

DOR BIOPHARMA INC
Form 10QSB
May 17, 2004

SEC 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, 2004

() 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 (I.R.S. Employer Identification
incorporation or organization) Number)

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

Issuer's telephone number, including area code (305) 534-3383
(Former name, former address and former fiscal year, if changed since last
report)

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 1, 2004, 42,042,943 shares of the registrant's common stock
(par value, \$.001 per share) were outstanding.

Transitional Small Business Disclosure Format (check one):

Yes [] No [X]

PART I. - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

DOR BioPharma, Inc.
(A Development Stage Company)
Consolidated Balance Sheets
(unaudited)

	March 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,959,546	\$ 4,117,539
Receivable	87,050	20,954
Prepaid expenses	65,950	155,844
Total current assets	6,112,546	4,294,337
Equipment, net of accumulated depreciation of \$147,203 and \$141,650	56,486	60,795
Licenses and patent costs, net of accumulated amortization of \$508,619 and \$384,333	1,893,275	1,896,934
Total assets	\$ 8,062,307	\$ 6,252,066
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 233,807	\$ 211,587
Accrued royalties	200,000	320,000
Accrued compensation and other expenses	94,389	116,638
Debt	347,845	359,067
Total current liabilities	876,041	1,007,292
Stockholders equity:		
Series B convertible preferred stock, \$.05 par value. Authorized 200,000 shares; 126,488 issued and outstanding in 2003, at liquidation value	-	12,648,768
Common stock, \$.001 par value. Authorized 100,000,000 shares;	42,044	34,894

42,042,943 and 34,893,765 issued, 41,870,601 and 34,721,423 outstanding		
Additional paid-in capital	82,754,365	67,005,276
Deficit accumulated during the development stage	(75,141,876)	(73,975,897)
	<u>7,654,533</u>	<u>5,713,041</u>
Less: Cost of 172,342 shares of common stock in treasury	(468,267)	(468,267)
Total stockholders equity	<u>7,186,266</u>	<u>5,244,774</u>
Total liabilities and stockholders equity	<u>\$ 8,062,307</u>	<u>\$ 6,252,066</u>

See accompanying notes to consolidated financial statements.

DOR BioPharma, Inc.
(A Development Stage Company)
Consolidated Statement of Operations
(unaudited)

	Three Months Ended March 31,		Cumulative Period February 15, 1985 (inception) to March 15, 2004
	2004	2003	
Grant revenue	\$ 66,095	\$ -	\$ 249,912
Expenses:			
Cost of revenue	59,486	-	221,851
Proprietary research and development	702,677	387,901	23,679,401
General and administrative	478,578	2,033,877	21,017,168
Write-off of acquired in-process research and development	-	-	10,181,000

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Total expenses	1,240,741	2,421,778	55,099,420
Loss from operations	(1,174,646)	(2,421,778)	(54,849,508)
Other income (expense):			
Interest income	16,712	6,672	3,616,715
Interest expense	(8,272)	(3,012)	(430,493)
Other income	565	-	237,065
Equity in joint ventures	-	-	(22,179,091)
Total other income (expense)	9,005	3,660	(18,755,804)
Net loss	(1,165,641)	(2,418,118)	(73,605,312)
Preferred stock dividends and charge for induced conversion	(503,195)	(231,028)	(7,763,826)
Net loss applicable to common stockholders	\$ (1,669,176)	\$ (2,649,146)	\$ (81,369,138)
Basic and diluted net loss per share applicable to common stockholders	\$ (0.05)	\$ (0.10)	
Basic and diluted weighted average common shares outstanding	36,796,223	27,261,478	

See accompanying notes to consolidated financial statements.

DOR BioPharma, Inc.
(A Development Stage Company)
Consolidated Statement of Cash Flows
(unaudited)

Cumulative Period

Three Months

February 15, 1985

Ended March 31,

(inception) to

2004

2003

March 31, 2004

Operating activities:

Net loss

\$

(1,165,641

)

\$

(2,418,118

)
 \$ (73,605,312
)

Adjustments to reconcile net loss to cash used in operating activities:

Depreciation and amortization

137,738

70,960

2,272,482

Gain on sale of marketable securities

-

-

(110,244)

)
 Non-cash stock compensation

-

1,479,385

2,123,554

Equity in (earnings) losses of joint ventures

-

-

22,179,091

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Amortization of fair value of warrants

-
-
3,307,546

Gain on sale of assets

225
-
22,084

Write-off patent issuance cost

-
-
499,065

Write-off of acquired research and development

-
-
10,181,000

Change in operating assets and liabilities:

Receivable

(66,096

)

-

(87,050

)

Prepaid expenses

	89,927
	33,871
)	(65,950)
Accounts payable and accrued expenses	
)	(120,062)
)	(33,011)
	499,196
Accrued compensation	
	-
	15,508
	29,000
<hr/>	
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Total adjustments	
	373,392
	1,566,713
	40,849,434
<hr/>	
<hr/>	
<hr/>	
Net cash used by operating activities	
)	(1,124,249)
	(851,405)

)

(32,755,878

)

Investing activities:

Cash received in acquisition of CTD, net

-

-

1,392,108

Patent issuance costs

(128,750

)

(70,077

)

(1,954,301

)

Investment in joint ventures

-

-

	(5,274,391
)	
Purchases of leasehold improvements and equipment	(1,245
)	
	-
	(1,889,297
)	
Proceeds from assets sold	-
	-
	108,197
Purchases of marketable securities	-
	-
	(11,004,080
)	
Proceeds from sale of marketable securities	-
	-
	11,114,324
<hr/>	
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Net Cash used by Investing Activities	(129,995
)	
	(70,077
)	

(7,507,440

)

Financing activities:

Net proceeds from issuance (costs incurred related to issuance) of common stock

3,045,500

(68,451

)

46,521,531

Proceeds from exercise of options

61,972

32,643

666,281

Proceeds from borrowings under line of credit

-

-

1,150,913

Repayment of amounts due under line of credit, notes payable and capital lease obligations

(11,222

)

(37,928

)

	(1,445,626
)	
Repayment of note payable issued in exchange for legal services	-
	-
	(71,968
)	
Purchase and retirement of common stock	-
	-
	(130,000
)	
Purchase of common stock for treasury	-
	-
	(468,267
)	
<hr/>	
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Net cash provided by (used in) financing activities	3,096,250
	(73,736
)	
	46,222,864
<hr/>	
<hr/>	
<hr/>	
Net increase (decrease) in cash and cash equivalents	

	1,842,006
)	(995,218
	5,959,546

Cash and cash equivalents at beginning of period

4,117,540
4,147,164
-

Cash and cash equivalents at end of period

\$	5,959,546
\$	3,151,946
\$	5,959,546

Supplemental disclosure of cash flow:

Cash paid for interest

\$ 1,521

\$ 3,012

Preferred stock dividends and charges

\$ 503,195

\$ 231,028

See accompanying notes to consolidated financial statements.

DOR BioPharma, Inc.
(A Development Stage Company)
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 footnote 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 as amended for the year ended December 31, 2003, as amended. 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. Certain prior year amounts have been reclassified to conform to the current period presentation, specifically the severance expense as presented as a separate line item in the statement of operations for the three months ended March 31, 2003, rather than as components of proprietary research and development and general and administrative costs.

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 7.5 million and 3.7 million shares of our common stock outstanding at March 31 2004, and 2003, 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:

	2004	2003
Net loss applicable to common stockholders as reported	\$ (1,669,176)	\$ (2,649,146)
Stock-based compensation as reported	-	1,479,385
Stock-based employee compensation expense determined under fair value method	(575,817)	(233,535)
Pro forma net loss	\$ (2,244,993)	\$ (1,403,296)
Net loss per share: as reported, basic and diluted	\$ (0.05)	\$ (0.10)
pro forma, basic and diluted	\$ (0.06)	\$ (0.05)

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 105% and 105% in 2004 and 2003, respectively, and average risk-free interest rates of 4.5% and 4.5% in 2004 and 2003, respectively.

In 2003, we granted options to employees and directors that were conditional upon stockholder approval of an amendment to our 1995 omnibus option plan, which occurred September 15, 2003. Accordingly, a measurement date did not exist until that approval occurred, and on a quarterly basis through the measurement date, we recorded expense or reversal of expense based on the difference between the exercise price and the current market price. This resulted in a charge of \$1,479,385 being recorded in the first quarter of 2003.

LICENSES AND PATENT COSTS

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 licenses and patent costs at March 31, 2004 ranged from 11 to 16 years. The following is a summary of License and Patent assets:

March 31, 2004	Weighted average Amortization Period	Cost	Accumulated	
			Amortization	Net

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Patents and Licenses	11.60 years	\$ 2,401,893	\$ 508,618	\$ 1,893,275
	Weighted average Amortization		Accumulated	
December 31, 2003	Period	Cost	Amortization	Net
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Patents and Licenses	11.85 years	\$ 2,281,267	\$ 384,333	\$ 1,896,934

Aggregate amortization expense for the three months ended March 31, 2004 was \$124,285 .

Estimated amortization for the years ending December 31:

2004	\$ 255,000
2005	135,000
2006	135,000
2007	135,000
2008	135,000

IMPAIRMENT OF LONG-LIVED ASSETS

Equipment, leasehold improvements, licenses and patent costs, and amortizable intangible assets are reviewed for impairment yearly and 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. Such analyses necessarily involve the making of significant judgments.

STOCKHOLDERS' EQUITY

On February 27, 2004, we entered into an agreement with Élan Pharmaceutical Investments Ltd., whereby Élan converted all of their outstanding shares of Series B preferred stock into shares of our common stock at a conversion price of \$5.11 per share of common stock. In addition, we issued to Élan an additional 376,886 shares of our common stock as an inducement to convert the Series B preferred stock at price significantly higher than what was available on the market.

On March 12, 2004, we completed a private placement of 4,113,924 shares of common stock at \$0.79 per share for total net proceeds of \$3,045,500. In addition, each investor received a warrant to purchase 0.40 shares of common stock at an exercise price of \$0.87 per share along with each share of common stock purchased in the placement. We also paid a commission to our placement agent of \$162,500 in cash and warrants to purchase 257,120 shares of common stock at an exercise price of \$0.87 per share.

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, 2003. 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 expressions; 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:

We are a biopharmaceutical company focused on the development of biodefense vaccines, and therapeutics intended for areas of unmet medical need. Through our biodefense program we are developing bioengineered vaccines designed to protect against the deadly effects of ricin toxin and botulinum toxin, both of which are considered serious bioterrorism threats. The underlying technologies are exclusively licensed by us from two leading university research centers.

Our lead therapeutic product, orBec® (oral Beclomethasone dipropionate), is in the final stages of a pivotal phase III clinical trial for the indication of treatment of grade II Graft-versus-Host Disease (GvHD) with gastrointestinal involvement, a frequent complication following allogeneic bone marrow transplant. OrBec® is a potent, topically-active corticosteroid and there are currently no Food and Drug Administration (FDA) approved products on the market indicated for Grade II GvHD with gastrointestinal involvement. The indication has been granted Fast Track status and received Orphan Drug Designation by the FDA. Our intent is to submit a New Drug Application (NDA) with the FDA by the end of 2004 for this indication. A clinical trial exploring the prophylactic potential of orBec® in acute intestinal GvHD is currently under consideration. OrBec® is also being considered for additional therapeutic indications that involve inflammatory conditions of the gut, including Crohn's Disease and Ulcerative Colitis.

We have developed lipid-based oral drug delivery systems for the delivery of proteins and water insoluble drugs. We have preclinical animal data demonstrating the oral delivery of the drug leuprolide, an FDA approved injectable anticancer product.

Plan of Operation:

Our business strategy is to (1) enhance the value of in-licensed technologies through research and development, specifically preclinical and clinical testing towards regulatory approval; (2) solicit government support for our biodefense program; (3) identify and acquire rights to new therapeutic compounds; (4) market biodefense vaccine products directly to the U.S. and European military and governmental agencies and; (5) sell or out-license therapeutic

products that have reached an advanced state of development or no longer meet our strategic criteria.

Our intent going forward is to (a) complete enrollment in the phase III orBec® clinical trial (b) prepare and submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for treatment of grade II Graft-versus-Host Disease with gastrointestinal (GI) involvement; (c) initiate additional clinical trials to explore the effectiveness of oral Beclomethasone Dipropionate in other therapeutic indications involving inflammatory conditions of the GI tract;; (d) identify a marketing and sales partner for orBec® in the U.S. and abroad; (e) win government funding for our biodefense programs through grant applications (f) identify and secure development and manufacturing partners for the biodefense vaccines and transition the biodefense programs from the academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts (h) acquire or license new clinical-stage compounds for development. The details of our plan of operation are outlined below.

The enrollment phase in our pivotal Phase III clinical trial for orBec® is nearing completion and our intent is to begin submitting an NDA for orBec® in 2004. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA preparation, including data collection and management, data analysis, medical writing, etc. In addition, manufacturing of the requisite batches of drug product (registration batches) is complete, and these batches are currently being tested for stability over an extended period of time, allowing a determination of the drug's shelf life.

We plan to evaluate additional clinical applications for orBec®, involving inflammatory conditions of the gut and liver, through investigational clinical trials. We have had preliminary discussions with a number of pharmaceutical companies, regarding the sale of orBec®, or a partnership for its marketing and distribution. It is our intent to secure a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®, and future development for potential additional indications.

With respect to our ricin vaccine program, work to date has been funded by us through a sponsored research agreement with the University of Texas Southwestern Medical Center. It is our intent to fund further development of the vaccine through government research grants and/or a strategic partnership with a commercial partner, however in the event that neither of these funding strategies are available, we will consider other options. The initial goal for this program is for our academic development partners, the University of Texas Southwestern Medical Center, to file an investigator sponsored Investigational New Drug (IND) application with the FDA for the purposes of conducting a safety and limited efficacy (phase I) clinical trial in healthy human volunteers. We anticipate the filing of this IND in within the next six months. Currently the vaccine is being developed for intramuscular delivery; as well as a parallel development program in which we are working on a formulation of the vaccine that would be delivered nasally. A nasally-delivered formulation would serve to facilitate rapid inoculation of large groups of people, and potentially confer protection to the mucosal surfaces of the body, including the gut and lungs.

Our botulinum vaccine program has made some important strides, in addition to ongoing work with the lead antigen which we have previously developed; we are working on an additional antigen to address a second serotype of the botulinum toxin. To date much of the work, which is taking place at Thomas Jefferson University (TJU), 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 will continue to apply for research grants from the U.S. government to initially fund the transition of the manufacturing of the lead antigen followed by subsequent antigens, from TJU to commercial facilities.

The goal of the biodefense program is to supply the United States government with qualified countermeasures to protect individuals against ricin toxin and botulinum toxin.

Finally, we are actively screening and pursuing potential in-licensing opportunities for clinical stage compound(s) for development

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 and defense of patents, as well as amounts paid allowing us to license additional methods of vaccine delivery through the Southern Research Institute patents, 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 yearly and 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.

Results of Operations:

We are a development stage company and to date have not generated any material revenues from operating activities.

For the three months ended March 31 2004, we had a net loss of \$1,165,641 which was a decrease in net loss of \$1,252,477, or 52%, as compared to a net loss of \$2,418,118 for the same period in 2003. After giving effect to dividends on preferred stock, which are paid-in-kind in the form of additional shares of preferred stock and preferred stock charges, net loss available to common stockholders decreased \$979,970, or 37%, to \$1,669,176, or \$0.05 per share, for the first three months of 2004 compared with \$2,649,146, or \$0.10 per share, for the same period of the prior year. This decrease was due primarily to stock compensation expense of \$1,479,385 for the three months ended March 31, 2003.

Research and development expenditures increased \$314,776, or 81%, to \$702,677, for the three months ended March 31, 2004, compared with \$387,901 for the corresponding period ended March 31, 2003. The first quarter increase reflected our continued focus on our phase III clinical trial, as well as the addition of our Ricin and Botulinum Toxin vaccine programs to our product pipeline.

General and administrative expenses decreased \$1,555,299, or 76%, to \$478,578 for the three months ended March 31, 2004, as compared to \$2,033,877 for the three months ended March 31, 2003. This decrease was due primarily to stock compensation expense of \$1,479,385 for the three months ended March 31, 2003. That expense resulted from non-cash charges associated with options granted to employees, directors, and consultants that did not have a measurement date until approval by stockholders at our annual meeting of stockholders in September 2003.

Interest income for the three months ending March 31, 2004 was \$16,712, an increase of \$10,040, or 150%, compared to \$6,672 for the same period in 2003. This increase was due to higher cash balances in the first three months of 2004.

FINANCIAL CONDITION AND LIQUIDITY:

On March 31, 2004, we had cash and cash equivalents of \$5,959,546, compared to \$4,117,539 at December 31, 2003. Working capital was \$5,236,505 at March 31, 2004, compared to \$3,287,045 at December 31, 2003.

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For the first three months of 2004, our cash outflows increased by \$270,247, or 27%, to \$1,265,465 compared to \$995,218 for the same period in 2003. The overall increase resulted primarily from a reduction of \$120,062 in our short term liabilities and an increase in our patent issuance costs of \$128,750.

On February 27, 2004, we entered into an agreement with Élan Pharmaceutical Investments Ltd., whereby Élan converted all of their outstanding shares of Series B preferred stock into shares of our common stock at a conversion price of \$5.11 per share of common stock. In addition, we issued to Élan an additional 376,886 shares of our common stock as an inducement to convert the Series B preferred stock at price significantly higher than what was available on the market.

On March 12, 2004, we completed a private placement of 4,113,924 shares of common stock at \$0.79 per share for total net proceeds of \$3,045,500. In addition, each investor received a warrant to purchase 0.40 shares of common stock at an exercise price of \$0.87 per share along with each share of common stock purchased in the placement. We also paid a commission to our placement agent of \$162,500 in cash and warrants to purchase 257,120 shares of common stock at an exercise price of \$0.87 per share.

Based on our current rate of cash outflows, we believe that our cash of \$5,959,546 at March 31, 2004, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. However, from time to time within this period we may decide to seek additional capital in the private and/or public equity markets to support a higher level of growth, to respond to competitive pressures, to develop new products and services and to support new strategic partnership expenditures. After that 12 month period, if any remaining cash balances and any cash generated from operations are insufficient to satisfy our liquidity requirements, we may need to raise additional funds through public or private financings, strategic relationships or other arrangements. 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. Further, we may not be able to obtain additional financing when needed or on acceptable terms. If we are unable to obtain additional 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 operation.

PART II. - OTHER INFORMATION.

Item 2. Changes in Securities and Use of Proceeds

On February 27, 2004, we entered into an agreement with Élan Pharmaceutical Investments Ltd., whereby Élan converted all of their outstanding shares of Series B preferred stock into shares of our common stock at a conversion price of \$5.11 per share of common stock. In addition, we issued to Élan an additional 376,886 shares of our common stock as an inducement to convert the Series B preferred stock at price significantly higher than what was available on the market.

On March 12, 2004, we completed a private placement of 4,113,924 shares of common stock at \$0.79 per share for total net proceeds of \$3,045,500. In addition, each investor received a warrant to purchase 0.40 shares of common stock at an exercise price of \$0.87 per share along with each share of common stock purchased in the placement. We also paid a commission to our placement agent of \$162,500 in cash and warrants to purchase 257,120 shares of common stock at an exercise price of \$0.87 per share.

Item 4. Submission of Matters to a Vote of Security Holders.

There were no items submitted to vote of security holders.

ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

- Certification of Chief Executive Officer pursuant to
- 31.1 Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
- Certification of Principal Financial Officer pursuant to
- 31.2 Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
- Certification of Chief Executive Officer pursuant to
- 32.1 Section 906 of the Sarbanes-Oxley Act of 2002.
- Certification of Principal Financial Officer pursuant to
- 32.2 Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 Risk Factors

Reports on Form 8-K:

We filed a Current Report on Form 8-K on January 16, 2004 to report the change in our accountants from Ernst & Young LLP to Sweeney, Gates & Co. (Item 4 of Form 8-K).

We filed a Current Report on Form 8-K on March 4, 2004 to report our entering into definitive agreements for the sale of securities in a private placement to selected institutional and accredited investors for gross proceeds of approximately \$3.25 million. We also reported the completion of the conversion of all our outstanding preferred stock into common stock (Item 5 of Form 8-K).

We filed a Current Report on Form 8-K on March 15, 2004 to report our completion of the sale of securities in a private placement to selected institutional and accredited investors for gross proceeds of approximately \$3.25 million (Item 5 of Form 8-K).

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 17, 2004 by /s/ Ralph M. Ellison

Ralph M. Ellison

Chief Executive Officer and President

May 17, 2004 by /s/ William D. Milling

William D. Milling

Controller (principal financial and accounting officer)