DOR BIOPHARMA INC
Form 10QSB
November 15, 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 September 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 incorporation or organization) | (I.R.S. Employer Identification 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 November 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)**

| | September 30, 2004 | December 31, 2003 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 3,137,830 | $ 4,117,539 |
| Receivable | - | 20,954 |
| Prepaid expenses | 69,405 | 155,844 |
| Total current assets | 3,207,235 | 4,294,337 |
| Equipment, net of depreciation amortization of $158,783 and $141,650, respectively | 49,335 | 60,795 |
| Licenses and patent costs | 1,946,349 | 1,896,934 |
| Total assets | $ 5,202,919 | $ 6,252,066 |
| **Liabilities and shareholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 474,526 | $ 211,587 |
| Accrued royalties | 100,000 | 320,000 |
| Accrued compensation and other expenses | 103,458 | 116,638 |
| Notes Payable | 115,948 | 359,067 |
| Total current liabilities | 793,932 | 1,007,292 |
| Shareholders' 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 | 82,853,011 | 67,005,276 |
| Deficit accumulated during the development stage | (78,017,802) | (73,975,897) |
| | 4,877,253 | 5,713,041 |
| Less: cost of 172,342 shares of common stock in treasury | (468,266) | (468,267) |
| Total shareholders' equity | 4,408,987 | 5,244,774 |

| | | |
|---|---|---|
| Total liabilities and shareholders' equity | $ 5,202,919 | $ 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 September 30, 2004 | 2003 |
|---|---|---|
| Grant revenue | $ - | $ - |
| Expenses: | | |
| Proprietary research and development | 894,384 | 786,847 |
| General and administrative | 526,162 | 287,730 |
| Total expenses | 1,420,546 | 1,074,577 |
| Loss from operations | (1,420,546) | (1,074,577) |
| Other income (expense): | | |
| Interest income | 16,514 | 4,287 |
| Interest expense | (2,379) | (840) |
| Other income | - | (55,072) |
| Total other income (expense) | 14,135 | (51,625) |
| Net loss | (1,406,411) | (1,126,202) |
| Preferred stock dividends | - | (236,162) |
| Net loss applicable to common shareholders | $ (1,406,411) | $ (1,362,364) |
| Basic and diluted net loss per share applicable to common shareholders | $ (0.03) | $ (0.05) |
| Basic and diluted weighted average common shares outstanding | 41,870,601 | 28,966,059 |

*See accompanying notes to consolidated financial statements.*

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

| | 2004 | Nine Months Ended September 30, 2003 | Cumulative Period February 15, 1985 (inception) to September 30, 2004 |
|---|---|---|---|
| Grant revenue | $ 66,095 | $ - | $ 249,912 |
| Expenses: | | | |
| Cost of revenue | 59,486 | - | 221,851 |
| Proprietary research and development | 2,583,431 | 1,923,515 | 25,560,154 |
| General and administrative | 1,503,360 | 2,144,386 | 22,041,949 |
| Write-off of acquired in-process research and development | - | - | 10,181,000 |
| Total expenses | 4,146,277 | 4,067,901 | 58,004,954 |
| Loss from operations | (4,080,182) | (4,067,901) | (57,755,042) |
| Other income (expense): | | | |
| Interest income | 55,357 | 14,284 | 3,655,360 |
| Interest expense | (17,552) | (4,948) | (439,773) |
| Other income | 525 | (49,639) | 237,025 |
| Equity in joint ventures | - | - | (22,179,091) |
| Total other income (expense) | 38,330 | (40,303) | (18,726,479) |
| Net loss | (4,041,852) | (4,108,204) | (76,481,521) |
| Preferred stock dividends | (503,195) | (700,785) | (7,763,826) |
| Net loss applicable to common shareholders | $ (4,545,047) | $ (4,808,989) | $ (84,245,347) |
| Basic and diluted net loss per share applicable to common shareholders | $ (0.11) | $ (0.17) | |
| Basic and diluted weighted average common shares outstanding | 40,024,065 | 27,750,852 | |

*See accompanying notes to consolidated financial statements.*

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

| | Nine Months Ended September 30, 2004 | 2003 | Cumulative Period February 15, 1985 (inception) to September 30, 2004 |
|---|---|---|---|
| **Operating activities:** | | | |
| Net loss | $ (4,041,852) | $ (4,108,204) | $ (76,481,521) |
| Adjustments to reconcile net loss to cash used in operating activities: | | | |
| Depreciation and amortization | 270,827 | 209,526 | 2,405,571 |
| Gain on sale of marketable securities | - | - | (110,244) |
| Non-cash stock compensation | 104,528 | 960,514 | 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 | 49,639 | 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 | 86,439 | 28,185 | (69,405) |
| Accounts payable and accrued expenses | (48,809) | (149,096) | 570,752 |
| Accrued compensation | 78,569 | (124,480) | 107,569 |
| | | | |
| Total adjustments | 512,733 | 974,288 | 41,320,774 |
| | | | |
| Net cash used by operating activities | (3,529,119) | (3,133,916) | (35,160,747) |
| | | | |
| **Investing activities:** | | | |
| Cash received in acquisition of CTD, net | - | - | 1,392,108 |
| Patent issuance costs | (303,334) | (324,351) | (2,128,885) |
| Investment in joint ventures | - | - | (5,274,391) |
| Purchases of leasehold improvements and equipment | (5,673) | (22,662) | (1,893,725) |
| Proceeds from assets sold | - | 80,157 | 108,197 |

| | | | |
|---|---|---|---|
| Purchases of marketable securities | - | - | (11,004,080) |
| Proceeds from sale of marketable securities | - | - | 11,114,324 |
| Net cash used by Investing Activities | (309,007) | (266,856) | (7,686,452) |
| **Financing activities:** | | | |
| Net proceeds from issuance (costs incurred related to issuance) of common stock | 3,039,564 | 4,791,178 | 46,515,595 |
| Proceeds from exercise of options | 61,972 | 143,119 | 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 | (243,119) | (345,631) | (1,677,525) |
| 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 | 2,858,417 | 4,588,666 | 45,985,029 |
| Net increase (decrease) in cash and cash equivalents | (979,709) | 1,187,894 | 3,137,830 |
| Cash and cash equivalents at beginning of period | 4,117,539 | 4,147,164 | - |
| Cash and cash equivalents at end of period | $ 3,137,830 | $ 5,335,058 | $ 3,137,830 |
| Supplemental disclosure of cash flow: | | | |
| Cash paid for interest | $ 17,552 | $ 4,948 | |
| Issuance of preferred stock dividends in kind | $ 503,195 | $ 700,785 | |

*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 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 and nine months ended September 30, 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 approximately 9 million and 7.5 million shares of our common stock outstanding at September 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 nine months ended September 30:

| | **2004** | **2003** |
|---|---|---|
| Net loss applicable to common shareholders as reported | $ (4,545,047) | $ (4,808,989) |
| Stock-based compensation as reported | - | 960,514 |
| Stock-based employee compensation expense determined under fair value based method | (1,508,453) | (1,361,814) |
| Pro forma net loss | $ (6,053,500) | $ (5,210,289) |

| | | | | |
|---|---|---|---|---|
| Net loss per share: | | | | |
| as reported, basic and diluted | $ | (0.11) | $ | (0.17) |
| pro forma, basic and diluted | $ | (0.15) | $ | (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 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 shareholder 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 $960,514 being recorded in the first nine 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 patent and license costs at September 30, 2004 ranged from 11 to 16 years. The following is a summary of patent and license assets:

| | Weighted average Amortization Period | Cost | Accumulated Amortization | Net |
|---|---|---|---|---|
| **September 30, 2004** | 11.15 years | $2,556,141 | $ 609,792 | $1,946,349 |
| **December 31, 2003** | 11.85 years | $2,281,267 | $ 384,333 | $1,896,934 |

Aggregate amortization expense:
for the nine months ended September 30, 2004 $225,459

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.

**ITEM 2 - MANAGEMENT S DISCUSSION AND ANALYSIS**

*The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-QSB, and the our audited consolidated financial statements and their notes and other information included in our Annual Report on Form 10-KSB for the year ended December 31, 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 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:**

DOR BioPharma, Inc. is a biopharmaceutical company focused on the development of biodefense vaccines and therapeutics for areas of unmet medical needs. Through its BioDefense Division, DOR is developing bioengineered vaccines designed to protect against the deadly effects of ricin toxin and botulinum toxin. DOR's lead therapeutic product, orBec® (an oral formulation of beclomethasone dipropionate), is a potent, locally-acting corticosteroid being developed for the treatment of iGVHD, a severe, life-threatening form of gastrointestinal inflammation. As previously announced, DOR completed the treatment phase of its pivotal Phase III clinical trial of orBec® and expects to announce top-line results of this trial before the end of the year and, pending a positive outcome, potentially filing an NDA for marketing authorization by April 2005. orBec® has been granted fast track status by the FDA for the treatment of iGVHD.

**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)**

Our company has completed the Phase III pivotal clinical trial in intestinal graft-versus-host-disease. We expect to release data from this trial in the fourth quarter of 2004. If the data is statistically and clinically significant, we plan to file an NDA with the FDA in the second 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. In the third quarter this year, we were awarded upto $5.2 million grant from the NIAID to further our program. Development funded under this grant include generation of a stable formulation of RiVax , development of a robust large scale process for purification of the vaccine, conduct of nonclinical toxicology studies, conduct of aerosol challenge studies to assess the capacity of RiVax to protect lung surfaces vulnerable to ricin exposure, and production of cGMP (current Good Manufacturing Processes) batches of RiVax . Currently the vaccine is being developed for intramuscular delivery; however a parallel development program exists, 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. One of our academic development partners, UT Southwestern, intends 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 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 have recently entered into a collaboration with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Under this agreement, USAMRIID is to 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 will potentially expedite the development of an alternate route of delivery for the vaccine, which may truncate the time to clinical testing for us and TJU. We hope to have future work funded through federal grants, and we are continuing to discuss partnerships for the purpose of selecting a manufacturer. The ultimate goal of the 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 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 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 significant revenues from operating activities.

For the three months ended September 30 2004, we had a net loss of $1,406,411 which was an increase in net loss of $280,209, or 25%, as compared to a net loss of $1,126,202 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 $44,047, or 3%, to $1,406,411, or $0.03 per share, for the three months ended September 30, 2004 compared to a net loss of $1,362,364 or $0.05 per share, for the same period of the prior year. For the nine months ended September 30, 2004, we had a net loss of $4,041,852 which was a decrease in net loss of $66,352, or 2%, as compared to a net loss of $4,108,204 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 $263,942, or 5%, to $4,545,047, or $0.11 per share, for the nine months

ended September 30, 2004 compared to $4,808,989 or $0.17 per share, for the same period of the prior year.

Research and development expenditures increased $107,537, or 14%, to $894,384, for the three months ended September 30, 2004, compared to $786,847 for the corresponding period ended September 30, 2003. Research and development expenditures increased $659,916, or 34%, to $2,583,431, for the nine months ended September 30, 2004, compared to $1,923,515 for the corresponding period ended September 30, 2003. The third quarter increase resulted from an increase in consulting costs involved in completion of the trial, and analysis of the data. The year to date increase also includes additional payments to the orBec trial sites and the addition of our ricin and botulinum programs.

General and administrative expenses increased $238,432 or 83%, to $526,162 for the three months ended September 30, 2004, as compared to $287,730 for the three months ended September 30, 2003. General and administrative expenses decreased $641,025 or 30%, to $1,503,360 for the nine months ended September 30, 2004, as compared to $2,144,386 for the nine months ended September 30, 2003. The third quarter increase was primarily due to severance payments and accrued severance due former employees in the amount of approximately $160,000, as well as payments of $25,000 to initiate Public Relations and Lobbying programs. The year to date decrease resulted primarily from a 2003 stock compensation expense of $960,514. 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 shareholders at our 2003 annual meeting of shareholders. In part this decrease was offset by severance paid and accrued in the amount of approximately $160,000.

Interest income for the three months ending September 30, 2004 was $16,514, an increase of $12,227, or 285%, as compared to $4,287 for the same period in 2003. Interest income for the nine months ending September 30, 2004 was $55,357, an increase of $44,073, or 309%, as compared to $14,284 for the same period in 2003. Both of these increases were due to in part to higher cash balances in 2004 from cash financing activities closed in 2004.

**FINANCIAL CONDITION AND LIQUIDITY**

As of September 30, 2004, we had cash and cash equivalents of $3,137,830, compared to $4,117,539 at December 31, 2003. Working capital was $2,413,303 at September 30, 2004, compared to $3,287,045 at December 31, 2003.

For the first nine months of 2004, our cash decreased by $929,710, or 22%, to $3,137,830 compared to $4,117,539 at December 31, 2003. The overall decrease resulted from $3,529,119 used in operating activities, $309,007 used in investing activities, and a net cash provided of $2,858,417 in financing activities.

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 and cash equivalents of $3,137,830 and our working capital of $2,413,303 at September 30, 2004 will only be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the first quarter of 2005. We anticipate that before the end of the first quarter of 2005 we will be required to raise additional capital in the private and/or public equity markets to support our operations. If we receive additional funds through the issuance of equity or equity-linked securities, stockholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which limit our ability to pursue certain courses of action. We may not be able to obtain such financing or on acceptable terms or at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our

operations. In addition, it is possible that if we are unable to secure and demonstrate the required cash flow for the at least 12 months that we may have going concern considerations.

Because we continue to incur losses from continuing operations in fiscal 2004, the stockholders equity standard applicable to us of the American Stock Exchange s ("AMEX") continued listing requirements is $6 million at the end of each fiscal year. Moreover, our net equity of $2.3 million as of June 30, 2003 did not satisfy the $4 million minimum stockholders equity requirement that was applicable to calendar quarters ending during 2003, and we received notification from the AMEX that we were no longer in compliance with their minimum listing requirements. On August 4, 2003 we submitted a compliance plan, and the AMEX accepted our plan and allowed us 18 months to regain compliance in accordance with the terms of our plan. As of September 30, 2004, our stockholders equity continues to be below the minimum equity requirement. If we do not conform to our plan, including, without limitation, the requirement that we meet the minimum listing requirements by December 26, 2004, we may be delisted from the AMEX. See "Risk Factors" accompanying this Form 10QSB.

**ITEM 3 - CONTROLS AND PROCEDURES**

Our Acting 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, 2004 our disclosures, the 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 September 30, 2004 that has materially affected or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION.**

**ITEM 4 - EXHIBITS**

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

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**Reports on Form 8-K:**

We filed a Current Report on Form 8-K on July 13, 2004 announcing that Ralph Ellison, the CEO has resigned for personal reasons.

We filed a Current Report on Form 8-K on September 16, 2004 announcing that we had been awarded upto a $5.2 million grant from the National Institute of Allergy and Infectious Diseases.

We filed a Current Report on Form 8-K on October 15, 2004 announcing that James Clavijo, was appointed as Controller, Treasurer and Corporate Secretary. Mr. Clavijo replaces William Milling, who resigned for personal reasons.

We filed a Current Report on Form 8-K on November 10, 2004 announcing that General Alexander M. Haig resigned as Chairman of the Board of Directors.

We filed a Current Report on Form 8-K on November 12, 2004 announcing that Alexander P. Haig was appointed as non-Executive Chairman of the Board of Directors. The report also announced that Evan Myrianthopoulos was appointed President and Acting Chief Executive Officer. Mr. Myrianthopoulos replaces Geoff Green, who resigned for personal reasons. The report also announced that General Alexander M. Haig will serve as Chairman of the Strategic Advisory Board. The report also announced that Drs. Arthur Asher Kornbluth, Peter Salomon, and Larry Kessel have resigned as directors of the Board of Directors, but that they will serve on the newly established Scientific Advisory Board for Biotherapeutics.

**SIGNATURES**

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

DOR BIOPHARMA, INC.

November 15, 2004 by /s/ Evan Myrianthopoulos
Evan Myrianthopoulos
President and Acting Chief Executive Officer

November 15, 2004 by /s/ James Clavijo
James Clavijo
Controller (principal financial and accounting officer)