DOR BIOPHARMA INC
Form 10QSB
November 14, 2005

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

FORM 10-QSB

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

For the Quarterly Period Ended September 30, 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	**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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).
Yes x No o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

At November 7, 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 [X]

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PART I. - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

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

Assets		
Current assets:		
Cash and cash equivalents	**$**	**1,833,128**
Accounts receivable		**390,685**
Prepaid expenses		**211,394**
Total current assets		**2,435,207**
Office and laboratory equipment, net		**42,682**
Intangible assets, net		**2,044,118**
Total assets	$	**4,522,007**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$	**783,835**
Accrued compensation and other expenses		**218,830**
Total current liabilities		**1,002,665**
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		**(82,576,462)**
Total shareholders' equity		**3,519,342**
Total liabilities and shareholders' equity	$	**4,522,007**

The accompanying notes are an integral part of these financial statements

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

		2005		2004
Revenues:	**$**	**733,892**	$	-
Cost of revenues		**(545,812)**		-
Gross profit		**188,080**		-
Operating expenses:				
Research and development		**964,398**		894,384
General and administrative		**441,489**		526,162
Total operating expenses		**1,405,887**		1,420,546
Loss from operations		**(1,217,807)**		(1,420,546)
Other income (expense):				
Interest and other income		**19,989**		16,514
Interest expense (note 5)		**39,567**		(2,379)
Total other income (expense)		**59,556**		14,135
Net loss	$	**(1,158,251)**	$	(1,406,411)
Basic and diluted net loss per share	$	**(0.02)**	$	(0.03)
Basic and diluted weighted average common shares outstanding		**49,399,734**		41,870,601

The accompanying notes are an integral part of these financial statements

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

		2005		2004
Revenues:	**$**	**2,370,135**	$	66,095
Cost of revenues		**(1,465,664)**		(59,486)
Gross profit		**804,471**		6,609
Operating expenses:				
Research and development		**2,431,289**		2,583,431
General and administrative		**1,207,297**		1,503,360
Total operating expenses		**3,638,586**		4,086,791
Loss from operations		**(2,834,115)**		(4,080,182)
Other income (expense):				
Interest and other income		**68,588**		55,357
Interest expense (note 5)		**36,549**		(17,027)
Total other income (expense)		**105,137**		38,330
Net loss		**(2,728,978)**		(4,041,852)
Preferred stock dividends		**-**		(503,195)
Net loss applicable to common shareholders	$	**(2,728,978)**	$	(4,545,047)
Basic and diluted net loss per share applicable to common shareholders	$	**(0.06)**	$	(0.11)
Basic and diluted weighted average common shares outstanding		**49,399,734**		40,024,065

The accompanying notes are an integral part of these financial statements

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

	2005	2004
Operating activities:		
Net loss	$ **(2,728,978)**	$ (4,041,852)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	**170,915**	270,827
Non-cash stock option compensation	**(284,855)**	104,528
Change in operating assets and liabilities:		
Accounts receivable	**352,302**	20,954
Prepaid expenses	**(151,790)**	86,439
Accounts payable	**(965,518)**	29,984
Total adjustments	**(878,946)**	512,732
Net cash used by operating activities	**(3,607,924)**	(3,529,120)
Investing activities:		
Acquisition of intangible assets	**(313,592)**	(303,334)
Purchases of equipment	**(11,191)**	(5,673)
Net cash used by investing activities	**(324,783)**	(309,007)
Financing activities:		
Net proceeds from issuance of common stock	**3,549,593**	3,039,564
Proceeds from exercise of options	**-**	61,972
Repayments of amounts due under line of credit and note payable	**(115,948)**	(243,119)
Net cash provided by financing activities	**3,433,645**	2,858,417
Net decrease in cash and cash equivalents	**(499,062)**	(979,710)
Cash and cash equivalents at beginning of period	**2,332,190**	4,117,540
Cash and cash equivalents at end of period	**$ 1,833,128**	$ 3,137,830
Supplemental disclosure of cash flow:		
Cash paid for interest	**$ 41,865**	$ 17,552
Non-cash transactions:		
Issuance of preferred stock dividend in kind	**$ -**	$ 503,195

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. 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, 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.

2. 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 10.2 million and 9.0 million shares of our common stock outstanding at September 30, 2005, and 2004, respectively.

3. 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.

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 nine months ended:

	September 30,	
	2005	2004
Net Loss applicable to common shareholders		
As reported	$(2,728,978)	$(4,545,047)
Add stock-based employee compensation expense related to stock options determined under fair value method	**(340,327)**	(1,508,453)
Pro forma net loss according to SFAS 123	**$ (3,069,305)**	$ (6,053,500)
Net loss per share:		
As reported, basic and diluted	**$ (0.06)**	$ (0.11)
Pro forma, basic and diluted	**$ (0.06)**	$ (0.15)

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.

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4. 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 September 30, 2005 ranged from 11 to 16 years. The following is a summary of patent and license assets:

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
September 30, 2005	10.5	$ 2,924,786	$ 880,668	$ 2,044,188
December 31, 2004	10.6	$ 2,611,195	$ 728,741	$ 1,882,454

Amortization expense was $45,785 and $151,927 for the three months and nine months ended September 30, 2005, respectively. The amortization expense for the same three month and nine month period in 2004, was $41,316 and $225,459, respectively.

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

	Amortization Amount
2005	$ 197,000
2006	177,000
2007	177,000
2008	177,000
2009	177,000

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 nine months ended September 30, 2005.

NOTE PAYABLE

	September 30, 2005	December 31, 2004
Note payable to pharmaceutical company	**-**	$ 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 paid in the third quarter of 2005. An agreement was reached with the pharmaceutical company whereby we paid the principal balance in full, but only paid 50% of the interest accrued as full and final payment. The total payment of principal and interest was $157,813. The agreement resulted in a recovery of interest of $41,864.

6. SIGNIFICANT CONCENTRATIONS

During the nine months ended September 30, 2005, the Company had one customer, the United States federal government. All revenues generated in the nine months ended September 30, 2005, were from one United States federal government grant from the National Institute of Health ("NIH").

7. BUSINESS SEGMENTS

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

	For the three months ended September 30,	
	2005	2004
Net Revenues		
BioDefense	**$ 733,892**	$ -
BioTherapeutics	**-**	-
Total	**$ 733,892**	$ -
Income (Loss) from Operations		
BioDefense	**$ (390,617)**	$ (299,445)
BioTherapeutics	**(399,842)**	(441,280)
Corporate	**(427,348)**	(680,621)
Total	**$ (1,217,807)**	$ (1,420,546)
Amortization and Depreciation Expense		
BioDefense	**$ 39,119**	$ 16,889
BioTherapeutics	**9,819**	49,374
Corporate	**3,152**	1,414
Total	**$ 52,090**	$ 67,677

	September 30, 2005	December 31, 2004
Identifiable Assets		
BioDefense	**$ 2,008,034**	$ 2,192,097
BioTherapeutics	**471,770**	230,048
Corporate	**2,042,203**	2,645,570
Total	**$ 4,522,007**	$ 5,067,715

	For the nine months ended September 30,	
	2005	2004
Net Revenues		
BioDefense	**$ 2,270,135**	$ 66,095
BioTherapeutics	**-**	-
Total	**$ 2,270,135**	$ 66,095
Income (Loss) from Operations		
BioDefense	**$ (548,941)**	$ (857,213)
BioTherapeutics	**(991,535)**	(1,267,473)
Corporate	**(1,293,639)**	(1,955,496)
Total	**$ (2,834,115)**	$ (4,080,182)
Amortization and Depreciation Expense		
BioDefense	**$ 67,316**	$ 63,191
BioTherapeutics	**94,105**	201,836
Corporate	**9,494**	5,800
Total	**$ 170,915**	$ 270,827

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, 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, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of intestinal Graft-versus-Host Disease, "iGVHD"; (b) consider prophylactic use studies of orBec® for the prevention of iGVHD; (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; and (i) acquire or in-license new clinical-stage compounds for development.

orBec®

We intend to file an NDA with the FDA for orBec® for the treatment of iGVHD by the first quarter 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.

We anticipate the market potential for orBec® 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®. We are seeking 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 evaluating an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

RiVax™

The scientific development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. We initiated a Phase I safety and immunogenicity trial in February of this year and in June we announced positive interim safety and immunogenicity data. In January of this year we entered into a manufacturing and supply agreement for RiVax™ 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™ 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.

Botulinum Programs

BT-VACC™

Our oral botulinum toxin vaccine program has made important strides this year. We are developing an oral 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 and B 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. Ongoing studies are focused on serotype E; multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals and 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 *Pseudomonas*-based technology that accelerates speed to market for vaccines and biotherapeutics by surpassing the quality and yield capabilities of existing microbial systems. In a very short duration, we have demonstrated successful high expression of soluble material from all three Hc50 fragments.

Botulinum Therapeutics

Early this year, we entered into an agreement with Blue Dolphin, LLC, a firm specializing in rational drug development, to apply computer-aided design to the discovery of small molecule drugs to counter the deadly effects of Botulinum toxin exposure. Under the agreement, Blue Dolphin is exploring novel drug-like inhibitors of Botulinum toxin by targeting a new site on the toxin's structure. Candidate molecules will be modeled for structural and chemical fit to the target site on the toxin using computer aided discovery techniques. The best fitting molecules will be experimentally tested for their effectiveness in treating Botulinum toxin exposure. By focusing on the structure of the Botulinum toxin, as opposed to derivatives of previously known inhibitors, this "virtual screening" will allow DOR to target new parts of the toxin with new candidate inhibitors. To date, we have identified several lead inhibitors. Planned studies will focus on initial profiling of hits and validation testing for activity against botulinum toxin exposure, in addition to investigating the mechanism of action of confirmed quality hits.

We will apply for research grants and contracts from the U.S. government to continue development of these programs. The goal of our biodefense programs is to supply the United States government with qualified countermeasures that can protect citizens against ricin toxin and botulinum toxin exposure.

Material Letter of Intent - Acquisition of Gastrotech Pharma

On October 28, 2005, DOR BioPharma, Inc. (the “Company”) entered into a binding letter of intent to acquire Gastrotech Pharma (“Gastrotech”), a private Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. In connection with the closing of the acquisition, the Company will issue the stockholders of Gastrotech $9 million in Company common stock priced at the 10-day volume weighted average price immediately prior to the closing. In no event will the Company issue less than 20 million or more than 30 million shares of its common stock to Gastrotech’s shareholders. This corresponds to a price collar on the transaction of between $0.30 and $0.45 per share of the Company’s common stock. In addition, the Company will pay Gastrotech shareholders another $30 million upon the occurrence of the following milestones: $4 million in stock priced at the time of initiation of a pivotal Phase 3 study of any of Gastrotech’s compounds, $6 million in stock priced at the time of filing of an NDA for any of Gastrotech’s compounds, $10 million payable in cash or stock when either of Gastrotech’s compounds achieves $50 million in sales in any calendar year, and $10 million payable in cash or stock when either of Gastrotech’s compounds achieves $200 million in sales in any calendar year. The parties intend that the acquisition would include the transfer of Gastrotech’s ongoing clinical programs to the Company as well as all intellectual property and facilities.

The closing of the acquisition is subject to the negotiation of definitive agreements between the parties containing representations, warranties, covenants, and conditions which are typically included in transactions of this nature. The Company has agreed to register the shares issued to the Gastrotech stockholders for resale under the Securities Act of 1933. The largest Gastrotech stockholder has agreed to limit its sales of the Company's common stock to 20% of its holdings per quarter. The Company has agreed to expand its Board of Directors to nine members, with three positions being appointed by the Gastrotech stockholders. There is a breakup fee of $1.0 million if either party breaches the

terms of the binding letter of intent.

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 and defense of patents, as well as amounts paid allowing us to license additional methods of vaccine delivery through the Southern Research Institute patents, costs of acquiring Élan's interest in the Innovaccine's Joint Venture, and amounts paid to University of Texas Southwestern Medical Center allowing us 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 National Institutes of Health ("NIH"). The new F&A rate for 2004 was 40%. The new F&A rate for 2005 was 30%. The result of this rate increase 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 $313,000. 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 our botulinum program.

Material Changes in Results of Operations

We are a research and development company. The 2005 revenues and associated expenses were from an 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.

On September 23, 2005 we were awarded a grant entitled “Oral BDP for the Treatment of GI GVHD” from the Food and Drug Administration. We will begin recognizing revenue for this grant beginning in the fourth quarter of 2005. The total amount of the one year grant is $318,750.

For the three months ended September 30, 2005 we had grant revenues of $733,892 as compared to zero in the three months ended September 30, 2004. For the nine months ended September 30, 2005, we had grant revenues of $2,270,135, an increase of $2,204,040, 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 September 30, 2005 was $545,812 compared to zero for the three months ended September 30, 2004. For the nine months ended September 30, 2005, the cost of revenues was $1,465,664, an increase of $1,406,178, as compared to cost of revenues of $59,486 for the same period in 2004. These costs relate to payments made to subcontractors and universities in connection with the 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 $188,080 and $804,471, for the three months and nine months ended September 30, 2005, respectively, includes $285,891 from 2004, as reimbursement in the second quarter of 2005 for the new F&A rate.

Research and development spending decreased $70,014, or 8%, to $964,398, for the three months ended September 30, 2005 as compared to $894,384 for the corresponding period ended September 30, 2004. Research and development expenses decreased $152,142, or 6%, to $2,431,289, for the nine months ended September 30, 2005, compared to $2,583,431 for the corresponding period ended September 30, 2004. In 2004, we incurred higher costs for research and development due to the completion of the pivotal Phase III clinical trial for orBec®. However, in the third quarter of 2005 our research and development costs showed an increase as compared to the same period in 2004. This was due to the increased regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®.

General and administrative expenses decreased $84,673, or 16%, to $441,489 for the three months ended September 30, 2005, as compared to $526,162 for the corresponding period ended September 30, 2004. General and administrative expenses decreased $296,063, to $1,207,297, or 20%, for the nine months ended September 30, 2005, compared to $1,503,360, for the nine months ended September 30, 2004. For the three months ended September 30, 2004 we had severance payments and accrued severance due former employees approximating $160,000. For the nine months ended September 30, 2005, the decrease was primarily attributed to a recovery of $284,855 from reported income in 2004 for the variable accounting treatment of options granted to new employees under the stock option plan that have exceeded the number of allowed stock options under the plan.

Interest and other income for the three months ended September 30, 2005 was $19,989 as compared to $16,514 for the three months ended September 30, 2004, representing an increase of $3,475 or 21%. Interest and other income for the nine months ended September 30, 2005 was $68,588, an increase of $13,231, or 24%, as compared to $55,357 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 September 30, 2005 was a $39,567 credit as compared to $2,379 expense for the three months ended September 30, 2004, an increase of $41,946 or 1,763%. Interest expense for the nine months ended September 30, 2005 was a $36,549 credit as compared to $17,027 expense for the nine months ended September 30, 2004, an increase of $53,576 or 315%. This decrease in the interest expense was due to recovery of interest because of an agreement reached with a pharmaceutical company for settlement of a note payable. This agreement required a payment of $41,865 in lieu of the $83,729 of interest we had accrued.

For the three months ended September 30, 2005, we had a net loss applicable to common shareholders of $1,158,251 as compared to a $1,406,411 net loss applicable to common shareholders for the three months ended September 30, 2004, which represents a decrease of $248,160, or 18%. For the nine months ended September 30, 2005, we had a net loss of $2,728,978, which represents a decrease in net loss of $1,816,069, or 40%, as compared to a net loss of $4,545,047 for the same period in 2004. For the nine months ended September 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 September 30, 2005, we had cash and cash equivalents of $1,833,128 as compared to $2,332,190 as of December 31, 2004, and working capital of $1,432,542 as compared to $1,050,649 as of December 31, 2004.

For the nine months ended September 30, 2005, our cash used in operating activities was $3,607,924, compared to $3,529,120 for the nine months ended September 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 $3,600,000. We anticipate grant revenues to offset research and development expenses of our ricin vaccine in the amount of approximately $2,500,000, pending completion of certain milestones.

As of September 30, 2005, we paid a note due of $115,948, which represents the remaining amount payable to a pharmaceutical company in connection with our joint ventures.

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

Contractual Obligations	Year 2005	Year 2006	Year 2007
Non-cancelable obligations (1)	$ 66,914	$ 52,628	-
TOTALS	**$ 66,914**	**$ 52,628**	**$ -**

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

In February 2005, we 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 $1,833,128 at September 30, 2005 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the middle 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 9 months 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

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SIGNATURES

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

DOR BIOPHARMA, INC.

November 15, 2005 by /s/ Michael T. Sember
Michael T. Sember
President and Chief Executive Officer

November 15, 2005 by /s/ Evan Myrianthopoulos
Evan Myrianthopoulos
Chief Financial Officer