DOR BIOPHARMA INC
Form 10QSB
May 16, 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 March 31, 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)

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 [X] No [ ]

At May 9, 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 Sheets

	March 31, 2005 (Unaudited)	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	**$ 4,534,627**	$ 2,332,190
Accounts receivable	**60,397**	742,987
Prepaid expenses	**94,279**	59,604
Total current assets	**4,689,303**	3,134,781
Office and laboratory equipment, net	**47,309**	50,480
Intangible assets, net	**2,002,763**	1,882,454
Total assets	**$ 6,739,375**	$ 5,067,715
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	**$ 1,258,059**	$ 1,668,958
Accrued royalties	**-**	100,000
Accrued compensation and other expenses	**146,349**	199,226
Notes payable	**115,948**	115,948
Total current liabilities	**1,520,356**	2,084,132
Shareholders' equity:		
Preferred stock, $.001 par value. Authorized 4,600,000		
shares; none issued and outstanding	-	-
Common stock, $.001 par value. Authorized 100,000,000		
shares; 50,612,504 and 42,418,404 issued and		
outstanding, respectively	**50,612**	42,218
Additional paid-in capital	**86,472,888**	83,216,533
Accumulated deficit	**(80,876,784)**	(79,847,471)
	5,646,716	3,411,280
Less treasury stock (120,642 shares)	**(427,697)**	(427,697)
Total shareholders' equity	**5,219,019**	2,983,583
Total liabilities and shareholders' equity	**$ 6,739,375**	$ 5,067,715

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the years ended March 31,

		2005 (Unaudited)		2004
Revenues:	**$**	**113,540**	$	66,095
Cost of revenues		**(90,213)**		(59,486)
Gross profit		**23,327**		6,609
Operating expenses:				
Research and development		**729,985**		702,677
General and administrative		**341,935**		478,578
Total operating expenses		**1,071,920**		1,181,255
Loss from operations		**(1,048,593)**		(1,174,646)
Other incomes (expense):				
Interest income		**21,596**		17,277
Interest expense		**(2,318)**		(8,272)
Total other income (expense)		**19,278**		9,005
Net loss		**(1,029,315)**		(1,165,641)
Preferred stock dividends		**-**		(503,195)
Net loss applicable to common shareholders	$	**(1,029,315)**	$	(1,668,836)
Basic and diluted net loss per share applicable to common shareholders	$	**(0.02)**	$	(0.05)
Basic and diluted weighted average common shares outstanding		**46,974,194**		36,796,223

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the years ending March 31,

	2005 (Unaudited)	2004
Operating activities:		
Net loss	$ **(1,029,315)**	$ (1,165,641)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	**65,517**	137,738
Non-cash stock option compensation	**(284,855)**	-
Change in operating assets and liabilities:		
Accounts receivable	**682,590**	(66,096)
Prepaid expenses	**(34,676)**	90,152
Accounts payable	**(563,776)**	(120,402)
Total adjustments	**(135,200)**	41,392
Net cash used by operating activities	**(1,164,515)**	(1,124,249)
Investing activities:		
Intangible assets	**(182,349)**	(128,750)
Purchases of equipment	**(2,856)**	(1,245)
Net cash used by investing activities	**(185,205)**	(129,995)
Financing activities:		
Net proceeds from issuance of common stock	**3,552,157**	3,045,500
Proceeds from exercise of options	**-**	61,972
Repayments of amounts due under line of credit, notes payable and capital lease obligations	**-**	(11,222)
Net cash provided by financing activities	**3,552,157**	3,096,250
Net increase in cash and cash equivalents	**2,202,437**	1,842,006
Cash and cash equivalents at beginning of period	**2,332,190**	4,117,540
Cash and cash equivalents at end of period	**$ 4,534,627**	$ 5,959,546
Supplemental disclosure of cash flow:		
Cash paid for interest	**$ -**	$ 3,383
Non-cash transactions:		
Non-cash stock options expense	**$ -**	$ 467,183
Issuance of preferred stock dividend in kind	**$ -**	$ 503,195
Issuance of common stock for intangible assets	**$ -**	$ 32,778
Options for increase in subsidiary ownership	**$ -**	$ 88,740

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 7.5 million shares of our common stock outstanding at March 31, 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 three months ended:

March 31,		
	2005	2004
Net Loss applicable to common shareholders		
As reported	$(1,029,315)	$(1,668,836)
Add stock-based employee compensation expense related to stock options determined under fair value method	**(91,197)**	-
Add amounts charged to recovery of expense	**(284,855)**	(575,817)
Pro forma net loss according to SFAS 123	**$ (1,405,367)**	$ (2,244,653)
Net loss per share:		
As reported, basic and diluted	**$ (0.02)**	$ (0.05)

Pro forma, basic and diluted	**$ (0.03)**	$ (0.06)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.49 and $0.49 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 3.6% and 3.5%, respectively.

Stock compensation expense for options granted to nonemployees 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 March 31, 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**
March 31, 2005	10.7	$ 2,792,368	$ 789,605	$ 2,002,763
December 31, 2004	10.6	$ 2,611,195	$ 728,741	$ 1,882,454

Amortization expense was $62,040 for the three months ended March 31, 2005.

Based on the balance of the intangibles at March 31, 2005, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
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.

NOTES PAYABLE

Notes payable were as follows:

	March 31, 2005	December 31, 2004
Note payable to pharmaceutical company	**$ 115,948**	$ 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 to a pharmaceutical company was not paid as of its due date at the end of December 31, 2004. The note is in default.

BUSINESS SEGMENTS

The Company had two active segments for the three months ended March 31, 2005 and 2004: BioDefense and BioTherapeutics. Summary data for the three months ended:

	March 31,	
	2005	2004
Net Revenues		
BioDefense	**$ 113,540**	$ 66,095
BioTherapeutics	**-**	-
Total	**$ 113,540**	$ 66,095
Loss from Operations		
BioDefense	**$(315,708)**	$(246,784)
BioTherapeutics	**(285,754)**	(364,893)
Corporate	**(447,131)**	(562,969)
Total	**$(1,048,593)**	$(1,174,646)
Amortization and Depreciation Expense		
BioDefense	**$ 31,792**	$ 32,138
BioTherapeutics	**30,712**	102,650
Corporate	**3,013**	2,950
Total	**$ 65,517**	$ 137,738

	March 31, 2005	December 31, 2004
Identifiable Assets		
BioDefense	**$ 1,649,587**	$ 2,192,097
BioTherapeutics	**443,573**	230,048
Corporate	**4,646,215**	2,645,570
Total	**$ 6,739,375**	$ 5,067,715

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 for orBec® 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®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (c) consider prophylactic use studies of orBec®; (d) identify a marketing and sales partner for orBec® 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®

In order to accomplish our goal of a New Drug Application for orBec® in 2005, we are implementing a number of strategies aimed at improving our FDA approval prospects. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the New Drug Application preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is ongoing and these batches are currently undergoing stability testing.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. It is our intent to 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®.

RiVax™

The scientific development of our ricin vaccine has progressed significantly in the past year. With our partner the University of Texas Southwestern Medical Center, the initial goal was met for this program to file an Investigational New Drug application with the FDA for the purposes of conducting a Phase I clinical trial in healthy human volunteers. A Phase I safety and immunogenicity trial is currently being conducted. The current vaccine is being developed for intramuscular delivery. We are 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™

The botulinum vaccine program has made important strides in the last year and we have identified a lead antigen against one serotype (serotype A) of botulinum toxin. We are in the process of validating the data and creating a multivalent botulinum vaccine through a CRADA (Cooperative Research and Development Agreement) with the U.S. Army and Thomas Jefferson University. To date much of the work at Thomas Jefferson University has been funded by us, and we plan to continue to fund the development of additional antigens against other serotypes of botulinum toxin. In addition, we have applied for and intend to continue to apply for research grants from the U.S. government to fund the transition of the manufacturing of the lead antigen from the academic center to commercial facilities. The goal of our biodefense program is to supply the United States government with qualified countermeasures that will protect its 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. 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.

Material Changes in Results of Operations

We are a research and development company. For the three months ended March 31, 2005 we had grant revenue of $113,540 as compared to $66,095 in the three months ended March 31, 2004. We also incurred expenses related to that revenue in 2005 and 2004 of $90,213 and $59,486, respectively. The 2005 revenue and associated expense was due to a National Institute of Health (NIH) Grant we received in September 2004 and the 2004 revenue and associated expense was due to a Small Business Innovation Research (SBIR) grant we received in September 2003 both for further research associated with our ricin vaccine. The total amount of NIH grant is $5,173,298 and the SBIR grant was $149,912.

For the three months ended March 31, 2005, we had a net loss applicable to common stockholders of $1,029,315 as compared to a $1,668,836 net loss applicable to common stockholders for the three months ended March 31, 2004, a decrease of $639,521, or 38%. Net loss applicable to common stockholders 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.

Research and development spending increased $27,308, or 4%, to $729,985, for the three months ended March 31, 2005 as compared to $702,677 for the corresponding period ended March 31, 2004. This increase was a result of an increase in expenses related to our ricin and botulinum programs.

General and administrative expenses decreased $136,643, or 29%, to $341,935 for the three months ended March 31, 2005, as compared to $478,578 for the corresponding period ended March 31, 2004. This decrease is attributed to a recovery of stock option expense for the variable accounting treatment of options for employees under the stock option plan this recovery was $284,855. Netting out this difference, overall there was an increase which is in part attributed to increased legal costs for the financing completed and costs associated with program management and corporate governance. In addition, there are more administrative personnel than in the first three months of 2004.

Interest and other income for the three months ended March 31, 2005 was $21,596 as compared to $17,277 for the three months ended March 31, 2004, an increase of $4,319 or 25%. This increase was primarily due to the increase in number of days of available cash balances to earn interest from the completed financing in February 8, 2005 compared to 2004, completed financing in March 12, 2004.

Interest expense for the three months ended March 31, 2005 was $2,318 as compared to $8,272 for the three months ended March 31, 2004, a decrease of $5,954 or 72%. The decrease was due to a reduction in accrued interest expense related to the decrease in the balance payable of our note payable.

FINANCIAL CONDITION:

As of March 31, 2005, we had cash and cash equivalents of $4,534,627 as compared to $2,332,190 as of December 31, 2004 and working capital of $3,168,947 as compared to $1,050,649 as of December 31, 2004. For the three months ended March 31, 2005, our cash used in operating activities was approximately $1.3 million, versus approximately $1.2 million for the three months ended March 31, 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 $2.9 million. We anticipate grant revenues to offset manufacturing and research expenditures for the development of our ricin vaccine in the amount of approximately $2.5 million, pending completion of certain milestones.

As of March 31, 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 in which we were required to make payments of $231,897 in June 2004 and $115,948 in December 2004. As of the date of this report we have not made the final payment. The note is in default.

The following summarizes our contractual obligations at March 31, 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	-
Debt (2)	115,948	-	-
TOTALS	**$ 182,862**	**$ 52,628**	**$ -**

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

(2) Debt consists of payment due to Élan as part of the dissolution of previous joint ventures

In March 2004, we supplemented our cash position by the issuance and sale of 4,113,924 shares of our common stock at $0.79 per share in a private placement to institutional investors. We also issued to such investors warrants to purchase an aggregate of 1,645,570 shares of our common stock at an exercise price of $0.87 per share. Our proceeds after related expenses and closing costs, were approximately $3.0 million.

In February 2005, we further supplemented 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 an aggregate of 6,297,075 shares of our common stock at an exercise price of $0.505 per share. Our 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 $4,534,627 at March 31, 2005 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the end of 2005. However, within the next six to twelve months we will be required to secure cash in order to secure the required cash flow for the next 12 months and avoid going concern considerations. We anticipate that within this 12 month period it is possible that in order to raise the required capital, 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 partnership expenditures. It is also possible that we receive capital pursuant to one or more corporate partnerships relating to orBec®. If we receive additional funds through the issuance of equity or equity-linked securities, stockholders 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 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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Reports on Form 8-K:

We filed a Current Report on Form 8-K on March 14, 2005 announcing the press release issued for the results of operations for the fourth quarter 2004.

We filed a Current Report on Form 8-K on February 9, 2005 announcing the completed issuance and sale of 8,396,100 shares of common stock at $0.45 and that the investors also received warrants to purchase an aggregate of 6,297,075 shares of common stock at $.505.

We filed a Current Report on Form 8-K on February 3, 2005 announcing that we had entered into a Securities Purchase Agreement for the sale of 8,396,100 shares of common stock at $0.45 and that the investors also received warrants to purchase an aggregate of 6,297,075 shares of common stock at $.505.

We filed a Current Report on Form 8-K on January 25, 2005 announcing the acceptance of the compliance plan by the American Stock Exchange and the extension to gain compliance until July 12, 2005.

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 16, 2005 by /s/ Michael T. Sember
Michael T. Sember
President and Interim Chief Executive Officer

May 16, 2005 by /s/ Evan Myrianthopoulos
Evan Myrianthopoulos
Chief Financial Officer