

DOR BIOPHARMA INC  
Form 10QSB  
August 15, 2005

---

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

**FORM 10-QSB**

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

**For the Quarterly Period Ended June 30, 2005**

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**

(State or other jurisdiction of  
incorporation or organization)

**41-1505029**

(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)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15 (d) of the Securities 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  No

At August 5, 2005, 50,612,504 shares of the registrant's common stock (par value, \$.001 per share) were outstanding.

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



**Table of Contents**

<b>Item</b>	<b>Description</b>	<b>Page</b>
<b>Part I</b>	<b>FINANCIAL INFORMATION</b>	
1.	Financial Statements.	3
2.	Management's Discussion and Analysis.	12
3.	Controls and Procedures.	17
<b>Part II</b>	<b>OTHER INFORMATION</b>	
4.	Exhibits.	18

---

**PART I. - FINANCIAL INFORMATION****ITEM 1 - FINANCIAL STATEMENTS**

DOR BioPharma, Inc.  
Consolidated Balance Sheet  
June 30, 2005  
(Unaudited)

**Assets**

## Current assets:

Cash and cash equivalents	\$	3,189,628
Accounts receivable		435,075
Prepaid expenses		55,604
Total current assets		3,680,307

Office and laboratory equipment, net		51,153
Intangible assets, net		2,051,188
Total assets	\$	5,782,648

**Liabilities and shareholders' equity**

## Current liabilities:

Accounts payable	\$	841,432
Accrued compensation and other expenses		148,373
Notes payable		115,948
Total current liabilities		1,105,753

## Shareholders' equity:

Preferred stock, \$.001 par value. Authorized 4,600,000 shares; none issued and outstanding		-
Common stock, \$.001 par value. Authorized 100,000,000 shares; 50,612,504 issued and outstanding		50,612
Additional paid-in capital		86,045,192
Accumulated deficit		(81,418,909)
Total shareholders' equity		4,676,895
Total liabilities and shareholders' equity	\$	5,782,648

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)

	<b>2005</b>	2004
Revenues:	\$ <b>1,422,703</b>	\$ -
Cost of revenues	<b>(829,639)</b>	-
Gross profit	<b>593,064</b>	-
Operating expenses:		
Research and development	<b>736,905</b>	990,013
General and administrative	<b>423,873</b>	498,894
Total operating expenses	<b>1,160,778</b>	1,488,907
Loss from operations	<b>(567,714)</b>	(1,488,907)
Other income (expense):		
Interest and other income	<b>27,002</b>	22,432
Interest expense	<b>(700)</b>	(6,901)
Total other income (expense)	<b>26,302</b>	15,531
Net loss	\$ <b>(541,412)</b>	\$ (1,473,376)
Basic and diluted net loss per share	\$ <b>( 0.01)</b>	\$ ( 0.04)
Basic and diluted weighted average common shares outstanding	<b>50,612,504</b>	41,870,601

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)

	2005	2004
Revenues:	\$ 1,536,243	\$ 66,095
Cost of revenues	(919,852)	(59,486)
Gross profit	616,391	6,609
Operating expenses:		
Research and development	1,466,891	1,689,524
General and administrative	765,808	977,471
Total operating expenses	2,232,699	2,666,995
Loss from operations	(1,616,308)	(2,660,386)
Other income (expense):		
Interest and other income	48,599	39,368
Interest expense	(3,018)	(15,173)
Total other income (expense)	45,581	24,195
Net loss	(1,570,727)	(2,636,191)
Preferred stock dividends	-	(503,195)
Net loss applicable to common shareholders	\$ (1,570,727)	\$ (3,139,386)
Basic and diluted net loss per share applicable to common shareholders	\$ ( 0.03)	\$ ( 0.08)
Basic and diluted weighted average common shares outstanding	48,793,349	39,100,797

**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)

	2005	2004
<b>Operating activities:</b>		
Net loss	\$ (1,570,727)	\$ (2,636,191)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	89,199	203,150
Non-cash stock option compensation	(284,855)	104,528
Change in operating assets and liabilities:		
Accounts receivable	307,912	20,954
Prepaid expenses	4,000	80,574
Accounts payable	(978,378)	8,437
Total adjustments	(862,122)	417,643
Net cash used by operating activities	(2,432,849)	(2,218,548)
<b>Investing activities:</b>		
Acquisition of intangible assets	(274,879)	(172,281)
Purchases of equipment	(13,358)	(5,673)
Net cash used by investing activities	(288,237)	(177,954)
<b>Financing activities:</b>		
Net proceeds from issuance of common stock	3,578,524	3,040,086
Proceeds from exercise of options	-	61,972
Repayments of amounts due under line of credit, notes payable and capital lease obligations	-	(254,783)
Net cash provided by financing activities	3,578,524	2,847,275
Net increase in cash and cash equivalents	857,438	450,773
Cash and cash equivalents at beginning of period	2,332,190	4,117,540
Cash and cash equivalents at end of period	\$ 3,189,628	\$ 4,568,313
<b>Supplemental disclosure of cash flow:</b>		
Cash paid for interest	\$ -	\$ 15,173
<b>Non-cash transactions:</b>		
Issuance of preferred stock dividend in kind	\$ -	\$ 171,535

The accompanying notes are an integral part of these financial statements

**DOR BioPharma, Inc.**  
**Notes to Consolidated Financial Statements**

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, 2004. In our 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.

#### NET LOSS PER SHARE

Net loss per share is presented in accordance with Statement of Financial Accounting Standards (SFAS) No. 128 for the current and prior periods. We had a net loss for all periods presented, which resulted in diluted and basic earnings per share being the same for all of those periods presented. The potential impact of warrants and stock options outstanding was not included in the calculation because their inclusion would have been anti-dilutive.

#### STOCK BASED COMPENSATION

We have stock-based employee compensation plans. SFAS No. 123, “Accounting for Stock-Based Compensation,” encourages, but does not require companies to record compensation cost for stock-based employee compensation plans at fair value. We have chosen to continue using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees,” and related interpretations, in accounting for our stock option plans.

We have potential common stock equivalents related to our outstanding stock options. These potential common stock equivalents were not included in diluted loss per share because the effect would have been anti-dilutive. Accordingly, basic and diluted loss per common share and the weighted average number of shares used in the computations are the same for each of the periods presented. There were options to purchase approximately 12.2 million and 8.5 million shares of our common stock outstanding at June 30, 2005, and 2004, respectively.

Had compensation cost been determined based upon the fair value at the grant date for awards under the stock option plans based on the provisions of SFAS No. 123, our pro forma net loss and net loss per share would have been as follows for the six months ended:

	<b>June 30,</b>	
	2005	2004
<b>Net Loss applicable to common shareholders</b>		
As reported	\$(1,570,727 )	\$(3,139,386 )
Add stock-based employee compensation expense related to stock options determined under fair value method	<b>(236,974 )</b>	(1,028,554)
Pro forma net loss according to SFAS 123	<b>\$ (1,807,701 )</b>	\$ ( 4,167,940 )
<b>Net loss per share:</b>		
As reported, basic and diluted	<b>\$ ( 0.03 )</b>	\$ ( 0.08 )
Pro forma, basic and diluted	<b>\$ ( 0.04 )</b>	\$ ( 0.11 )



The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was \$0.48 and \$0.56 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 128% and 129% in 2005 and 2004, respectively and average risk-free interest rates in 2005 and 2004 of 3.4% and 3.5%, 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, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," 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.

## INTANGIBLE ASSETS

Patent costs, principally legal fees, are capitalized and, upon issuance of the patent, are amortized on a straight-line basis over the shorter of the estimated useful life of the patent or the regulatory life. Licenses of technology with alternative future use are capitalized and are amortized on a straight-line basis over the shorter of the estimated useful life or the regulatory life. Licenses of technology with no alternative future use are expensed as incurred. The useful lives of our patent and license costs at June 30, 2005 ranged from 11 to 16 years. The following is a summary of patent and license assets:

	<b>Weighted Average Amortization period (years)</b>	<b>Cost</b>	<b>Accumulated Amortization</b>	<b>Net Book Value</b>
June 30, 2005	10.7	\$ 2,886,072	\$ 834,884	\$ 2,051,188
December 31, 2004	10.6	\$ 2,611,195	\$ 728,741	\$ 1,882,454

Amortization expense was \$44,103 and \$106,143 for the three months and six months ended June 30, 2005, respectively.

Based on the balance of the intangibles at June 30, 2005, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	<b>Amortization Amount</b>
2005	\$ 193,000
2006	173,000
2007	173,000
2008	173,000
2009	173,000

## Impairment of Long-Lived Assets

Office and laboratory equipment, and intangible assets are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes

impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets 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 recognize any impairment in the quarter ended June 30, 2005.

#### NOTE PAYABLE

Note payable was as follows:

	<b>June 30, 2005</b>	December 31, 2004
Note payable to pharmaceutical company	<b>\$ 115,948</b>	\$ 115,948

On June 29, 2002, DOR and a pharmaceutical company signed an agreement for the dissolution of their joint ventures. Based on this agreement, DOR retained the joint venture entities, InnoVaccines and Newco. In connection with the settlement, the Company's balance of \$2,042,833 due to joint ventures at December 31, 2001 was restructured into payments totaling \$1,104,242: \$524,500 paid immediately in cash and the remaining \$579,742 payments of principal and interest of \$231,897 were due on June 30, 2003, \$231,897 on June 30, 2004 and \$115,948 on December 30, 2004, respectively.

The note payable of \$115,948 to a pharmaceutical company was not paid as of its due date at the end of December 31, 2004. The note is in default. Interest continues to accrue at 8%. We are expecting to pay the note in full by the end of the third quarter 2005.

#### SIGNIFICANT CONCENTRATIONS

During the six months ended June 30, 2005, the Company had one customer, the United States federal government. All revenues generated in the six months ended June 30, 2005, were from one United States federal government grant from the NIH.

**BUSINESS SEGMENTS**

The Company had two active segments for the six months ended June 30, 2005 and 2004: BioDefense and BioTherapeutics. Summary data for the three months and six months ended:

	<b>For the three months ended June 30,</b>	
	<b>2005</b>	<b>2004</b>
<b>Net Revenues</b>		
BioDefense	\$ 1,422,703	\$ -
BioTherapeutics	-	-
<b>Total</b>	<b>\$ 1,422,703</b>	<b>\$ -</b>
<b>Income (Loss) from Operations</b>		
BioDefense	\$159,234	\$(312,807)
BioTherapeutics	(297,654)	(462,516)
Corporate	(429,294)	(713,584)
<b>Total</b>	<b>\$( 567,714)</b>	<b>\$(1,488,907)</b>
<b>Amortization and Depreciation Expense</b>		
BioDefense	\$ 33,948	\$ 15,262
BioTherapeutics	31,292	48,749
Corporate	3,329	1,401
<b>Total</b>	<b>\$ 68,569</b>	<b>\$ 65,412</b>
	<b>June 30, 2005</b>	<b>December 31, 2004</b>
<b>Identifiable Assets</b>		
BioDefense	\$ 2,058,592	\$ 2,192,097
BioTherapeutics	450,995	230,048
Corporate	3,273,061	2,645,570
<b>Total</b>	<b>\$ 5,782,648</b>	<b>\$ 5,067,715</b>

	For the six months ended June 30,	
	2005	2004
<b>Net Revenues</b>		
BioDefense	\$ 1,536,243	\$ 66,095
BioTherapeutics	-	-
<b>Total</b>	<b>\$ 1,536,243</b>	<b>\$ 66,095</b>
<b>Income (Loss) from Operations</b>		
BioDefense	\$ ( 68,672 )	\$ (558,925 )
BioTherapeutics	(557,623 )	(826,426 )
Corporate	(990,013 )	(1,275,035 )
<b>Total</b>	<b>\$( 1,616,308 )</b>	<b>\$(2,660,386 )</b>
<b>Amortization and Depreciation Expense</b>		
BioDefense	\$ 65,740	\$ 47,400
BioTherapeutics	39,026	151,399
Corporate	6,342	4,351
<b>Total</b>	<b>\$ 111,108</b>	<b>\$ 203,150</b>

---

## **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 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, 2004. 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 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 for orBec<sup>®</sup> with the U.S. Food and Drug Administration for the treatment of acute Graft-versus-Host Disease with gastrointestinal involvement; (b) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec<sup>®</sup>) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (c) consider prophylactic use studies of orBec<sup>®</sup>; (d) identify a marketing and sales partner for orBec<sup>®</sup> in the U.S. and abroad; (e) secure government funding for each of our biodefense programs through grants and procurement contracts; (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; and (i) acquire or in-license new clinical-stage compounds for development.

### **orBec<sup>®</sup>**

We intend to file a New Drug Application (“NDA”) with the FDA for orBec<sup>®</sup> for the treatment of intestinal Graft versus Host Disease (iGVHD) by the fourth quarter 2005. 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.

We anticipate the market potential for orBec<sup>®</sup> for the treatment of iGVHD to be at least 50 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<sup>®</sup>. We are seeking a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec<sup>®</sup>. We also intend to seek a partner for the other potential indications of orBec<sup>®</sup>. We are also evaluating an alternative strategy of a commercial launch of orBec<sup>®</sup> by ourselves in the U.S.

### **RiVax<sup>™</sup>**

The scientific development of RiVax<sup>™</sup>, our ricin toxin vaccine, has progressed significantly this year. We initiated a Phase I safety and immunogenicity trial in February of this year and we have recently announced positive interim safety and immunogenicity data. In January of this year we entered into a manufacturing and supply agreement for RiVax<sup>™</sup> with Cambrex Corporation. We recently announced that Cambrex has successfully achieved the first milestone of fermentation and downstream process development under their development and manufacturing agreement. RiVax<sup>™</sup> is being developed for intramuscular delivery. We are also working on a formulation technology that could permit the vaccine to be delivered nasally, with the objective of providing immunity in the respiratory tract.

### **BT-VACC<sup>™</sup>**

Our oral botulinum toxin vaccine program has made important strides this year and we have identified a lead antigen against Serotypes A and B of botulinum toxin. Additionally we are working towards a lead antigen against Serotype E, the third deadly serotype of botulinum toxin. We are in the process of validating the data and creating a multivalent botulinum vaccine with Thomas Jefferson University. To date much of the work at Thomas Jefferson University has been funded by us and we have applied for and intend to continue to apply for research grants from the U.S. government. We have also recently entered into a joint development agreement with Dowpharma. Dowpharm will provide process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC<sup>™</sup> using its Pfēnex Expression Technology<sup>™</sup>, a *Pseudomonas*-based technology that accelerates speed to

market for vaccines and biotherapeutics by surpassing the quality and yield capabilities of existing microbial systems.

The goal of our biodefense program is to supply the United States government with qualified countermeasures that can protect citizens against ricin toxin and botulinum toxin exposure.

### **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.

### **Research and Development Costs**

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 of patents, as well as amounts paid allowing us to license additional methods of vaccine delivery through the Southern Research Institute patents, shares issued to acquire Élan's interest in the Innovaccine's Joint Venture, and amounts paid to University of Texas Southwestern Medical Center allowing us the ability to license certain patents related to a vaccine protecting against ricin toxin. 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.

### **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. This F&A rate is a rate that provides funding for overhead expenses. In the second quarter of 2005, a new renegotiated F&A rate was established with the NIH. The F&A rate for 2004 was 40%. The F&A rate for 2005 was 30%. The result of this rate was an increase to the original grant of \$5,173,298 to \$6,433,316. 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.

### **Intangibles**

We capitalize and amortize intangibles over a period of 11 to 16 years. In the current year intangibles have increased by approximately \$268,000. This increase is attributed to 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. In the current year the primary increase was attributed to the initial filings for our botulinum program.

### **Material Changes in Results of Operations**

We are a research and development company. The 2005 revenues and associated expenses were from a National Institute of Health (NIH) Grant which we received in September 2004. The 2004 revenues and associated expenses resulted from a Small Business Innovation Research (SBIR) grant we received in September 2003. Both grants were for further research 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 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.

For the three months ended June 30, 2005 we had grant revenues of \$1,422,703 as compared to zero in the three months ended June 30, 2004. For the six months ended June 30, 2005, we had grant revenues of \$1,536,243, an increase of \$1,470,148, as compared to revenues of \$66,095 for the same period in 2004. The 2005 revenue includes \$285,891 that was attributed to the NIH reimbursement for overhead expenses for 2004 in the second quarter of 2005.

Our cost of revenues for the three months ended June 30, 2005 was \$829,639 compared to zero for the three months ended June 30, 2004. For the six months ended June 30, 2005, the cost of revenues was \$919,852, compared to \$59,486 for the same six month period ended June 30, 2004. These costs relate to payments made to subcontractors and universities in the aforementioned grants.

Although we have a gross profit, the gross profit is a result of the increase in the NIH award for a higher and more comprehensive F&A rate to provide for overhead expenditures. In addition, the gross profit of \$593,064 and \$616,391, for the three months and six months ended June 30, 2005, respectively, includes \$285,891 as reimbursement in the second quarter of 2005 for the new F&A rate.

Research and development spending decreased \$253,108, or 26%, to \$736,905, for the three months ended June 30, 2005 as compared to \$990,013 for the corresponding period ended June 30, 2004. Research and development expenses decreased \$222,633, or 13%, to \$1,466,891, for the six months ended June 30, 2005, compared to \$1,689,524 for the corresponding period ended June 30, 2004. In 2004, we incurred higher costs for research and development from the completion of the pivotal Phase III clinical trial for orBec®.

General and administrative expenses decreased \$75,021, or 15%, to \$423,873 for the three months ended June 30, 2005, as compared to \$498,894 for the corresponding period ended June 30, 2004. General and administrative expenses decreased \$211,663, to \$765,808, or 22%, for the six months ended June 30, 2005, compared to \$977,471, for the six months ended June 30, 2004. This decrease in both quarters of 2005 is primarily attributed to a recovery of \$284,855 from reported income in 2004 for the variable accounting treatment of options to employees under the stock option plan that have exceeded the number of allowed stock options under the plan. In the first six months of 2004, we also took an option expense for warrants of \$104,260. Eliminating the treatment of the stock options, general and administrative expenses for the second quarter would have increased by \$29,239, or 7%, compared to the second quarter of 2004. In addition, for the six months ended June 30, 2005, general and administrative expenses would have increased by \$177,451, or 20%, compared to the first six months ended June 30, 2004. Approximately \$165,000 of this increase is attributed to increased legal costs.

Interest and other income for the three months ended June 30, 2005 was \$27,002 as compared to \$22,432 for the three months ended June 30, 2004, representing an increase of \$4,570 or 20%. Interest and other income for the six months ended June 30, 2005 was \$48,599, an increase of \$9,231, or 23%, as compared to \$39,368 for the same period in 2004. This increase was primarily due to an increase in the number of days of available interest bearing cash balances in 2005 as compared to 2004.

Interest expense for the three months ended June 30, 2005 was \$700 as compared to \$6,901 for the three months ended June 30, 2004, a decrease of \$6,201 or 90%. Interest expense for the six months ended June 30, 2005 was \$3,018 as compared to \$15,173 for the six months ended June 30, 2004, a decrease of \$12,155 or 80%, due to a decrease in the balance of our note payable.

For the three months ended June 30, 2005, we had a net loss applicable to common shareholders of \$541,412 as compared to a \$1,473,376 net loss applicable to common shareholders for the three months ended June 30, 2004,

which represents a decrease of \$931,964, or 63%. For the six months ended June 30, 2005, we had a net loss of \$1,570,727, which represents a decrease in net loss of \$1,568,659, or 50%, as compared to a net loss of \$3,139,386 for the same period in 2004. For the six months ended June 30, 2005 the net loss applicable to common shareholders included the impact of preferred stock dividends, which was zero in 2005, as compared to \$503,195 in 2004. The decrease in preferred stock dividends was due to the conversion of all outstanding Series C preferred stock to 1.25 million shares of common stock in March 2004.

---



**FINANCIAL CONDITION:**

As of June 30, 2005, we had cash and cash equivalents of \$3,189,628 as compared to \$2,332,190 as of December 31, 2004, and working capital of \$2,574,553 as compared to \$1,050,649 as of December 31, 2004.

For the six months ended June 30, 2005, our cash used in operating activities was \$2,432,849 million, compared to \$2,218,548 million for the six months ended June 30, 2004.

We expect our research and development expenditures for 2005, under existing product development agreements and license agreements pursuant to letters of intent and option agreements, to approximate \$3,700,000. We anticipate grant revenues to offset research and development expenses of our ricin vaccine in the amount of approximately \$2,100,000, pending completion of certain milestones.

As of June 30, 2005, we had a note due of \$115,948, which represents the remaining amount payable to a pharmaceutical company in connection with our joint ventures. As of the date of this report we have not made the final payment. The note is in default. Interest continues to accrue at 8%. We are expecting to pay the note in full by the end of the third quarter 2005.

The following summarizes our contractual obligations at June 30, 2005, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

<b>Contractual Obligations</b>	<b>Year 2005</b>	<b>Year 2006</b>	<b>Year 2007</b>
Non-cancelable obligations (1)	\$ 66,914	\$ 52,628	-
Debt (2)	115,948	-	-
<b>TOTALS</b>	<b>\$ 182,862</b>	<b>\$ 52,628</b>	<b>\$ -</b>

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

(2) Debt due to a pharmaceutical company as part of the dissolution of previous joint ventures

In February 2005, we further increased our cash position by the issuance and sale of 8,396,100 shares of our common stock at \$0.45 per share in a private placement to institutional investors. Such investors also received warrants to purchase 6,297,075 shares of our common stock at an exercise price of \$0.505 per share. The proceeds after related expenses and closing costs were approximately \$3.5 million. Based on our current rate of cash outflows, we believe that our cash of \$3,189,628 at June 30, 2005 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the end of the first quarter 2006. However, within the next six to twelve months we will be required to raise cash in order to meet cash flow requirements for the next year and to avoid going concern considerations. It is possible that within the upcoming three quarters we will seek additional capital in the private and/or public equity markets to support our operations, 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.



**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.

August 15, 2005 by /s/ Michael T. Sember

Michael T. Sember

President and Interim Chief Executive Officer

August 15, 2005 by /s/ Evan Myriantopoulos

Evan Myriantopoulos

Chief Financial Officer