastrointestinal Graft-versus-Host disease. In addition, the Company has several other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs. DOR's biodefense business segment consists of the development of RiVax™, DOR's vaccine against ricin toxin and BT-VACC™, DOR's vaccine against botulinum toxin. DOR's biodefense segment focuses on converting biodefense vaccine programs from early stage development to advanced development and manufacturing.

During the quarter ending March 31, 2006, the Company had one customer, the U.S. Federal Government. All revenues were generated from two U.S. Federal Government Grants. As of March 31, 2006 all outstanding receivables were from the U.S. Federal Government, National Institute of Health and The Food and Drug Administration ("Government").

2. Summary of Significant Accounting Policies

Basis of Presentation

These unaudited interim consolidated financial statements of DOR BioPharma, Inc. ("we" or "us") were prepared under the rules and regulations for reporting on Form 10-QSB. Accordingly, we omitted some information and note disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with our audited consolidated financial statements and their notes included in our annual report on Form 10-KSB for the year ended December 31, 2005. 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 Government that were billed in the month subsequent to period end. The Company considers accounts receivable to be fully collectible; accordingly, no allowance for doubtful accounts has been established. If accounts become uncollectible, the balances will be charged to operations at the time the determination is made.

Intangible Assets

Intangible assets consist of patent costs, principally legal fees, and, upon application for the patent, are amortized on a straight-line basis over the shorter of the estimated useful life of the patent or the regulatory life.

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.

The Company did not record impairment of intangible assets for the quarter ended March 31, 2006 and 2005, respectively.

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 three months ended March 31, 2006 was $108,695 lower than if it had continued to account for share-based compensation under APB No. 25. Basic and diluted earnings per share for the three months ended March 31, 2006 would not have changed if the Company had not adopted SFAS No. 123R.

The fair value of each option grant at March 31, 2006 is estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. 200,000 stock options were granted for the three months ended March 31, 2006.

Pro forma information, assuming the Company had accounted for its employee and director stock options granted under the fair value method prescribed by SFAS NO. 123R for the three months ended March 31, 2005 is presented below:

Net Loss applicable to common shareholders	
As reported	$(1,029,315)
Add stock-based employee compensation expense related to stock options determined under fair value method	(91,197)
Amounts (credited) charged to income	(284,855)
Pro forma net loss according to SFAS 123	$ (1,405,367)
Net loss per share:	
As reported, basic and diluted	$ (0.02)
Pro forma, basic and diluted	$ (0.03)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.38 and $0.43 for 2006 and 2005, 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 127% and 128% in 2006 and 2005, respectively and average risk-free interest rates in 2006 and 2005 of 3.43% and 3.60%, 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 periodically remeasured as the options vest.

Net Loss Per Share

In accordance with accounting principles generally accepted in the United States, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during respective periods (excluding shares that are not yet issued). The effect of stock options, warrants and convertible preferred stock is antidilutive for all periods prescribed. There were options to purchase approximately 9.8 million and 12.2 million shares of the Company's common stock outstanding at March 31, 2006, and 2005, respectively.

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.29 and $0.55 for 2005 and 2004, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 120% and 105% in 2005 and 2004, respectively and average risk-free interest rates in 2005 and 2004 of 3.96% and 4.00%, 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 periodically remeasured as the options vest.

---

3. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
March 31, 2006	10.1	$ 2,697,442	$ 847,452	$ 1,849,990
December 31, 2005	10.2	$ 2,605,472	$ 802,452	$ 1,803,020

Amortization expense was $45,000 and $45,785 for the quarters ended March 31, 2006 and 2005.

Based on the balance of the intangibles at March 31, 2006, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
2006	$ 170,000
2007	170,000
2008	170,000
2009	170,000
2010	170,000

License fees and royalty payments are expensed annually.

4. Shareholders' Equity

During the period ended March 31, 2006, 504,100 stock options were exercised to purchase shares of common stock.

During the period ended March 31, 2006, the Company issued 81,018 shares of common stock as payment to vendors for consulting services. An expense of $21,909 was recorded which approximated the shares' fair market value on the date of issue. During the period ended March 31, 2006, the Company issued 155,665 shares of common stock as part of severance payments to terminated employees. An expense of $63,146 was recorded, which approximated the shares' fair market value on the date of issue. These shares of common stock issued are covered by the Company's Form S-8 Registration Statement filed with the SEC on December 30, 2005.

On January 17, 2006, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). Fusion Capital agreed to purchase on each trading day $20,000 of common stock up to an aggregate of $6,000,000 million over approximately a 15-month period, subject to earlier termination at the Company's discretion. During the period, the Company sold 329,540 shares of common stock to Fusion Capital for $125,000 and issued 512,500 shares of common stock as a commitment fee. Pursuant to the terms of the April 2006 private placement, the Company may not access the funds available under the Fusion Capital commitment by selling shares of common stock to Fusion Capital without the prior consent of Iroquois until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the New Drug Application for orBec® or (ii) the date the FDA responds to the New Drug Application for orBec®. If and when the Company resumes selling stock to Fusion Capital, it may elect to sell less common stock to Fusion Capital than the daily amount and may increase the daily amount as the market price of the stock increases. The Company may sell shares of common stock to Fusion Capital based upon the future market price of the common stock without any fixed discount. Fusion Capital does not have the right or the obligation to purchase shares of DOR common stock in the event that the price of the common stock is less than $0.12. The Company only has the right to receive $20,000 per trading day under the agreement with Fusion Capital unless the stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of the common stock increases.

5. Contingencies

On October 28, 2005, the Company entered into a letter of intent to acquire Gastrotech Pharma A/S ("Gastrotech"), a private Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. The letter of intent provided for a $1,000,000 breakup fee in the event a party notified the other of its intention not to proceed with the transaction. On January 26, 2006, the Company advised Gastrotech that the Company was not renewing the Company's letter of intent with Gastrotech, which had expired in accordance with its terms on January 15, 2006. The Company has been advised by the attorney representing Gastrotech that if the Company is not willing to comply with the terms in the letter of intent, the Company will be in material breach of its obligations under the letter of intent and will be obligated to pay Gastrotech a break-up fee of $1,000,000. The Company's position is that it does not owe Gastrotech such break-up fee.

6. Subsequent Events

On May 10, 2006, we completed a merger pursuant to which Enteron, the common stock of which we held 89.13% prior to the merger, was merged into a wholly-owned subsidiary of ours. Pursuant to this transaction, we issued 3,068,183 shares of our common stock to the Enteron Shareholders in exchange for all of the outstanding common stock of Enteron that we did not already own.

On April 10, 2006, the Company completed the sale of 13,099,964 shares of common stock to institutional and other accredited investors for a purchase price of $3,630,000. The investors also received warrants to purchase an aggregate of 13,099,964 shares of common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. Pursuant to a registration rights agreement, we agreed to file a registration statement with the Securities and Exchange Commission in order to register the resale of the shares.

7. Business Segments

The Company had two active segments for the three months ended March 31, 2006 and 2005: BioDefense and BioTherapeutics.

	For the three months ended March 31,	
	2006	2005
Revenues		
BioDefense	**$ 1,341,533**	$ 113,540
BioTherapeutics	**46,099**	-
Total	**$ 1,387,632**	$ 113,540
Income (Loss) from Operations		
BioDefense	**$ 153,278**	$ (315,708)
BioTherapeutics	**(1,050,331)**	(285,754)
Corporate	**(813,337)**	(447,131)
Total	**$ (1,710,390)**	$ (1,048,593)
Amortization and Depreciation Expense		
BioDefense	**$ 37,407**	$ 31,792
BioTherapeutics	**10,408**	30,712
Corporate	**2,816**	3,013
Total	**$ 50,631**	$ 65,517
Identifiable Assets		
BioDefense	**$ 2,724,037**	$ 1,649,587
BioTherapeutics	**321,434**	443,573
Corporate	**412,248**	4,646,215
Total	**$ 3,457,719**	$ 6,739,375

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, 2005. 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 biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of gastrointestinal Graft-versus-Host Disease, "GVHD" as well as to prepare submission of a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicine Agency ("EMEA"); (b) consider prophylactic use studies of orBec® for the prevention of gastrointestinal GVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; (i) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs as resources permit; and (j) acquire or in-license new clinical-stage compounds for development. We were incorporated in 1987. We maintain two active segments; BioTherapeutics and BioDefense.

orBec®

Our goal is to file an NDA for orBec® (oral beclomethasone dipropionate) with the FDA for the treatment of gastrointestinal GVHD in the second quarter of 2006. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA 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.

In our pivotal phase 3 clinical trial of 129 post-bone marrow transplant patients presenting with Grade II gastrointestinal GVHD, orBec® demonstrated a strong positive trend on the primary endpoint of median time to treatment failure at study day 50 and a statistically significant result in the prospectively defined endpoint of median time to treatment failure at study day 80 (p-value 0.0226). Perhaps of greater clinical relevance, orBec® demonstrated a 67% reduction in mortality, registering only 5 deaths or 8%, during the prospectively defined Day 200 post-transplant period versus 16 deaths or 24%, for the placebo group (p-value 0.011). Based upon separate analysis conducted by us, there is also a statistically significant correlation between treatment failure and mortality. In the earlier Phase II trial, there were reductions in the risk of mortality of 55% and 43% at transplant day-200 and one year post-randomization among patients randomized to oral beclomethasone dipropionate, respectively.

We anticipate the market potential for orBec® for the treatment of gastrointestinal GVHD to be between 50 and 70 percent of the approximately 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 may seek a marketing partner 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 an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

RiVax™

The development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. Our academic partner, The University of Texas Southwestern led by Dr. Ellen Vitetta recently completed a Phase I safety and immunogenicity trial of RiVax™ in human volunteers. The results of the Phase I 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 recently 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. We recently announced that Cambrex has successfully achieved the second milestone of our collaboration of fermentation and downstream process development under their development and manufacturing agreement.

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a mucosal 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. Our preclinical data to date, demonstrates that Hc50, A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. 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. 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.

Ongoing studies are focused on serotype E and multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals. Further, we are engaged in formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™, a high yield expression system based on *Pseudomonas fluorescens.* Up to this point we have successfully demonstrated successful high expression of soluble material from all three Hc50 vaccine candidates.

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 I 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.

LPM™ - Leuprolide

LPM™ - Leuprolide is an oral dosage formulation of the peptide drug leuprolide, a hormone-based drug that is among the leading drugs used to treat endometriosis and prostate cancer, which utilizes a novel drug delivery system composed of safe and well characterized ingredients to enhance intestinal absorption. The LPM™ system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides. Although both small molecules and large molecules can be incorporated into our system, there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with hydrophilic drugs/peptides below 5,000 Daltons in molecular weight. Utilizing a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

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

We were developing 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.

Material Letter of Intent - Acquisition of Gastrotech Pharma

On October 28, 2005, we entered into a binding letter of intent to acquire Gastrotech Pharma A/S ("Gastrotech"), a private Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. On January 26, 2006, we advised Gastrotech that we were not renewing the letter of intent, which had expired in accordance with its terms on January 15, 2006. The letter of intent provided for a $1 million break-up fee in the event a party notifies the other of its intention not to proceed with the transaction. On January 30, 2006, we were advised by the attorney representing Gastrotech that if we were not willing to comply with the terms of the letter of intent, we would be in material breach of our obligations under the letter of intent and would be obligated to pay Gastrotech a break-up fee of $1 million. Our position is that we do not owe Gastrotech such break-up fee.

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 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.

Research and Development Costs

Research and Development costs are charged to expense when incurred and 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. Similar to many cost-reimbursable grants, these governmental grants are typically subject to audit and adjustment by the government.

Revenue Recognition

We recognize revenue from Government grants. These revenues are recorded in the period in which they are earned. The consideration we receive is based upon a cost plus Facilities and Administrative (F&A) rate that provides funding for overhead expenses.

Material Changes in Results of Operations

We are a research and development company. The 2006 revenues and associated expenses were from an NIH Grant which we received in September 2004 and for an FDA grant which we received in September 2005. The NIH grant was associated with our ricin vaccine. The original amount of the 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 new renegotiated F&A (facilities and administrative) rate with the NIH. Part of this increase was attributed to the NIH reimbursement for overhead expenses for 2004 in the amount of $285,891 in the second quarter of 2005. This new rate provided a fixed rate for facilities and administrative costs (overhead expenditures) that is applied against all costs associated with the grant awarded. The FDA grant was awarded on September 23, 2005 for the "Oral BDP for the Treatment of GI GVHD." We began recognizing revenue for this grant in the fourth quarter of 2005. The total amount of the one-year grant is $318,750.

For the three months ended March 31, 2006 we had grant revenues of $1,387,632 as compared to $113,540 in the three months ended March 31, 2005, an increase of $1,274,092, or 1122%. Progress of the grant has 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 2006 and 2005 of $1,039,404 and $90,213, respectively, an increase of $949,191, or 1052%. 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 March 31, 2006 was $348,228 as compared to $23,327 in the three months ended March 31, 2005, an increase of $324,901, or 1393%.

For the three months ended March 31, 2006, we had a net loss of $1,706,901 as compared to a $1,029,315 net loss for the three months ended March 31, 2005, a decrease of $677,586, or 66%.

Research and development expenditures increased $495,440, or 68%, to $1,225,425, for the three months ended March 31, 2006 as compared to $729,985 for the corresponding period ended March 31, 2005 due to the increased regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®.

General and administrative expenses increased $491,258, or 144%, to $833,193 for the three months ended March 31, 2006, as compared to $341,935 for the corresponding period ended March 31, 2005. This increase was primarily attributed to a recovery of $284,855 in 2005 from reported income in 2004 for the variable accounting treatment of options granted to new employees under the stock option plan that exceeded the number of allowed stock options under the plan. The increase was also due to stock option expense of $108,695 for stock options vested and issued in the period ending March 31, 2006 under the new accounting treatment under SFAS No. 123R. Additionally, we had non-recurring acquisition costs of approximately $116,000 associated with the acquisition of a pharmaceutical company.

Interest income for the three months ended March 31, 2006 was $3,489 as compared to $21,596 for the three months ended March 31, 2005, representing a decrease of $18,107 or 84%. This decrease was primarily due to a lower interest bearing cash balances in 2006 as compared to 2005.

Interest expense for the three months ended March 31, 2006 was zero as compared to $2,318 for the three months ended March 31, 2005, a decrease of $2,318 or 100%. This decrease was due to a note payable paid in the third quarter of 2005.

FINANCIAL CONDITION:

As of March 31, 2006, we had cash and cash equivalents of $328,109 as compared to $821,702 as of December 31, 2005, and negative working capital of $1,635,881 as compared to negative working capital of $319,675 as of December 31, 2005 an increase of $1,316,206. For the three months ended March 31, 2006, our cash used in operating activities was $639,908, compared to $1,164,515 for the three months ended March 31, 2005.

We expect our research and development expenditures for 2006, under existing product development agreements and license agreements pursuant to letters of intent and option agreements, to approximate $3,600,000. We anticipate grant revenues to offset research and development expenses of our ricin vaccine in the amount of approximately $1,000,000 with $550,000 contributing towards our overhead expenses. This revenue will be available pending the completion of certain milestones.

The following summarizes our contractual obligations at March 31, 2006, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligations	Year 2006	Year 2007	Year 2008
Non-cancelable obligations (1)	$ 52,628	$ -	$ -
TOTALS	**$ 52,628**	**$ -**	**$ -**

(1) 3 year lease on corporate office entered into in 2003 and expiring in 2006.

On April 10, 2006, we completed the sale of 13,099,964 shares of our common stock to institutional and other accredited investors for a purchase price of $3,630,000. The investors also received warrants to purchase an aggregate of 13,099,964 shares of our common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. We have agreed to file a registration statement with the Securities and Exchange Commission in order to register the resale of the shares.

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC. Fusion has agreed to purchase on each trading day $20,000 of our common stock up to an aggregate of $6,000,000 million over approximately a 15-month period, subject to earlier termination at our discretion. We have sold 329,540 shares of common stock to Fusion Capital. Pursuant to the terms of our April 2006 private placement, we may not access the funds available under the Fusion Capital commitment by selling our shares of common stock to Fusion Capital without the prior consent of Iroquois Capital until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the New Drug Application for orBec® or (ii) the date the FDA responds to the New Drug Application for orBec®. If and when we resume selling stock to Fusion Capital, we may elect to sell less of our common stock to Fusion Capital than the daily amount and we may increase the daily amount as the market price of our stock increases. We will sell our shares of common stock to Fusion Capital based upon the future market price of the common stock without any fixed discount. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12. We only have the right to receive $20,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of our common stock increases.

Based on our current rate of cash outflows, and provided we have access to the Fusion continuous secondary facility, we believe that our cash will be sufficient to meet our anticipated cash needs for working capital and capital

expenditures through the second quarter of 2007. 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.

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 significant changes in our internal controls over financial reporting or other factors that could significantly affect such controls subsequent to the date of their evaluation, 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.
32.2 Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1 Risk Factors

SIGNATURES

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

DOR BIOPHARMA, INC.

May 12, 2006 by /s/ Michael T. Sember
Michael T. Sember
President and Chief Executive Officer

May 12, 2006 by /s/ Evan Myrianthopoulos
Evan Myrianthopoulos
Chief Financial Officer