

Edgar Filing: DOR BIOPHARMA INC - Form 10QSB

DOR BIOPHARMA INC  
Form 10QSB  
November 14, 2003

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 September 30, 2003

( ) 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 registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of incorporation or organization)

41-1505029  
(I.R.S. Employer Identification Number)

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

33139  
(Zip Code)

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

28101 N Ballard Dr., Suite F, Lake Forest, IL  
(Former name, former address and former fiscal year, if changed since last report)

60045

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 November 1, 2003, 34,636,908 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

# Edgar Filing: DOR BIOPHARMA INC - Form 10QSB

DOR BIOPHARMA, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)  
CONDENSED CONSOLIDATED BALANCE SHEETS

	SEPTEMBER 30, 2003 (UNAUDITED)	DECEMBER 31, 2002
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,335,058	\$ 4,147,164
Prepaid expenses	76,148	104,333
	-----	-----
Total current assets	5,411,206	4,251,497
Leasehold improvements and equipment, net of accumulated amortization of \$131,378 and \$1,162,247	75,875	262,921
Patent issuance costs, net of accumulated amortization of \$98,215 and \$46,100	1,700,464	1,097,341
Intangible assets, net of accumulated amortization of \$214,209 and \$137,710	148,942	226,441
	-----	-----
<b>TOTAL ASSETS</b>	<b>\$ 7,336,487</b>	<b>\$ 5,838,200</b>
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 549,024	\$ 698,120
Accrued compensation	--	124,480
Current portion of note payable	268,388	382,122
	-----	-----
Total current liabilities	817,412	1,204,722
Long-term portion of note payable	115,948	347,845
	-----	-----
Total Liabilities	933,360	1,552,567
Stockholders' equity/(deficit):		
Preferred stock, \$.001 par value. Authorized 4,600,000 shares; none issued and outstanding	--	--
Series C convertible preferred stock, \$.05 par value. Authorized 200,000 shares; none issued and outstanding	--	--
Series B convertible preferred stock, \$.05 par value. Authorized 200,000 shares; 124,126 and 117,118 issued and outstanding at liquidation value	12,412,607	11,711,822
Common stock, \$.001 par value. Authorized 100,000,000 shares; 34,809,250 and 26,794,642 issued, 34,636,908 and 26,622,300 outstanding	34,637	26,795
Additional paid-in capital	67,226,357	61,315,985
Common stock held in escrow, none and 375,498 shares	--	436,812
Unearned compensation	(6,637)	(50,148)
Deficit accumulated during the development stage	(72,795,570)	(68,687,366)
	-----	-----
	6,871,394	4,753,900
Less:		
Treasury stock, at cost, 172,342 shares	(468,267)	(468,267)
	-----	-----

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Total Stockholders' Equity	6,403,127	4,285,633
	-----	-----
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 7,336,487	\$ 5,838,200
	=====	=====

See accompanying condensed notes to condensed consolidated financial statements.

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DOR BIOPHARMA, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)

	Nine Months Ended September 30,		Cumulative from February 15, 1985 (date of inception) to September 30, 2003
	2003	2002	
Revenue:			
SBIR contract revenue	\$ --	\$ --	\$ 100,000
Expenses:			
SBIR contract research and development	--	--	86,168
Proprietary research and development	1,923,515	2,401,600	22,002,263
General and administrative (includes \$960,514 in non-cash stock compensation in 2003)	2,013,674	1,817,802	19,434,496
Write-off of acquired in-process research and development	--	--	10,181,000
Severance costs	130,712	748,598	911,960
Total operating expenses	4,067,901	4,968,000	52,615,887
Loss from operations	(4,067,901)	(4,968,000)	(52,515,887)
Equity in net income (loss) of joint ventures	--	787,275	(22,179,091)
Interest income	14,284	87,139	3,585,580
Interest expense	(4,948)	(7,923)	(363,201)
Other income (expense), net	(49,639)	--	213,250
Net loss	(4,108,204)	(4,101,509)	(71,259,349)
Preferred stock dividends	(700,785)	(1,195,657)	(7,024,471)
Net loss available to common stockholders	\$ (4,808,989)	\$ (5,297,166)	\$ (78,283,820)
Basic and diluted net loss per share	=====	=====	=====

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available to common stockholders	\$	(0.17)	\$	(0.25)
Basic and diluted weighted average common shares outstanding		27,750,852		21,179,037

See accompanying condensed notes to condensed consolidated financial statements.

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DOR BIOPHARMA, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)

	Three months Ended September 30,	
	2003	2002
Revenue:		
SBIR contract revenue	\$ --	\$ --
Expenses:		
SBIR contract research and development	--	--
Proprietary research and development	786,847	326,162
General and administrative (includes \$80,100 in non-cash stock compensation 3rd Quarter 2003)	287,730	220,605
Severance costs	--	118,598
Total operating expenses	1,074,577	665,365
Loss from operations	(1,074,577)	(665,365)
Equity in net income of joint ventures	--	20,041
Interest income	4,287	20,795
Interest expense	(840)	(100)
Other expense, net	(55,072)	--
Net loss	(1,126,202)	(624,629)
Preferred stock dividends	(236,162)	(402,932)
Net loss available to common stockholders	\$ (1,362,364)	\$ (1,027,561)
Basic and diluted net loss per share available to common stockholders	\$ (0.05)	\$ (0.05)
Basic and diluted weighted average common shares outstanding	28,966,059	21,520,812

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See accompanying condensed notes to condensed consolidated financial statements.

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DOR BIOPHARMA, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

	Nine Months Ended September 30,		Cumulative P February 15, (Inception) September 30
	2003	2002	September 30
<b>OPERATING ACTIVITIES:</b>			
Net Loss .....	\$ (4,108,204)	\$ (4,101,509)	\$ (71,259)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization .....	209,526	229,420	2,118
Gain on the sale of marketable securities.....	--	--	(110)
Non-cash stock compensation .....	960,514	--	2,079
Equity in net income(loss) of joint ventures .....	--	(787,276)	22,179
Amortization of fair value of warrants .....	--	--	3,307
Net Loss on sale of assets .....	49,639	--	45
Write off patent issuance costs .....	--	--	439
Write off of acquired research and development .....	--	--	10,181
Changes in operating assets and liabilities:			
Receivable from third party .....	--	(23,706)	
Prepaid expenses .....	28,185	12,210	(72)
Accounts payable and accrued expenses .....	(149,096)	(856,496)	494
Accrued compensation .....	(124,480)	844	
Due to joint ventures .....	--	(151,315)	(1,635)
Net cash used in operating activities .....	(3,133,916)	(5,677,828)	(32,233)
<b>INVESTING ACTIVITIES:</b>			
Cash received in acquisition of CTD, net .....	--	--	1,392
Patent issuance cost .....	(324,351)	(130,552)	(1,712)
Investment in joint ventures .....	--	--	(3,638)
Organizational costs incurred .....	--	--	
Purchases of leasehold improvements and equipment .....	(22,662)	(83,972)	(1,892)
Proceeds from assets sold .....	80,157	--	84
Purchases of marketable securities .....	--	--	(11,004)
Proceeds from sale of marketable securities .....	--	--	11,114
Net cash used in investing activities .....	(266,856)	(214,524)	(5,656)
<b>FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of common stock .....	4,791,178	--	43,542
Proceeds from exercise of options .....	143,119	--	560
Proceeds from borrowings under line of credit .....	--	--	1,150

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Repayment of amounts under line of credit .....	(113,734)	(29,794)	(1,177)
Repayment of note payable .....	(231,897)	--	(231)
Proceeds from long-term note receivable .....	--	--	50
Repayment of note payable issued in exchange for legal service .....	--	--	(71)
Purchase and retirement of common stock .....	--	--	(130)
Purchase of common stock for treasury stock .....	--	--	(468)
	-----	-----	-----
Net cash provided by (used in) financing activities .....	4,588,666	(29,794)	43,224
	-----	-----	-----
Net increase (decrease) in cash and cash equivalents .....	1,187,894	(5,922,146)	5,335
Cash and cash equivalents at beginning of period .....	4,147,164	9,942,053	
	-----	-----	-----
Cash and cash equivalents at end of period .....	\$ 5,335,058	\$ 4,019,907	\$ 5,335
	=====	=====	=====

SUPPLEMENTAL DISCLOSURE OF CASH

FLOW INFORMATION:

Cash paid for interest .....	\$ 4,948	\$ 7,924
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NON-CASH INVESTING AND FINANCING TRANSACTIONS

Issuance of preferred stock dividends in kind .....	\$ 700,785	\$ 1,195,657
Issuance of common stock for patent licenses and vendor payments .....	\$ 330,887	--
Issuance of note payable to settle joint venture liabilities .....	--	\$ 579,742
Non-cash compensation on variable stock options .....	\$ 960,514	--

See accompanying condensed notes to condensed consolidated financial statements.

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DOR BIOPHARMA, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)  
NOTES TO CONDENSED 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 for the year ended December 31, 2002. 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

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severance expense as presented as a line item in the statement of operations in the three and nine months ended September 30, 2002, rather than components of proprietary research and development and general and administrative costs.

### NET LOSS PER SHARE

Net loss per share is presented in the Condensed Consolidated Statements of Operations 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 the periods presented. There were 7.5 million and 3.7 million options outstanding at September 30, 2003, and 2002 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:

### STOCK-BASED COMPENSATION

	Three Months Ended September 30,		Nine Months Ended September	
	2003	2002	2003	2003
Net loss applicable to common stockholders as reported	\$(1,362,364)	\$(1,027,561)	\$(4,808,989)	\$
Stock-based compensation as reported	80,100	--	960,514	
Stock-based employee compensation expense determined under fair value based method	(101,700)	--	(1,361,814)	
Pro forma net loss	<u>\$(1,383,964)</u>	<u>\$(1,027,561)</u>	<u>\$(5,210,289)</u>	<u>\$</u>
Net loss per share:				
as reported, basic and diluted	\$ (0.05)	\$ (0.05)	\$ (0.17)	\$
pro forma, basic and diluted	\$ (0.05)	\$ (0.05)	\$ (0.19)	\$

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 148% and 105% in 2003 and 2002, respectively, and average risk-free interest rates of 4.0% and 4.5% in 2003 and 2002, respectively. Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force (EITF) 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees that vest over future periods is periodically remeasured over the vesting period.

We also 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.

#### SEVERANCE COSTS

In June 2002, the Board of Directors authorized management to restructure the Company and implement a cost reduction program to reduce future operating costs and preserve the Company's existing working capital. As a result, we reduced headcount from 22 to 5 employees. The Company communicated all severance benefits to employees before June 30, 2002.

Severance charges recorded in the consolidated statement of operations during the year ended December 31, 2002 totaled \$781,248, which was based on management's best estimate of probable costs to be incurred under severance agreements with the terminated employees. During the nine months ended September 30, 2003, our total actual expense for severance included an additional \$130,712. This has been recorded as an expense in the first quarter 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 licenses and patent costs at September 30, 2003 ranged from 15 to 17 years.

#### IMPAIRMENT OF LONG-LIVED ASSETS

Equipment, leasehold improvements, licenses and patent costs, and amortizable 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. Such analyses necessarily involve the making of significant judgments.



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### RELATED PARTY TRANSACTIONS

On July 18, 2003, we entered into subscription agreements for a private placement of 6,796,919 shares of Common stock at \$0.796 per share for total gross proceeds of \$5,410,395. Closure of this placement was contingent on shareholder approval, which we received at our September 15, 2003 annual meeting. In connection with the private placement, we agreed to issue warrants to purchase 248,814 shares of our Common Stock to Evan Myriantopoulos, a member of our Board of Directors, and to pay Mr. Myriantopoulos \$62,025, both in consideration for placement services rendered. In addition, Mr. Steve H. Kanzer, a member of our Board of Directors, purchased 125,628 shares of Common Stock and warrants to purchase 125,628 shares of Common Stock for \$100,000, on the same terms and conditions as were offered to the other subscribers in this private placement.

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### 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 Company's 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, 2002. 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 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 development stage pharmaceutical company specializing in the clinical development of drugs for unmet medical needs. In addition we have a biodefense program focused on the development of vaccines against potential bioterror agents. Currently we are working on vaccines against ricin toxin and botulinum toxin.

Our lead pharmaceutical product is orBec(R), an oral locally acting corticosteroid, that is currently in a pivotal Phase III clinical trial for the treatment of intestinal graft-vs.-host disease ("iGvHD"), a life threatening complication of bone marrow transplantation. We are also planning a Phase II

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program using orBec(R) to extend the indications beyond treatment of iGvHD into prevention of iGvHD. In addition, data generated in animal models suggests that there may be utility in using Beclomethasone Dipropionate, the active ingredient in orBec(R)) for the treatment of a subgroup of patients with irritable bowel syndrome. Based on this data we are planning to conduct a proof of principle study in this indication in the near future. In October 2003, we signed a license agreement with the University of Texas for the rights to a patent application covering the use of Beclomethasone Dipropionate and other anti-inflammatories for the treatment of irritable bowel syndrome.

We have developed oral drug delivery systems, named LPM(TM), PLP(TM), and LPE(TM) 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. We have preclinical animal data demonstrating the oral delivery of the drug Paclitaxel, 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; (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.

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We have assembled an experienced management team that oversees the human clinical trials necessary to establish preliminary evidence of effectiveness and seeks partnerships with pharmaceutical and biotechnology companies for late-stage development and marketing of our product candidates. We supplement our management team through a network of consultants and contractors. By operating in this manner, we believe we can efficiently utilize our capital resources to advance our drug and vaccine products to market. To advance our product candidates, we utilize subsidiary companies such as DOR Vaccines, Inc., which is the successor in interest to InnoVaccines Corporation, our former joint venture, and forms the basis of our biodefense business initiative; Enteron Pharmaceuticals, Inc. and Oradel Systems, Inc., which together form the basis of our biotherapeutics initiative. Enteron is a subsidiary which holds the intellectual property relating to orBec(R). Oradel is a subsidiary which holds the intellectual property relating to the LPM(TM), LPE(TM), and PLP(TM) drug delivery systems. We plan to continue to develop our later stage product opportunities while seeking to manage our earlier stage product pipeline through collaborative licensing arrangements.

We have entered into a sponsored research agreement with Thomas Jefferson University for one year of research, for our botulinum vaccine program in exchange for \$300,000, payable by us quarterly beginning in July 2003. Additionally, in July 2003, we executed a worldwide exclusive license for patent applications with the University of Texas Southwestern Medical Center for the injectable rights to a ricin vaccine, for \$200,000 of our common stock and certain future licensee payments. Additionally we have an option agreement with the University of Texas Southwestern Medical Center for the exclusive rights to nasal, pulmonary and oral uses of a non-toxic ricin vaccine.

During the 2003 third quarter, our ricin program and our platform delivery technology were the subject of \$2.7 million in grants from the National

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Institutes of Health, \$2.6 million of which is being funded to the exclusive licensor of our non-toxic ricin vaccine technology, the University of Texas Southwestern Medical Center.

In September 2003, we moved our principal executive offices from Lake Forest, Illinois to a 2,400 square foot facility in Miami, Florida.

### 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 Elan'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.

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### RESULTS OF OPERATIONS:

We are a development stage company and to date have not generated any material revenues from operating activities. Although our product portfolio includes a phase III drug that we believe may be attractive to potential pharmaceutical partners, we have no active discussions under way with any such potential partners.

For the three months ended September 30, 2003, we had a net loss of \$1,126,202 which was an increase of \$501,573, or 80%, as compared to a net loss of \$624,629 for the same period in 2002. For the nine month period ended September 30, 2003, we had a net loss of \$4,108,204, which was approximately the same as the net loss of \$4,101,509 for the nine months ended September 30, 2002. After giving effect to dividends on preferred stock, which are paid-in-kind in the form of additional shares of preferred stock, net loss available to common stockholders decreased \$488,177 or 9%, to \$4,808,989, or \$0.17 per share, for the first nine months of 2003 compared with \$5,297,166, or \$0.25 per share, for the same period of the prior year.

Research and development expenditures increased \$460,685, or 141%, to \$786,847, for the three months ended September 30, 2003, compared with \$326,162 for the corresponding period ended September 30, 2002. Research and development expenditures decreased \$478,085, or 20%, to \$1,923,515, for the nine months ended September 30, 2003, compared with \$2,401,600 for the corresponding period ended September 30, 2002. The third quarter increase in research and development spending reflects our increased expenditures in our Phase III clinical trial and manufacturing costs of orBec(R) as well as additional spending for our Ricin and Botulinum Toxin vaccine programs, while the decrease on a year to date basis

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comes from the reduction in the number of early stage programs we are working on in the first half of 2002. For the near term, we expect research and development costs to remain in line with our third quarter 2003 expense.

General and administrative expenses increased \$67,125, or 30%, to \$287,730 for the three months ended September 30, 2003 as compared to \$220,605 for the three months ended September 30, 2002. General and administrative expenses increased \$195,872, or 11%, to \$2,013,674 for the first nine months of 2003 as compared to \$1,817,802 for the nine months ended September 30, 2002. This increase was due to non-cash stock compensation of \$80,100 for the three months ended September 30, 2003 and \$960,514 for the first nine months of 2003. This 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 September 15, 2003 annual meeting, as described in the footnotes to the condensed consolidated financial statements included in this quarterly report.

Severance costs decreased \$118,598, or 100%, to \$0 in the three months ended September 30, 2003 as compared to \$118,598 for the same period in 2002. Severance costs decreased \$617,886 or 83% to \$130,712 for the nine months ended September 30, 2003 compared to 748,598 for the nine months ended September 30, 2002. The severance cost in 2002 was due to a substantial restructuring in June 2002, while 2003 costs represent a single employee and some residual costs associated with the prior year's restructuring.

Interest income for the three months ending September 30, 2003 was \$4,287, a decrease of \$16,508, or 79%, compared to \$20,795 for the same period in 2002. Interest income for the nine months ending September 30, 2003 was \$14,284, a decrease of \$72,855, or 84%, compared to \$87,139 for the same period in 2002. These decreases were due to decreases in interest rates on investment instruments versus the prior year, as well as lower cash balances in the first nine months of 2003.

### FINANCIAL CONDITION AND LIQUIDITY:

On September 30, 2003, we had cash and cash equivalents of \$5,335,058, compared to \$4,147,164 at December 31, 2002. Working capital was \$4,593,794 at September 30, 2003, compared to \$3,046,775 at December 31, 2002.

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For the first nine months of 2003, we lowered our cash burn rate by \$1,949,594, or 33%, to \$3,972,552 compared to \$5,922,146 for the same period in 2002. We had an operating loss of \$4,067,901, of which \$960,514 represented non-cash stock compensation. The overall reduction in our cash burn was attributable to a substantial reduction in payroll and operating expenses, coupled with the granting of options as opposed to cash to attract and retain qualified personnel.

On July 18, 2003 we entered into subscription agreements for a private placement of 6,796,919 shares of Common Stock at \$0.796 per share for total gross proceeds of \$5,410,395. In addition, each investor received a warrant to purchase a share of Common Stock for \$0.8756 along with each share purchased in the placement. We also paid a commission to our placement agent of \$393,068 in cash and warrants to purchase 1,359,382 shares of Common stock at \$.8756 per share. Closure of this private placement was contingent on stockholder approval, which we received at our September 15, 2003 annual meeting.

Based on our current cash burn rate our cash and cash equivalents of \$5,335,058 at September 30, 2003 should be sufficient to meet our anticipated cash needs

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for working capital and capital expenditures for the next 12 months. However, 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 such financings, private financing, 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 terms favorable to our stockholders or us. 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 in existence.

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### ITEM 4. CONTROLS AND PROCEDURES

Our Chief Executive Officer and Controller (our principal executive officer and principal financial officer, respectively) concluded, based on an evaluation of our disclosure controls and procedures performed by our management with participation of our Chief Executive Officer and Controller, that as of September 30, 2003 our disclosures, controls, and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports we filed or submit by under the Securities Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Any control system, no matter how well designed and operated, can provide only reasonable (not absolute) assurance that its objectives will be met. Furthermore, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

There was not any change in our internal control over financial reporting during the quarter ended September 30, 2003 that has materially affected or is reasonably likely to materially affect, our internal control over financial reporting.

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## PART II. - OTHER INFORMATION.

### ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

On July 18, 2003 we entered into subscription agreements for a private placement of 6,796,919 shares of Common Stock at \$0.796 per share for total gross proceeds of \$5,410,395. In addition, each investor received a warrant to purchase a share of Common Stock for \$0.8756 for each share purchased in the placement. We also paid a commission to our placement agent of (i) \$393,068 in cash and (ii)

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warrants to purchase 1,359,382 shares of Common stock at \$.8756 per share. This placement was done pending stockholder approval, which we received at our September 15, 2003 annual meeting. We issued these securities in transactions exempt from registration under the Securities Act of 1933 in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering. Each of the parties that acquired the securities represented to us that it was an "accredited investor" under Rule 501(a) of Regulation D.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

An annual meeting of stockholders was held on September 15, 2003.

Our stockholders voted as follows with respect to a proposal to elect eight directors to serve until the next annual meeting of stockholders until their successors are duly elected and qualified:

DIRECTORS -----	FOR -----	AUTHORITY WITHHELD -----
Alexander M. Haig Jr.	21,601,488	1,578,521
Steve H. Kanzer	21,601,516	1,578,493
Ralph M. Ellison	21,601,502	1,578,507
Paul D. Rubin(1)	21,601,510	1,578,499
Larry Kessel	21,601,516	1,578,493
Arthur Asher Kornbluth	21,601,516	1,578,493
Evan Myrianthopoulos	21,601,516	1,578,493
Peter Salomon	21,601,502	1,578,507

(1) Dr. Rubin declined his appointment to the board after being elected

The Company's stockholders voted as follows with respect a proposal to approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock from 50,000,000 to 100,000,000;

FOR ---	AGAINST -----	ABSTENTIONS -----	BROKER NON-VOTES -----
21,478,501	265,865	1,435,643	n/a

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The Company's stockholders voted as follows with respect to a proposal to approve the sale and issuance of (i) 6,796,919 shares of Common Stock at \$0.796 per share and (ii) warrants exercisable for 6,796,919 shares of Common Stock, to selected institutional and accredited investors, in a private placement exempt from registration under the Securities Act of 1933;

FOR ---	AGAINST -----	ABSTENTIONS -----	BROKER NON-VOTES -----
11,162,828	157,708	1,443,193	10,383,609

The Company's stockholders voted as follows with respect to a proposal to

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approve an amendment to our Amended and Restated 1995 Omnibus Incentive Plan to increase the number of shares of Common Stock available for issuance under the 1995 Plan from 4,708,257 to 10,000,000 shares of Common Stock and increase from 750,000 to 2,500,000 the maximum number of shares of Common Stock for which any participant may receive options or separately exercisable stock appreciation rights in the aggregate per calendar year;

FOR	AGAINST	ABSTENTIONS	BROKER NON-VOTES
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10,862,501	408,551	1,491,677	10,383,609

The Company's stockholders voted as follows with respect to a proposal To ratify the appointment of Ernst and Young LLP as our independent auditors for the year ending December 31, 2003.

FOR	AGAINST	ABSTENTIONS	BROKER NON-VOTES
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21,711,668	10,294	1,458,047	n/a

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### ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

- 3.1 Amended and Restated Certificate of Incorporation.
- 10.1 Amended and Restated 1995 Omnibus Incentive Plan.
- 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

### REPORTS ON FORM 8-K:

We filed a Current Report on Form 8-K on July 18, 2003 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 \$5.4 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.

November 14, 2003

/s/ Ralph M. Ellison

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Ralph M. Ellison  
Chief Executive Officer and President

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November 14, 2003

/s/ William D. Milling

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William D. Milling

Controller

(principal financial and accounting officer)