DOR BIOPHARMA INC
Form 10QSB
August 13, 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 June 30, 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

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 August 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)**

| | June 30, 2004 | December 31, 2003 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 4,568,313 | $ 4,117,539 |
| Receivable | - | 20,954 |
| Prepaid expenses | 75,270 | 155,844 |
| Total current assets | 4,643,583 | 4,294,337 |
| Equipment, net of accumulated depreciation of $152,757 and $141,650, respectively | 55,361 | 60,795 |
| Licenses and patent costs, net of accumulated amortization of $568,477 and $384,333, respectively | 1,876,947 | 1,896,934 |
| Total assets | $ 6,575,891 | $ 6,252,066 |
| Liabilities and stockholders equity | | |
| Current liabilities: | | |
| Accounts payable | $ 455,297 | $ 211,587 |
| Accrued royalties | 100,000 | 320,000 |
| Accrued compensation and other expenses | 101,140 | 116,638 |
| Notes Payable | 115,948 | 359,067 |
| Total current liabilities | 772,385 | 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; 42,042,943 and 34,893,765 issued, 41,870,601 and 34,721,423 outstanding | 42,044 | 34,894 |
| Additional paid-in capital | 82,841,870 | 67,005,276 |
| Deficit accumulated during the development stage | (76,612,141) | (73,975,897) |
| | 6,271,773 | 5,713,041 |
| Less: Cost of 172,342 shares of common stock in treasury | (468,267) | (468,267) |
| Total stockholders equity | 5,803,506 | 5,244,774 |
| Total liabilities and stockholders equity | $ 6,575,891 | $ 6,252,066 |

See accompanying notes to consolidated financial statements.

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

| | Three Months Ended June 30, | |
|---|---|---|
| | **2004** | **2003** |

| | | |
|---|---|---|
| Grant revenue | $ - | $ - |
| | | |
| Expenses: | | |
| Proprietary research and development | 990,013 | 748,767 |
| General and administrative | 498,894 | (177,221) |
| | | |
| Total expenses | 1,488,907 | 571,546 |
| | | |
| Loss from operations | (1,488,907) | (571,546) |
| | | |
| Other income (expense): | | |
| Interest income | 22,132 | 3,325 |
| Interest expense | (6,901) | (1,096) |
| Other income | 300 | 5,433 |
| | | |
| Total other income (expense) | 15,531 | 7,662 |
| | | |
| Net loss | $ (1,473,376) | $ (563,884) |
| | | |
| Preferred stock dividends | - | (233,596) |
| | | |
| Net loss applicable to common stockholders | $ (1,473,376) | $ (797,480) |
| | | |
| Basic and diluted net loss per share applicable to common stockholders | $ (0.04) | $ (0.03) |
| | | |
| Basic and diluted weighted average common shares outstanding | 41,870,601 | 27,282,768 |

See accompanying notes to consolidated financial statements.

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

| | Six Months Ended June 30, | | Cumulative Period February 15, 1985 (inception) to |
|---|---|---|---|
| | 2004 | 2003 | June 30, 2004 |
| Grant revenue | $ 66,095 | $ - | $ 249,912 |
| Expenses: | | | |
| Cost of revenue | 59,486 | - | 221,851 |
| Proprietary research and development | 1,689,524 | 1,136,668 | 24,666,248 |
| General and administrative | 977,471 | 1,856,656 | 21,516,061 |
| Write-off of acquired in-process research and development | - | - | 10,181,000 |
| Total expenses | 2,726,481 | 2,993,324 | 56,585,160 |
| Loss from operations | (2,660,386) | (2,993,324) | (56,335,248) |
| Other income (expense): | | | |
| Interest income | 38,843 | 9,997 | 3,638,846 |
| Interest expense | (15,173) | (4,108) | (437,394) |
| Other income | 525 | 5,433 | 237,025 |
| Equity in joint ventures | - | - | (22,179,091) |
| Total other income (expense) | 24,195 | 11,322 | (18,740,614) |
| Net loss | (2,636,191) | (2,982,002) | (75,075,862) |

| | | | |
|---|---|---|---|
| Preferred stock dividends | (503,195) | (464,624) | (7,763,826) |
| Net loss applicable to common stockholders | $ (3,139,386) | $ (3,446,626) | $ (82,839,688) |
| Basic and diluted net loss per share applicable to common stockholders | $ (0.08) | $ (0.13) | |
| Basic and diluted weighted average common shares outstanding | 39,100,797 | 27,176,773 | |

*See accompanying notes to consolidated financial statements.*

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

| | Six Months Ended June 30, 2004 | 2003 | Cumulative Period February 15, 1985 (inception) to June 30, 2004 |
|---|---|---|---|
| Operating activities: | | | |
| Net loss | $ (2,636,191) | $ (2,982,002) | $ (75,075,862) |
| Adjustments to reconcile net loss to cash used in operating activities: | | | |
| Depreciation and amortization | 203,150 | 164,340 | 2,337,894 |
| Gain on sale of marketable securities | | - | (110,244) |
| Non-cash stock compensation | 104,528 | 1,010,414 | 2,228,082 |
| Equity in (earnings) losses of joint ventures | - | - | 22,179,091 |

| | | | |
|---|---|---|---|
| Amortization of fair value of warrants | - | - | 3,307,546 |
| Gain on sale of assets | 225 | (5,433) | 21,747 |
| Write-off patent issuance cost | - | - | 499,065 |
| Write-off of acquired research and development | - | - | 10,181,000 |
| Change in operating assets and liabilities: | | | |
| Receivable from related party | 20,954 | - | - |
| Prepaid expenses | 80,574 | 43,020 | (75,270) |
| Accounts payable and accrued expenses | 8,212 | (129,633) | 627,774 |
| Accrued compensation | - | (96,760) | 29,000 |
| Total adjustments | 417,643 | 985,948 | 41,225,685 |
| Net cash used by operating activities | (2,218,548) | (1,996,054) | (33,850,177) |
| Investing activities: | | | |
| Cash received in acquisition of CTD, net | - | - | 1,392,108 |
| Patent issuance costs | (172,281) | (302,224) | (1,997,832) |
| Investment in joint ventures | - | - | (5,274,391) |
| Purchases of leasehold improvements and equipment | (5,673) | - | (1,893,725) |
| Proceeds from assets sold | - | - | 108,197 |
| Purchases of marketable securities | - | - | (11,004,080) |
| Proceeds from sale of marketable securities | - | - | 11,114,324 |
| Net cash used by investing activities | (177,954) | (302,224) | (7,555,399) |
| Financing activities: | | | |
| Net proceeds from issuance (costs incurred related to issuance) of common stock | 3,040,086 | (114,626) | 46,516,117 |

| | | | |
|---|---|---|---|
| Proceeds from exercise of options | 61,972 | 140,494 | 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 | (254,783) | (307,728) | (1,689,187) |
| 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) |
| Net cash provided by (used in) financing activities | 2,847,275 | (281,860) | 45,973,889 |
| Net increase (decrease) in cash and cash equivalents | 450,773 | (2,580,138) | 4,568,313 |
| Cash and cash equivalents at beginning of period | 4,117,540 | 4,147,164 | - |
| Cash and cash equivalents at end of period | $ 4,568,313 | $ 1,567,026 | $ 4,568,313 |
| Supplemental disclosure of cash flow: | | | |
| Cash paid for interest | $ 15,173 | $ 4,108 | |
| Supplemental disclosure of non-cash investing and financing activites: | | | |
| Issuance of preferred stock dividends in kind | $ 171,535 | $ 464,624 | |

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. 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 that was presented as a separate line item in the statement of operations for the three months and six months ended June 30, 2003, are now reported as a component of 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 8.4 million and 3.9 million shares of our common stock outstanding at June 30, 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 six months ended June 30:

| | 2004 | 2003 |
|---|---|---|
| Net loss applicable to common stockholders as reported | $ (3,139,386) | $ (3,446,626) |

| | | |
|---|---|---|
| Stock-based compensation as reported | - | 880,414 |
| Stock-based employee compensation expense determined under fair value based method | (1,028,554) | (460,714) |
| Pro forma net loss | $ (4,167,940) | $ (3,026,926) |
| Net loss per share: | | |
| as reported, basic and diluted | $ (0.08) | $ (0.13) |
| pro forma, basic and diluted | $ (0.11) | $ (0.11) |

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 4.0% 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 $880,414 being recorded in the first six months 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 June 30, 2004 ranged from 11 to 16 years. The following is a summary of License and Patent assets:

| June 30, 2004 | Weighted Average Amortization Period | Cost | Accumulated Amortization | Net |
|---|---|---|---|---|
| Patents and Licenses | 11.40 years | $ 2,445,424 | $ 568,477 | $ 1,876,947 |

| | Weighted Average |
|---|---|

| December 31, 2003 | Amortization Period | Cost | Accumulated Amortization | Net |
|---|---|---|---|---|
| Patents and Licenses | 11.85 years | $ 2,281,267 | $ 384,333 | $ 1,896,934 |

Aggregate amortization expense for the six months ended June 30, 2004 was $184,143.

Estimated amortization for the years ending December 31:

| | |
|---|---|
| 2004 | $ 300,000 |
| 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 June 17, 2004, we purchased certain shares from a minority holder in our Enteron subsidiary. In exchange for the holder's shares, we issued warrants for the purchase of 200,000 shares of common stock at an exercise price of $0.58 and $11,141 in cash. In connection with this transaction the Company recorded a charge of approximately $105,000 which is recorded as a General and Adminstrative expense.

SUBSEQUENT EVENT

On July 9, 2004, we accepted the resignation of Ralph M. Ellison, M.D. as President, Chief Executive Officer, and a Director. Dr. Ellison was appointed CEO in March 2003 and resigned for personal reasons. The company anticipates a payments of approximately $200,000 in severence costs over the next two quarters, and will take a charge for the entire amount in the third quarter for these severence costs.

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, as amended, 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 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 aw 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 oral therapeutic products intended for areas of unmet medical need.

Through our Biodefense Division, we are working to develop biomedical countermeasure vaccines for ricin toxin and botulinum toxin, both of which are considered bioterrorism threats by the Centers for Disease Control (CDC). With the recent passage of Project Bioshield Act 2004, which is legislation that offers incentives for companies to develop countermeasures to the CDC-identified bioterror threats including the creation of a Strategic National Stockpile, we hope to provide the U.S. Government with qualified vaccines for procurement and inclusion in the Strategic National Stockpile.

Through our Biotherapeutics Division, we are developing oral therapeutic products to treat unmet medical needs. Our lead product, orBec® (oral beclomethasone dipropionate), has recently completed enrollment in a multicenter, pivotal phase III clinical trial for the treatment of acute intestinal graft-vs-host disease, a form of serious and life-threatening gastrointestinal inflammation. Data from the pivotal clinical trial are expected in the fourth quarter of 2004. If the data are statistically and clinically significant, we plan to file a New Drug Application (NDA) with the Food and Drug Administration (FDA) in the first quarter of 2005. OrBec® is a highly potent, topically-active glucocorticoid. The indication has previously been designated fast track status and received Orphan Drug Designation by the FDA.

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 and apply for support for our biodefense vaccine development programs in the form of government grants; (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.

orBec® (Oral Beclomethasone dipropionate)

As announced on July 14, 2004, we have completed enrollment in our Phase III pivotal clinical trial for our lead product orBec®, and the treatment phase will conclude in September 2004. We expect to release data from this trial in the fourth quarter of 2004. If the data from this trial are statistically and clinically significant, we plan to file an NDA with the FDA in the first quarter of 2005. Since our program involves a single pivotal trial, the filing of an NDA will be dependent upon the results of this Phase III trial. OrBec® is being developed to treat post-allogeneic bone marrow

transplant-related Graft-versus-Host Disease with gastrointestinal involvement.

RiVax (Ricin Toxin Vaccine)

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 (UT Southwestern), as well as a $2.6 million National Institute of Allergy and Infectious Diseases (NIAID) grant previously awarded to UT Southwestern. 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 is available, we will consider other options, including additional funding from us. Currently the vaccine is being developed for intramuscular delivery; there is however a parallel development program, which was funded through a Phase I Small Business Innovations Research grant (SBIR), in which oral and nasal administration of the vaccine candidate is being explored. Our academic development partners, UT Southwestern, intend to initiate a Phase I clinical trial for the injected vaccine in healthy human volunteers this year. The ultimate goal of the RiVax program is to develop a qualified countermeasure for ricin toxin, and to solicit a procurement contract from the U.S. Government for addition of the vaccine to the Strategic National Stockpile pursuant to the new legislation Project Bioshield Act 2004.

BT-VACC (Botulinum Toxin Vaccine)

Our botulinum vaccine program is focused on the development of an orally- or nasally-delivered, multivalent vaccine to potentially prevent botulism. We have previously demonstrated that our vaccine candidate for botulinum neurotoxin serotype A has shown efficacy in animals after nasal inoculation. Oral administration of the same antigen has shown promising results. We are continuing to evaluate both the oral and nasal route of delivery of this antigen, and our intent is to file an Investigational New Drug application for the purposes of conducting a Phase I clinical trial in healthy volunteers. In order to advance the development of a potential oral or nasal multivalent botulinum vaccine, we recently entered into a collaboration with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Under this agreement, USAMRIID will provide Dr. Lance Simpson of Thomas Jefferson University (TJU) with previously manufactured antigens for testing oral and nasal administration in animals. The collaboration with USAMRIID and TJU may expedite the development of an alternate route of delivery for the vaccine, potentially truncating the time to clinical testing. We are pursuing the funding of future work through federal grants, and we are continuing to discuss partnerships for the purpose of selecting a manufacturer. The ultimate goal of our BT-VACC program is to develop a preventative countermeasure for the biothreat botulinum toxin, and to solicit a procurement contract from the U.S. Government for addition of the vaccine to the Strategic National Stockpile.

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 have capitalized all outside legal and filing costs incurred in the procurement and defense of patents, as well as amounts paid in licensing additional methods of vaccine delivery through the Southern Research Institute patents, and amounts paid to University of Texas Southwestern Medical Center giving us the option to license certain patents related to a vaccine protecting against ricin toxin. These intangible assets are reviewed for impairment annually 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 revenues from operating activities.

For the three months ended June 30 2004, we had a net loss of $1,473,376, which represented an increase in net loss of $909,492, or 161%, as compared to a net loss of $563,884 for the same period in 2003. After giving effect to dividends on preferred stock, which were paid-in-kind in the form of additional shares of preferred stock, net loss available to common stockholders increased $675,896, or 85%, to $1,473,376, or $0.04 per share, for the three months ended June 30, 2004, compared to $797,480, or $0.03 per share, for the same period of the prior year. For the six months ended June 30, 2004, we had a net loss of $2,636,191, which represented a decrease in net loss of $345,811, or 12%, as compared to a net loss of $2,982,002 for the same period in 2003. After giving effect to dividends on preferred stock, which were paid-in-kind in the form of additional shares of preferred stock, net loss available to common stockholders decreased $307,240, or 9%, to $3,139,386, or $0.08 per share, for the three months ended June 30, 2004, compared to $3,446,626, or $0.13 per share, for the same period of the prior year.

Research and development expenses increased $241,246, or 32%, to $990,013, for the three months ended June 30, 2004, compared to $748,767 for the corresponding period ended June 30, 2003. Research and development expenses increased $552,856, or 48%, to a $1,689,524, for the six months ended June 30, 2004, compared to $1,136,668 for the corresponding period ended June 30, 2003. The second quarter of 2004 increase resulted from payments due to study sites as we completed enrollment in our phase III clinical trial, as well as a toxicology study for safety in ricin. The year to date increase includes the addition of our ricin and botulinum programs.

General and administrative expenses increased $676,115, to $498,894 for the three months ended June 30, 2004, as compared to a credit of $177,221 for the three months ended June 30, 2003. General and administrative expenses decreased $879,185, to $977,471, or 47%, for the six months ended June 30, 2004, as compared to $1,856,656 for the six months ended June 30, 2003. The increase in the second quarter of 2004 was due to $104,528 non-cash charge for the purchase of shares in a subsidiary from one of its minority stockholders, as well as a stock compensation credit of $599,165 for the three months ended June 30, 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 2003 annual meeting of stockholders. The year to date decrease resulted primarily from a 2003 stock compensation expense of $880,414.

Interest income for the three months ending June 30, 2004 was $22,132, an increase of $18,807, or 566%, as compared to $3,325 for the same period in 2003. Interest income for the six months ending June 30, 2004 was $38,843, an increase of $28,846, or 289%, as compared to $9,997 for the same period in 2003. Both of these increases were due to higher cash balances in 2004, as well as an increased interest rate on investment instruments.

FINANCIAL CONDITION AND LIQUIDITY:

On June 30, 2004, we had cash and cash equivalents of $4,568,313, compared to $4,117,539 at December 31, 2003. Our working capital was $3,871,198 at June 30, 2004, compared to $3,287,045 at December 31, 2003.

For the first six months of 2004, our cash outflows decreased by $69,347, or 3%, to $2,651,285 compared to $2,720,632 for the same period in 2003. The overall decrease resulted primarily from an decrease in our patent issuance costs of $129,943, partially offset by an increase in prepaid expenses of $37,554.

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 $3,040,086. In addition, each investor received a warrant to purchase 0.25 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 $4,568,313 at June 30, 2004 will not be sufficient to meet our anticipated cash needs for working capital and capital expenditures for the next 12 months. We anticipate that we will seek additional capital in the private and/or public equity markets, strategic partnerships, or other alternative financing sources to support our operations, to respond to competitive pressures, and to support new strategic partnership expenditures. 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 operations.

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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 the participation of our Chief Executive Officer and Controller, that as of June 30, 2004 our disclosure controls, and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit 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 June 30,2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. - OTHER INFORMATION

**Item 2. Changes in Securities and Small Business Issuer Purchases of Equity Securities**

On June 17, 2004 we purchased the certain shares from a minority holder in our Enteron subsidiary. In exchange for the holder's shares, we issued warrants for the purchase of 200,000 shares of common stock at an exercise price of $0.58 and $11,141 in cash. In connection with this transaction the Company recorded a charge of approximately $105,000 which is recorded as a General and Administrative expense.

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

An annual meeting of stockholders was held on June 11, 2003.

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

| DIRECTORS | FOR | AUTHORITY WITHHELD |
|---|---|---|
| Alexander M. Haig Jr. | 25,763,890 | 558,965 |
| Steve H. Kanzer | 25,791,041 | 532,814 |
| Ralph M. Ellison | 25,766,127 | 556,728 |
| Larry Kessel | 25,791,041 | 532,814 |
| Arthur Asher Kornbluth | 25,791,041 | 532,814 |
| Evan Myrianthopoulos | 25,791,027 | 532,828 |
| Peter Salomon | 25,791,034 | 532,821 |
| James Kuo | 25,791,041 | 532,814 |
| Stuart Sedlack | 21,791,025 | 532,830 |

The Company's stockholders voted as follows with respect to a proposal to ratify the appointment of Sweeney, Gates & Co. as our independent auditors for the year ending December 31, 2004.

| FOR | AGAINST | ABSTENTIONS | BROKER NON-VOTES |
|---|---|---|---|
| 26,046,933 | 231,846 | 44,076 | n/a |

Item 6 - Exhibits and Reports on Form 8-K

**(a) 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 |

(b) Reports on Form 8-K:

We did not file any reports on Form 8-K during the three months ended June 30, 2004.

SIGNATURES

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

**DOR BioPharma, Inc**

August 13, 2004 By: /s/ Geoff Green

President and Acting Chief Executive Officer

August 13, 2004

By: /s/ William Milling

Controller (principal financial and accounting officer)